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Bundle 18 – Documents referred to in the expert report of Dr J.T. Walker

Volume 1 (of 2)

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Microbial Biofilm Formation and Contamination of Dental-Unit Water Systems in General Dental Practice

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Dental-unit water systems (DUWS) harbor bacterial biofilms, which may serve as a haven for pathogens. The aim of this study was to investigate the microbial load of water from DUWS in general dental practices and the biofouling of DUWS tubing. Water and tube samples were taken from 55 dental surgeries in southwestern England. Contamination was determined by viable counts on environmentally selective, clinically selective, and pathogen-selective media, and biofouling was determined by using microscopic and image analysis techniques. Microbial loading ranged from 500 to 10^5 CFU · ml^{-1}; in 95% of DUWS water samples, it exceeded European Union drinking water guidelines and in 83% it exceeded American Dental Association DUWS standards. Among visible bacteria, 68% were viable by *Bac*Light staining, but only 5% of this "viable by *Bac*Light" fraction produced colonies on agar plates. *Legionella pneumophila*, *Mycobacterium* spp., *Candida* spp., and *Pseudomonas* spp. were detected in one, five, two, and nine different surgeries, respectively. Presumptive oral streptococci and *Fusobacterium* spp. were detected in four and one surgeries, respectively, suggesting back siphonage and failure of antiretraction devices. Hepatitis B virus was never detected. Decontamination strategies (5 of 55 surgeries) significantly reduced biofilm coverage but significantly increased microbial numbers in the water phase (in both cases, $P < 0.05$). Microbial loads were not significantly different in DUWS fed with soft, hard, deionized, or distilled water or in different DUWS (main, tank, or bottle fed). Microbiologically, no DUWS can be considered "cleaner" than others. DUWS deliver water to patients with microbial levels exceeding those considered safe for drinking water.

The water obtained from dental units via 3-in-1 syringes, air rotors, and low-speed handpieces may be heavily contaminated with microorganisms and thus may be a potential source of infection for both practice staff and patients (5, 34). The range of microorganisms isolated includes both environmental organisms (e.g., *Moraxella* spp. and *Flavobacterium* spp.) and opportunistic and true human pathogens (e.g., *Pseudomonas aeruginosa*, *Legionella pneumophila*, *Mycobacterium* spp., and *Staphylococcus* spp.) (10, 14, 16, 21, 30). Such organisms may originate from incoming local water supplies, although organisms commonly found in the oral cavity have also been recovered (37, 38), suggesting that some bacteria may be derived from the patient following back siphonage. The most common cause of dental-unit water contamination is believed to be the formation and subsequent sloughing off of microbial biofilms from the surfaces of tubing within dental-unit water systems (DUWS) (22, 36). To date viruses have not been detected in DUWS (37).

Microorganisms persist in DUWS by growing as a multispecies biofilm on the inner surface of the plumbing (14, 16, 21). Biofilms may be difficult to remove from surfaces, and the bacteria within biofilms are more resistant to antimicrobial agents (12, 17, 25) than planktonic cells. This antimicrobial resistance is a result of a number of factors that may include (i) binding of the agent, (ii) a lack of penetration of inhibitors, (iii) the localization of neutralizing enzymes, (iv) the low growth rate of the microbes, and (v) the expression of a resistant phenotype due to surface growth (9). Biofilms may also enhance the survival of fastidious pathogens such as *L. pneumophila* in water distribution systems (32). Up to 25% of DUWS have been shown to be contaminated with this bacterium (8).

There are currently no rational, evidence-based guidelines available to dentists for the control of DUWS contamination. This study is the first to focus on DUWS in typical general dental practices and to compare systematically different types of DUWS (bottle, main, or header tank fed) and units supplied with deionized, distilled, soft, or hard water. Biofilms play an important role in the microbial contamination of water systems; therefore, we have investigated biofilms using conventional viable counting of bacteria, as well as microscopy and image analysis and vital staining, in parallel with equivalent (planktonic) water samples. We also assessed the nature of the microbial contamination by detecting "environmental" and oral organisms as well as a range of potential pathogens, including the hepatitis B virus surface antigen (HBsAg).

MATERIALS AND METHODS

Survey of general dental practices. Fifty-five DUWS were selected for study in 21 general dental practices in southwestern England. The units selected represented units in use and included 32 supplied by bottled water, 20 supplied by mains water, and 3 supplied by header tank systems. Of these, 33 were supplied with hard water, 11 with soft water, 9 with deionized water, and 2 with distilled water. Five of the sampled DUWS (all bottle fed) were reported to have been sanitized. The sanitization regimens in four cases consisted of a weekly 5-min addition of a 1:10 dilution of Milton sterilizing fluid (neat solution contains 2% [wt/wt] sodium hypochlorite and 16.5% [wt/wt] NaCl; Procter & Gamble Ltd., Weybridge, Surrey, United Kingdom). The other sanitized unit was treated by the continuous addition of 1:10 diluted Corsodyl (neat solution contains 0.2% [wt/vol] chlorhexidine gluconate; SmithKline Beecham, Brentford, United Kingdom).

Sampling of DUWS. Samples were taken from four points in each device at approximately mid-morning: (i) the 3-in-1 syringe's (the pistol-like device de-

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signed to deliver air, water, or air/water into the mouth during dental treatment) distal outlet (the water line sample), (ii) a section of the water line tubing supplied to the 3-in-1 syringe for biofilm analysis (the water line biofilm), (iii) the air rotor water line (the air rotor water sample), and (iv) the air line (as a control sample for detection of background contamination of the tubing—the air line biofilm).

Water samples were processed in the following way. Approximately 100 ml of water was passed through a sterile nozzle into a sterile water bottle containing 0.1 g of sodium thiosulfate to remove any residual disinfectant (3) (Abinghurst Ltd., Northampton, United Kingdom). The samples were returned to the laboratory in a cool box (4 to 8°C) within 3 h and then filtered through 100-ml-capacity, 0.2-μm-pore-size analytical test filter funnels (Techware, Poole, United Kingdom) in order to recover the waterborne microorganisms. The membrane was removed from the funnel with sterile forceps and placed in a screw-cap sterile container (Elkay Products Inc., Shrewsbury, Mass.). Organisms were washed from the membrane by vortexing the container for 1 min in 10 ml of sterile phosphate-buffered saline (PBS).

Biofilm samples were taken using the following procedure. External DUWS tubing surfaces were wiped with a sterile alcohol wipe (CS Dental Supplies, Redhill, United Kingdom) and approximately 5 cm of the tubing was cut off with presterilized (121°C for 15 min) scissors. The tubing section was then placed in a bottle containing enough sterile water to cover the samples. All samples were again transferred in a cool box to the laboratory within 3 h. Tubing was sectioned to obtain a specimen representing 1 cm^2. The surfaces were rinsed in nonflowing sterile PBS to remove planktonic cells. Using sterile (121°C for 15 min) dental probes, the surface biofilm was scraped into 1 ml of sterile PBS. The scraping was checked by microscopy to determine that all the biofilm had effectively been removed from the surface.

Viable counts of selected bacteria. Total viable counts were carried out on decimal dilutions of the water and biofilm samples (in sterile PBS) and were used as the definitive measure of total microbial contamination of the water passing through the DUWS. This was compared with both the European Union standard for potable water (3) and the American Dental Association standards for DUWS (1). Samples of appropriate dilutions of biofilm and water samples were plated onto a range of selective and nonselective agar media. The media were (i) Columbia blood agar for oral streptococci, *Actinomyces* spp., and oral anaerobes (incubated anaerobically at 37°C for up to 10 days under a gas phase of 80% [vol/vol] CO_2–10% [vol/vol] H_2–10% [vol/vol] N_2) (colonies were assessed morphologically and by Gram staining); R2A agar for environmental isolates (29), incubated at 37°C for up to 7 days; (iii) CFC supplement SR103 for *Pseudomonas* spp. (27), incubated at 37°C for up to 48 h; (iv) MacConkey agar CM7 for enterobacteria (15), incubated at 37°C for up to 48 h; and (v) Sabouraud dextrose agar for *Candida* spp. (26), incubated for up to 7 days.

For the enumeration of *Legionella* and *Mycobacterium* spp., aliquots of the samples were pretreated either with heat (at 50°C in a water bath for 30 min) or with acid (1 ml of sample added to 1 ml of 1 M HCl for 15 min and then neutralized with KOH [4, 13]). Aliquots of untreated and treated samples were then plated onto BCYE agar for the enumeration of *Legionella* spp. (11), and the plates were incubated aerobically at 37°C for up to 10 days. Colonies morphologically typical of *Legionella* spp. were counted, and the serogroup was determined using a latex agglutination kit (Pro-Lab Diagnostic, Neston, United Kingdom). Similar aliquots were dispensed onto Middlebrook agar plus OADC 7H10 for *Mycobacterium* spp. (24) (incubated aerobically at 37°C for up to 30 days). Representative colonies were assessed using the Ziehl-Neelsen technique for the detection of acid-fast bacilli and examined microscopically.

Detection of viruses. Aliquots of each unfiltered water sample were frozen (−20°C) and transported frozen to the University of Liverpool. The level of HBsAg was measured by the Monolisa Ag HB Plus assay (Sanofi Pasteur, Guildford, United Kingdom). Samples (50 μl) were processed according to the manufacturer's instructions, and the resultant chromophore was read on a Dynex MR7000 plate reader at 420 and 620 nm. Positive and negative controls were included in every batch.

Microscopy and image analysis. The extent of biofouling in DUWS tubing was assessed by using image analysis. Lengths of tubing were aseptically sectioned into thin strips (approximately 2 to 3 mm wide) and stained for 1 min with 50 μl of prefiltered (0.2-μm pore size; Sartorious, Epsom, United Kingdom) propidium iodide (1 mg of stock · ml of sterile distilled $water^{-1}$; Sigma Poole, United Kingdom) before being gently rinsed twice in nonflowing sterile distilled water to remove planktonic and loosely adhered cells. The tubing surface was then examined using a Nikon Labophot 2 microscope with episcopic fluorescence and a 50× water immersion lens (33). Ten representative images were captured as computer images (TIFF) for analysis of percentage of coverage, using Optimas Software (Optimas Datacell, Finchhampstead, United Kingdom).

Viability assay. A 3-cm length of DUWS tubing was aseptically sectioned horizontally into four equal sections, with the control sample immersed in 4% (vol/vol) formalin (Western Solvents, Westbury, United Kingdom) for 10 min. Equal volumes of *Bac*Light (Molecular Probes, Eugene, Oreg.) reagents A and B were added to PBS to prepare the viability probe (final concentration, 3 μg/ml) (20). Control (killed) and test (untreated) samples were assayed with the *Bac*Light live/dead viability probe. Following a 15-min reaction, the samples were rinsed in nonflowing PBS to remove excess stain and assessed using the microscopy system described above. Microscopic counts of the stained cells were also carried out using an improved Neubauer counting chamber (Hawksley, London, United Kingdom) with the results compared against total plate counts.

Statistical analysis. Statistical analyses were carried out using Excel (Microsoft Office) and Statgraphics (STSC Inc., Rockville, Md.). Bacterial loads in different types of water (deionized, distilled, soft, and hard) and from DUWS with different water sources (main, bottle, or tank fed) were compared using a two-way analysis of variance (ANOVA) on log-transformed viable counts. Where significant differences were indicated by ANOVA, individual groups were then compared by the least-significant-difference method. Percentage coverage data were compared using the nonparametric Kruskal-Wallis test. Biofilm and planktonic counts from the same surgeries were also analyzed for correlation using the nonparametric Kendall rank correlation analysis. Statistical significance was assumed at a P value of <0.05.

RESULTS

Survey of general dental practices and sampling of DUWS. Fifty-five water line and air rotor water line fluid (planktonic) samples and 47 water line and air line biofilm samples were taken during the survey. Eleven surgeries used soft (<50 ppm $CaCO_3$) water, 33 used hard (>250 ppm $CaCO_3$) water, 9 used deionized water, and 2 used distilled water. Only 3 surgeries had tank-fed (break tank) DUWS, 32 used bottle-fed systems, and 20 had main-fed systems. Five of the 55 surgeries reported recent disinfection of their DUWS. For the purposes of clarity, each surgery was assigned a number, to which appropriate sections of the results refer.

Bacterial contamination of DUWS. (i) Water line microbial contamination. A geometric mean of 2.9×10^3 CFU of bacteria · ml^{-1} was recovered from the water of the DUWS (range, 7 CFU · ml^{-1} to 6.4×10^4 CFU · ml^{-1}). The number of bacteria recovered varied with the type of water supplied to the DUWS. Viable counts from distilled water were greater than those from hard, soft, or deionized water (Table 1). Similarly, more bacteria were recovered from units supplied by bottles than from those supplied by mains or tanks. However, the differences between DUWS types and between units supplied with different types of water were not significant at the 95% confidence level (two-way ANOVA, $P = 0.28$ and 0.58, respectively).

Surgeries 13, 14, 15, 16, and 43 had units that were reportedly sanitized (Fig. 1). Significantly greater numbers of bacteria were found in the water phase of units treated with disinfectant than in the untreated units (ANOVA, $P = 0.048$). A geometric mean of 1.6×10^4 CFU · ml^{-1} (range, 6.0×10^3 CFU · ml^{-1} to 3.6×10^4 CFU · ml^{-1}) was recovered from treated units' water, compared with a geometric mean of 2.8×10^3 CFU · ml^{-1} (range, 7.0 CFU · ml^{-1} to 6.4×10^4 CFU · ml^{-1}) from the untreated systems.

Notable bacterial species isolated from the water lines of the DUWS were slow-growing *Mycobacterium* spp. from surgeries 21, 22, and 44, *Fusobacterium* spp. from surgery 19, and fluorescent *Pseudomonas* spp. from surgeries 16, 32, 35, 47, and 48.

(ii) Air rotor water line microbial contamination. Similar numbers of bacteria (geometric mean, 3.3×10^3 CFU · ml^{-1}; range, not detectable to 9.5×10^4 CFU · ml^{-1}) (Table 1) were found in the water from the air rotor water line and the water line. The numbers of bacteria in air rotor line water were significantly different for different DUWS types (two-way ANOVA, $P = 0.04$), with the numbers of microorganisms from main-fed units being significantly greater than from the bottle-supplied units ($P < 0.05$). Higher numbers of bacteria were recovered from hard water than from deionized, distilled, or soft water (Table 1), though these differences did not quite reach significance (two-way ANOVA, $P = 0.055$).

The following specific microorganisms were detected from air rotor water line samples: *Candida* spp. from surgery 21 and fluorescent *Pseudomonas* spp. from surgeries 7, 16, 33, 35, 44, 47, and 49.

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TABLE 1. Comparison of viable counts from the DUWS water samples

Sample	Viable count (CFU · ml^{-1}) from water samples taken from:						*n*
	Water lines			Air rotor water lines			
	Geometric mean	Minimum	Maximum	Geometric mean	Minimum	Maximum	
Water type							
Soft	2,590	7	31,000	1,224	0	40,000	11
Hard	3,290	32	64,000	5,063	0	95,000	33
Deionized	1,740	68	40,000	2,699	55	30,000	9
Distilled	5,970	4,400	8,100	2,013	1,350	3,000	2
Supply type							
Tank fed	1,550	480	3,700	1,881	360	7,400	3
Bottle fed	3,583	7	36,000	1,802	0	95,000	32
Main fed	2,217	32	64,000	4,914	42	40,000	20
Total	2,874	7	64,000	3,325	0	95,000	55

(iii) Water line biofilm. A geometric mean of 9.2×10^2 CFU · cm^{-2} (range, not detectable to 6.4×10^4 CFU · cm^{-2}) was recovered from the water line biofilm of the DUWS (Table 2). More bacteria were recovered from the distilled-water units than from the hard-, soft-, or deionized-water units; similarly, more were recovered from the main-fed units than from those supplied with either bottled or tank water (Table 2). However, the differences between the numbers of CFU recovered from biofilms in different DUWS types and from units supplied with different types of water were not significant (two-way ANOVA, $P = 0.89$ and 0.91, respectively). The numbers of bacteria in biofilms were significantly associated with the numbers in the corresponding planktonic phase (Kendall rank correlation; $\tau = 0.31$, $P = 0.04$).

The numbers of bacteria recovered from the biofilms in the "sanitized" units (surgeries 13, 14, 15, 16, and 43) were significantly lower than the numbers recovered from the untreated surgeries (ANOVA, $P = 0.04$). *Mycobacterium* spp. were recovered from the biofilms of surgeries 4 and 23.

(iv) Air line biofilm. Significantly lower numbers of bacteria were found in the DUWS air lines than in the water lines. A geometric mean of 5.1×10^1 CFU · cm^{-2} (range, not detectable to 3.0×10^4 CFU · cm^{-2}) were recovered from the air lines, compared with a geometric mean of 9.2×10^2 CFU · cm^{-2} from the water line (paired *t* test, $P \ll 0.0001$) (Table 2).

However, a number of medically important bacteria were detected in air line biofilm samples: *L. pneumophila* in surgery

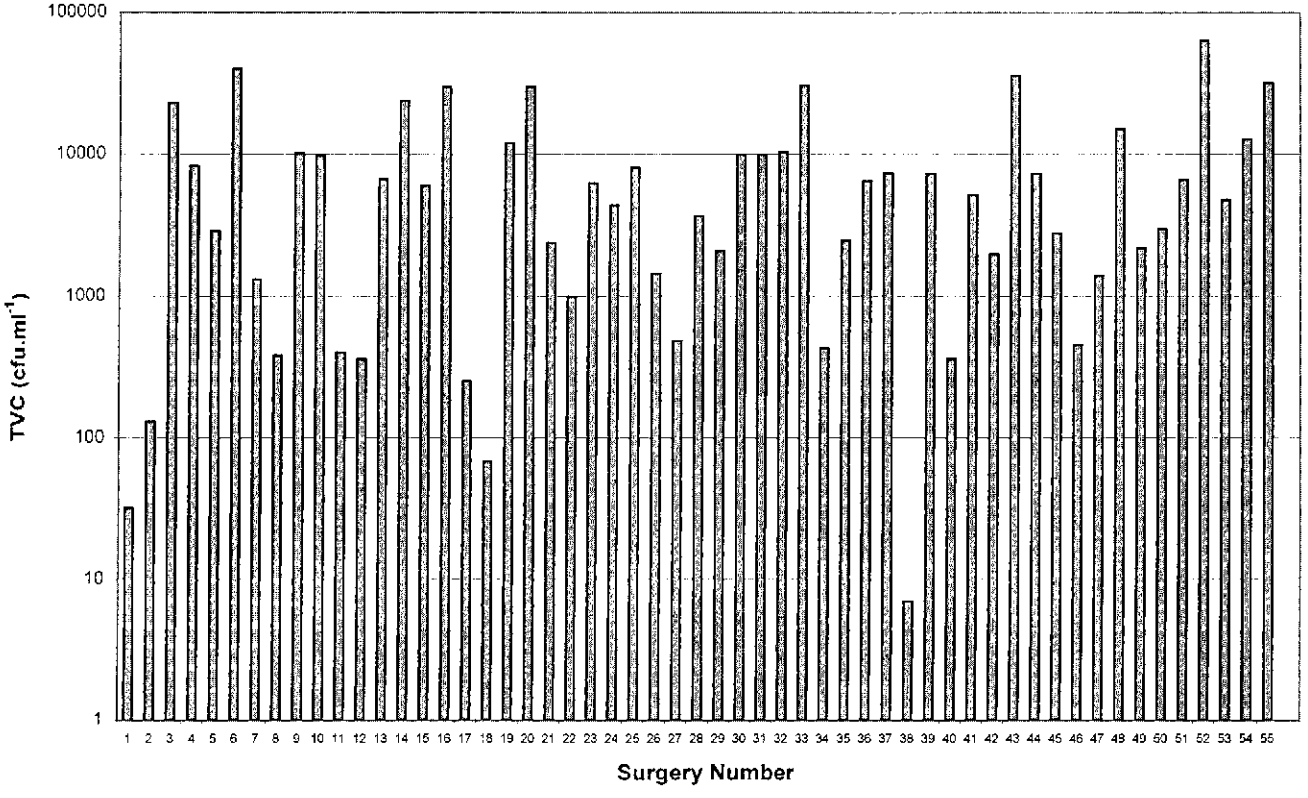

FIG. 1. Total viable counts (TVC) of water samples from DUWS in different dental surgeries.

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TABLE 2. Comparison of viable counts from the DUWS biofilm samples

Sample	Viable count (CFU · cm^{-2}) from biofilm samples taken from:						*n*
	Water lines			Air lines			
	Geometric mean	Minimum	Maximum	Geometric mean	Minimum	Maximum	
Water source							
Soft	892	2	42,000	33	0	30,000	10
Hard	1,103	0	64,000	85	0	3,200	27
Deionized	411	5	500	10	0	1,600	8
Distilled	2,200	1,100	4,400	259	12	5,600	2
Supply type							
Tank fed	1,268	40	8,800	33	0	2,000	3
Bottle fed	717	2	42,000	26	0	30,000	29
Main fed	1,383	0	64,000	199	0	30,000	15
Total	917	0	64,000	51	0	30,000	47

24, *Candida* spp. in surgery 30, and *Lactobacillus* spp. and *Streptococcus* spp. in surgery 19.

(v) Percentage of biofilm coverage in water and air lines. The average coverage of water line surfaces was 43% (range, 0.01 to 94%) (Table 3). Significantly less coverage was observed on the DUWS units supplied with soft water than on those supplied with hard, distilled, or deionized water (Kruskal-Wallis test, $P = 0.035$). The highest coverage was found on those units supplied with deionized water, followed by those using hard, distilled, and soft water (Table 3). There was no significant difference among units with different types of water supply, although it was observed that a higher percentage of coverage was recorded in the units supplied by water mains than in bottle- or tank-fed systems.

The results of the percent coverage analysis of the air line demonstrated that the average coverage was 5.2% (range, 0.1 to 74%) (Table 3). A higher degree of biofouling was observed on the tubing surfaces of those DUWS that were supplied with hard water than in those supplied by deionized, distilled, or soft water (Table 3). This difference was statistically significant (Kruskal-Wallis test, $P = 0.04$). In terms of the type of water supply, more extensive biofouling coverage was observed on those units supplied by mains water than on those supplied by tanks or bottles, although this difference was not significant (Kruskal-Wallis test, $P = 0.35$).

TABLE 3. Comparison of percentage of coverage from the DUWS biofilm samples

Sample	% Coverage from biofilm samples taken from:						*n*
	Water lines			Air lines			
	Avg	Minimum	Maximum	Avg	Minimum	Maximum	
Water source							
Soft	21	0.1	62	0.0	0.1	0.1	10
Hard	48	0.01	94	8.8	0.1	74	27
Deionized	54	0.5	94	1.9	0.1	6.4	8
Distilled	44	5	83	0.1	0.1	0.1	2
Supply type							
Tank fed	33	25	50	3.5	0.1	8	3
Bottle fed	41	10	94	2.9	0.1	64	29
Main fed	50	0.1	92	10	0.1	74	15
Total	43	0.01	94	5.2	0.1	74	47

(vi) Assessment of viability. Due to fluorescein binding to the DUWS tubing surfaces, viable cells could not be discriminated against the background; therefore, biofilm counts could not be assessed in situ using the *Bac*Light technique. Resuspended biofilm samples were analyzed and a mean of 68% of the total visible bacterial population was determined to be viable. A mean of 5% (three determinations) of this "viable by *Bac*Light" fraction produced viable colonies on agar plates.

(vii) Detection of viruses. None of the samples taken from the DUWS were positive for HBsAg.

DISCUSSION

Water supplied by 95% of general dental practice DUWS units failed current European Union potable-water guidelines on microbial load (i.e., loads were >100 CFU · ml^{-1}) (2), and 83% failed American Dental Association recommendations for DUWS water quality (<200 CFU · ml^{-1}) (1). The bacterial numbers reported here were comparable to those found in a number of other studies (6, 28) and lower than some (19, 35). These values probably underestimate the true microbial load to which a patient is exposed, since we also demonstrated that only 3% of the microscopically visible bacteria produced colonies on agar plates. Other bacteria may be either in a temporarily nonculturable state or may represent the large fraction of the microflora from many natural habitats which remain "as yet uncultured" (as discussed in the review by Barer and Harwood [7]).

The most common pathogens detected were fluorescent *Pseudomonas* spp. (16% of samples were positive). *L. pneumophila* was isolated on only one occasion, which was far less frequent than reported in previous studies in a dental hospital and in a mixture of institutional and private practices (25 and 6% isolation frequencies, respectively) (4, 8). Larger water distribution systems are known frequently to harbor this organism (C. L. Bartlett, J. B. Kurtz, J. G. Hutchison, G. C. Turner, and A. E. Wright, Letter, Lancet **ii:**1315, 1983). We detected *Mycobacterium* spp. in ca. 5% of surgeries, a lower detection rate than that reported by a previous study (30). These isolates were not identified, so their pathogenic potential is unknown, although several non-*Mycobacterium tuberculosis*, non-*Mycobacterium avium* species of mycobacteria are associated with a variety of infections in humans (18). Presumptive oral streptococci were identified in 7% of DUWS water samples, suggesting the failure of antiretraction devices in these systems and thus raising the possibility of cross-infec-

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tion between successive patients. No HBsAg was detected in any sample.

Some dentists perceive that certain types of DUWS may be less prone to microbial contamination than others. We found no significant differences between different DUWS systems, regardless of whether these systems were main, bottle, or header tank fed or whether the water supplied to them was hard, soft, deionized, or distilled. Thus, no DUWS can be considered superior in microbiological terms to any other or can be called microbiologically "clean." Water from air rotor lines and from 3-in-1 handpieces was contaminated to a similar degree, emphasizing that air rotors should not be used as an aid in any dental surgical procedures.

The significant correlation between the numbers of bacteria recovered from biofilms and from water samples from the same units suggests that the biofilms may seed the water with bacteria and vice versa. Strategies developed for the control of DUWS contamination must eliminate both the biofilms and the waterborne bacteria in these systems (23, 31, 36). In addition, although significantly lower levels of biofilm contamination were found in the five units reported to have been recently decontaminated, more bacteria were recovered from the water phase in these systems. Decontamination with detergents or with inorganic acids (including hypochlorous acid) could increase the risk of release of organisms from biofilms and thus increase the numbers of bacteria in the water phase (J. S. Colborne, P. J. Dennis, J. V. Lee, and M. R. Bailey, Letter, Lancet **i:**684, 1987). Inadequate decontamination regimens may thus increase the hazards associated with DUWS water.

In conclusion, improved, evidence-based practical methods for controlling the microbial contamination of DUWS are urgently needed. This is particularly important in view of the increasing numbers of medically compromised and immunocompromised patients receiving regular dental treatment.

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Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020

Overview of sample numbers and test results

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Introduction

The Queen Elizabeth University Hospital (QEUH) campus consists of two new hospital buildings, QEUH Adults and the Royal Hospital for Children (RHC), as well as several retained buildings that were already present on the site prior to the opening of the new buildings to patients in May 2015. This report focuses specifically on the new buildings, QEUH Adults and RHC, and covers the period January 2015 to December 2020. Data from the retained buildings are summarised in a separate report, *Water testing summary for the whole Queen Elizabeth University Hospital campus, 2015-2020* (DL Chaput). Legislation and guidance applicable to water testing on the QEUH campus are outwith the scope of this report but are summarised in a separate document, *Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC* (DL Chaput).

Section 1: Water testing gives a detailed summary of all water sampling conducted for microbiological analysis in the new buildings over this period. It includes routine and reactive test numbers and results for Legionella, Pseudomonas, potable water, fungi, Cupriavidus and other Gram negative bacteria, atypical mycobacteria, and other organism-specific tests. Water testing data were obtained from the QEUH Estates Department, from DMA Canyon Ltd, and from TelePath, the GG&C Laboratory Information Management System (see Appendices for a detailed list of data sources).

Section 2: Other environmental testing summarises additional environmental testing that was undertaken over this period in the new buildings, including swabs of drains, sinks, showers, and various dry surfaces. Environmental testing data were obtained from TelePath.

Data processing and analysis were carried out in R version 4.2.0, as detailed in the Appendices, and this report was written in Rmarkdown.

Section 1: Water testing

Protocols: Water sampling and microbiological testing

Water sampling

Collection of water samples from across the QEUH campus over the period 2015-2020 was carried out by two contractors, ALcontrol Laboratories and DMA Canyon Ltd, and by GG&C clinical staff in specific areas.

ALcontrol Laboratories (2015-2017)

ALcontrol Laboratories (hereafter referred to as ALcontrol) were a UKAS accredited water and environmental analysis service, contracted to carry out sampling and testing in the QEUH new buildings from April 2015 to January 2017. They were acquired by ALS Global in November 2016, and their website (www.alcontrol.com) now redirects to SGS Analytics.

ALcontrol collected water samples from the new buildings for Legionella testing on a monthly basis from April 2015 to June 2017. They sampled for potable water testing in April-May and Oct-Nov 2015, and again in Jan 2017. They also sampled for Pseudomonas testing every month from Nov 2015 to Mar 2016, with some additional Pseudomonas sampling in Sept 2016.

DMA Canyon Ltd (2016-2020)

DMA Canyon Ltd (hereafter referred to as DMA) are specialists in plumbing, water treatment, and water hygiene monitoring, contracted by GG&C to carry out water sampling on the QEUH campus over the period 2015-2020. They are registered with SNIPEF (Scottish and Northern Ireland Plumbing Employers' Federation), WaterSafe, and the Legionella Control Association, and hold ISO 9001 (quality management system), OHSAS 18001 (occupational health and safety), and ISO 14001 (environmental management system) certifications.

From January 2015 to August 2016, DMA conducted water sampling only in the retained buildings on the QEUH campus, while ALcontrol Laboratories sampled and tested water from the new buildings. From September 2016 onward, DMA's sampling schedule included the new buildings, but only for Pseudomonas or specific organism testing at the request of IPC/IMTs (e.g. Serratia, *Elizabethkingia miricola*, Stenotrophomonas). DMA began collecting samples on a monthly basis for routine Legionella testing in the new buildings in July 2017 (taking over from ALcontrol), and began sampling for potable testing in the new buildings in April 2018.

DMA followed industry standard methods for water sample collection, with protocols specific to the type of outlet being sampled (tap, shower, storage tank, etc., hot, cold or mixed, with or without point-of-use filter, etc.) and to the type of microbiological analysis required (e.g. potable, Pseudomonas, Legionella). Where applicable, DMA's protocols aligned with those described in the Scottish Health Technical Memoranda (SHTM), notably *SHTM 04-01 Water safety for healthcare premises Part B: Operational management (2014)*, as well as meeting the requirements set out in relevant Health and Safety Executive documents specific to Legionella control (see separate report for overview of applicable guidance and legislation).

Specialist units (new buildings)

A small number of specialist units in the QEUH new buildings had specific sampling and testing arrangements: the aseptic pharmacies in QEUH Adults and RHC, and the RHC Theatre 8, for cardiology procedures. In these areas, waters were (and continue to be) sampled routinely by GG&C clinical teams onsite. There is no involvement of Estates or external sampling contractors in this arrangement.

Testing laboratories

ALcontrol

Water samples collected by ALcontrol over the period 2015-2017 were analysed by their own UKAS accredited microbiological testing laboratory. The results were not entered into the GG&C TelePath system. Data sheets generated by ALcontrol were held by QEUH Estates.

GG&C Environmental Laboratory

The NHS GG&C Environmental Laboratory (hereafter referred to as the Environmental Laboratory) forms part of the Clinical Microbiology Department, located in the New Lister Building at the Glasgow Royal Infirmary. It is UKAS-accredited to ISO/IEC 17025:2017 for analysis of potable, endoscopy and renal waters, and air samples. Target microorganisms covered by this accreditation include *Legionella* species, coliforms and *Escherichia coli*, *Pseudomonas* species, atypical mycobacteria, as well as yeasts and moulds. Gram negative investigations are not specifically covered by the current UKAS accreditation but most of the methods involved are covered by other accredited protocols. The Environmental Laboratory has been UKAS-accredited for *Legionella* testing for many years and has therefore maintained high quality, training and calibration standards. Accreditation for the other tests was granted in April 2020 following a UKAS assessment in September 2019. Prior to this, the Environmental Laboratory was working towards UKAS accreditation for these tests and was therefore operating to these standards.

The Environmental Laboratory has had a long-standing arrangement with the clinical teams in the specialist units described above (the aseptic pharmacies and RHC Theatre 8). From 2015 onward, samples collected from these units were sent to the Environmental Laboratory for testing. Results were reported directly back to the clinical teams.

The Environmental Laboratory was also the main microbiological testing laboratory for both routine and reactive samples collected by DMA throughout the period 2015-2020. Results were reported back to DMA, who incorporated the microbiological findings into spreadsheets with sampling metadata (sampling date, location, type of outlet, etc.) and then sent the completed data sheets to QEUH Estates Department and, from mid-2018 onward, to contacts in Microbiology and IPC.

In addition to sending testing results back to the requestor (specialist unit clinical teams or DMA), the Environmental Laboratory maintained paper copies from 2015 to March 2017. From April 2017, all results from the Environmental Laboratory were uploaded to

the GG&C TelePath system, and earlier results from 2015 to March 2017 were retrospectively entered into TelePath.

Intertek

Intertek is a global quality assurance company that provides testing services for numerous industries, including water and air quality monitoring. Its water microbiology analysis service is carried out to Drinking Water Directive 98/83/EC standards (Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, European Union legislation).

From December 2018 onward, due to the large increase in the number of water samples collected from the new buildings for microbiological analysis, a subset of the routine water samples collected by DMA from sentinel outlets was sent to Intertek for testing instead of the Environmental Laboratory, who tested the remaining routine and reactive samples.

Intertek reported its results to DMA, who incorporated them into the data sheets with sampling metadata and results from the Environmental Laboratory, then disseminated to Estates and contacts in IPC and Microbiology. Since Intertek is an external contractor, its microbiological test results were not uploaded to the GG&C TelePath system, which only holds water testing data from the Environmental Laboratory.

Microbiological test types

Water testing can be broadly classified as either routine (for monitoring purposes) or reactive (for investigation). Routine water samples collected by ALcontrol, DMA, or clinical teams in specialist units underwent one or more of the standard microbiological investigations listed in Table 1. Routine Legionella, Pseudomonas, and potable testing occurred throughout 2015-2020, while other routine tests were added at various points in specific areas of the new buildings. Testing for Cupriavidus and other Gram negative bacteria (GNBs) began with a large reactive sampling effort in early 2018, followed by implementation of routine testing for these organisms from Dec 2018. Routine fungal testing began in Dec 2018, and testing for atypical mycobacterial species (AMS) in specific areas of the new buildings began in Apr 2019. Where reactive sampling was carried out specifically to assist IPC/IMTs, *ad hoc* tests for specific microorganisms were instead ordered, often in conjunction with one or more of the routine tests.

Table 1 shows the routine water tests commonly carried out in QEUH Adults and RHC. All three laboratories (Environmental Laboratory, ALcontrol, and Intertek) performed the standard potable, Pseudomonas and Legionella tests, though Intertek did not include a separate PA100 in its Pseudomonas testing, and the Environmental Laboratory and ALcontrol included it only in a subset of their Pseudomonas tests. Routine fungal testing was carried out by both the Environmental Laboratory and Intertek, whereas routine testing for other organisms, some of which was bespoke to GG&C (e.g. Cupriavidus/GNBs) was carried out by the Environmental Laboratory. The Environmental Laboratory SOP entitled *LP538 Non Legionella Water Testing: Potable Water & Endoscopy Analysis (LP538)* details its testing, control, and reporting procedures, as well as its operating thresholds for out-of-spec results. The SOP has a procedure in place for *ad hoc* investigations requested by IPC teams. Legionella testing is covered by

the Environmental Laboratory's SOP entitled *LP532 Detection & Enumeration of Legionella by Filtration*.

For the purpose of microbiological water testing and reporting, specific areas in the new buildings have been designated as high risk by the QEUH Estates Department and IPC, as detailed in the QEUH Estates Department SOP entitled *WQS-017 Procedures in the event of out of specification sample for Legionella and other monitored bacteria, moulds etc.*. High-risk areas include transplant and haematology units, intensive care and high dependency units, and others (see Supplemental Information for details on which wards are classified as high risk). Stricter water testing thresholds are applied in these areas (Table 1). In addition, the specialist units within the new buildings (aseptic pharmacies and RHC Theatre 8) that have their own testing arrangements also have different thresholds. Outwith these high-risk and specialist areas, general microbiological thresholds are applied across the new buildings.

Table 1. Routine water tests and count thresholds for out-of-spec results

Test	Type	Description	Thresholds (general)	Thresholds (high risk)	Thresholds (specialist)
Legionella	Legionella	Legionella count per 1L (any species/serogroup)	Any count	Any count	Any count
PS100	Pseudomonas	Pseudomonas species count per 100 ml	10 CFU/100 ml	Any count	Any count
PA100	Pseudomonas	*Pseudomonas aeruginosa* count per 100 ml	10 CFU/100 ml	Any count	Any count
TVC37	potable	Total viable count (37°C) per 1 ml	100 CFU/ml	10 CFU/ml	10 CFU/ml
TVC22	potable	Total viable count (22°C) per 1 ml	100 CFU/ml	10 CFU/ml	100 CFU/ml
CF100	potable	Coliform count per 100 ml	Any count	Any count	Any count
EC100	potable	*Escherichia coli* count per 100 ml	Any count	Any count	Any count
SAB30	fungi	Fungal count at 30°C	10 CFU/100 ml	10 CFU/100 ml	NA
SAB22	fungi	Fungal count at 22°C	10 CFU/100 ml	10 CFU/100 ml	NA
GNB	Gram negative bacteria incl. Cupriavidus	GNB count per 100 ml	Any count	Any count	NA
AMS	Atypical mycobacteria	AMS count per 100 ml	Any count	Any count	Any count

The thresholds shown in Table 1 are those currently applied to different areas of the new buildings. Not all of these thresholds would have been in place throughout the period 2015-2020. Routine fungal and GNB testing began in Dec 2018, whereas AMS testing began in Apr 2019, and the more stringent TVC thresholds for high-risk areas were

introduced in Dec 2018. A large amount of reactive testing specifically for Cupriavidus was carried out in March-Apr 2018, but routine testing for this organism was only described in WQS-017 in Dec 2018. An outline of the thresholds used for each routine test throughout the period 2015-2020 can be found in the report entitled *Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC*.

Water testing numbers 2015-2020

Table 2 shows the annual numbers of water samples collected and the numbers of different microbiological tests that were carried out in the new buildings. There was a marked increase in sample and test numbers in 2019-2020 compared with the earlier years, due to the expanded programme of sampling and testing that was implemented in the new buildings in Dec 2018 to coincide with the installation of on-site chlorine dioxide dosing systems.

Table 2. Annual numbers of water samples and microbiological tests carried out in the QEUH new buildings (Adults and RHC)

Year	Number of samples[1]	Legionella tests	Pseudomonas tests	Potable tests	Fungal tests	Cupriavidus/ GNB tests[2]	AMS tests	Other specific tests
2015	2189	1280	390	637	0	0	0	0
2016	1885	1542	390	181	0	0	0	50
2017	1097	706	379	166	0	0	0	161
2018	3968	1548	547	554	400	2027	0	81
2019	4753	2916	3893	4194	3211	652	412	81
2020	6625	2926	5532	5628	2429	3504	517	124
Total	20 517	10 918	11 131	11 360	6040	6 183	929	497

[1]Samples were frequently booked in for more than one type of test.
[2]Reactive testing for Cupriavidus and other GNBs was predominantly carried out in Mar-Apr 2018, with routine testing for these organisms implemented in Dec 2018.

Samples were often booked in for more than one type of test, so there is some incomplete overlap between test numbers. A summary of all test requests is shown in Figure 1. This includes the routine tests as well as each of the reactive tests for a specific named microorganism and *ad hoc* tests, such as TVC per 100 mL. The largest number of samples underwent only Legionella testing, followed by the number of samples that underwent two or more of the standard tests (Legionella, Pseudomonas, potable, fungi). Monthly test numbers in different areas of the new buildings are shown in the following section (Microbiological test results) for each routine test.

Although a broad distinction can be made between routine and reactive water testing, in reality, over the period 2015-2020, this distinction was more nuanced due to variations in the tests ordered by IPC teams during reactive sampling, which differed among IPC doctors and also with the nature of the IMT investigation. In some instances, the reactive tests ordered were for one or two specific microorganisms, but in other cases, a broader suite of general tests was requested instead of or alongside specific microorganism tests. Occasionally, rather than requesting tests for a specific organism, IPC/IMTs requested an *ad hoc* version of a general test, notably TVC per 100 ml, which is carried out by filtration and allows subsequent identification of any colonies that grow, rather than the standard TVC per ml, carried out by the pour plate method, where colonies are embedded in agar and cannot subsequently be identified.

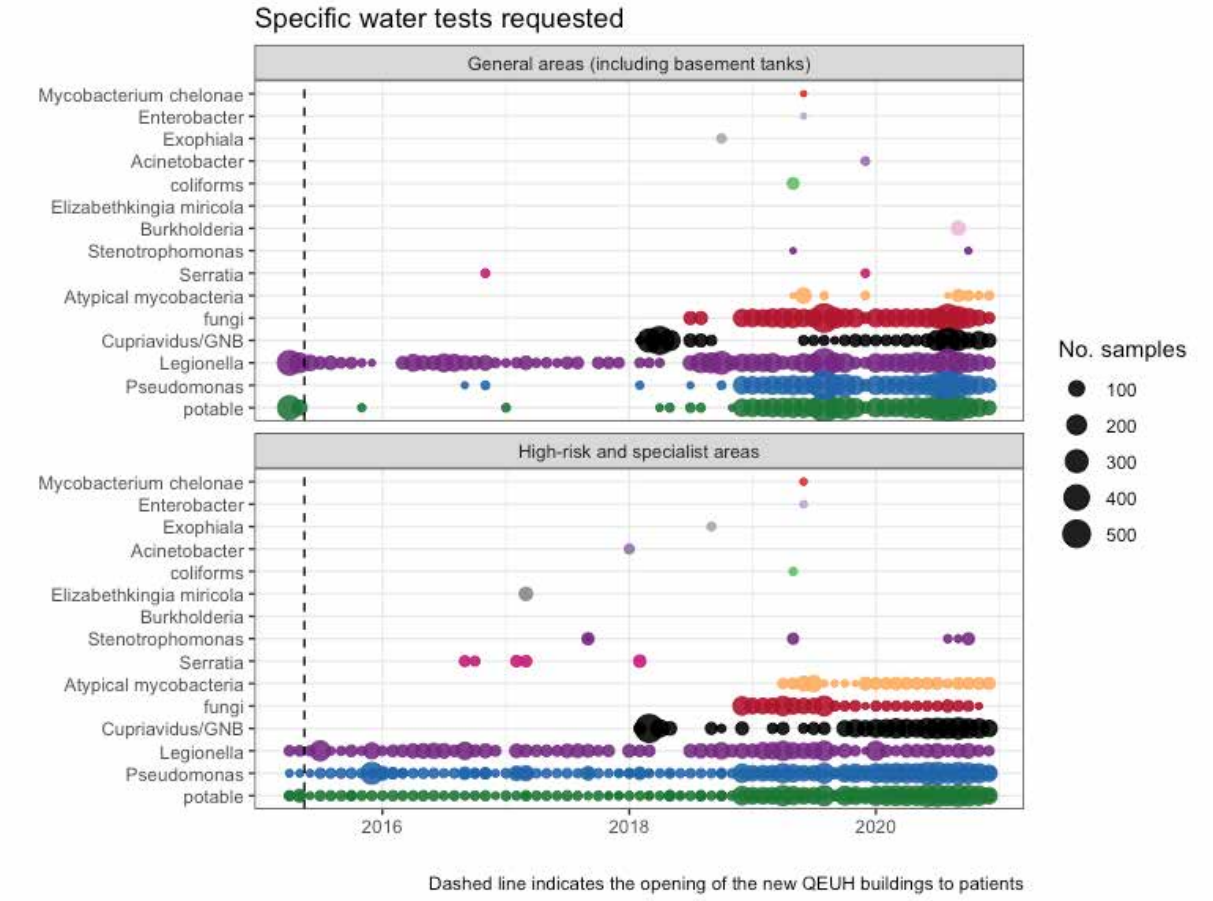

Figure 1. Types of microbiological tests requested across general and high-risk areas of QEUH Adults and RHC, 2015-2020. Specialist units are grouped with high-risk areas. Circle size is proportional to the number of tests per month.

Figure 1 shows the tests that were requested at the time of sampling, not an indication of the microbiological results that were subsequently reported (microbiological results are presented in the next section). The test(s) requested on the sample login sheets did not generally constrain the identification of microorganisms, as the Environmental Laboratory routinely identified organisms that grew in general tests, as well as non-target species that grew in specific tests (see below).

Microbiological results: Out-of-spec samples

This section shows the number of samples classified as passes or out of spec on Legionella, Pseudomonas, potable, fungal, Cupriavidus/GNB, and AMS tests over the period 2015-2020 (a sample is deemed out of spec when the microbial counts exceeded the thresholds set by GG&C, outlined in Table 1). Samples are split into four groups: general areas; high-risk areas (including specialist units); and two parts of the basement tank system that feeds both QEUH Adults and RHC – pre/intra-filtration (including any dip or drain sample from the raw water storage tanks or the sampling points within the filter units) and post-filtration (including any dip or drain sample from the bulk filtrate tanks, where water is stored after filtration but before supplementation with chlorine dioxide).

However, while this section gives a broad overview of sample numbers, it does not delve further into the nature of the out-of-spec samples or the sampling context - whether a point-of-use (POU) filter was fitted and if so, whether the sample was taken through the POU filter or after its removal, whether the sample was collected before or after outlet flushing, whether it was a repeat sampling following an earlier out-of-spec result, etc. A more detailed summary of all named organism results, including target and non-target species reported from specific tests, will be shown in the following section.

Of the routine microbiological water tests carried out by GG&C, only those for Legionella and Pseudomonas have required or recommended thresholds in applicable legislation and guidance, and the GG&C thresholds in Table 1 meet or exceed those requirements or recommendations (for more details, refer to the report entitled *Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC*). Coliform and *E. coli* tests, included in the potable water panel of tests, also have legal thresholds for water to meet potable standards (any count is considered out of spec), but routine potable testing is not required in healthcare settings except in specific circumstances (see the summary of legislation and guidance report).

The thresholds used in this section to classify samples as passes or out of spec are those currently in place for the QEUH campus and listed in Table 1, with appropriate thresholds applied to samples depending on whether they were from general, high-risk, or specialist areas. However, it is important to note that here, in order to allow a valid comparison of water results over the period 2015-2020, the current thresholds are being applied retrospectively to samples that were collected before some of these thresholds were in place, including the more stringent high-risk TVC22 threshold (10 CFU/mL) that was implemented in Dec 2018. This will classify some samples as out of spec that would not have been considered out of spec at the time, but a temporal comparison is only valid if the same thresholds are applied throughout the period under consideration. Table 3 shows the percent of samples classified as out of spec per year (using current thresholds) on each microbiological test.

Table 3. Percent of samples out of spec for each test, using current thresholds

Year	Legionella	Pseudomonas (reported)[1]	Pseudomonas (corrected)[1]	Potable	Fungi	Cupriavidus[2]	Other GNB[3]	AMS
2015	10.70	11.54	7.95	32.18				
2016	13.55	24.36	4.87	3.31				
2017	0.42	0.00	0.00	12.05				
2018	1.42	0.18	0.18	1.44	4.50	11.05	24.72	
2019	0.17	0.85	0.85	6.08	8.13	3.22	5.52	20.15
2020	0.07	0.40	0.40	3.07	13.42	0.86	11.36	0.39

[1]Some Pseudomonas counts reported in 2015-2016 are likely transcription errors. This column is based on corrected entries, without transcription errors (see Pseudomonas section below for details).
[2]Cupriavidus (which is a GNB) and other GNBs are detected on the same microbiological test, but as they tend to be reported as two separate results, they are given separate columns here.
[3]Other GNB includes only the samples that were negative for Cupriavidus but positive for another GNB. It does not include the small number of samples that were Cupriavidus-positive and also positive for another GNB, since these are already counted in the Cupriavidus column.

The current process for dealing with out-of-spec water results on the QEUH campus is detailed in the QEUH Estates Department SOP WQS-017. Briefly, when the Environmental Laboratory and Intertek send microbiological results to DMA, any out-of-spec samples are flagged and their details entered in a dedicated spreadsheet (out-of-spec summary sheet). Full results, including the out-of-spec summary sheet, are shared with QEUH Estates, GG&C Microbiology, and contacts in IPC. Any serious issues are immediately reported to the Lead Authorised Person (LAP) in QEUH Estates. For all out-of-spec samples, the LAP logs an Incident Report, which triggers a work request for remedial action. All remedial work is logged on the out-of-spec summary sheet, and DMA continue sampling the affected outlets until a minimum of three clear results are obtained.

Legionella test results

Overall, 10 918 samples from the new buildings underwent Legionella testing over the period 2015-2020. Here, any detection of Legionella was considered out of spec, regardless of location, species or serogroup, a stricter threshold than in applicable legislation and guidance. Over the period 2015-2020, there were 378 out-of-spec samples in total (3.5% of samples). The majority of out-of-spec samples were from general areas (360 out-of-spec samples out of 5798, i.e. 6.2%) and were concentrated in the earlier part of the period, in 2015-2016. High-risk areas had 17 out-of-spec samples over the entire period 2015-2020, out of 3909 samples (0.43%). There were no Legionella detected in the 824 samples from the basement tank system (pre/intra-filtration), and one Legionella positive sample out of 387 from the post-filtration basement tanks (0.26%). Monthly numbers of Legionella samples that were out of spec versus those that passed are shown in Figure 2.

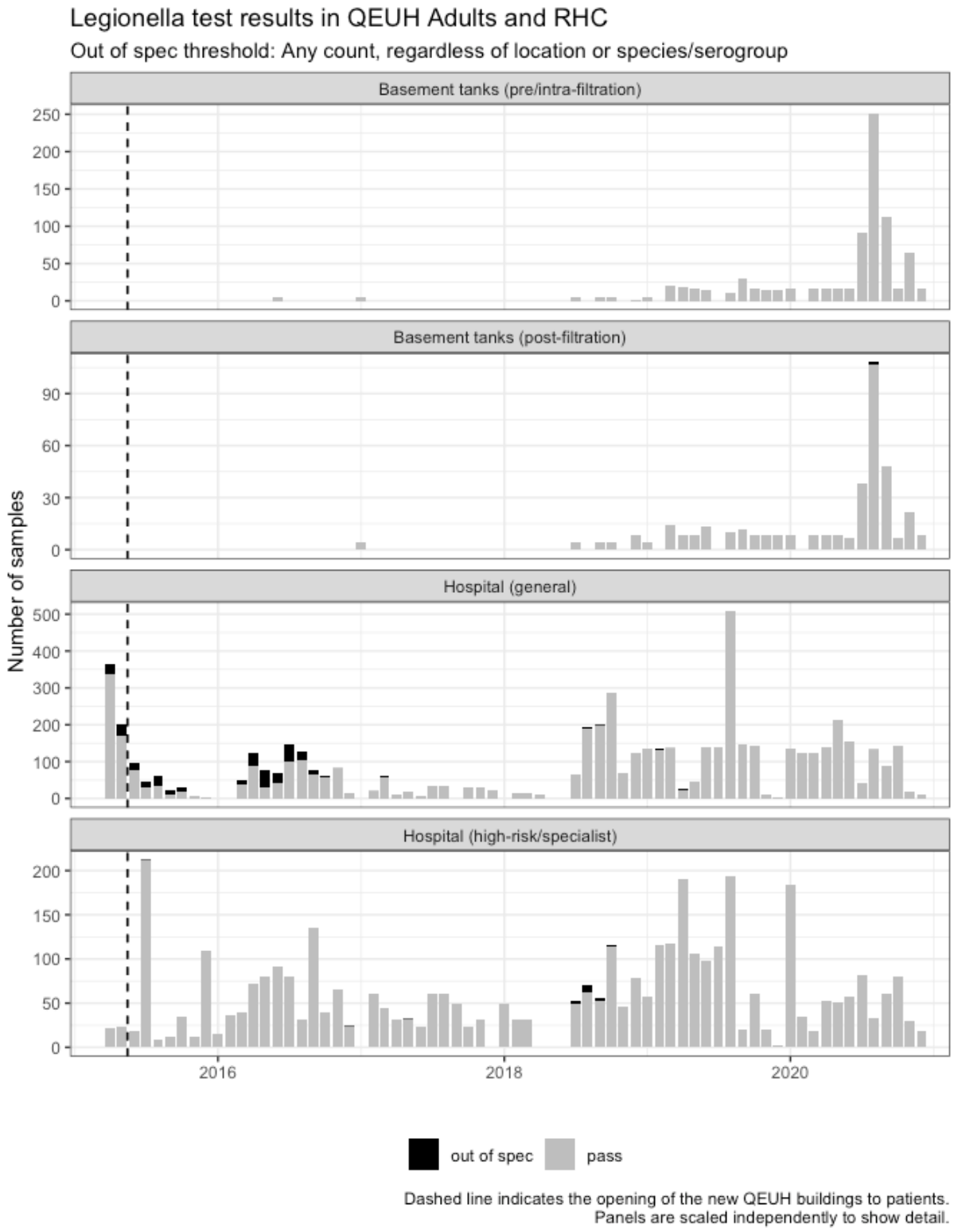

Figure 2. Number of Legionella tests out of spec per month in different areas of QEUH Adults and RHC. Panels are scaled independently to show detail.

Figure 2 gives the number and distribution of samples that had any Legionella count, regardless of species and serogroup. However, when Legionella counts are detected, the testing laboratories provide additional species and serogroup information to distinguish

between the following: *Legionella pneumophila* serogroup 1, the variant that causes approximately 95% of human cases (Lp.1), *Legionella pneumophila* serogroups 2 to 14 (Lp.2-14), or other Legionella species (L.species). Figure 3 shows the species/serogroup results for these out-of-spec samples.

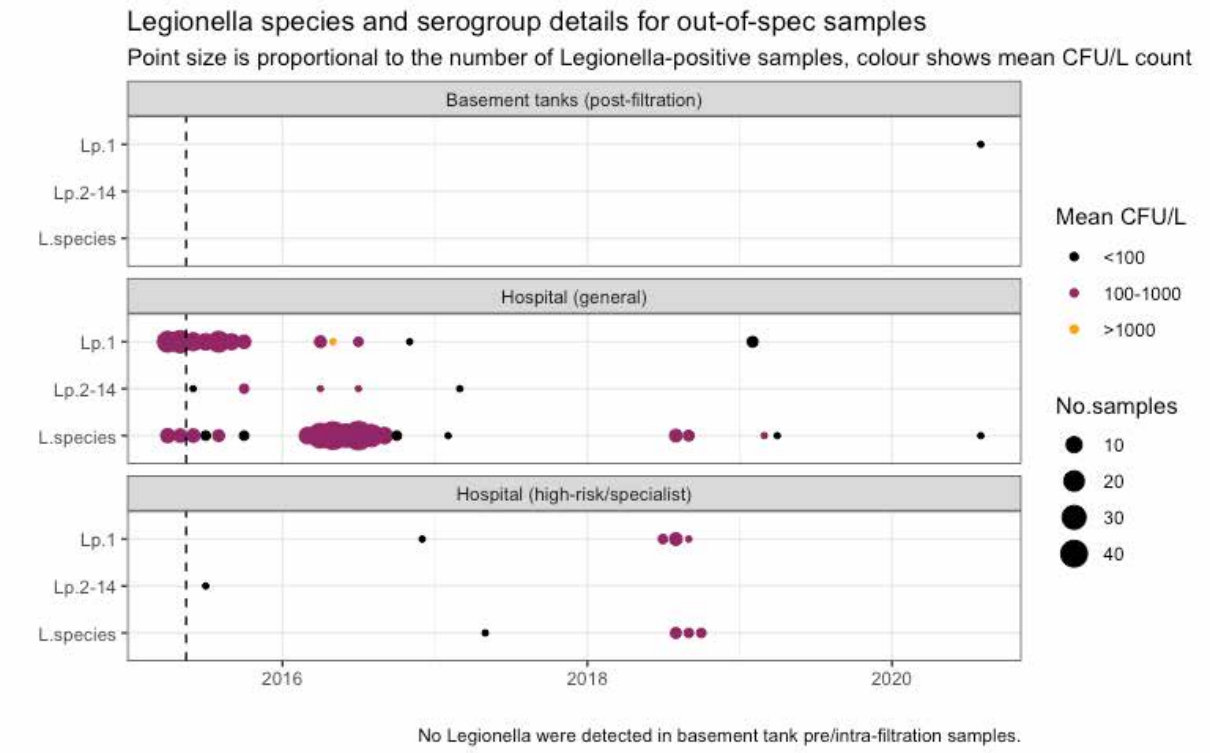

Figure 3. Legionella species and serogroup details for out of spec samples in QEUH Adults and RHC.

Legionella pneumophila serogroup 1 (Lp.1) was rarely detected in the new buildings after late 2015. Samples testing positive for Lp.1 were concentrated in the months prior to and immediately following opening. *Legionella pneumophila* serogroups 2-14 were almost absent from the new buildings over the entire period, and other Legionella species were detected only sporadically, with the largest occurrence in 2016.

Pseudomonas test results

It is important to note a possible data entry or transcription error that might be inflating the Pseudomonas out-of-spec results in 2015-2016. In the new buildings, out-of-spec Pseudomonas results were reported mostly over the period Jul 2015 to Sep 2016, with few out-of-spec Pseudomonas results after that date. Most of these samples were from the new building aseptic pharmacies, apart from the larger number of samples collected in Dec 2015 from other areas. Closer inspection of the data recorded in TelePath shows that for most of the CFU counts recorded in the PS100 column for the aseptic pharmacies and for Ward 1D (PICU) over this period, an identical number was also entered in another data column reserved for other named organisms, next to a named species (often

Cupriavidus pauculus but occasionally other species, including *Comamonas testosteroni*, *Achromobacter denitrificans*, and *Alcaligenes faecalis*). This exact duplication of counts suggests that the numbers reported in the PS100 column from Jul 2015 to Sept 2016 (excluding Dec 2015) were the total colonies on the Pseudomonas agar plates, not those that had been confirmed as Pseudomonas, and that these colonies were subsequently identified as belonging to other species. If this were the case, most of the Pseudomonas out-of-spec samples over this period would instead be passes. This section shows both the reported Pseudomonas results, including these likely transcription errors, and the corrected Pseudomonas results, where these duplicated counts are excluded.

Overall, 11 131 samples from the new buildings underwent Pseudomonas testing. Thresholds for Pseudomonas tests (PS100 or PA100) differ by location (Table 1): 10 CFU/100 mL in general areas, and no count in high-risk and specialist areas. Over the period 2015-2020, there were 196 reported out-of-spec samples in total (1.8% of samples), though this number drops to 106 out-of-spec samples (0.95%) when likely transcription errors are corrected (transcription errors only affected samples from specialist and high-risk areas - the aseptic pharmacies and PICU).

In the basement tank system, most Pseudomonas out-of-spec results were in the pre/intra-filtration samples (32 samples out of 930, or 3.4%) and not in the post-filtration tank samples (2 samples out of 401, or 0.5%). In general areas, 3 samples out of 3758 (0.08%) were out of spec, whereas in high-risk areas and specialist areas, where the stricter threshold applies, 159 samples out of 6042 (2.6%) were out of spec, though this drops to 69 samples (1.1%) when likely transcription errors are taken into account. Total Pseudomonas passes and out-of-spec results (both reported and corrected) in these four areas of the new buildings, grouped by month, are shown in Figure 4.

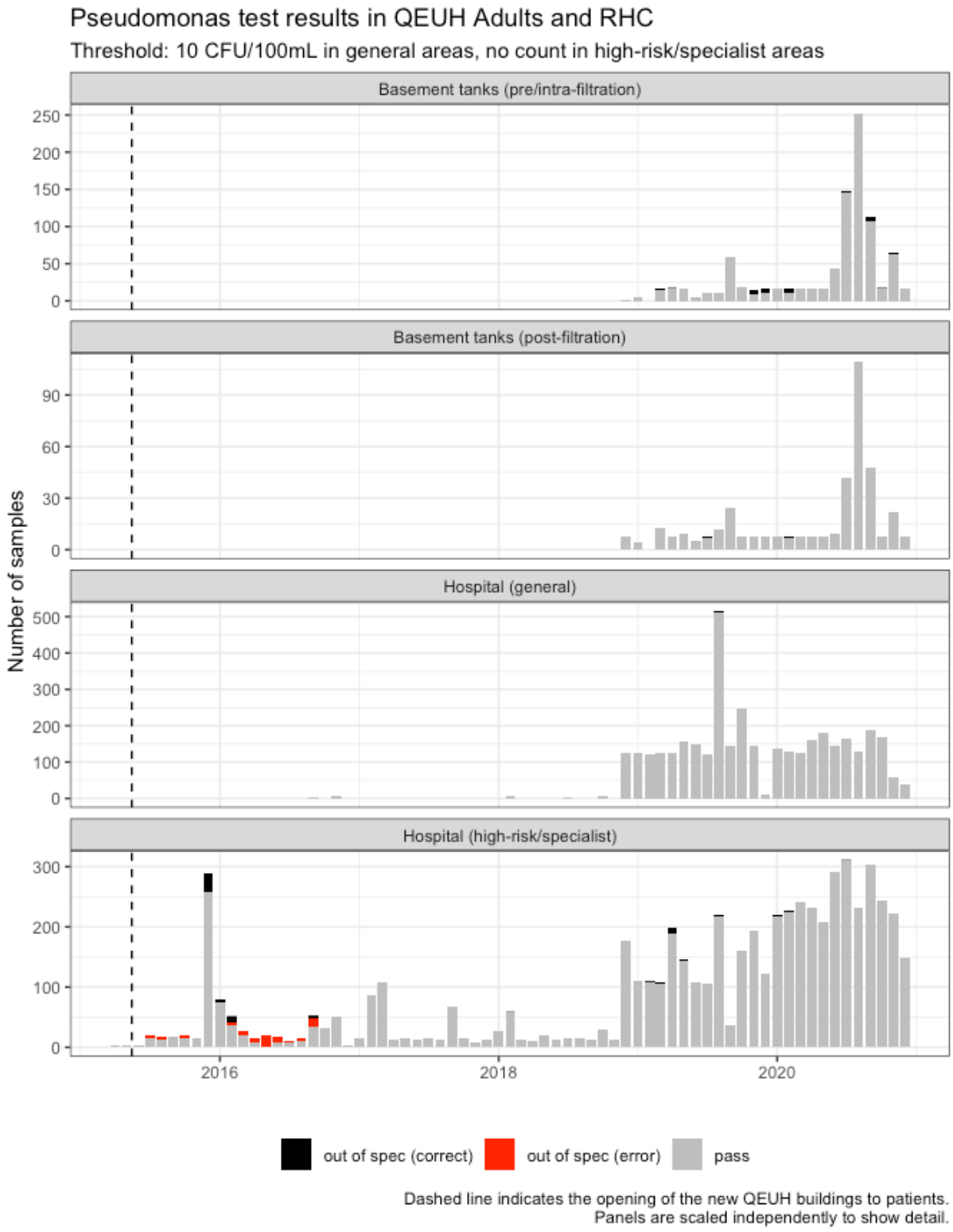

Figure 4. Number of Pseudomonas tests out of spec per month in QEUH Adults and RHC. Panels are scaled independently to show detail. Black bars show true out-of-spec samples, red bars show samples with reported counts that are likely transcription errors and should be considered passes.

Potable water tests

Potable water samples include all those with microbiological results for TVC37, TVC22, CF100 and EC100. Of the 11 360 potable tests carried out in the new buildings over the period 2015-2020, 667 (5.9%) were out of spec (using the current thresholds). The majority of out-of-spec samples were due to elevated TVC22 (476 samples in total, i.e. 4.2%) and/or TVC37 (364 samples in total, i.e. 3.2%) (Figure 5). CF100 (coliforms per 100 mL) counts were less often responsible for out-of-spec results (59 samples in total, i.e. 0.52%), and EC100 counts (*Escherichia coli* per 100 mL) were only observed in three samples (0.026%).

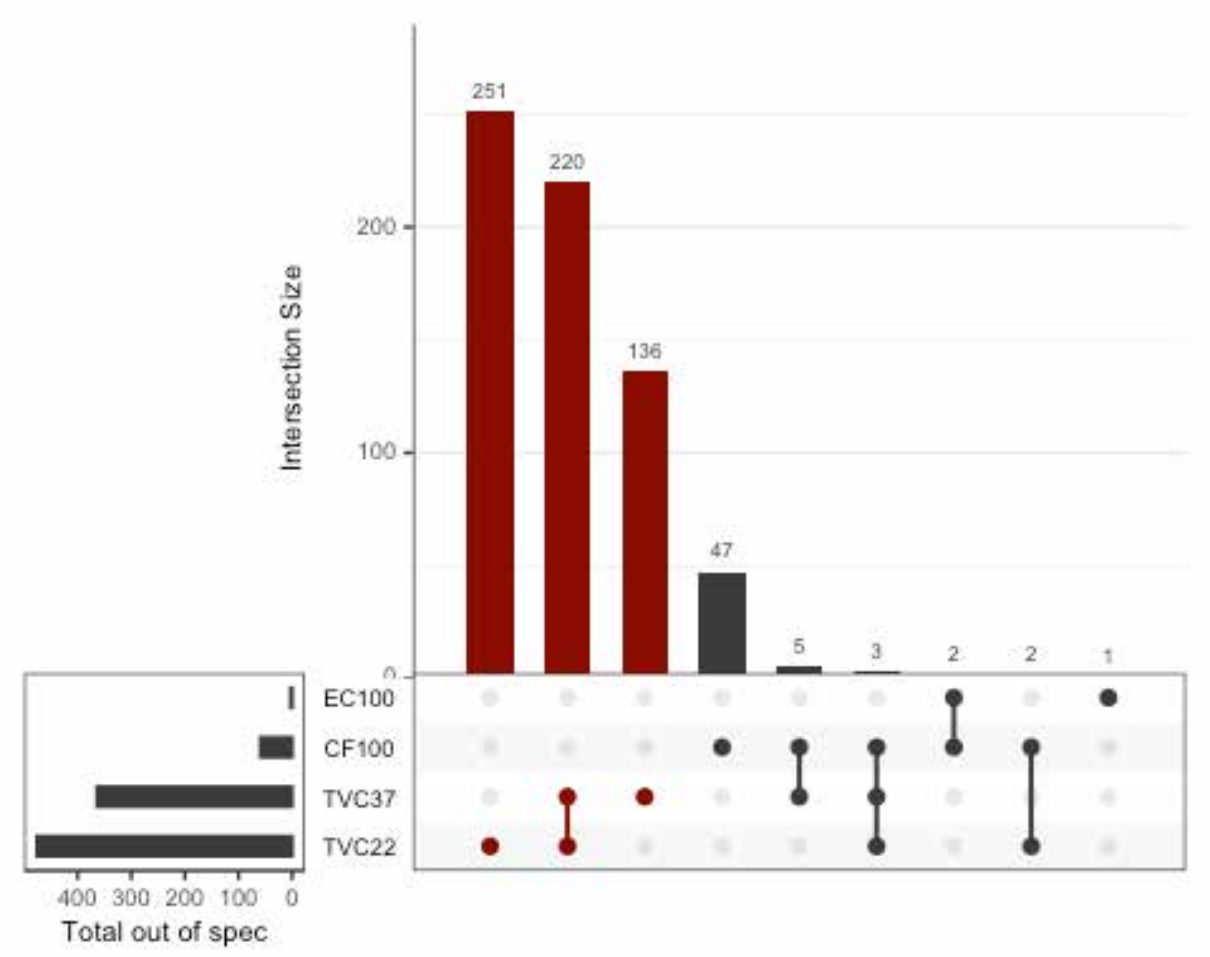

Figure 5. Specific tests responsible for potable water out-of-spec results in the new buildings 2015-2020. Red bars indicate the number of samples that were out of spec on TVCs only, black bars show number of samples with out-of-spec results in CF100 and/or EC100.

Thresholds currently in place for potable testing vary by location, with the strictest ones being applied in high-risk areas (10 CFU/mL on both TVC22 and TVC37), intermediate ones in specialist units (10 CFU/mL on TVC37, 100 CFU/mL on TVC22), and less stringent ones in general areas (100 CFU/mL on both TVC37 and TVC22). Coliform and *E. coli* counts must be zero in all areas.

The highest percentage of potable out-of-spec results was in the pre/intra-filter basement tank samples (81 out of 953 samples, i.e. 8.5%), whereas the proportion out of spec was lower in the post-filtration basement tanks (12 out of 420 samples, i.e. 2.9%). General areas had a slightly higher proportion of out-of-spec samples (268 out of 4367 samples, i.e. 6.1%) than high-risk and specialist areas (306 out of 5620 samples, i.e. 5.4%), despite the latter having stricter thresholds.

Figure 6 shows the number of potable water samples, grouped by month, that passed all four potable tests, versus the number that were out of spec according to the current thresholds (i.e. they exceeded thresholds on one or more of the four tests).

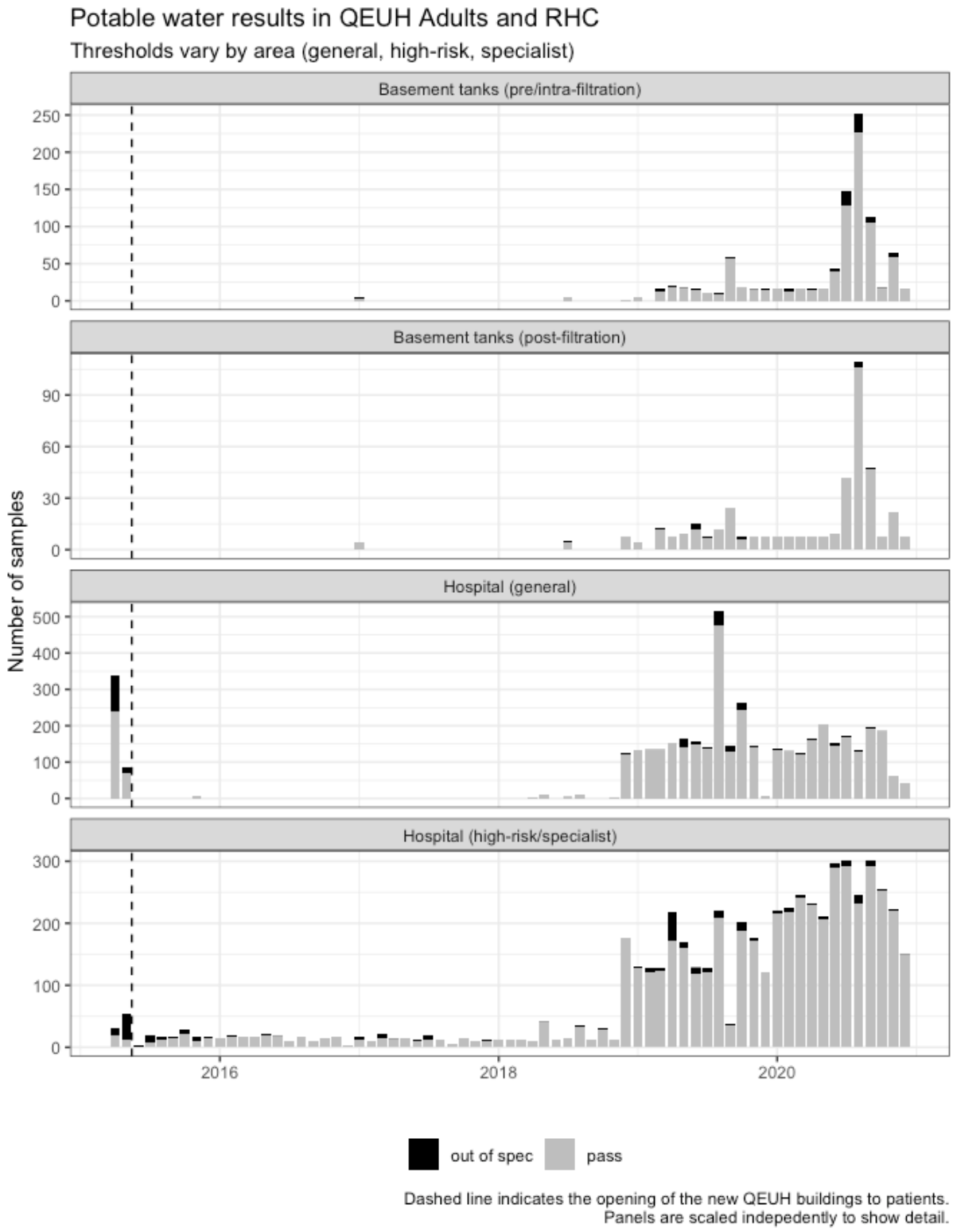

Figure 6. Number of potable tests out of spec per month in QEUH Adults and RHC. Panels are scaled independently to show detail.

Fungal test results

Routine fungal testing (SAB30 and SAB22 tests) began in December 2018. There are currently no recommended thresholds for this type of testing in guidance or legislation, so GG&C apply the threshold listed in Table 1: 10 CFU/100 mL in general and high-risk areas (routine fungal testing is not carried out in the specialist units).

Overall, 6040 samples from the new buildings underwent fungal testing over the period 2015-2020. There were 605 out-of-spec samples in total (10.0% of samples). Over half of all out-of-spec results were from the pre/intra-filter basement tank samples, where the percent out of spec was 37.5% (348 out of 927 samples). The percent out of spec dropped to 6.1% in the post-filtration basement tanks (24 out of 396 samples). Samples from the hospital areas had a lower percent out of spec than the post-filtration basement tanks, with general areas being slightly higher in proportion of out-of-spec samples (167 out of 3284 samples, i.e. 5.1%) than high-risk areas (66 out of 1433 samples, i.e. 4.6%).

Figure 7 shows the number of fungal samples, grouped by month, from each of the four areas (basement pre/intra-filtration, basement post-filtration, hospital general, and hospital high-risk).

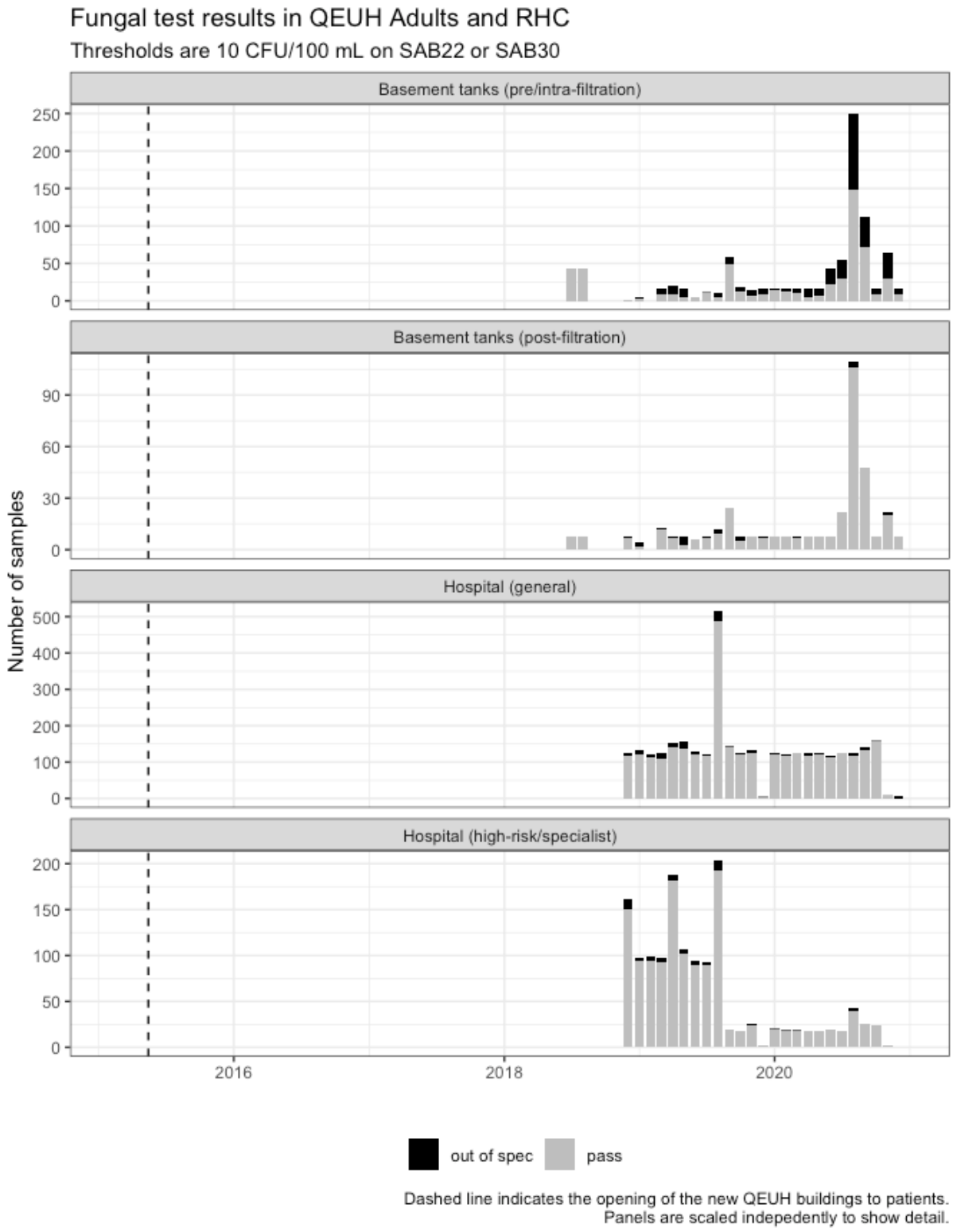

Figure 7. Number of fungal tests out of spec per month in QEUH Adults and RHC

Cupriavidus and other Gram negative bacteria

Although Cupriavidus and other Gram negative bacteria (GNBs) were occasionally noted as non-target taxa in other tests (e.g. see Pseudomonas section above), testing *specifically* for Cupriavidus and other GNBs began in February 2018 with reactive testing in RHC Ward 2A (35 samples) and in the basement tanks (five samples, exact location pre- or post-filter unspecified). While the requested test was for Cupriavidus, the Environmental Laboratory was asked to identify and report any GNB that grew (the test name was later changed to GNB to reflect this). The five basement tank samples did not grow Cupriavidus or any other GNB, but 24 out of the 35 samples from Ward 2A (68.6%) grew one or more Cupriavidus species, with three of these 24 samples also testing positive for an additional GNB. A further 9 of these 35 samples did not grow Cupriavidus but were positive for other GNBs. Only 2 of the 35 samples from Ward 2A were negative. As a result, a larger sampling effort was undertaken across QEUH Adults and RHC in March-April 2018, with 1484 samples tested specifically for Cupriavidus and other GNBs. Overall, 191 (12.9%) were positive for Cupriavidus (48 of these also grew an additional GNB), and a further 358 (24.1%) did not grow Cupriavidus but were positive for other GNBs, meaning the positivity rate for any GNB, including Cupriavidus, was 37.0%.

Including these samples and those collected from May 2018 onwards, 6183 samples from the new buildings underwent testing specifically for Cupriavidus and other GNBs over the period 2018-2020. Of these, 275 (4.4%) grew Cupriavidus and 935 (15.1%) did not grow Cupriavidus but were positive for other GNBs (giving an overall positivity rate of 19.5% for any GNB). The distribution over time of GNB/Cupriavidus test numbers, Cupriavidus-positive samples, and samples that did not grow Cupriavidus but were positive for other GNBs is shown in Figure 8, split into different areas of the new buildings. Cupriavidus-positive samples occasionally reported other GNBs as well, with 56 samples overall reporting both Cupriavidus and at least one other GNB. There was no precedent for this type of testing in GG&C prior to Feb 2018, and in the absence of recommended thresholds or interpretive criteria, GG&C currently treat any detected Cupriavidus species or other GNB as out of spec, regardless of where samples were collected. As in earlier sections, this threshold is applied retrospectively here in order to examine temporal and spatial trends.

Cupriavidus species were only rarely detected in the basement tanks, with 0.73% (7 samples out of 960) of pre/intra-filtration tank samples and 0.84% (3 samples out of 358) of post-filtration tank samples testing positive. In contrast, the proportion of samples that tested negative for Cupriavidus but positive for other GNBs was considerably higher, with 33.6% (323 samples out of 960) of pre/intra-filtration tank samples and 15.6% (56 samples out of 358) of post-filtration tank samples growing one or more GNBs.

From general hospital areas, 80 out of 1323 samples (6.0%) were positive for Cupriavidus, with a further 312 samples (23.6%) negative for Cupriavidus but positive for another GNB. This pattern was different in high-risk areas; a similar percent overall, 5.2%, was positive for Cupriavidus (185 out of 3542 samples), but the percent of samples that were Cupriavidus-negative but positive for other GNBs was considerably lower, 6.9% (244 out of 3542 samples). The Cupriavidus out-of-spec samples from high-risk areas were predominantly from the Feb-Apr 2018 sampling effort. When looking only at the 2850 samples from high-risk areas tested specifically for Cupriavidus and other GNBs from May 2018 onwards, 45 (1.6%) had any detectable Cupriavidus species, and a further 108 (3.8%) had other GNBs.

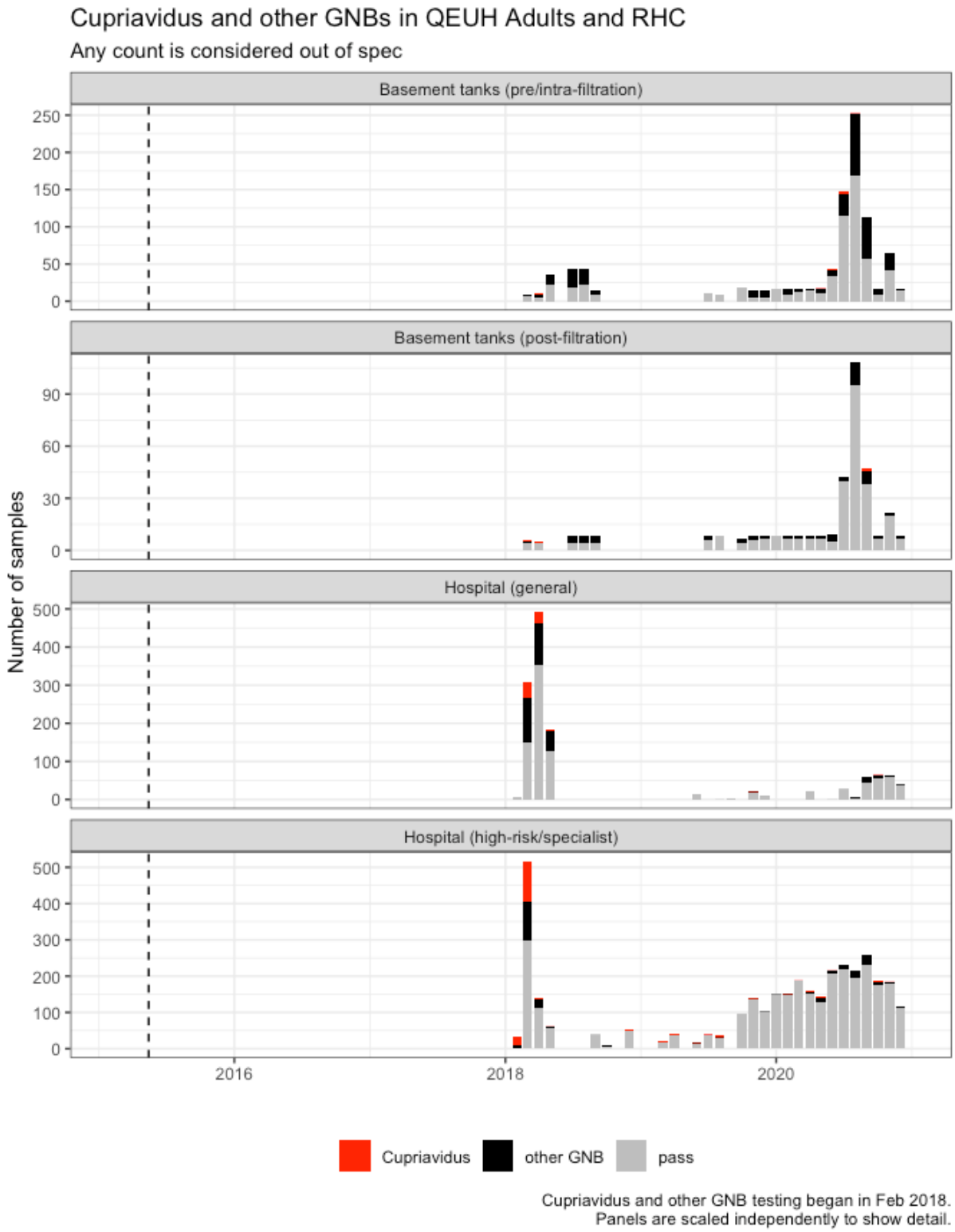

Figure 8. Number of Cupriavidus and other GNBs out of spec per month in QEUH Adults and RHC. Panels are scaled independently to show detail. The 'other GNB' category does not include the small number of samples that were positive for Cupriavidus plus one or more additional GNBs, since these are already counted in the 'Cupriavidus' category.

Atypical mycobacteria test results

Overall, 929 samples from the new buildings underwent AMS testing over the period 2015-2020, though these tests were all carried out in the latter part of the period, 2019-2020, and predominantly in high-risk areas. There were 85 out-of-spec samples in total (9.1% of samples). Sampling in the basement tanks and in general areas was limited to a handful of time points. A single sample from the pre/intra-filter basement tanks was out of spec, out of 12 samples (8.3%), and none of the 16 samples from the post-filtration basement tanks were out of spec. Samples from general hospital areas had the highest proportion out of spec, 34 out of 167 samples (20.4%). These were almost entirely from a sampling effort carried out in June 2019, with the out-of-spec samples being predominantly from the 1st floor theatres. More regular and sustained AMS testing occurred in the high-risk areas, where 50 out of 734 samples (6.8%) were out of spec. Total AMS passes and out-of-spec results, grouped by month, are shown in Figure 9.

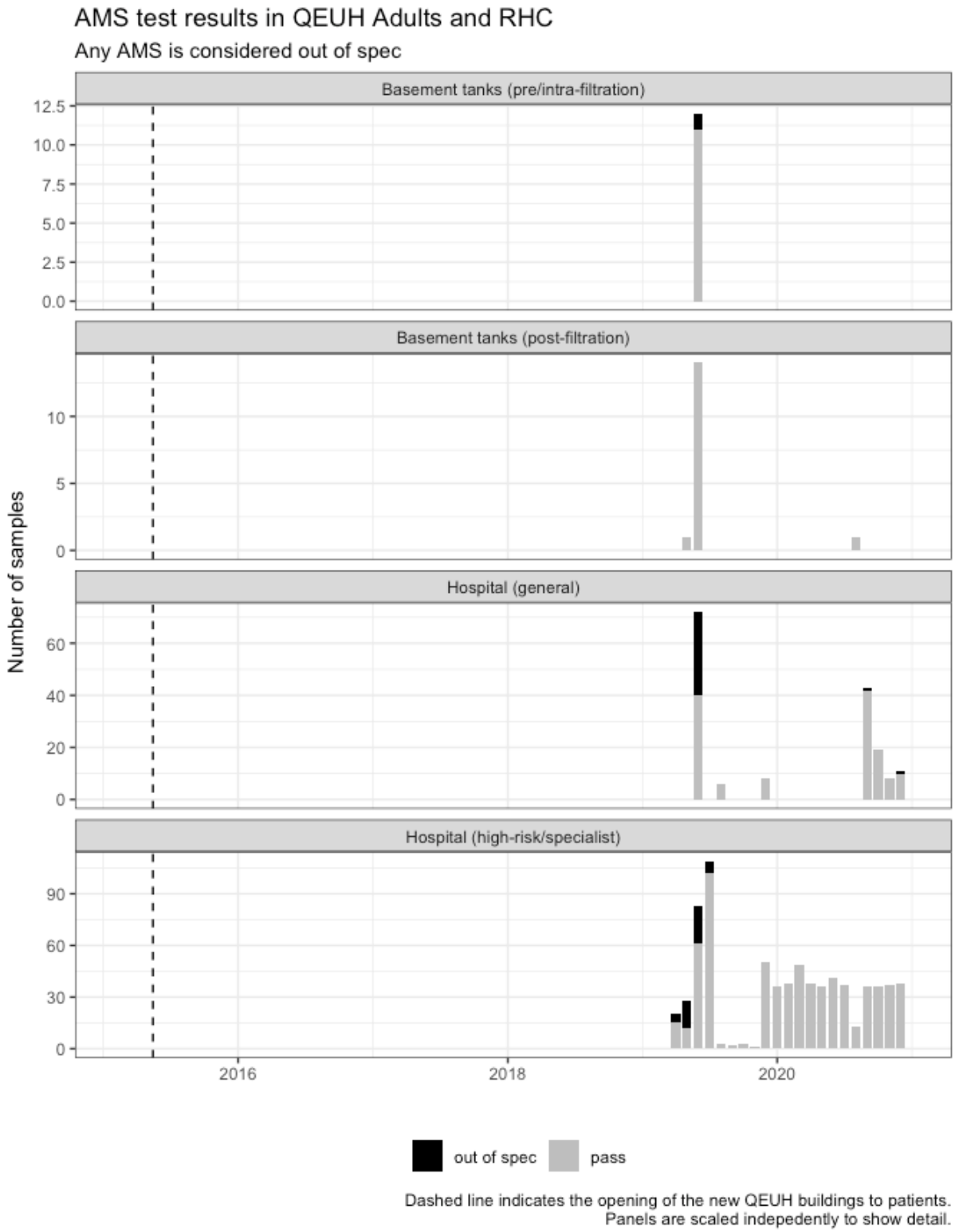

Figure 9. Number of AMS tests out of spec per month in QEUH Adults and RHC.

Results of reactive tests for other organisms

In addition to the tests described in the previous sections (Legionella, Pseudomonas, potable, fungi, Cupriavidus/GNB, AMS), water samples were occasionally booked in for other types of test, usually in the context of reactive sampling requested by IMTs/IPCTs. Numbers, locations and results of these other tests, those for specific organisms, are shown in Table 4. None of these tests were positive for the organism requested, though three of the four tests for *Mycobacterium chelonae* reported atypical mycobacteria (species unspecified).

Table 4. Organism-specific ad hoc tests requested across the new buildings

Specific test	Ward	Number of tests	Number with the target org.
Acinetobacter	1D PICU (RHC)	16	0
	other	8	0
Burkholderia	other	72	0
coliforms	other	40	0
Elizabethkingia miricola	2A/2B (RHC)	56	0
Enterobacter	6A (Adults)	3	0
	other	1	0
Exophiala	2A/2B (RHC)	1	0
	other	20	0
Mycobacterium chelonae	6A (Adults)	3	0
	other	1	0
Serratia	1D PICU (RHC)	105	0
	2A/2B (RHC)	16	0
	4B (Adults)	28	0
	other	17	0
Stenotrophomonas	1D PICU (RHC)	6	0
	2A/2B (RHC)	40	0
	6A (Adults)	34	0
	other	42	0

Microbiological results: Named microorganisms

The tests listed above generally looked for specific organisms (except for TVCs and fungal tests, which counted total colonies). The microbiological growth media used in organism-specific tests are designed to encourage the growth of these organisms while inhibiting non-target species. However, this is not perfect; non-target species commonly grow in organism-specific tests, so laboratories use other methods to confirm the identity of colonies before reporting results. Depending on the laboratory, the presence and identity of non-target species may or may not be recorded and included in the final report.

ALcontrol and Intertek did not generally report named microorganisms from cultures obtained during routine potable, Pseudomonas, and fungal testing. However, the GG&C Environmental Laboratory did keep records in TelePath relating to the identification of non-target species, often in free-text data fields called 'Laboratory Comments' or 'Laboratory Comments - Not Reported'. In the earlier years, 2015-2017, these non-target species would have been found during potable, Pseudomonas, or reactive testing for other specific species (see Pseudomonas section above, where counts of non-target organisms appear to have been reported as Pseudomonas in error, indicating the growth of these taxa on the Pseudomonas plates). When the Cupriavidus/GNB and fungal tests were introduced at various points in 2018, the number and diversity of named organisms in the data sheets increased markedly, since these tests require laboratory staff to identify all growth on the agar plates.

This section focuses on the named organism data from the GG&C Environmental Laboratory, including target and non-target organisms regardless of which type of test was performed on the water sample. It is important to note that the numbers and types of test performed were not consistent over the period 2015-2020, and that the abundance and diversity of named organisms are dictated by sample numbers, test types and reporting criteria. From 2018, there was a large increase in sample numbers and in the effort taken by the laboratory to identify all organisms.

Environmental organisms with mandatory reporting

The National Infection Prevention and Control Manual (NIPCM), Appendix 13, describes the nationally agreed mandatory minimum list of alert organisms for infections to be reported to Infection Prevention and Control Teams and includes certain organisms under the heading "Environmental bacteria". The NIPCM does not mandate routine testing for or reporting of the presence of these organisms in environmental samples outwith investigations into clinical cases. The four organisms currently listed under this heading in Appendix 13 are: *Pseudomonas aeruginosa*, Acinetobacter species, *Stenotrophomonas maltophilia*, and *Serratia marcescens*, though the guidance recognises that this list is not exhaustive. These environmental organisms were added to the NIPCM on 30 June 2017, and were added to the GG&C ICNet alert list in August 2017 after going through the necessary IPC governance committees.

Across all 10 311 QEUH Adults and RHC water samples tested by the Environmental Laboratory from 2015-2020 (which does not include samples tested only for Legionella), no *Serratia marcescens* were detected, and *Pseudomonas aeruginosa* were named in a total of 8 samples (only those out-of-spec Pseudomonas tests that confirmed the identification as *P. aeruginosa* are included here, since other Pseudomonas species can grow in those test). *Stenotrophomonas maltophilia* occurred in 76 samples,

predominantly in the basement tanks pre/intra-filtration (Table 5), whereas 7 distinct Acinetobacter species were observed across 73 samples, also predominantly in the basement tanks pre/intra-filtration. *Acinetobacter lwoffii* and *Acinetobacter ursingii* were the most common Acinetobacter species detected (36 and 22 samples, respectively).

Other environmental organisms

The NIPCM guidance recognises that the list of environmental alert organisms is not exhaustive. As expected with potable water, which is not naturally a sterile environment, many more taxa were identified in all test types. Across all 10 311 samples from QEUH Adults and RHC tested by the Environmental Laboratory over the period 2015-2020, 99 bacterial taxa were identified (plus 1 non-taxonomic grouping, 'Environmental GNB', which was reported when the standard laboratory methods were unable to identify colonies), as well as 23 fungal taxa (plus 7 non-taxonomic groupings). Of these, 29 bacterial and 9 fungal groups were rare, occurring in only one sample across the entire data set.

Tables 5 and 6 list all bacterial and fungal groups detected in the new buildings, in decreasing order of abundance (number of samples with the organism). Of the 100 bacterial groups detected across all samples, 20 were found only in the basement tanks (with 14 of these detected only in the pre/intra-filtration tanks, not in the post-filtration tanks). Of the 30 fungal groups detected across all samples, 5 were found only in the basement tanks (with 4 of these detected only in the pre/intra-filtration tanks, not in the post-filtration tanks). Some of the entries are not true taxonomic groups, but broad categories that likely encompass a wide diversity of organisms (e.g. Environmental GNB, Saprophytic fungi). True taxonomic names are shown in italics, and entries ending in 'species' were resolved only to the coarser genus level.

Table 5. All bacterial taxa detected in water samples from QEUH Adults and RHC, with number of positive samples from each area.

Bacterial ID	Basement (pre-filter)	Basement (post-filter)	Hospital (general)	Hospital (high-risk)	Total[1]
Cupriavidus pauculus	9	3	67	361	440
Sphingomonas paucimobilis	65	14	58	69	206
Environmental GNB (unspecified)	21	3	80	89	193
Delftia acidovorans	57	26	45	40	168
Comamonas testosteroni	1		41	77	119
Stenotrophomonas maltophilia	44	4	8	20	76
Atypical mycobacteria	1		24	31	56
Sphingobium xenophagum	4		33	10	47
Pseudomonas veronii	44	1			45
Cupriavidus gilardii			19	22	41

Bacterial ID	Basement (pre-filter)	Basement (post-filter)	Hospital (general)	Hospital (high-risk)	Total[1]
Acinetobacter lwoffii	9	3	6	18	36
Pseudomonas fluorescens	19	1	9	1	30
Mycobacterium chelonae			10	19	29
Acinetobacter ursingii	21	1			22
Brevundimonas species	1		11	10	22
Enhydrobacter aerosaccus	10	1	1	10	22
Brevundimonas diminuta/vesicularis	1		16	4	21
Bordetella bronchiseptica	2		12	5	19
Achromobacter xylosoxidans			11	7	18
Acidovorax delafieldii	8		4	6	18
Blastomonas ursincola			9	6	15
Chryseobacterium indologenes		1	5	6	12
Roseomonas mucosa	3		1	7	11
Sphingobium yanoikuyae			9	2	11
Achromobacter denitrificans	2		4	3	9
Bordetella hinzii			2	7	9
Roseomonas gilardii			8	1	9
Brevundimonas diminuta	4		2	2	8
Brevundimonas vesicularis	6		1	1	8
Pseudomonas aeruginosa			1	7	8
Rhizobium radiobacter			1	7	8
Acidovorax temperans			1	6	7
Acinetobacter johnsonii	7				7
Alcaligenes faecalis				6	6
Microbacterium oxydans	6				6
Pseudomonas anguilliseptica	6				6
Pseudomonas oleovorans	3		3		6
Pseudomonas species	3	2		1	6
Staphylococci				6	6
Enterobacter cloacae		1		4	5
Lelliottia amnigena	5				5

Bacterial ID	Basement (pre-filter)	Basement (post-filter)	Hospital (general)	Hospital (high-risk)	Total[1]
Pantoea agglomerans	2	1		2	5
Pseudomonas putida		2		3	5
Pseudoxanthomonas mexicana	1		4		5
Ralstonia pickettii			3	2	5
Achromobacter species	2		1	1	4
Acinetobacter species	1		1	2	4
Alcaligenes species				4	4
Cupriavidus species				4	4
Microbacterium flavescens	2			2	4
Microbacterium flavescens/laevaniformans	4				4
Burkholderia gladioli				3	3
Klebsiella pneumoniae		1	1	1	3
Morganella morganii			1	2	3
Pseudomonas chlororaphis	1	1	1		3
Ralstonia insidiosa	1			2	3
Raoultella terrigena	3				3
Serratia fonticola	2			1	3
Sphingobacterium thalpophilum			1	2	3
Sphingomonas species				3	3
Aeromonas salmonicida	1	1			2
Burkholderia species				2	2
Cronobacter sakazakii	1	1			2
Gardnerella species				2	2
Pantoea species			1	1	2
Pseudomonas alcaligenes	1			1	2
Pseudomonas pseudoalcaligenes				2	2
Shewanella putrefaciens			1	1	2
Sphingobacterium multivorum			2		2
Sphingomonas adhaesiva			2		2
Sphingomonas melonis				2	2
Acinetobacter calcoaceticus	1				1

Bacterial ID	Basement (pre-filter)	Basement (post-filter)	Hospital (general)	Hospital (high-risk)	Total[1]
Acinetobacter gyllenbergii		1			1
Acinetobacter haemolyticus	1				1
Acinetobacter radioresistens	1				1
Aeromonas media				1	1
Aeromonas species				1	1
Bacillus species				1	1
Burkholderia cepacia			1		1
Burkholderia mallei			1		1
Cedecea lapagei			1		1
Chryseobacterium species				1	1
Citrobacter species				1	1
Clostridium beijerinckii	1				1
Corynebacterium species				1	1
Delftia species				1	1
Enterobacter species	1				1
Kluyvera intermedia	1				1
Leclercia adecarboxylata				1	1
Microbacter species				1	1
Moraxella species				1	1
Mycobacterium szulgai				1	1
Myroides species			1		1
Neisseria animaloris			1		1
Paenibacillus durus			1		1
Paracoccus yeei			1		1
Pseudomonas oryzihabitans		1			1
Raoultella species	1				1
Rothia dentocariosa			1		1
Sphingobacterium spiritivorum	1				1

[1]Number of samples with organism out of 10 311 samples tested by the Environmental Laboratory 2015-2020, excluding those tested only for Legionella (1054 from the pre/intra-filtered basement tank system, 436 from the post-filtered basement tanks, 2085 from general hospital areas and 6736 from high-risk hospital areas).

Table 6. All fungal taxa detected in water samples from QEUH Adults and RHC, with number of positive samples from each area.

Fungal ID	Basement (pre-filter)	Basement (post-filter)	Hospital (general)	Hospital (high-risk)	Total[1]
Saprophytic fungi	126	25	396	253	800
Dematiaceous hyphomycete	165	42	2	30	239
Mycelia sterilia	178	30	3	28	239
Hyaline hyphomycete	109	15		30	154
Cladosporium species	44	10		6	60
Exophiala species	38	2	8	9	57
Fungi	21	8	5	23	57
Aspergillus fumigatus	4	6	18	26	54
Aspergillus niger	10	2	1	14	27
Purpureocillium lilacinum	9	4		13	26
Aspergillus versicolor	11	6	6	1	24
Acremonium species	17	2		2	21
Penicillium species	7	9	1	3	20
Exophiala equina	15				15
Rhodotorula species	5	8		2	15
Fusarium species	6	1	3	1	11
Yeast		4		5	9
Aspergillus species	4	3	1		8
Exophiala dermatitidis			2	6	8
Paecilomyces species				8	8
Mould	2	1		1	4
Absidia species			1		1
Aspergillus flavus			1		1
Aspergillus glaucus	1				1
Candida famata		1			1
Candida parapsilosis				1	1
Neoscytalidium dimidiatum				1	1
Phoma species	1				1

Fungal ID	Basement (pre-filter)	Basement (post-filter)	Hospital (general)	Hospital (high-risk)	Total[1]
Scytalidium hyalinum	1				1
Verticillium species				1	1

[1]Number of positive samples out of 10 311 samples tested by the Environmental Laboratory 2015-2020, excluding those tested only for Legionella (1054 from the pre/intra-filtered basement tank system, 436 from the post-filtered basement tanks, 2085 from general hospital areas and 6736 from high-risk hospital areas).

All named bacteria and fungi present in more than five samples over the entire data set are shown in Figures 10 and 11. There is a clear increase in the diversity of identified taxa during the large peak in Cupriavidus/GNB testing effort that occurred in March-April 2018, as well as from December 2018 onwards, when sample numbers and the types of test performed routinely both increased markedly.

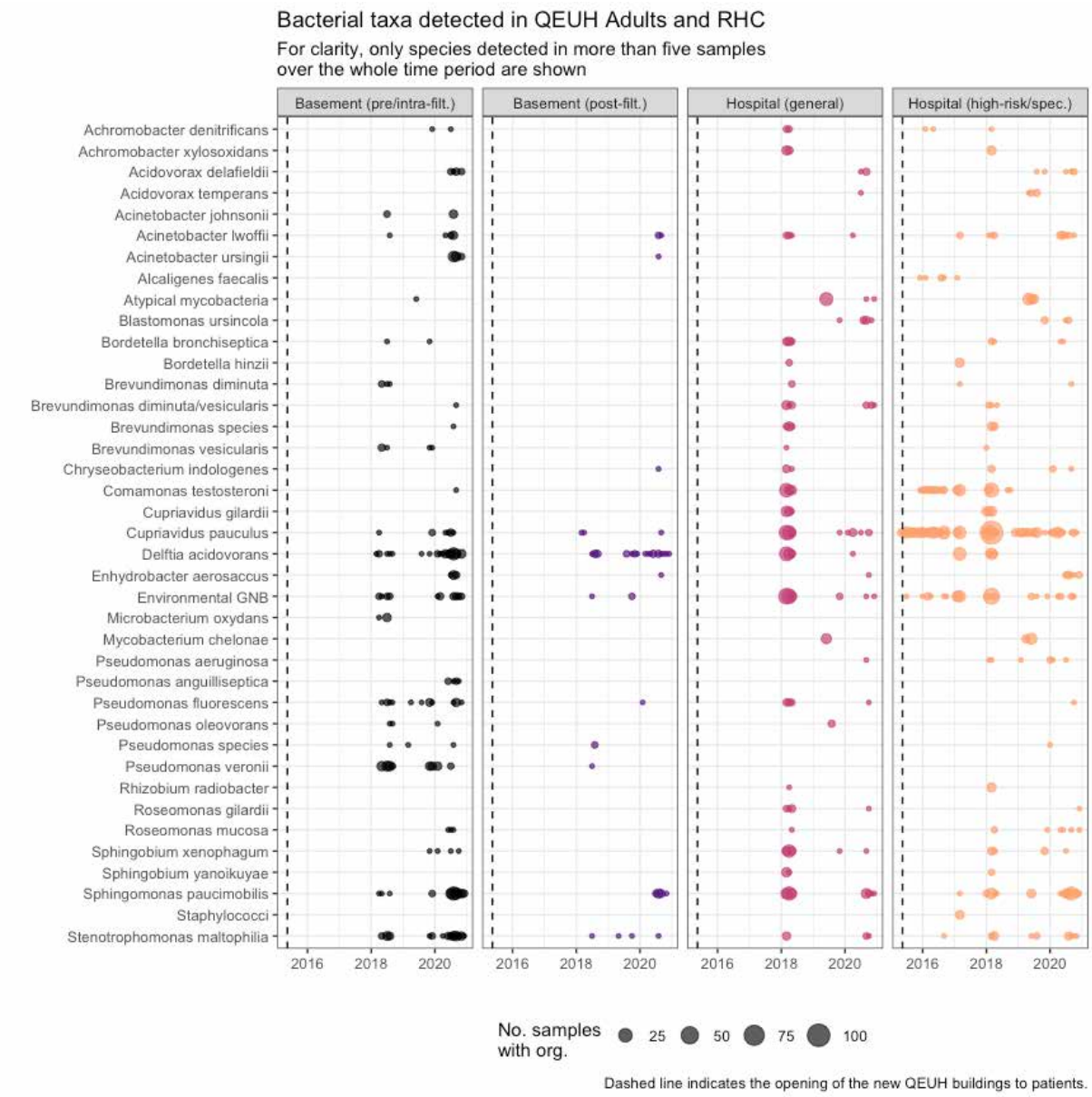

Figure 10. Bacterial taxa identified in different areas of QEUH Adults and RHC over the period 2015-2020.

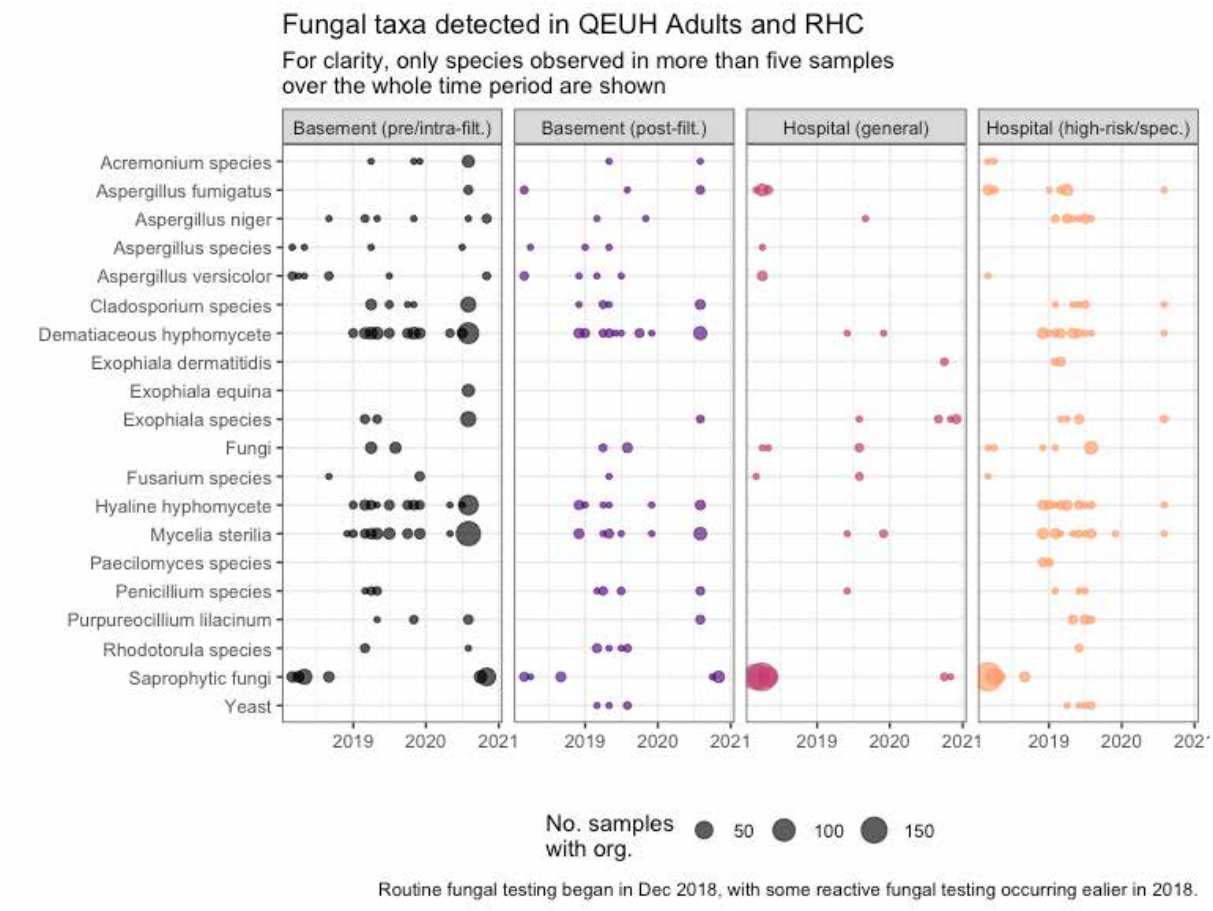

Figure 11. Fungal taxa identified in different areas of QEUH Adults and RHC over the period 2015-2020.

Named organisms were more frequently reported in high-risk than in general areas, and in pre/intra-filtration rather than post-filtration basement tanks. However, this finding could be explained by differences in sample numbers and by the suite of microbiological tests that were performed in each area. In particular, a large number of taxa were detected during the peak sampling effort in Mar-Apr 2018 - not only were samples tested in far greater numbers than usual, but the laboratory was instructed to report the identification of all colonies that grew in the Cupriavidus/GNB test performed on all these samples. Later in 2018, this Cupriavidus/GNB test became routine and was carried out more intensively in high-risk areas, resulting in more named organisms being reported.

It is important to note that identifying environmental organisms is not always straightforward, as the procedures used in routine laboratories are optimised for clinical isolates. The Environmental Laboratory identifies unknown organisms using a MALDI-TOF MS system (Biomerieux), which compares spectra obtained from unknown colonies to those in databases of reference organisms. When the MALDI-TOF system fails to identify an organism, a second system, Vitek (Biomerieux), is used, which carries out a series of biochemical tests in an automated manner to give an organism ID.

Both the MALDI-TOF MS and the Vitek perform well in a clinical laboratory setting, but as their reference databases are heavily biased towards human pathogens, they may perform less well at identifying environmental organisms that are rarely found in a

clinical context. For example, further typing by whole genome sequencing showed that numerous isolates identified as *Cupriavidus pauculus* were either other Cupriavidus species, or were not members of the genus Cupriavidus at all but belonged to other genera. Furthermore, when both systems failed to give an organism ID, the Environmental Laboratory reported 'Environmental GNB'. Table 5 shows that Environmental GNB was the third most common bacterial group detected in the new buildings over the period 2015-2020, with 193 occurrences out of 1918 reports of named bacterial taxa. This means that for 10.1% of the organisms that grew from these water samples, a reliable identification could not be obtained using the MALDI-TOF MS and Vitek platforms.

Ward-specific water sampling

The data presented above encompasses all samples collected across the QEUH Adults and RHC. This section focuses on a subset of these samples, those collected from wards 2A/2B (RHC), 4B (Adults), 6A (Adults), and 1D (PICU, RHC). These wards were all classified as high risk, so the stricter microbiological thresholds were applied.

Legionella results in key wards

Overall, 2089 samples from the key wards underwent Legionella testing over the period 2015-2020. There was a single out-of-spec sample in ward 2A and none in the other wards (0.048% of samples). Monthly numbers of Legionella samples are shown in Figure 12. A single sample from Ward 2A/2B, taken shortly after opening in 2015, tested positive for Legionella. No other sample from these key wards had any detectable Legionella over the period 2015-2020.

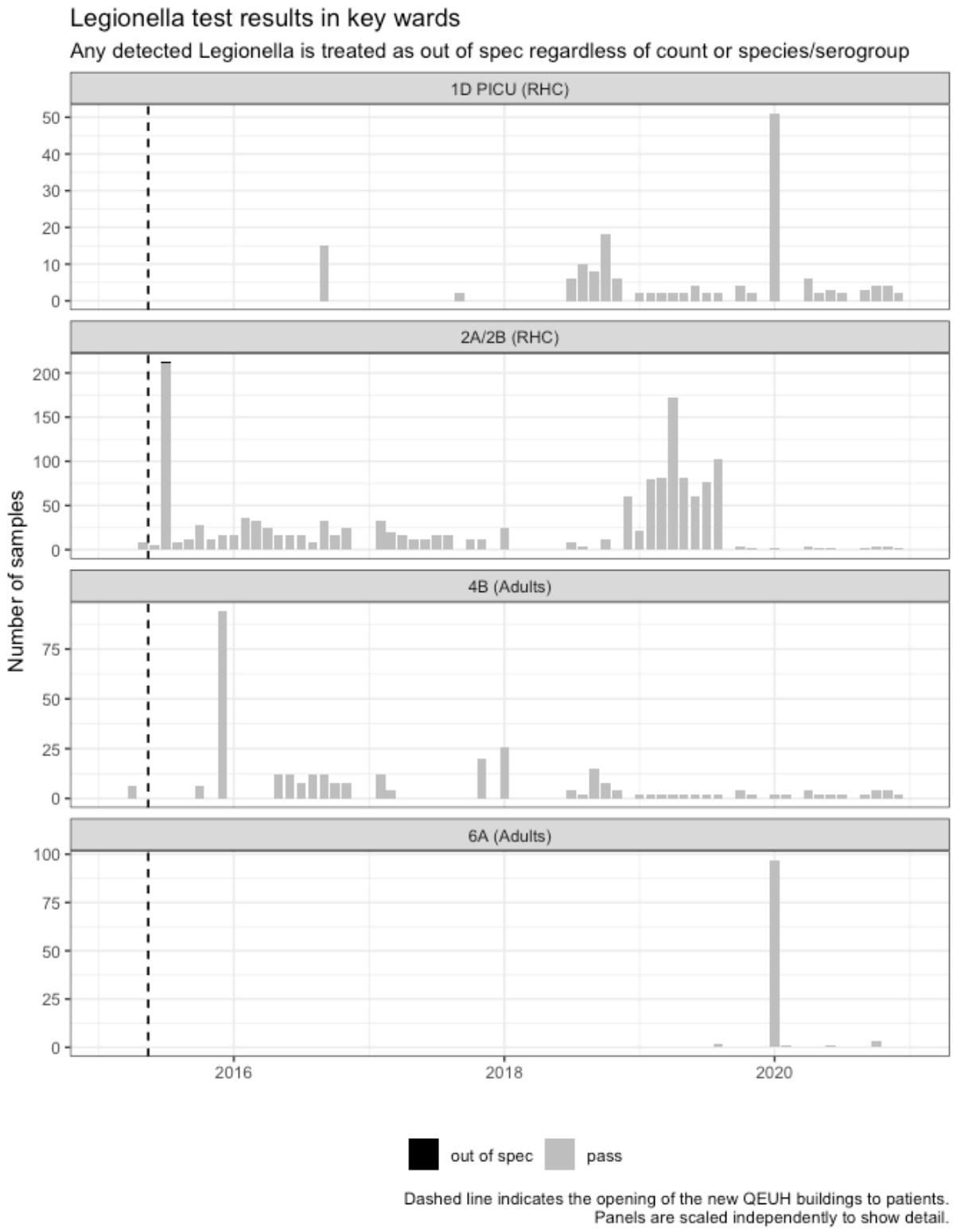

Figure 12. Number of Legionella tests out of spec per month in key wards. A single sample from Ward 2A/2B was out of spec in early 2015. Panels are scaled independently to show detail.

Pseudomonas results in key wards

Overall, 3985 samples from the key wards underwent Pseudomonas testing over the period 2015-2020. With high-risk thresholds, where any Pseudomonas count is considered out of spec, there were 75 reported out-of-spec samples in total (1.9% of samples), though this number drops to 64 out-of-spec samples (1.6%) when likely transcription errors are corrected (transcription errors only affected samples from PICU, not from the other key wards).

Ward 4B had the lowest number of Pseudomonas tests (445 samples) but the highest number out of spec (44 samples, i.e. 9.9%). These were concentrated in the earlier part of the time period, December 2015 to February 2016. The other key wards had lower proportions of Pseudomonas samples out of spec: 13 out of 1056 samples from ward 2A (1.2%), 2 out of 1565 samples from ward 6A (0.13%), and 16 out of 919 samples from PICU (1.7%), which drops to 5 samples when likely transcription errors are excluded (0.54%).

Total Pseudomonas passes and out-of-spec results in these key wards, grouped by month, are shown in Figure 13.

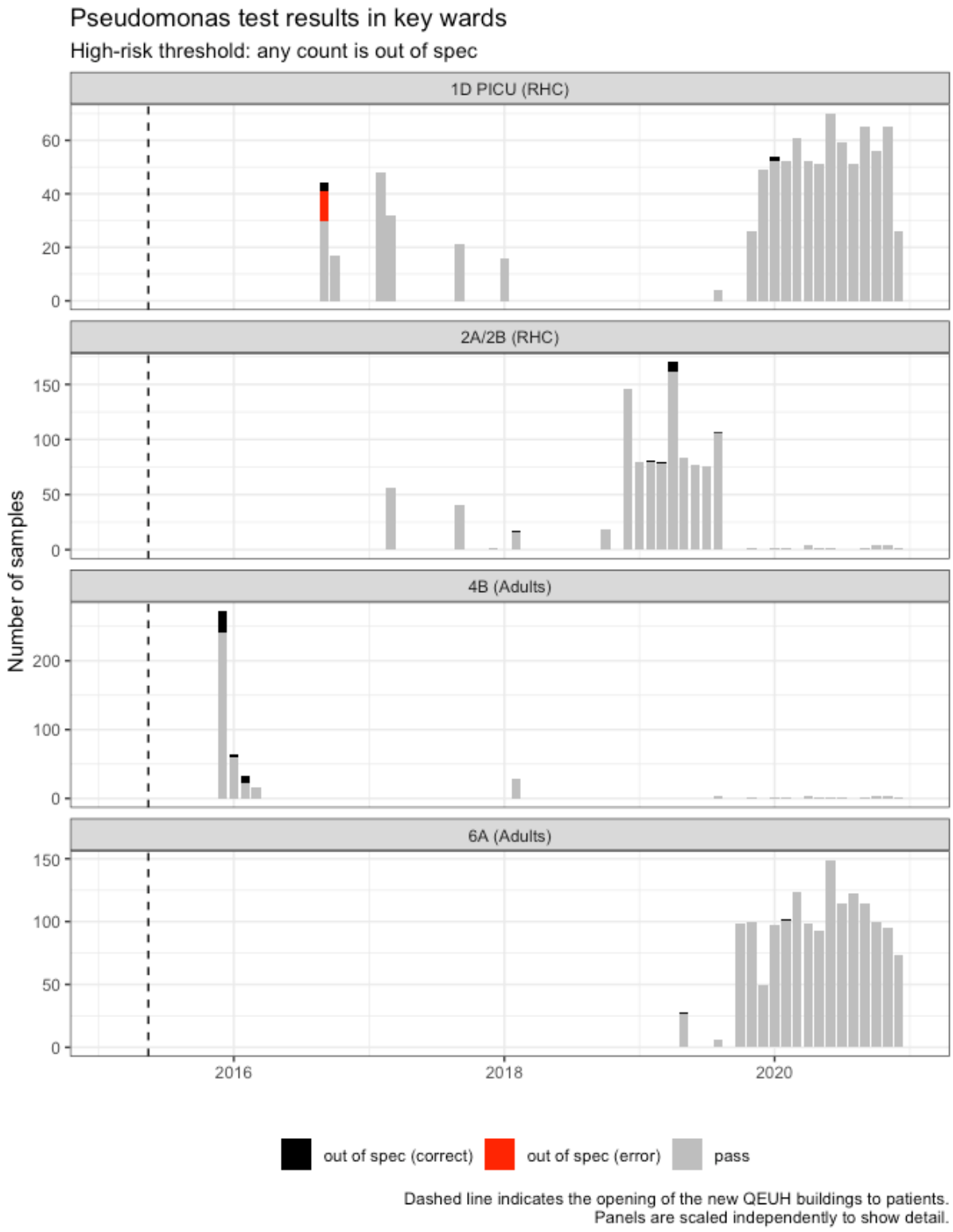

Figure 13. Number of Pseudomonas tests out of spec per month in key wards. Panels are scaled independently to show detail. Black bars show true out-of-spec samples, red bars show samples with reported counts that are likely transcription errors and should be considered passes.

Potable results in key wards

Overall, 3410 samples from the key wards underwent potable water testing over the period 2015-2020. This includes testing for TVC per mL at 22°C and 37°C, coliforms per 100 mL and *E.coli* per 100 mL. High-risk thresholds in place since December 2018 specify 10 CFU/mL for both TVC tests and no counts on coliform and *E.coli* tests. When these high-risk thresholds are applied retrospectively across the entire period 2015-2020 (to allow for comparison over time), 162 samples would be out of spec (4.8% of samples).

Like with Pseudomonas testing, Ward 4B had the lowest number of potable tests (64 samples) but the highest proportion out of spec (7 samples, i.e. 10.9%). The other key wards had lower proportions of potable samples out of spec: 97 out of 979 samples from ward 2A (9.9%), 24 out of 1574 samples from ward 6A (1.5%), and 34 out of 793 samples from PICU (4.3%).

Total potable passes and out-of-spec results in these key wards, grouped by month, are shown in Figure 14.

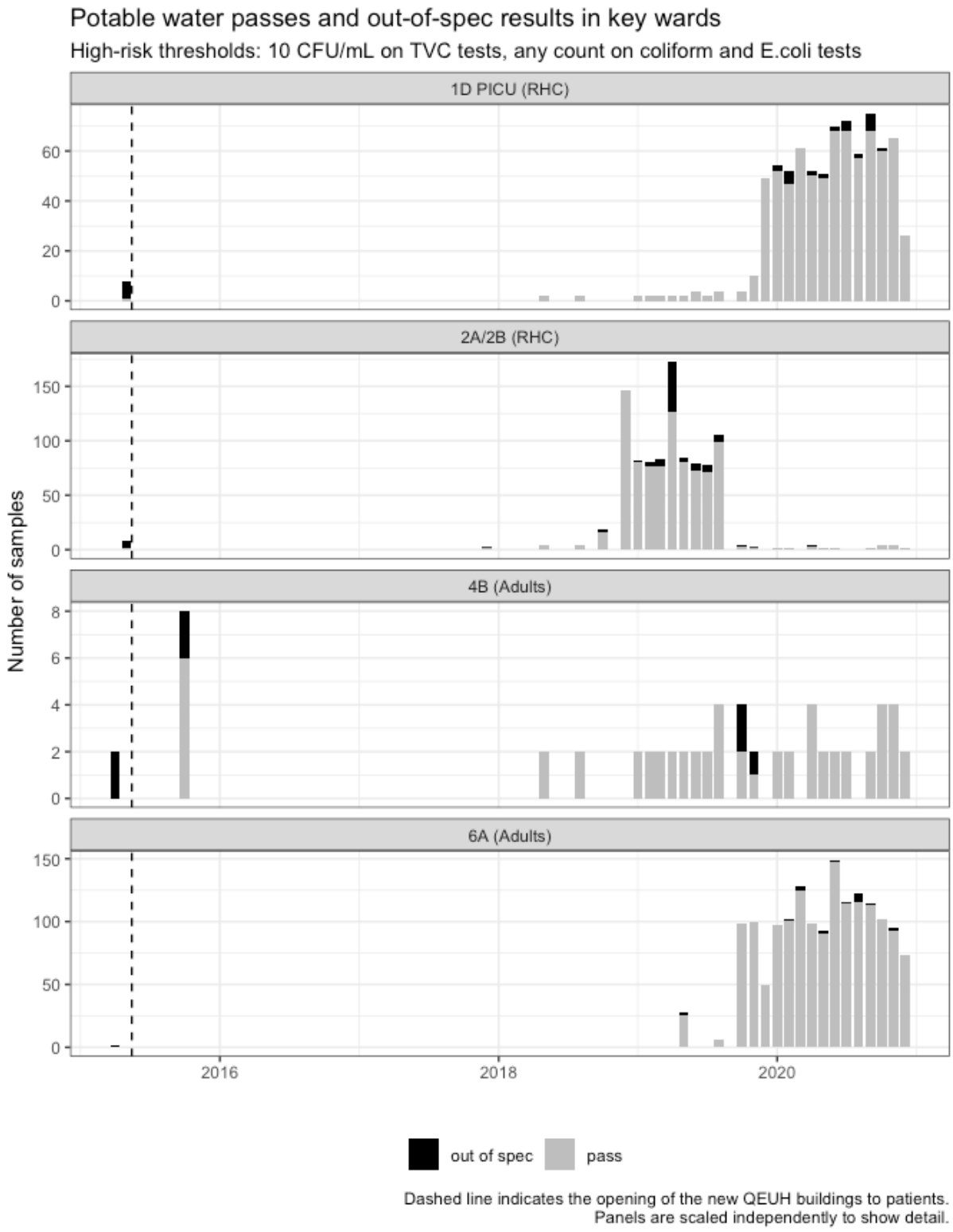

Figure 14. Number of potable tests out of spec per month in key wards. Panels are scaled independently to show detail.

Fungal results in key wards

Overall, 951 water samples from the key wards underwent fungal testing over the period 2015-2020, though this testing occurred in the later part of the time period, from December 2018 onwards. Thresholds in place since December 2018 specify 10 CFU/100mL for both fungal tests (SAB30 and SAB22). With these thresholds, 47 samples were out of spec (4.9% of samples).

However, this sampling was mostly carried out in ward 2A/2B, where 46 out of 895 samples were out of spec (5.1%). The numbers of fungal tests carried out in the other key wards were much lower: Ward 4B had only 4 fungal tests, of which none were out of spec, PICU had 20 fungal tests, with none out of spec, and 6A had 32 fungal tests, with one out of spec (3.1%).

Total fungal passes and out-of-spec results in these key wards, grouped by month, are shown in Figure 15.

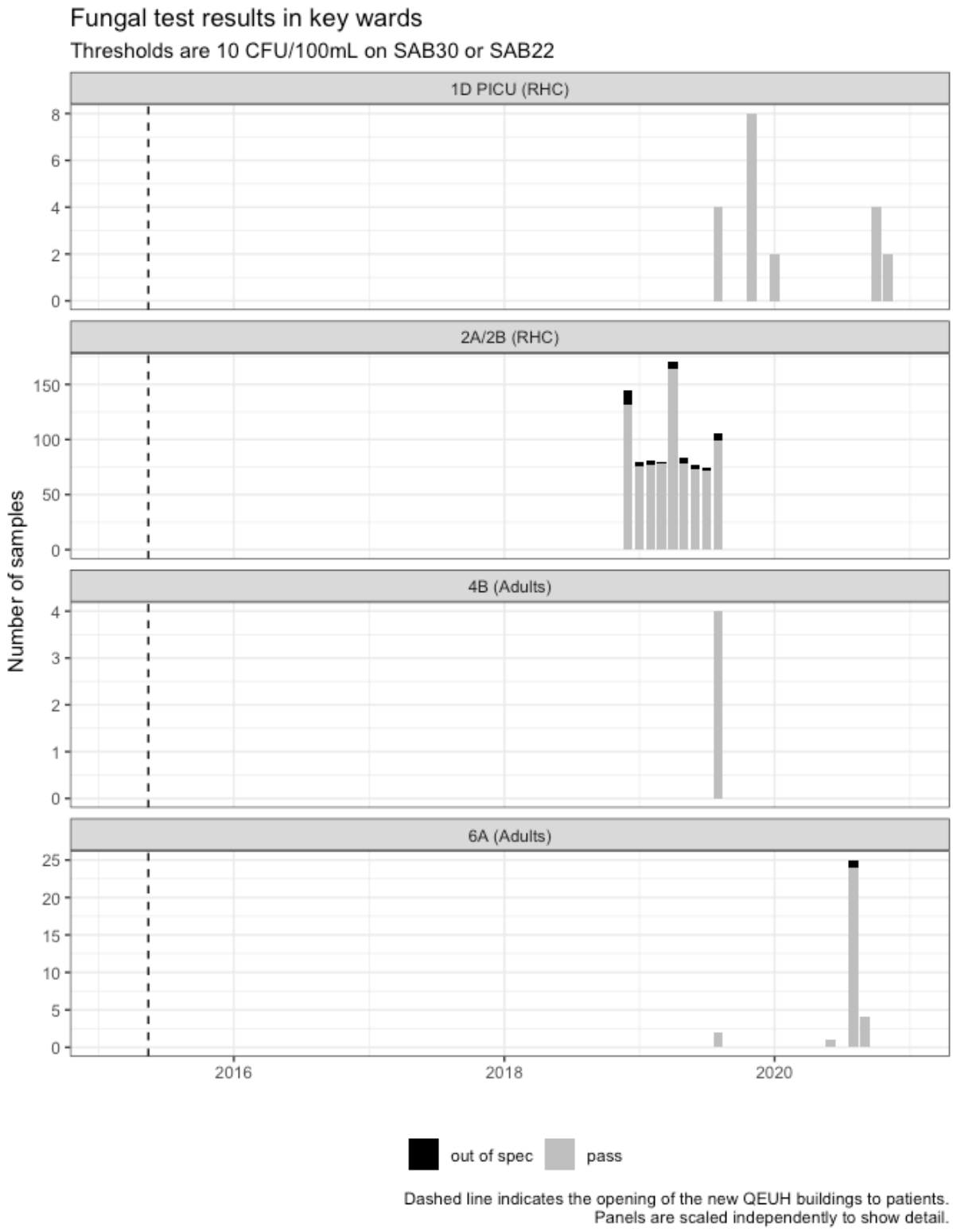

Figure 15. Number of fungal tests out of spec per month in key wards. Panels are scaled independently to show detail.

Cupriavidus and GNB results in key wards

Overall, 3254 samples from the key wards underwent Cupriavidus/GNB testing over the period 2015-2020, beginning with the reactive testing in Ward 2A in February 2018 and specified as part of the routine panel of tests in December 2018. Of these, 171 samples (5.3%) grew Cupriavidus and a further 191 samples (5.9%) were negative for Cupriavidus but positive for one or more other GNBs, giving an overall positivity rate of 11.2% for any GNB.

While these are the overall proportions across the four key wards, the proportions of Cupriavidus-positive samples and samples positive for other GNBs were markedly different in some of these wards (Figure 16). In PICU and Ward 6A, Cupriavidus-positive samples accounted for 1.6% and 0.99%, respectively (14/858 and 16/1611 samples), while samples positive for other GNBs accounted for 6.3% and 3.4%, respectively (54/858 and 54/1611 samples). In contrast, while Ward 4B had a comparable percent of Cupriavidus-positive samples (2.0%, i.e. 2 out of 101), 21.8% of samples were Cupriavidus-negative but positive for at least one other GNB (22 out of 101 samples, most of which were tested during the first large reactive sampling effort in March-April 2018). In Ward 2A/2B, 139 out of 684 samples (20.3%) were positive for Cupriavidus, and a further 61 samples (8.9%) were Cupriavidus negative but grew other GNBs. This means the overall positivity rate for any GNB (including Cupriavidus) in these four wards was 7.9% in PICU, 4.4% in Ward 6A, 23.8% in Ward 4B, and 29.2% in Ward 2A/2B.

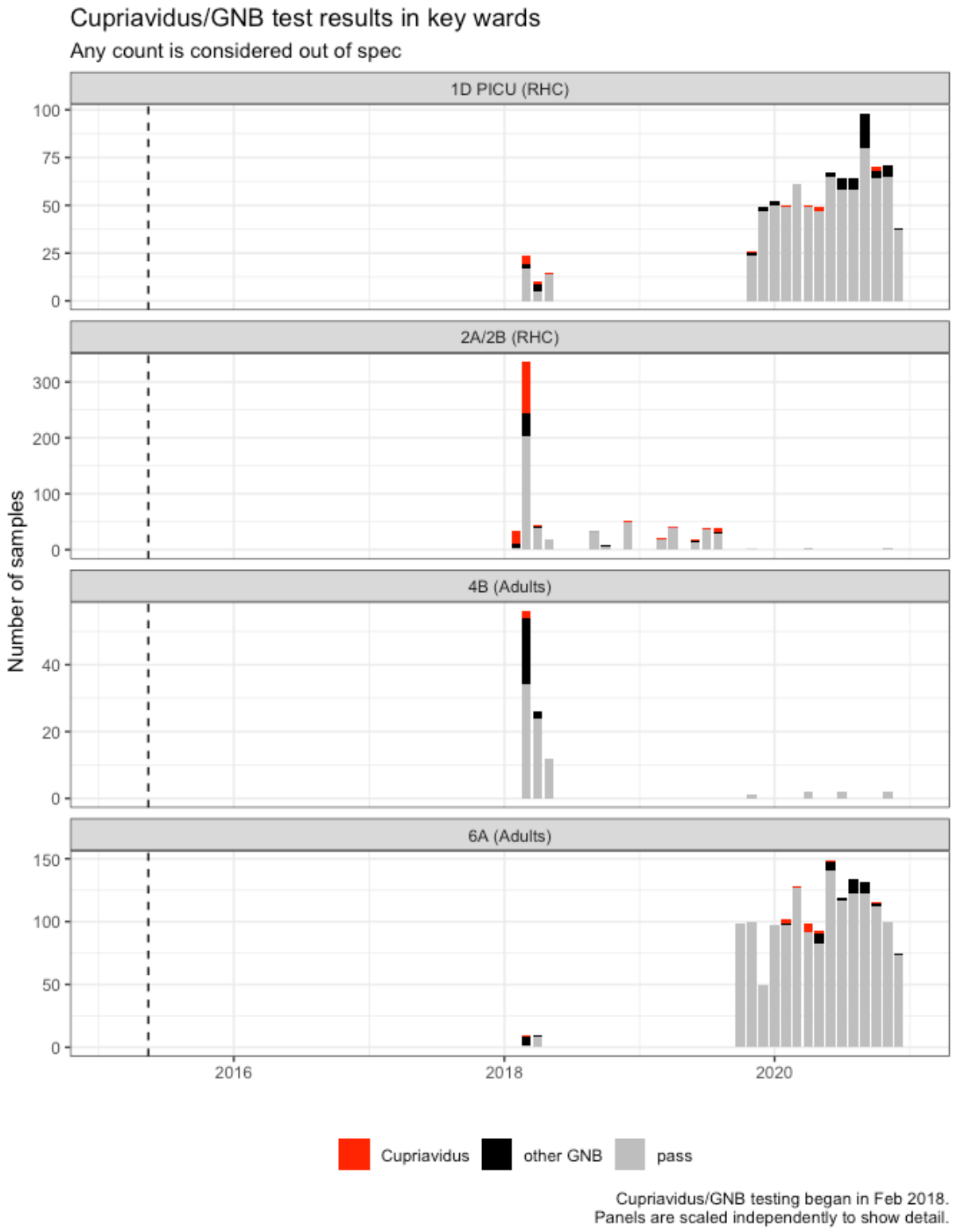

Figure 16. Number of Cupriavidus/GNB tests out of spec per month in key wards. Panels are scaled independently to show detail.

Atypical mycobacteria results in key wards

Overall, 724 samples from the key wards underwent AMS testing over the period 2015-2020, though this type of testing only began in April 2019. Any AMS count was considered out of spec on this test. In total, 50 samples from key wards were out of spec (6.9%). These were all collected during a reactive sampling effort in April-June 2019. No AMS were detected in samples collected after June 2019.

Testing for AMS was not carried out consistently across the four key wards. Ward 4B had no AMS tests, and only 20 samples from ward 2A/2B were tested for AMS, of which 5 were out of spec (25%). In PICU, 187 samples underwent AMS testing, with none out of spec. The most extensive AMS testing was carried out in 6A, where 45 out of 517 samples (8.7%) were out of spec.

Total AMS passes and out-of-spec results in these key wards, grouped by month, are shown in Figure 17.

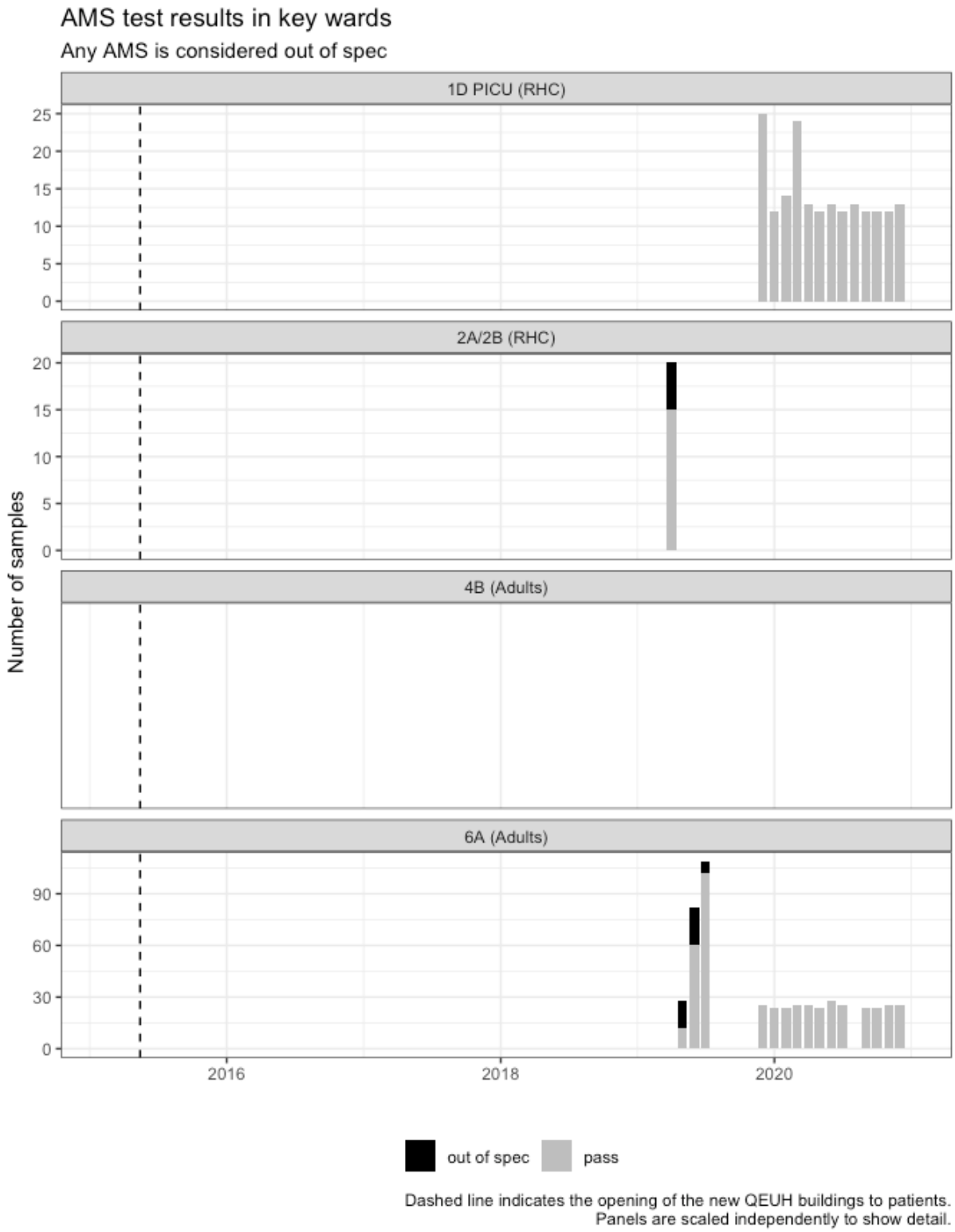

Figure 17. Number of AMS tests out of spec per month in key wards. Panels are scaled independently to show detail.

Named organisms in key wards

Named bacteria identified in all routine and reactive water samples from these wards are shown in Figure 18, and named fungi are shown in Figure 19. No named organisms were reported in 2015 or 2016. Circles show the total number of samples per month with the named organism. These are not normalised by the number of samples collected, so there are more organisms reported during the large spikes in sampling effort (notably in March-April 2018). Among the four key wards, fungal testing was predominantly carried out in Ward 2A/2B (see Figure 15 for sample numbers per ward).

Figure 18. Bacterial taxa identified in key wards in QEUH Adults and RHC.

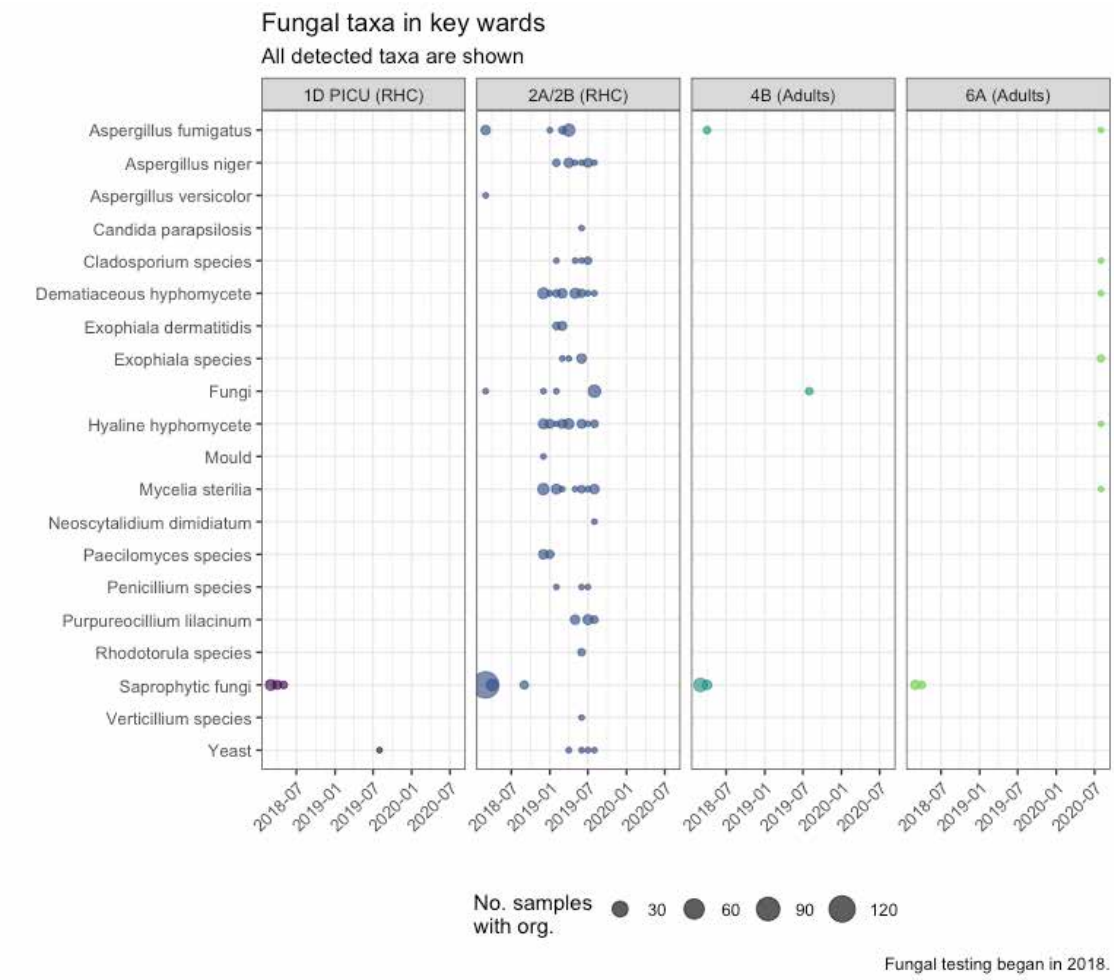

Figure 19. Fungal taxa identified in key wards in QEUH Adults and RHC.

Water data summary

1. *Sampling and testing*: Water sampling in QEUH Adults and RHC over the period 2015-2020 was carried out by ALcontrol Laboratories, by DMA Canyon Ltd, and by GG&C clinical teams, depending on the location. Most microbiological testing was performed by the GG&C Environmental Laboratory, with a subset of samples tested by ALcontrol and by Intertek.
2. *Types of test*: Water samples were either routine (for monitoring) or reactive (for investigation). Samples were booked in for one or more of the following tests: Legionella, Pseudomonas, potable water (consisting of four separate tests for TVCs, coliforms and *E.coli*), and from 2018 onward, fungal, Gram negative bacteria including Cupriavidus, and atypical mycobacterial species, as well as *ad hoc* tests for other specific organisms.
3. *Test thresholds*: GG&C set thresholds for Legionella, Pseudomonas, potable, fungal, Cupriavidus/GNB and AMS testing. Where recommended thresholds exist in applicable legislation or guidance, the GG&C thresholds meet or exceed these. For most of the tests, especially those bespoke to GG&C (e.g. Cupriavidus/GNB), there are no recommended thresholds in guidance or legislation. GG&C adapted some thresholds to the specific areas being sampled, with stricter cutoffs in wards classified as high risk. Outwith the high-risk areas and a few specialist units (aseptic pharmacies and RHC Theatre 8), general microbiological thresholds are applied.
4. *Test numbers 2015-2020*: Routine Legionella, Pseudomonas and potable water testing occurred throughout the period 2015-2020, though in the earlier years, the latter two were predominantly carried out in specific high-risk areas. An expanded programme of testing was implemented in December 2018, with additional routine tests (fungal, Cupriavidus/GNBs) and more thorough, systematic sampling across the new buildings, resulting in a large increase in monthly sample numbers.
5. *Legionella results*: 10 918 samples from the new buildings were tested for Legionella over the period 2015-2020, of which 378 were out of spec (3.5%). The majority of out-of-spec samples were from general areas (360 out of 5798 samples, i.e. 6.2%) and were concentrated in the earlier part of the period, in 2015-2016. High-risk areas had 17 out-of-spec samples over the entire period 2015-2020, out of 3909 samples (0.43%). *Legionella pneumophila* serogroup 1, the variant that is responsible for around 95% of human clinical cases, was only rarely detected after late 2015, with most occurrences clustered in the months prior to and immediately following opening of the new buildings. Across the four key wards, a single Legionella out of spec sample occurred in ward 2A/2B.
6. *Pseudomonas results*: Overall, 11 131 samples underwent Pseudomonas testing. There were 196 reported out-of-spec samples in total (1.8% of samples), though this number drops to 106 out-of-spec samples (0.95%) when likely transcription errors are corrected. Proportion out of spec was highest in the pre/intra-filter basement tank samples (3.4%), but considerably lower in the post-filtration tank samples (0.5%) and in the hospital areas (0.08% and 1.1% in general and high-risk areas, respectively). Across the key wards, 4B had the highest proportion out of spec (9.9%). The other key wards had out of spec proportions well below 2%.
7. *Potable results*: Of the 11 360 potable tests carried out in the new buildings over the period 2015-2020, 667 (5.9%) were out of spec according to current

thresholds. Pre/intra-filter basement tank samples had the highest proportion of out-of-spec samples (8.5%), whereas the proportion out of spec in the post-filtration basement tanks was 2.9%. General areas had a higher proportion of out-of-spec samples (6.1%) than high-risk and specialist areas (5.4%), despite the latter having stricter thresholds. Of the key wards, 4B had the smallest number of samples tested (64) and the highest proportion out of spec (10.9%). Proportions out of spec in the other key wards were 9.9% (2A/2B), 4.3% (PICU) and 1.5% (6A).

8. *Fungal results*: Of the 6040 samples from the new buildings that underwent fungal testing from 2018-2020, 10.0% overall were out of spec. Over half of all out-of-spec results were from the pre/intra-filter basement tank samples, where the percent out of spec was 37.5%. This percentage dropped in the post-filtration basement tanks to 6.1%, and was even lower in the general and high-risk areas of the new buildings (5.1% and 4.6%, respectively). Of the key wards, only 2A/2B underwent substantial fungal testing, with 5.1% out of spec.
9. *Cupriavidus and other Gram negative test results*: Over the period 2018-2020, 6183 samples underwent testing for Cupriavidus and other GNBs after a small amount of reactive testing in ward 2A in February 2018 showed a high positivity rate (68.6%). Of these 6183 samples, Cupriavidus species were detected in 4.4%, with a further 15.1% testing negative for Cupriavidus but positive for other GNBs. Cupriavidus were rare in the basement tanks (0.73% of pre/intra-filtration samples and 0.84% of post-filtration samples), but other GNBs were detected in a much greater proportion of basement tank samples (33.6% of pre/intra-filtration samples and 15.6% of post-filtration samples). In general hospital areas, 6.0% of samples grew Cupriavidus and a further 23.6% were Cupriavidus-negative but grew at least one other GNB. In high-risk areas, Cupriavidus species were detected in 5.2% of samples, with a further 6.9% of samples being Cupriavidus-negative but positive for another GNB. Most of the Cupriavidus-positive samples in high-risk wards were from the Feb-Apr 2018 sampling effort, as the proportion out of spec in high-risk areas from May 2018 onwards was 1.6%. Among the key wards, 2A/2B had the highest percent of samples with detectable Cupriavidus, 20.3%. In contrast, PICU, 4B and 6A had lower proportions with Cupriavidus, at 1.6%, 2.0%, and 0.99%, respectively. Samples testing negative for Cupriavidus but positive for other GNBs accounted for 6.3% of PICU samples, 8.9% of samples from Ward 2A/2B, and 3.4% from Ward 6A, but 21.8% of samples from Ward 4B, though the latter had only a small number of samples tested for Cupriavidus/GNBs during the large sampling effort in March-April 2018.
10. *Atypical mycobacteria results*: Overall, 929 samples underwent AMS testing in 2019-2020, of which 9.1% were out of spec. AMS testing was carried out predominantly in hospital high-risk areas, where 6.8% of samples were out of spec. General areas had a high percent out of spec, 20.4%, almost entirely from a sampling effort carried out in June 2019 in the 1st floor theatres. Among the key wards, PICU and 6A accounted for most of the sampling effort, with out of spec proportions of 6.3% and 3.4%, respectively.
11. *Other organism-specific tests*: In addition to the routine tests, samples were occasionally submitted for organism-specific testing at the request of IPC/IMTs. Specific organisms included Acinetobacter, Burkholderia, *Elizabethkingia miricola*, Enterobacter, Exophiala, *Mycobacterium chelonae*, Serratia, and Stenotrophomonas. None of these requested tests grew the target organism over

the period 2015-2020, though three of the four *M. chelonae* tests grew atypical mycobacteria.

12. *Number of samples with notifiable taxa*: The mandatory alert organism list in the NIPCM contains four taxa for which, when clinical cases are identified, an environmental source should be considered. Of these four taxa, Acinetobacter species were detected in 73 samples, *Stenotrophomonas maltophilia* in 76 samples, *Pseudomonas aeruginosa* in 8 samples, and *Serratia marcescens* was not detected at all, across all 10 311 water samples tested by the Environmental Laboratory from 2015-2020.
13. *Total number of bacterial and fungal taxa*: Across all 10 311 water samples tested by the Environmental Laboratory over the period 2015-2020, 99 bacterial taxa and one non-taxonomic group (Environmental GNBs) were detected as target or non-target organisms in various routine and reactive tests. In addition, 23 fungal taxa and 7 non-taxonomic groups were detected. Of these, 29 bacterial and 9 fungal taxa were rare, occurring in only one sample across the entire data set.
14. *Most prevalent bacterial and fungal taxa*: Across all 10 311 water samples tested by the Environmental Laboratory over the period 2015-2020, the most prevalent bacterial taxa were *Cupriavidus pauculus* (440 samples), *Sphingomonas paucimobilis* (206 samples), *Delftia acidovorans* (168 samples), *Comamonas testosteroni* (119 samples), and *Stenotrophomonas maltophilia* (76 samples). Most prevalent fungal taxa, excluding non-taxonomic groups, were *Cladosporium species* (60 samples), *Exophiala species* (57 samples), *Aspergillus fumigatus* (54 samples), *Aspergillus niger* (27 samples), and *Purpureocillium lilacinum* (26 samples).

Section 2: Other environmental testing

Background

The previous section focused on water samples collected from QEUH Adults and RHC from 2015 to 2020. In addition to this water testing, other environmental samples were collected over this period for microbiological testing, including swabs of sinks, drains, showers, and various dry surfaces.

This section gives an overview of numbers, dates and locations, types, and microbiological findings from these environmental samples. It is important to note that this sampling was entirely reactive and not carried out in a routine, systematic manner, nor did sampling follow a standard procedure. The findings are therefore specific to the times and locations of sampling and cannot be used to draw more general conclusions about the taxa present across the QEUH site. Samples were collected by clinical teams and not by specialist contractors like with the water samples.

Overview of sample numbers

Over the 2015-2020 period, 1463 distinct environmental samples from the new buildings were tested, with an additional 4 samples having been collected but not processed by the lab due to missing information or to the sample being sent in a non-sterile container. The distribution of samples among key wards and sample types is shown in Table 7.

Table 7. Environmental sample types collected from key wards over the period 2015-2020

Sample type	1D PICU (RHC)	2A/2B (RHC)	4B (Adults)	6A (Adults)	other wards	Total
Drain	76	31	27	148	53	335
Shower	0	8	5	48	11	72
Sink	86	14	4	58	57	219
POU filter	64	7	4	148	17	240
Wet (other)	4	5	13	2	40	64
Chilled beam	0	12	0	89	21	122
Dry surfaces	69	2	3	13	117	204
other sample types	9	47	14	34	103	207
	308	126	70	540	419	1463

The distribution of these samples over time, in each key ward, is shown in Figure 20. No environmental samples were collected in 2015. The earliest samples were collected on 2016-01-21, and the latest samples in the data set were collected on 2020-10-28.

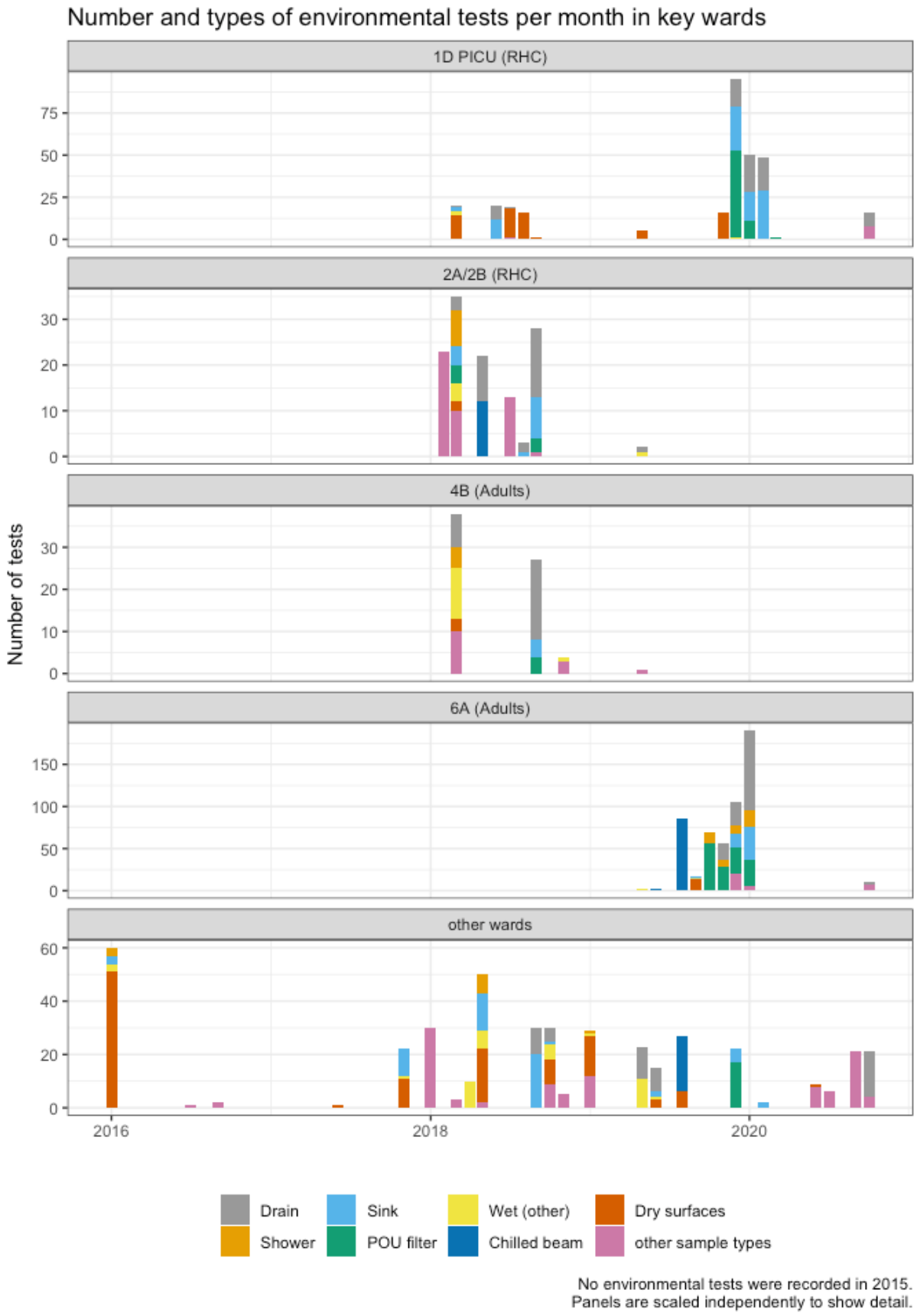

Figure 20. Number and types of environmental tests per month in key wards. Panels are scaled independently to show detail.

Sampling did not occur regularly over this period, but rather was concentrated over short intervals that coincided with IMT investigations. There was no systematic, routine environmental sampling as seen with water testing.

Microbiological results

Numbers and proportions with any detectable growth

The number of environmental samples with and without detectable growth, in each sample type category, is shown in Figure 21. Across all 1463 samples, 1074 had no reported organisms, 187 had a single reported organism, and the rest had more than one reported organism, up to a maximum of six.

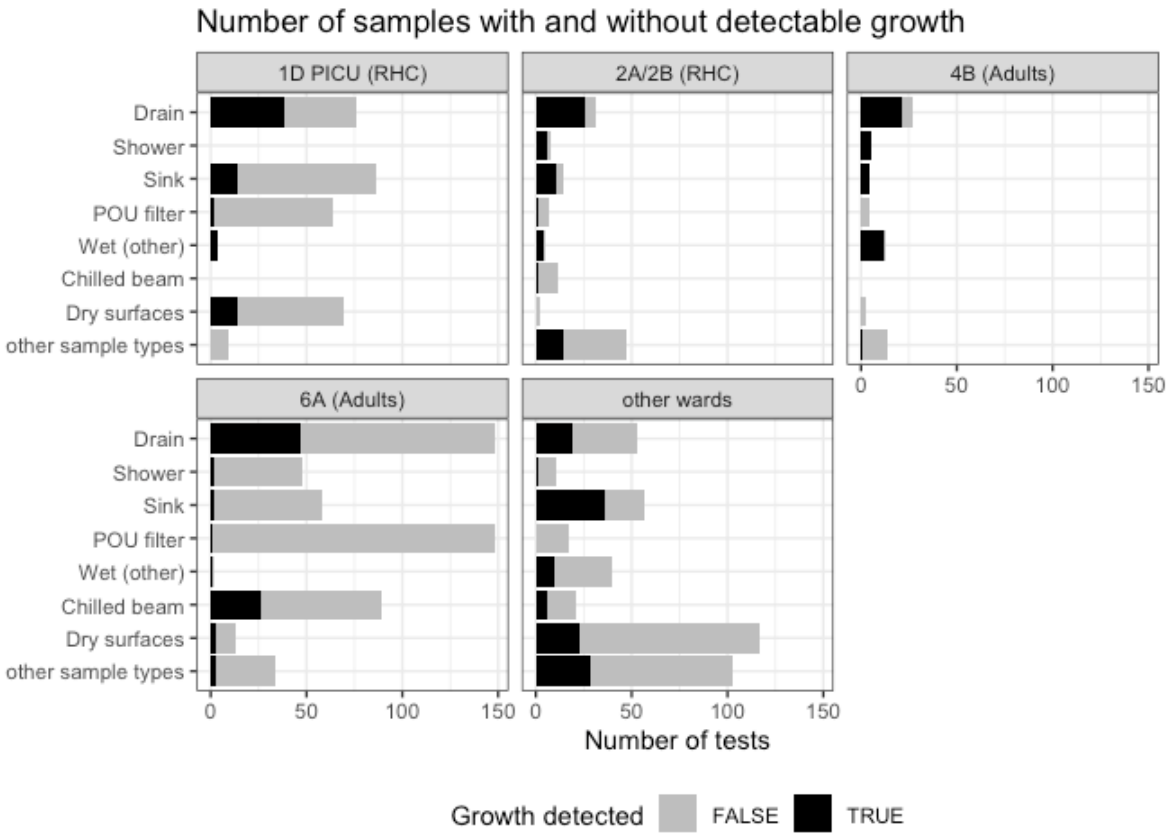

Figure 21. Number and type of environmental samples with and without detectable microbiological growth.

Named organisms

Across the whole data set, 128 distinct named organisms were detected, though 11 of these are not true taxonomic groupings but broad categories (e.g. Gram negative bacilli, mixed coliforms).

Of these 128 distinct named organisms (including non-taxonomic groupings), 57 were rare, occurring in only one sample out of 1463. All taxa detected in the environmental samples, along with their numbers in the water samples collected over the same period (see Section 1), are shown in Table 8.

Table 8. All taxa detected in environmental samples 2015-2020, and their numbers in the water data

Organism	Number in env. data[1]	Number in water data[2]
Pseudomonas aeruginosa	77	8
Cupriavidus pauculus	56	440
Fungi	54	57
Enterobacter cloacae	52	5
Stenotrophomonas maltophilia	40	76
Pseudomonas fluorescens	24	30
Staphylococcus epidermidis	23	not detected
Yeast species	21	not detected
Sphingomonas paucimobilis	18	206
Serratia marcescens	15	not detected
Delftia acidovorans	14	168
Micrococcus luteus	12	not detected
Pantoea species	12	2
Staphylococcus hominis	12	not detected
Klebsiella pneumoniae	11	3
Bacillus cereus	10	not detected
Chryseobacterium indologenes	9	12
Coliforms (lactose fermenting)	9	not detected
Mould	9	4
Pseudomonas putida	9	5
Kluyvera intermedia	8	1
Elizabethkingia meningoseptica	7	not detected
Pantoea agglomerans	7	5

Organism	Number in env. data[1]	Number in water data[2]
Acinetobacter lwoffii	6	36
Burkholderia cepacia	6	1
Sphingomonas species	6	3
Burkholderia species	5	2
Enterobacter kobei	5	not detected
Klebsiella oxytoca	5	not detected
Mixed Coliforms	5	not detected
Aspergillus species	4	8
Candida guilliermondii	4	not detected
Candida parapsilosis	4	1
Citrobacter freundii	4	not detected
Coliform bacilli	4	not detected
Enterococcus faecium	4	not detected
Gram negative bacilli	4	not detected
Mixed Organisms	4	not detected
Ochrobactrum anthropi	4	not detected
Staphylococcus (coagulase negative)	4	not detected
Staphylococcus capitis	4	not detected
Acinetobacter haemolyticus	3	1
Acinetobacter radioresistens	3	1
Bacillus species	3	1
Brevundimonas species	3	22
Burkholderia vietnamiensis	3	not detected
Candida albicans	3	not detected
Candida species	3	not detected
Moraxella species	3	1
Paenibacillus pabuli	3	not detected
Pseudomonas oleovorans	3	6
Rhodotorula mucilaginosa	3	not detected
Rhodotorula species	3	15
Serratia fonticola	3	3
Staphylococcus simulans	3	not detected
Acinetobacter baumannii complex	2	not detected

Organism	Number in env. data[1]	Number in water data[2]
Acinetobacter genomospecies TU13	2	not detected
Acinetobacter gyllenbergii	2	1
Aerococcus viridans	2	not detected
Aspergillus niger	2	27
Bacillus licheniformis	2	not detected
Comamonas testosteroni	2	119
Dermacoccus nishinomiyaensis	2	not detected
Enterobacter hormaechei	2	not detected
Enterococcus species	2	not detected
Exophiala dermatitidis	2	8
Geotrichum species	2	not detected
Gram positive bacilli	2	not detected
Pseudomonas chlororaphis	2	3
Pseudomonas species	2	6
Staphylococcus aureus	2	not detected
Achromobacter species	1	4
Achromobacter xylosoxidans	1	18
Acinetobacter calcoaceticus	1	1
Acinetobacter johnsonii	1	7
Acinetobacter junii	1	not detected
Acinetobacter species	1	4
Acinetobacter ursingii	1	22
Aeromonas salmonicida	1	2
Bacillus cereus group	1	not detected
Bacillus firmus	1	not detected
Bacillus simplex	1	not detected
Bordetella bronchoseptica	1	not detected
Brevibacillus species	1	not detected
Brevundimonas diminuta	1	8
Burkholderia cenocepacia	1	not detected
Burkholderia cepacia group	1	not detected
Burkholderia gladioli	1	3
Candida glabrata	1	not detected

Organism	Number in env. data[1]	Number in water data[2]
Candida intermedia	1	not detected
Candida lipolytica	1	not detected
Chryseobacterium species	1	1
Coliforms (non lactose fermenting)	1	not detected
Corynebacterium species	1	1
Dematiaceous hyphomycete	1	239
Enterobacter cloacae complex	1	not detected
Escherichia coli	1	not detected
Escherichia vulneris	1	not detected
Ewingella americana	1	not detected
Exophiala species	1	57
Gram negative bacilli (oxidase positive)	1	not detected
Gram positive cocci	1	not detected
Haemophilus parahaemolyticus	1	not detected
Kluyvera ascorbata	1	not detected
Kocuria rhizophila	1	not detected
Lactococcus lactis	1	not detected
Methylobacterium fujisawaense	1	not detected
Microbacterium paraoxydans	1	not detected
Mycelia sterilia	1	239
Prevotella species	1	not detected
Proteus species	1	not detected
Pseudomonas alcaligenes	1	2
Pseudomonas luteola	1	not detected
Pseudomonas stutzeri	1	not detected
Psychrobacter phenylpyruvicus	1	not detected
Ralstonia species	1	not detected
Raoultella ornithinolytica	1	not detected
Sphingobacterium thalpophilum	1	3
Staphylococcus caprae	1	not detected
Staphylococcus cohnii ssp *cohnii*	1	not detected
Staphylococcus haemolyticus	1	not detected
Staphylococcus pettenkoferi	1	not detected

Organism	Number in env. data[1]	Number in water data[2]
Staphylococcus saprophyticus	1	not detected
Staphylococcus sciuri	1	not detected
Staphylococcus warneri	1	not detected
Streptococcus mitis/oralis	1	not detected
Streptococcus salivarius	1	not detected
Streptococcus type *Viridans*	1	not detected

[1]Out of 1463 environmental samples.
[2]Out of 10 311 water samples tested by the Environmental Laboratory.

The distribution of detected organisms across key wards and in the main sample types is shown in Figure 22, with the point sizes indicating the proportion of samples with the detected organism.

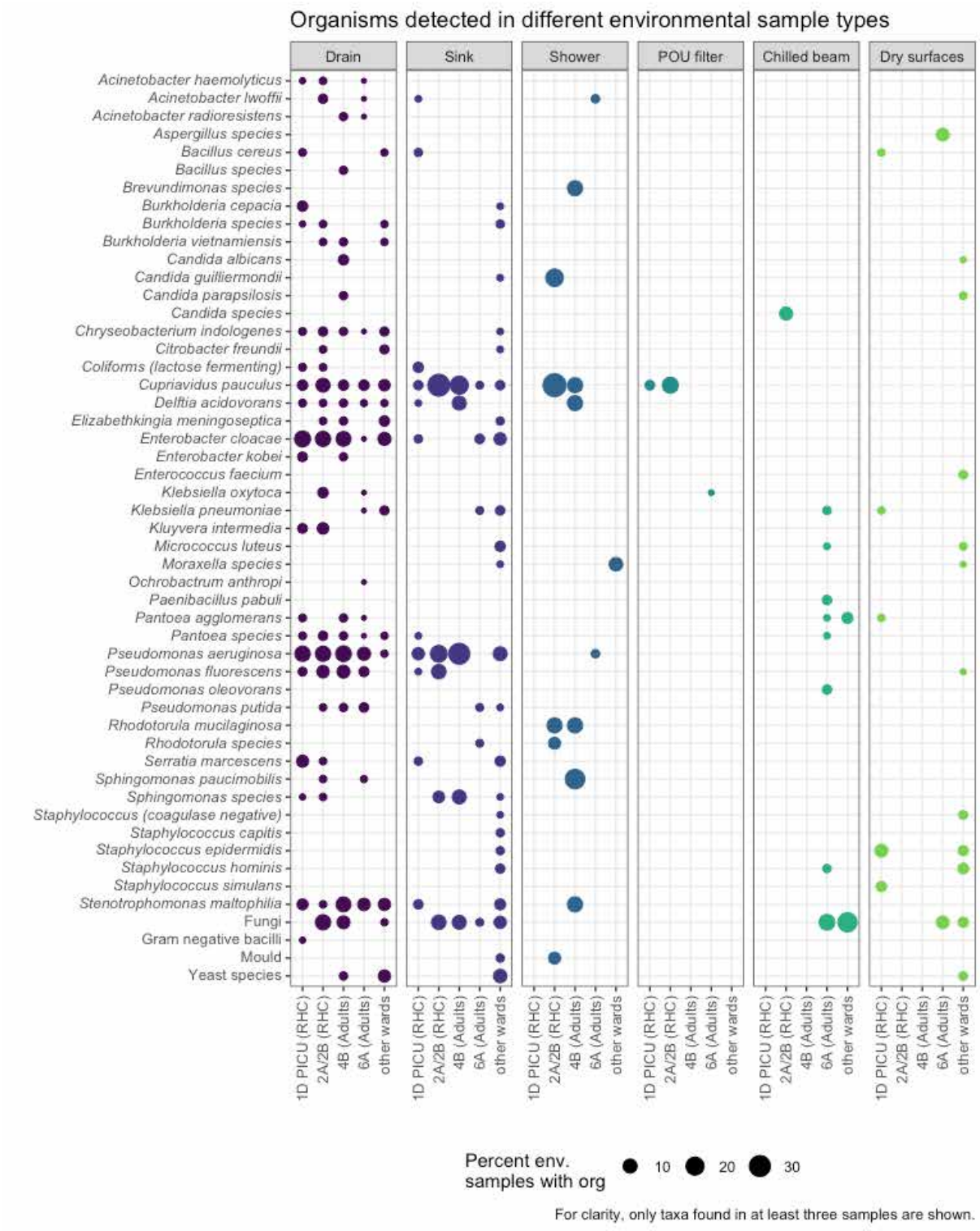

Figure 22. Organisms detected in different types of environmental samples from key wards.

Drain samples had the greatest diversity of detected organisms, and the specific taxa detected were similar in wards 2A/2B, 6A, 4B, and PICU. While many of the taxa detected in drains were also common in the water data, others were rare or had never been detected in water samples from the QEUH Adults and RHC over the period 2015-2020.

Fewer taxa were present in sink and shower samples, though the ones that were detected tended to be the most prevalent ones in water samples (*Cupriavidus pauculus*, *Delftia acidovorans*, *Sphingomonas paucimobilis*, *Stenotrophomonas maltophilia*). In contrast, the taxa found in samples from chilled beams and from dry surfaces were only rarely or never found in the water data, indicating a different source.

Swabs of the outer and inner surfaces of POU filters rarely grew any organisms. Out of 240 POU filter samples, 4 had any detected taxa - *Cupriavidus pauculus* (3 samples) and *Klebsiella oxytoca* (1 sample).

Environmental data summary

1. Environmental sampling was carried out in a reactive rather than routine manner, resulting in distinct clusters of samples collected from specific locations during short time frames rather than extensive systematic sampling at regular intervals.
2. The largest proportion of samples did not have any detectable microorganisms.
3. Samples from wet environments, especially drains, had a greater diversity of taxa than samples from dry sites.
4. There were differences between wards, with a greater proportion of wet samples from 2A/2B and 4B showing growth than from 6A. However, the sampling effort was not equal across these wards, and far more samples were collected from 6A than from any other ward.
5. Some of the most prevalent taxa in the environmental data set were also among the most common in the water data set (see Section 1), but other prevalent taxa in the environmental samples had never been seen in any water sample over the period 2015-2020.
6. The collection of taxa observed in drains was similar in 2A/2B, 6A, 4B, and PICU.

Appendices: Glossary, data sets, and processing steps

Glossary

Table 9. Acronyms and abbreviations used in this report

Abbreviation	Definition
AMS	Atypical mycobacteria
CF100	Coliform counts per 100 mL
CFU	Colony-forming unit
DMA	DMA Canyon Ltd, water monitoring contractor
E.coli	*Escherichia coli*
EC100	*E.coli* counts per 100 mL
GG&C	NHS Greater Glasgow & Clyde
GNB	Gram negative bacteria
IEC	International Electrotechnical Commission
IMT	Incident Management Team
IPC	Infection Prevention & Control
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System, i.e. TelePath
Lp	*Legionella pneumophila*
MALDI-TOF MS	Matrix-assisted laser desorption/ionization time-of-flight mass spectrometer, an instrument for rapid identification of unknown organisms in the clinical microbiology laboratory
NIPCM	National Infection Prevention and Control Manual
PA100	*Pseudomonas aeruginosa* counts per 100 mL
PICU	Paediatric intensive care unit
POU	Point of use, e.g. POU filter attached to a tap
PS100	Pseudomonas counts per 100 mL
QEUH	Queen Elizabeth University Hospital
RHC	Royal Hospital for Children
SAB	Sabouraud's agar (used for selective culturing of fungi)
SAB22	Fungal counts after incubation at 22°C, which encourages the growth of moulds
SAB30	Fungal counts after incubation at 30°C, which encourages the growth of yeasts
SOP	Standard Operating Procedure
TVC	Total viable count
TVC22	Total viable count (CFU/mL) after incubation at 22°C, which selects for environmental organisms

Abbreviation	Definition
TVC37	Total viable count (CFU/mL) after incubation at 37°C, which selects for organisms that might be more adapted to human body temperature
UKAS	UK Accreditation Service

Water testing data processing

Raw data sources

Water sampling data sheets used in this report were obtained from QEUH Estates Department, from the GG&C TelePath system, and directly from DMA. All raw data files are listed below.

Table 10. Original water testing data files included in this summary report

Original data file	Year	Source
2015 Potable Water Master File Complete 13.11.20.xls	2015	LIMS
Alcontrol 18 08 2015 samples.xls	2015	Alcontrol
2016 Potable Water Master File Complete 13.11.20.xls	2016	LIMS
Alcontrol Water Sample 06 01 2016.xls	2016	Alcontrol
2017 Potable Water Master File Complete 13.11.20.xlsx	2017	LIMS
2017 NHS QEUH Sample Login Template (Inc Ps).xls	2017	DMA
Alcontrol 20 01 2017 samples.xls	2017	Alcontrol
2018 Potable Water Master File Complete 13.11.20.xlsx	2018	LIMS
2018 NHS QEUH Adult Sample Login Template (Inc Ps&R).xls	2018	DMA
2018 NHS QEUH Childrens Sample Login (Inc Ps&R).xlsm	2018	DMA
2019 Potable Water Master File Complete 13.11.20.xlsx	2019	LIMS
2019 (01-06) QEUH A&C Sample Login (Inc AMS).xls	2019	DMA
2019 (07-12) QEUH A&C Sample Login (Inc AMS).xls	2019	DMA
DC QEUH NON-DMA SAMPLES 1.1.20 - 31.12.20.xlsx	2020	LIMS
2020 NHS QEUH AC (01-06) Sample Login Sheet (002) 210720.xlsm	2020	DMA
2020 NHS QEUH AC (07-12) Sample Login Sheet (016) 301220.xlsm	2020	DMA
2020 NHS QEUH Ward 1D PICU Samples (008) 241220.xlsm	2020	DMA
2020 NHS QEUH Ward 6A Samples (00A) 241220.xlsm	2020	DMA

Locations and associated out of spec threshold categories

The following location codes were used to recode and standardise location data across all samples. The associated out of spec thresholds, based on risk level, are as outlined in WQS-017 Water Management Procedure (QEUH Estates Department). Recoding of location data was based on unique outlet ID, where available, and on data in various other fields, which varied across the years and data sources. There were occasional inconsistencies among data sheets from different years, where the same unique ID was associated with entries from different wards, buildings, new vs retained, and/or risk levels. Where inconsistencies were identified, these were repaired based on the following hierarchy:

1. Unique IDs on dedicated location sheets (e.g. PICU, Ward 6A)
2. Consensus location based on numerous separate sheets
3. Clarity of entries in other fields on the same sheet
4. Most recent sheets

Table 11. Buildings, wards, and associated microbiological threshold categories

New or retained	Building	Ward[1]	Threshold category
new	Adults	4B	high risk
new	Adults	4C	high risk
new	Adults	6A	high risk
new	Adults	7A	high risk
new	Adults	7D	high risk
new	Adults	HDU	high risk
new	Adults	other	general
new	Adults RHC	basement bed wash	general
new	Adults RHC	basement tanks	general
new	Adults RHC	drains risers calorifiers	general
new	Adults RHC	external	general
new	RHC	1D PICU	high risk
new	RHC	2A 2B	high risk
new	RHC	2C	high risk
new	RHC	3A	high risk
new	RHC	3B	high risk
new	RHC	3C	high risk
new	RHC	NICU	high risk
new	RHC	other	general

New or retained	Building	Ward[1]	Threshold category
new specialist	Adults	Aseptic pharmacy	specialist
new specialist	RHC	Aseptic pharmacy	specialist
new specialist	RHC	Theatre8	specialist

[1]Wards not specifically listed as high risk were grouped under 'other'.

Water data curation and re-coding for consistency

The data sheets from ALcontrol were first processed in Excel to separate Legionella from potable and Pseudomonas test results, remove formatting and non-numeric symbols from numeric test result entries, and re-code the locations manually by cross-referencing with location data from DMA, since ALcontrol provided only outlet ID numbers with little additional information about which building or ward the sample had been collected from.

All other data sheets (those from DMA and TelePath) were locked to prevent editing, and were instead read directly into R version 4.2.0 using the readxl package, along with the processed ALcontrol data sheets. Data preparation and curation were carried out entirely in R, as detailed in the separate Rmarkdown notebook 01_Water_data_upload_and_preparation_v3_2021.Rmd.

Briefly, it involved the following:

1. Loading each Excel file, adjusting variable names so as to be consistent across the data set, and joining files into a single data object
2. Removing duplicate entries, i.e. those that were present in both the TelePath data and DMA sheets
3. Removing entries for samples that were not collected or tested, or for which results were not recorded, indicated by free text 'No sample taken', 'No access', 'Results not available', or similar character strings in one or more of the metadata columns
4. Moving character strings from numeric columns into free-text columns
5. Re-coding location data into new consistent variables (New or retained, Ward) using a series of automated string detection steps
6. Re-coding test requested data into consistent variables, based on the results in the numeric columns as well as string detection steps in free-text columns.

Named organism data were re-coded manually from the main data set into a separate Excel sheet, as there was no consistency in how these data were entered. This Excel sheet was subsequently loaded into R and joined to the main data set. Final curation steps corrected obvious errors, including duplicate Lab.Reference numbers for samples that were clearly different, mis-typed sample dates where digits were reversed or added to the year of sampling, and entries where an organism was reported using an outdated name (e.g. *Pseudomonas paucimobilis*, which is an old name for *Sphingomonas paucimobilis*).

Environmental testing data processing

Data preparation overview

All data used in this analysis are from a single file (2015 - 5.11.20 Environmental Samples Master File Complete 13.11.20.xls), which was compiled directly from TelePath, the Laboratory Information Management System used by Microbiology to report results of microbiological testing.

Location information

Most entries have information on the hospital building (QEUH, RHC, or PHILLIPSHILL) and the ward. More specific location information (room, bed, etc.) is sometimes included in one of the other free-text columns, but data entry is inconsistent and often missing. For this overview, locations will be limited to the ward level rather than specific rooms within wards, with a focus on key wards 2A/2B, 6A, 4B, PICU and NICU, and the remaining wards grouped under 'other wards'.

Sample type information

Sample type does not have a dedicated column in this data set, so it had to be deduced from free-text entries in the columns called 'Site of specimen', 'Specimen identifier', 'Specimen Ref No/identifier', and the 'Comment' columns. I created a new variable called 'Sample.type', with the following values:

- *Air* - included settle plates, air filters, vent dust
- *Env.soil* and *Env.drop* - soil and pigeon dropping samples
- *Cons* - consumables, including disinfectant wipes, creams, soaps, detergents, etc.
- *Line.site* - consumables associated with lines, including curos caps, SmartSite and Vadsite ports, etc.
- *Surf.equip* - swabs of medical equipment, including scanners, ventilators, incubators, etc.
- *Surf.fixed* - fixed surfaces, including walls, floors, bed rails, bedsite tables, call buttons, phones, etc.
- *Trolley* - trolleys used by medical, catering, and facilities staff
- *Wet.drain* - any type of drain sample, including sink and shower drains
- *Wet.pouf* - any sample from the inside or outside of a POU filter
- *Wet.sink* - any sample linked to sinks, excluding drains and POU filters, including basin and taps
- *Wet.shower* - any sample linked to showers, excluding drains and POU filters, including shower chairs and shower heads
- *Wet.toilet* - any sample from a toilet, including the seat and flush handle
- *Wet.dishwash* - any sample from inside or outside a dishwasher
- *Wet.plumb* - any sample from a plumbing component leading to a tap, including flow straighteners and flow directors
- *Wet.other* - samples from wet environments that don't fit into the other categories, including water fountains, water from leaks, baby baths, damp mops, etc.
- *Chilled.beam* - any sample from the air conditioning system linked to chilled beams

- *other* - any sample that does not fit into these categories, or that has insufficient information to determine sample provenance

Due to very small numbers of samples in some of these categories, they were further simplified to the following:

- Drains
- Sinks
- Showers
- POU filters
- Wet.other (toilet, dishwasher, plumbing, other)
- Chilled.beam
- Dry.surfaces (fixed, equipment, trolleys)
- other

Microbiological data

There are two data columns that give the results of microbiological testing, with some additional information occasionally found in the free-text 'Comment' columns.

The column called 'Growth' has the following possible values:

- *CY* for Culture yields (i.e. growth detected)
- *Enrichment* for Enrichment culture yields
- *NFI* for No fungi isolated
- *NG* for No growth
- *NSG* for No significant growth
- *NG2D* for No growth after 2 days incubation
- *NG5D* for No growth after 5 days incubation
- *NG1W* for No growth after 1 week's incubation

For simplicity, the growth column was recoded into a binary variable (Growth: TRUE or FALSE), with CY and Enrichment as TRUE and the others as FALSE.

Where growth was detected, the variable called 'Organism' gives the identification reported by the laboratory. When multiple organisms were grown from the same sample, each organism has its own entry in the data set.

Final data sets were loaded into the Rmarkdown script used to generate this report.

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Date Work Commenced

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Purpose of Work Undertaken

Investigation into the possible contamination of flow Straighteners. Flow straighteners are commonly used in the hospital environment as an additional control for water flow. This project was done to asses the levels of contamination occurring over time and the potential of the flow straightener to become a source of contamination if not properly maintained. The flow straighteners tested in this investigation were all from a live system that had been noted for having poor water quality when compared against drinking water standards.
For this project three parameters were initially looked at:

1. Total bacterial levels.
2. Biofilm levels.
3. Visual soiling.

The flow straighteners were supplied after various times in use, from the same water system, with a time range of:

- New- unused as supplied by the manufacture
- 1 week in use
- 1 month in use
- 2 months in use
- 3 months in use
- > 3 years in use

On receipt of the flow straighteners and initial visual inspection was performed to assess for soling. The flow straightener was then placed into a sterile bag and 200ml of sterile deionised water added, this was then agitated for 30 seconds. The flow straightener was then removed. The liguid was then tested for Total bacterial count and Pseudomonas. The flow straightener was then tested for the presence of biofilm using Biofinder™.

These results were graphically plotted to give a visual representation of the levels and rate of contamination so that a potential timeline could be established. Initial results included at the end of the report.

Further analysis of the total bacteria plates was performed during testing. Ie, colony morphology was determained from the plates that where organisms were deemed to be dominant. These organisms were sent for identification and the information derived from this was used to see if the types of organisms changed with the levels of contamination.

Analysis method

An initial visual inspection of each flow straightener was performed looking for presence of soiling and potential contamination of the flow straightener. A rating was given to each flow straightener to reflect the level of soiling

Soiling assessment:
No= nNo visible soiling all holes appear clear with no ingress.
Light= Some visible soiling, no detachment during washing, >70% of holes appear clear with no ingress.
Moderate= Visible soiling, some detachment during washing, no more than 50% of holes showing indication of ingress.
Heavy= Heavy visible soiling, large fragments detached during washing, all holes show significant ingress or blockage.

Microbiological Analysis

A modified Bio-Burden test was used to analyse the flow straighteners.

a. 200ml of sterilised deionised water (SDW) was added to the bag containing the flow straightener and the bag was agitated for 30 seconds. The 200ml of liquid was then classed as the sample.

b. 1ml of the sample is used to create a serial dilution. Neat and 1:10 dilution was tested for total viable count (TVC)

c. 100ml of sample was filtered and the filter transferred to a TVC plate

d. The remainder of sample was filtered and transferred to a Pseudomonas aeruginosa specific plate

e. All plates were incubated at 35oC for 48 hours to stimulate bacterial growth.

f. After the incubation period all visible colonies were counted and recorded (any unusual growth types on the *P. aeruginosa* plates was recorded as non-typical (NT#)

Biofilm assessment

For the assessment of bioburden, a specialist product (Biofinder™) was used

Biofinder™ is a transparent yellow liquid which is sprayed onto a surface. When coming into contact with the biofilm protein structure produces a catalase reaction.

Assessment of the levels of biofilm was made based on the strength and speed of the reaction

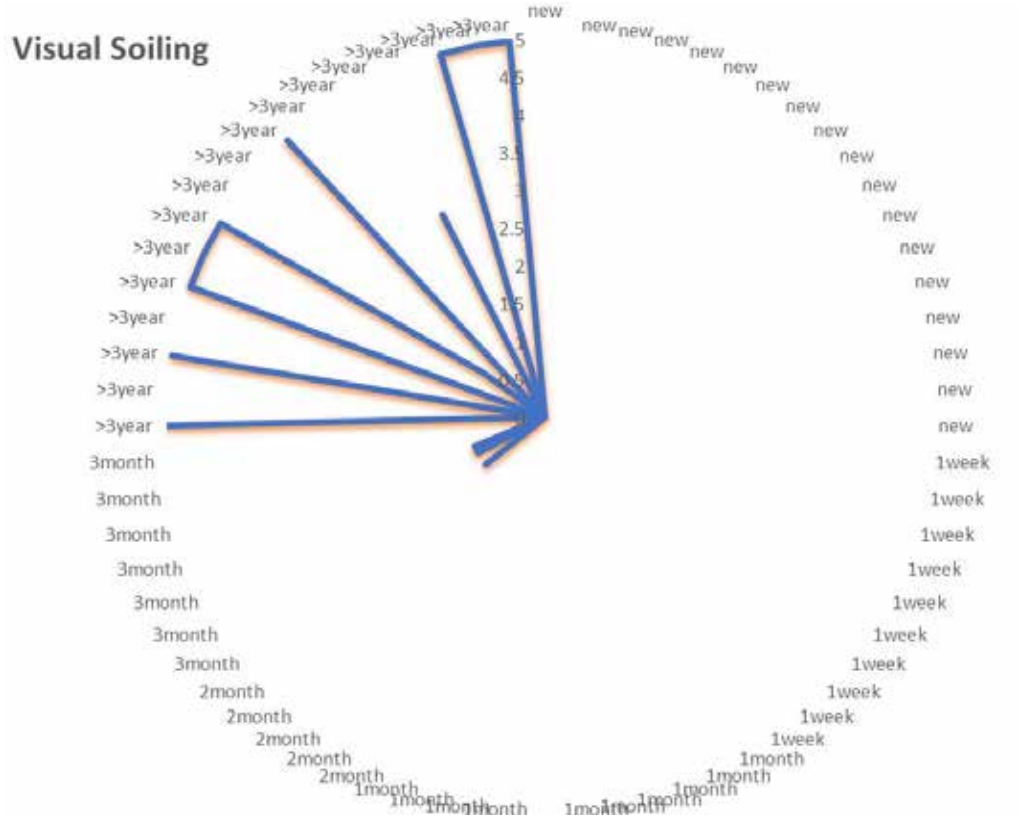
<u>Biofilm assessed on a score 0-5.</u>
0= No reaction. No biofilm presence
5= Strong instant reaction large biofilm presence/ mature biofilm

fig1 complete and dismantled flow straightener

All flow straighteners tested in this project were of the same design and from the same manufacturer. The flow straighteners are made up of 6 internal parts that fit into a grey plastic casing measuring 22mm diameter and 11mm depth. The flow straightener is made up of all plastic parts and 2 rubber gaskets. The straighteners are screwed into the spout of the tap and are used as both a strainer and to even the flow of water coming from the tap.

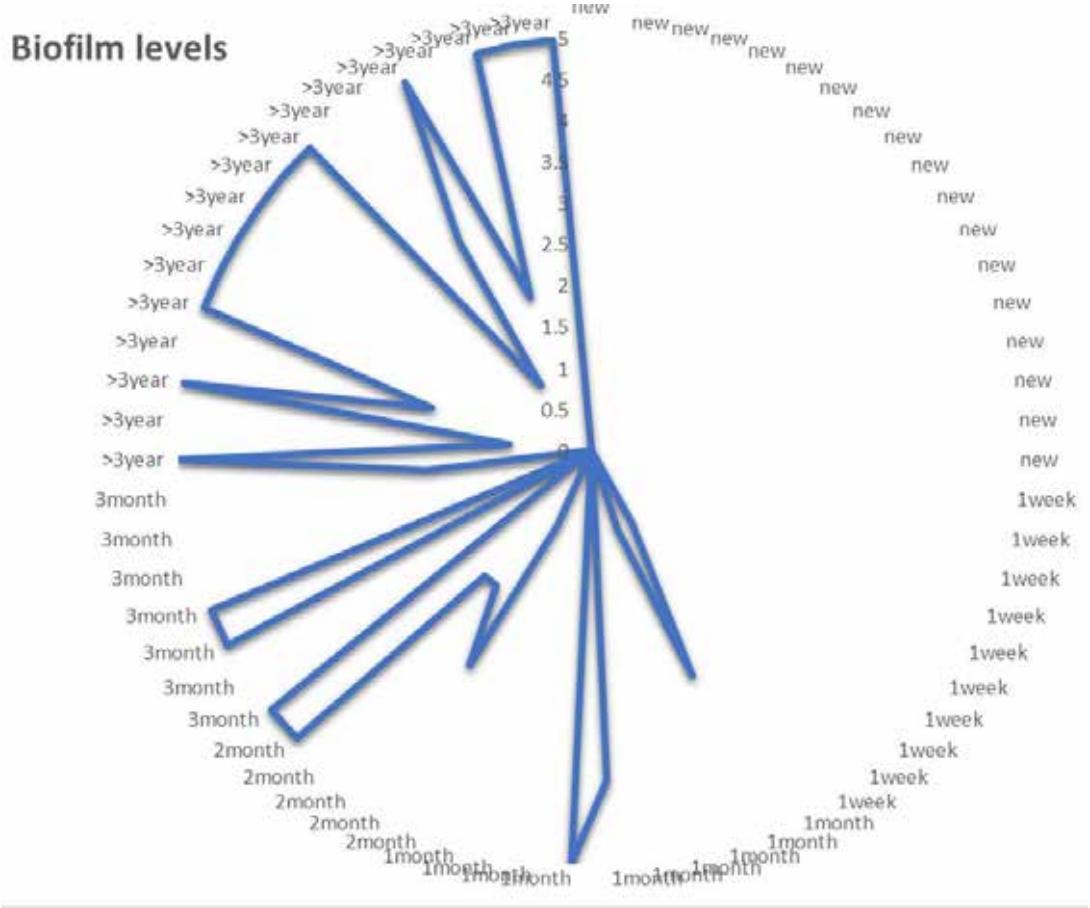
Results

Visual Soiling



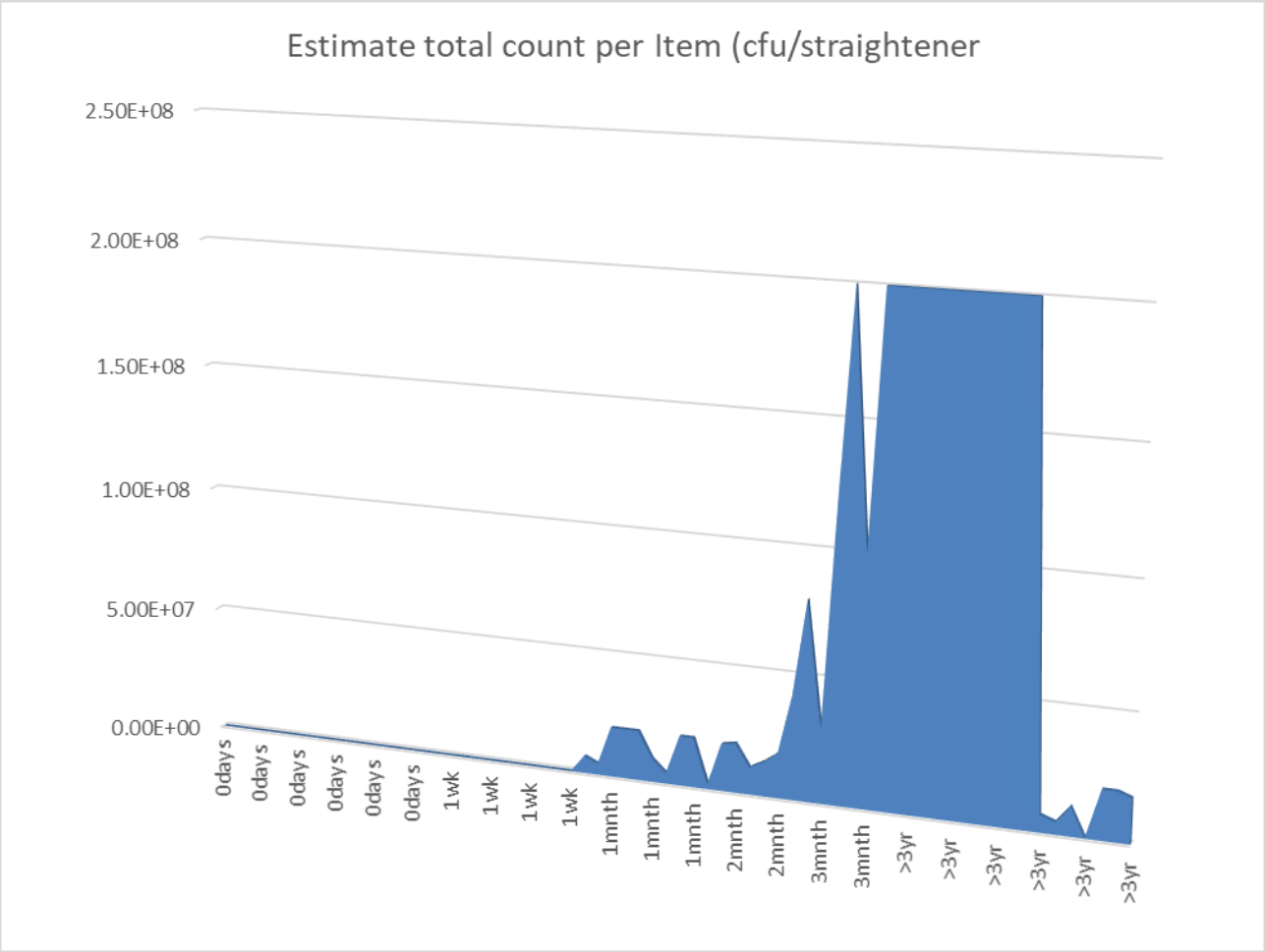
All soiling inspections were performed by the same analyst so that consistence was maintained throughout the project. No visual soiling appeared on the flow straighteners until the third month of use. On the third month of testing only light soiling was visible on the straighteners on 40% of the samples.

Biofilm Levels



The first indication of biofilm formation was detected after 1 month of inline flow straightener use. The levels of biofilm present were variable between the straighteners from no to heavy contamination and 50% of the samples returned a positive result.

Total Bacteria Levels



A larger number of samples of unused straighteners were tested so that a reliable baseline could be established for this test. All the unused samples returned similar results in the low hundreds ≈ 300cfu/unit. The increase in total bacterial levels on the flow straighteners was rapid, ie: within the first month of use these straighteners reached counts between 10*6 and 10*7. After 2 months counts often exceeded the maximum count of 2.0 10*8.

Organism Identifications

On the occasions where isolates were taken for identification a set protocol was followed.

The morphology of the colonies grown was noted and the 6 most dominant morphologies were chosen to be put forward for identification. In addition, 2 sample colonies from each set of plates that had been set up for Pseudomonas were sent for identification as the colonies did not illustrate typical Pseudomonas morphology.

After 1 month of use

Blastomonas ursincola,
Cupriavidus pauculus,
Chryseobacterium spp

After >3 years of use

Sphingomonas paucimobils,
Micobacterium laevaniformans,
Stenotrophomonas multophilia,
Acidovorax temperans,
Chryseobacterium spp,
Caulobacter

Non-Typical Pseudomonas growth

Stenotrophomonas multophilia,
Cupriavidus pauculus

Conclusion

The analysis being performed in this investigation was on a live system the number of samples provided was limited to what was available. Despite this enough data was gathered to analyse for trending and proivde some initial conclusions.

The flow straightener micro-organism analysis demonstrated that within the first month of use, the microbial contamination increased significantly from 10*2 to 10*6/7. This trend continued on the flow straighteners after 2 and 3 months and samples from flow straighteners used for over 3 years, had counts exceeding 10*8, it should be noted that the rate of increase did slow down the longer the straighteners were on the system and this may be due to the organisms reaching their optimum levels for the environment so further increase would be unlikely although small fluctuations would occur.

Visual soiling did not occur on any of the slow straighteners until they had been in use for 3 months and at this point the soiling was only light. The heavy build-up of soiling was not seen until the flow straighteners had been in use for three years. Given the micro-organism analysis, a visual inspection of flow straighteners to assess the condition would not be reliable method to determine straightener hygiene.

The presence of biofilm started to be detected on the flow straighteners as early as 1 month of use and by 3 months over 50% of the flow straighteners tested showed signs of biofilm contamination. When the flow straighteners were tested, all flow straighteners showed some level of biofilm and over 50% showed high levels (5 on the assessment scale). These results also show that biofilms can be present on the flow straighteners and not be immediately obvious when visually inspecting.

Organisms identified.

The organism identification results demonstrate that there is a change in dominant organisms over time. This may be attributed to environmental conditions changing as the biofilms mature thus creating more suitable environments to different organisms. There does appear to be a single organism (Chryseobacterium) which appears to be present in high numbers throughout the testing. Previously classified as Flavobacterium, it is well documented for its ability to form biofilms

The flow straighteners as a unit consist of 8 parts seven of which come into direct contact with the water. Given the design and number of parts each flow straightener contains these items have a large uneven surface area in contact with the water and so create ideal conditions for the formation of biofilms

Using the data derived from this work the maximum length of use for a flow straightener on this system, without maintenance should not exceed 1 month.

Result data.

Visual Soiling assesment

Age	soiling visual	Age	soiling visual	Age	soiling visual	Age	soiling visual	Age	soiling visual	Age	soiling visual
new	0	1week	0	1month	0	2month	0	3month	1	>3year	5
new	0	1week	0	1month	0	2month	0	3month	0	>3year	0
new	0	1week	0	1month	0	2month	0	3month	1	>3year	5
new	0	1week	0	1month	0	2month	0	3month	1	>3year	0
new	0	1week	0	1month	0	2month	0	3month	0	>3year	5
new	0	1week	0	1month	0			3month	0	>3year	5
new	0	1week	0	1month	0			3month	0	>3year	5
new	0	1week	0	1month	0					>3year	1
new	0	1week	0	1month	0					>3year	0
new	0	1week	0	1month	0					>3year	5
new	0									>3year	0
new	0									>3year	0
new	0									>3year	3
new	0									>3year	0
new	0									>3year	5
new	0									>3year	5
new	0									>3year	5
new	0										

Biofilm Levels

Age	Biofilm Assessment	Age	Biofilm Assessment	Age	Biofilm Assessment	Age	Biofilm Assessment	Age	Biofilm Assessment	Age	Biofilm Assessment
new	0	1week	0	1month	1	2month	1	3month	5	>3year	5
new	0	1week	0	1month	3	2month	3	3month	0	>3year	1
new	0	1week	0	1month	1	2month	2	3month	5	>3year	5
new	0	1week	0	1month	0	2month	2	3month	5	>3year	2
new	0	1week	0	1month	0	2month	5	3month	0	>3year	5
new	0	1week	0	1month	4			3month	0	>3year	5
new	0	1week	0	1month	5			3month	2	>3year	5
new	0	1week	0	1month	0					>3year	5
new	0	1week	0	1month	0					>3year	5
new	0	1week	0	1month	0					>3year	5
new	0									>3year	1
new	0									>3year	3
new	0									>3year	5
new	0									>3year	2
new	0									>3year	5
new	0									>3year	5
new	0									>3year	5
new	0										

Total Bacteria Levels

Age	Total Bacteria	Age	Total Bacteria	Age	Total Bacteria	Age	Total Bacteria	Age	Total Bacteria	Age	Total Bacteria
new	5.00E+02	1week	5.00E+03	1month	7.00E+06	2month	1.90E+07	3month	4.20E+07	>3year	2.00E+08
new	4.00E+02	1week	3.01E+04	1month	4.40E+06	2month	2.00E+07	3month	8.00E+07	>3year	2.00E+08
new	7.20E+02	1week	5.00E+03	1month	2.00E+07	2month	1.10E+07	3month	3.00E+07	>3year	2.00E+08
new	1.40E+03	1week	5.00E+03	1month	2.00E+07	2month	1.40E+07	3month	1.20E+08	>3year	2.00E+08
new	8.00E+01	1week	0.00E+00	1month	2.00E+07	2month	1.80E+07	3month	2.00E+08	>3year	2.00E+08
new	1.40E+01	1week	4.00E+03	1month	9.40E+06			3month	1.00E+08	>3year	2.00E+08
new	2.40E+01	1week	2.40E+02	1month	4.20E+06			3month	2.00E+08	>3year	2.00E+08
new	1.08E+02	1week	4.50E+02	1month	2.00E+07					>3year	2.00E+08
new	2.00E+01	1week	1.10E+02	1month	2.00E+07					>3year	2.00E+08
new	1.40E+01	1week	4.00E+03	1month	2.00E+06					>3year	2.00E+08
new	1.16E+02									>3year	7.00E+06
new	8.00E+01									>3year	5.00E+06
new	4.20E+02									>3year	1.20E+07
new	3.00E+01									>3year	4.00E+05
new	1.40E+02									>3year	2.00E+07
new	4.20E+02									>3year	2.00E+07
new	2.08E+02									>3year	1.80E+07
new	1.50E+02										

Client Details

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Report By

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Date Work Commenced

17/06/2019

Date Of Report

08/07/2019

Signed By:

D. Holloway

D. Holloway BSc (Hons) MRSPH

Background

Fourteen samples were received into the laboratory from Glasgow Queen Elizabeth Hospital. The samples comprised of parts from the portable water system and suspected contaminants taken from within the potable water system. Instructions supplied with the sample were to investigate any potential microbial contamination and identify any organisms present. To investigate overall condition of the water system parts.

Samples received

1. Water collected from inside expansion bladder
2. Holding plate from top of expansion bladder
3. Expansion bladder
4. Debris from booster set 1 from expansion vessel
5. Debris from booster set 1 pump number 5 non return valve
6. Output side of pump body from 5
7. Plant room 21 Calorifier 21/03 shunt pump
8. Plant room 33 Calorifier 1
9. Plant room 32 renal water meter soft nodules
10. Plant room 31 PRV
11. Plant room 22 non return valve
12. Plant room 31 pump
13. Plant room 41 non return valve
14. Water from pipe at 13

The investigation of these samples looked at three initial parameters:

1. Visual assessment
2. Biofilm levels
3. Bacteriological investigation

Visual Assessment

A visual assessment of water samples was not performed as this would offer very little relevant information.

Holding Plate from top of expansion bladder.

The holding plate from the expansion bladder was received with part of the rubber bladder attached. This was removed and assessed as part of the expansion bladder. Significant corrosion was observed on the internal surface of the holding plate. To properly assess the level of corrosion and any further effect on the holding plate one side of the holding plate was scraped clear of surface corrosion. The surface corrosion was found to be between 1mm and 3mm depth covering the entire surface of the holding plate. The surface of the holding plate exposed was found to

have significant pitting. The pitting continues around the edge of the holding plate and to the other side. It was noted that there was a distinct clear line where the corrosion stopped. This indicates that the seals holding the plate to the expansion bladder were intact and no water was leaking from the bladder to cause corrosion outside.

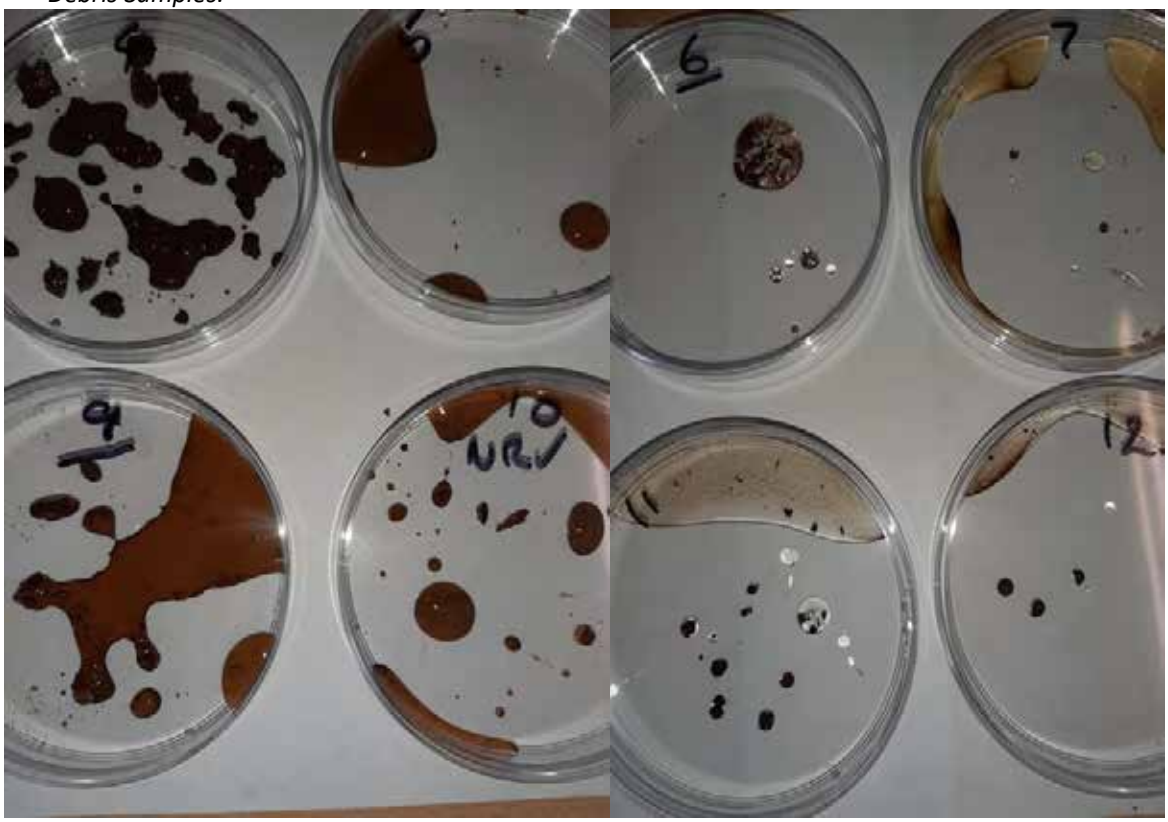
Expansion Bladder

The expansion bladder had the following manufacturer markings.

200/300 LT SE/FA EPDM Butile Made in Italy. B 7 8

The internal surface of the expansion bladder was assessed. There was no visual damage to the internal surface of the bladder observed. The internal surface of the bladder had 4 distinct visual differences. Some sections of the bladder appeared to have white/cream deposits on the surface. These had a glistening appearance and were not visible when the area was dry.
Some sections of the bladder appeared to have reddish brown deposits on the surface, these had a dry and dusty appearance and were visible in both dry and wet conditions.
Some sections of the bladder appeared to have reddish brown granular deposits on the surface. These deposits were focused around the base of the bladder.
The other sections of the bladder did not appear to have any visual deposits on the surface. These areas were observed in both wet and dry conditions with no change in appearance.

Debris Samples.



Debris samples were assessed together. All samples appeared to have fragments of various sizes. These appeared to be fragments of corroded metal, the largest fragments were found in the debris sample from booster set number 1 from expansion vessel. Given the size of the fragments it would be reasonable to assume that the corrosion on this part was significant. On samples 5 and 9 the sterile water added to the samples to maintain any bacterial content had taken on a significant amount of solids in suspension. This was enough to fully colour the liquid and change the viscosity. This indicated that the samples were not made up solely of solid fragments but also contained other particulate matter.

Biofilm Assessment.
For the assessment of bioburden, a specialist product (Biofinder™) was used

Biofinder™ is a transparent yellow liquid which is sprayed onto a surface. When in contact with the biofilm protein structure produces a catalase reaction.

Assessment of the levels of biofilm was made based on the strength and speed of the reaction

Biofilm assessed on a score 0-5.
0= No reaction. No biofilm presence
5= Strong instant reaction large biofilm presence/ mature biofilm

Holding plate.
There were two potentials for biofilm testing of the holding plate.
1/ the surface corrosion
2/ the surface area of the holding plate where the surface corrosion had been removed.

sample	BIOFILM ASSESMENT
holding plate corrosion	5
holding plate cleared	5

Biofilm was present in both the surface corrosion and the cleared surface of the holding plate. This demonstrates that the surface corrosion attachment is partly due to the presence of biofilm. It is not unreasonable to assume that the biofilm is also partly responsible for the corrosion and the pitting seen in the surface of the holding plate.

Expansion bladder

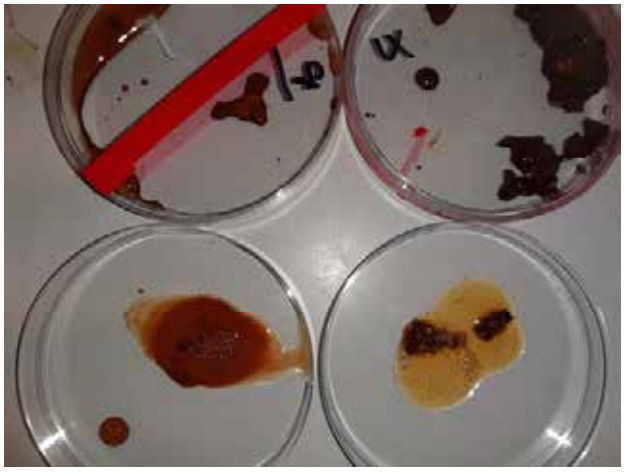
There were four sections of the expansion bladder that were chosen for biofilm assessment.

1. White/cream deposits
2. Reddish/ brown deposits with dry appearance
3. Reddish/ brown granular deposits
4. No visible deposits

A fifth section was also chosen for testing. This sample was chosen to act as a control sample. This would be from the outside surface of the bladder and cleaned using Industrial mentholated spirit prior to testing to remove any possible contamination. This was done to ensure that there was no cross reaction between the Biofinder™ and the bladder material.

sample	BIOFILM ASSESMENT
control	0
white cream deposits	5
reddish brown deposits dry appearance	5
reddish brown deposits granular appearance	5
no visible deposits	5

Debris Deposits
Samples 4 and 9 were chosen for biofilm testing as representative of the debris samples received. These contained larger fragments of debris so the potential to get a reaction was greater while allowing for the dilution of the water present in the sample.



Although the reaction from the Biofinder™ was light it was still possible to determine that a biofilm was present in these samples.

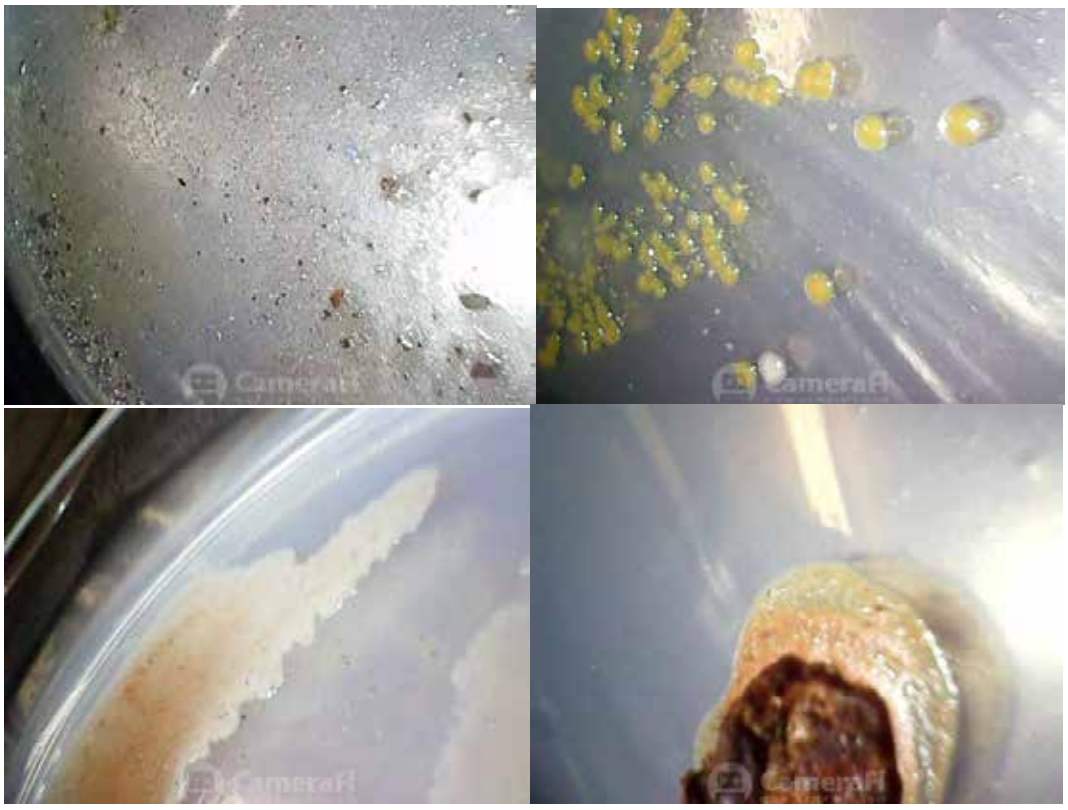
Conclusion
From the biofilm testing it is possible to state that all the water system parts, and debris samples sent to the laboratory were contaminated with biofilm.

Microbiological assessment.
Due to the amount of biofilm identified in the previous work carried out on these samples' organism levels would not be practical. On this occasion it was decided that an assessment of the types of organism's present would be the appropriate course.

To recover viable organisms from a potential biofilm is not always possible. The organisms can enter a life cycle stage where although they are viable organisms, they are not culturable.
To give the best possible chance to recover these organisms' additional steps have been added to the swabbing procedure the best possible chance of recovery.

Sections were cut from the bladder (6 areas) each section measured approximately 8cmX8cm.
These were placed into a sterile bag and a maximum recovery diluent was used to moisten the surface of the section of bladder.
The bags were closed but not sealed so as not to create an anaerobic condition a sterile straw was placed into the bag to prevent the bag sealing.
The sections were then left overnight at room temperature to allow the organisms to enter a reproductive stage therefore allowing them to be recovered on agar plates.
After the samples had stood overnight the surface of the sample was swabbed using a sponge swab this swab was then placed into 100ml of buffered peptone water and incubated at 30oC overnight. These combined steps should allow the best possible chance for the organisms to be recovered when plated. the samples were then plated onto a non-selective agar and incubated at 30oC for 48 hours. After the 48 hours the plates were inspected for growth.

After incubation the plates were inspected for growth



On inspection of the plates it was noted that all visible colonies displayed the same morphology.

Reddish/yellow in colour glistening appearance entire edge and convex shape.

It is extremely unlikely that a biofilm would be a monoculture. It was hypothesised that the most likely cause of the similarities I the morphology of the colonies was that the rust appearance of the deposits in the samples tested had resulted in staining of the colonies making them all appear the same.

In an attempt to remove or dilute the staining from the colonies multiple colonies from each plate were taken and streaked onto fresh non-selective agar and incubated for a further **24** hours to purify the colonies**.**

After the 24 hour incubation the plates were removed and inspected.

It was observed that the staining of the colonies had been reduced but not sufficiently to confidently identify individual morphologies.

The purification step was repeated to further clean the organisms to where the individual morphologies could be identified.

After the second purification step the morphology of the individual colonies could be identified.

From the purified plates a total of 15 isolates were taken to be sent for identification.
These were chosen against the following parameters

Location
Morphology
Oxidase
Dominance (where more than one morphology appeared dominant all dominant morphologies were taken)

Isolates for typing		Oxidase
A1	Holding Plate morphology 1	positive
A2	Holding Plate morphology 2	N/A
	Bladder	
B1	around fixing screw area	positive
B2	cream coloured deposits	negaitve
B3	rust coloured deposits	positive
B4	light mixed deposits	negative
B5	no visible deposits	negative
B6	cream coloured deposits	negative
	debris	
C1	Water collected internal from bladder	postitive
C2	Booster set number 2 pump number 5 - non return valve	positive
C3	Output side of pump body from (5)	positive
C4	Plant Room 32 - Renal water meter (removed nodules from both ends - very	negaitve
C5	Plant room 31 PRV	positive
C6	water from pipe at 13	negaitve
C7	Plant Room 32 - Renal water meter (removed nodules from both ends - very	positive

The full results for the typing of the organisms are due on 10th July 2019. Report certificates will be forwarded over on receipt and a second report will be sent shortly after containing background information on the organisms identified.

As the organism typing is being performed by MALDI-TOF. It is recognised that the database used is not exhaustive. Because of this a second set of isolates have been retained, frozen, by the laboratory should any further investigation be deemed necessary.

NHS National Services Scotland

Scottish Health Technical Memorandum 04-01:

Water safety for healthcare premises: Part C: TVC Testing Protocol

Health Facilities Scotland
Engineering and Environment

February 2014

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Contents

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Acknowledgements

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Preface

About Scottish Health Technical Memoranda

Engineering Scottish Health Technical Memoranda (SHTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of SHTM guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle: Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Scottish Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to repeat unnecessarily international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of eight subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

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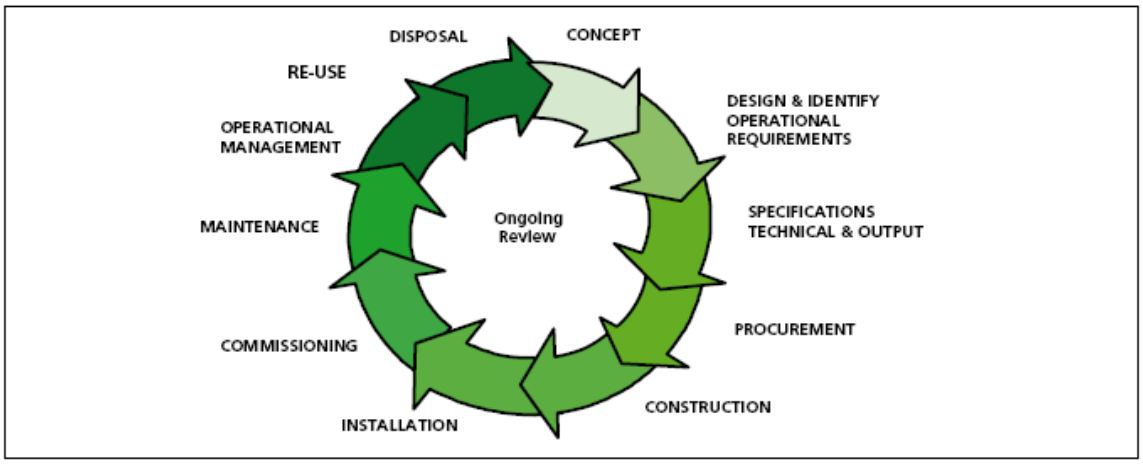

Healthcare building life-cycle

Structure of the Scottish Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of eight core subjects:

Scottish Health Technical Memorandum 00: Policies and principles (applicable to all Scottish Health Technical Memoranda in this series).

Scottish Health Technical Memorandum 01: Decontamination

Scottish Health Technical Memorandum 02: Medical gases

Scottish Health Technical Memorandum 03: Heating and ventilation systems

Scottish Health Technical Memorandum 04: Water systems

Scottish Health Technical Memorandum 05: Reserved for future use

Scottish Health Technical Memorandum 06: Electrical services

Scottish Health Technical Memorandum 07: Environment and sustainability

Scottish Health Technical Memorandum 08: Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Scottish Health Technical Memorandum 06-02 Part A will represent: Electrical safety guidance for low voltage systems.

In a similar way Scottish Health Technical Memorandum 07-02 will simply represent: Environment and Sustainability – EnCO_2de.

All Scottish Health Technical Memoranda are supported by the initial document Scottish Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

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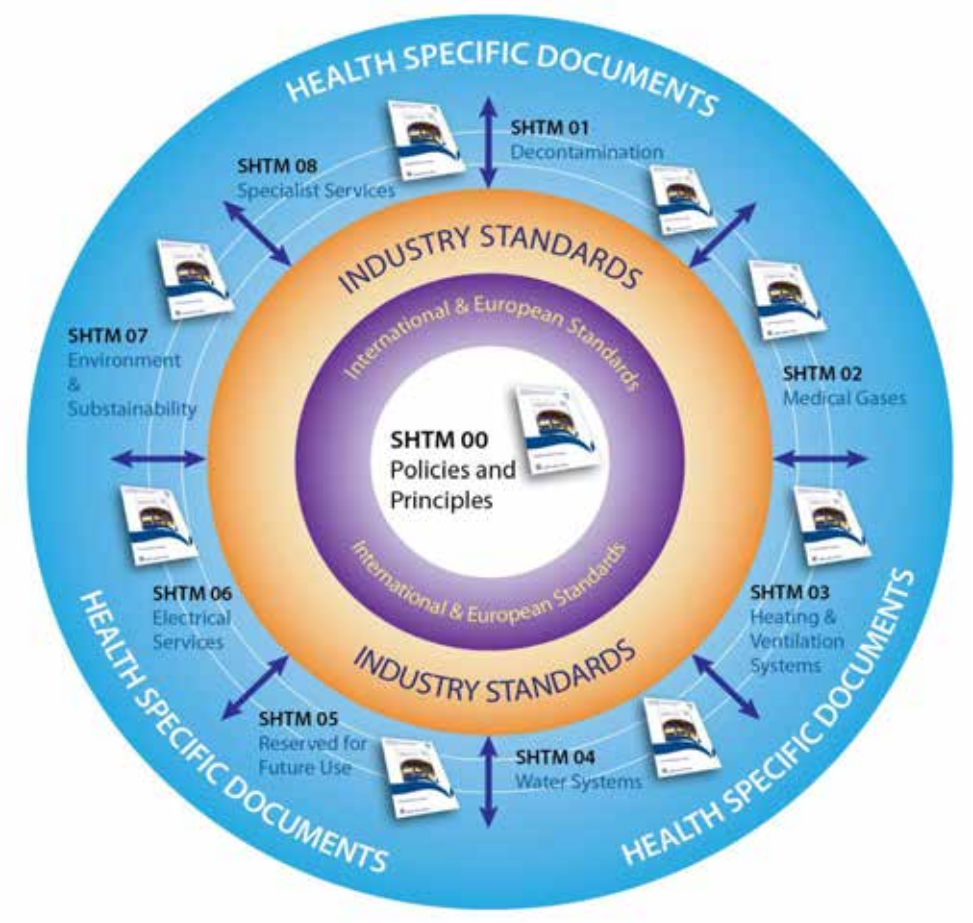
Some variation in style and structure is reflected by the topic and approach of the different review working groups.

Health Facilities Scotland wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.



Engineering guidance structure

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1. Introduction

Preamble

1.1 Although Scottish Health Technical Memorandum (SHTM) 04-01 Part B paragraph 9.1 states that routine quality control microbiological testing for TVCs is no longer considered to be necessary (other than where there are taste or odour problems), many estates personnel invariably have them undertaken on a regular basis after acceptance of installations as a ‘rule of thumb’ indicator by which an abnormal change assists in identifying potential problems at an early stage. This narrative sets out procedures to be followed.

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2. Collection procedure and location of samples

Samples collection procedure

2.1 Sampling points should be selected on the basis of risk assessments relating to system configuration or patient susceptibility.

- mark all sampling locations on up to date “As Fitted” drawings;
- allocate each sampling location a unique reference number;
- follow the procedures set out in The European Directive 98/83/EC.

Location of samples

2.2 Samples should be taken from:

- inlet and outlet at cold water storage tanks;
- incoming main, close to meter, where facilities exist to do so;
- possible stagnant areas within tanks pending rectification of any identified
- problem;
- beginning, mid-point and end of cold distribution system (i.e. sentinel
- outlets);
- special supplies to kitchens, pharmacies, etc;
- calorifier outlet;
- nearest hot water tap to calorifier;
- most distant hot water tap from calorifier (i.e. sentinel outlet);
- return to calorifier;
- typical samples from heated circulating water.

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3. Frequency of sampling

General

3.1 This should be carried out quarterly

- although TVCs are in themselves innocuous the testing procedures are intended to provide an early warning system whereby elevated TVCs should trigger some form of action to determine the identity of the organism and implement the appropriate treatment;
- this could inform adjustment of disinfection doses, cleaning and flushing procedures.

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4. Sampling organisation

General

4.1 United Kingdom Accreditation Service (UKAS) or ISO 9002 accredited laboratories should always be used for analysis.

4.2 Sampling should be undertaken in accordance with European and British Pharmacopoeia requirements to test the total number of bacteria, yeasts and moulds within water services distribution pipework.

Sampling (following BS7592: 2008 guidelines)

Sample Containers

4.3 For testing samples of Coliforms, Escherichia coli, Pseudomonas Aeruginosa, Aerobic Colony Counts and Environmental Mycobacteria 1 x sterile 500ml plastic bottle should be used containing a pre-dosed standard volume of neutraliser to neutralise any residual disinfectant in the water.

Note: The most commonly used neutraliser, which is appropriate for chlorinated or brominated water systems and those using ozone or hydrogen peroxide, is sodium thiosulphate. For mains water and hydrotherapy pools, 18 mg/litre sodium thiosulphate should be added. However, for cooling towers, 180 mg/litre (i.e. sufficient to neutralise 50mg chlorine per litre) must be used. If alternative disinfection methods are used, the laboratory should be contacted to obtain the appropriate neutraliser, if one is available.

For testing samples of *Legionella* (and other pathogenic bacteria such as Salmonella, Campylobacter and E.coli O157) 1 x sterile 1 litre plastic bottle (NB: using 2 x 500ml plastic bottles might be more practical) should be used containing standard amounts of pre-dosed neutraliser (dependent on bottle capacity) to neutralise any residual disinfectant in the water, all as above. Sampling procedures should be adhered to rigorously.

The same sample bottle is often used for *Legionella* and TVC counts testing but separate bottles for each are advised to be technically correct.

Sampling for Indicator Organisms (TVCs) should be undertaken as laid down in “The Microbiology of Drinking Water, 2010, Part 2: “Practice and procedures for sampling” published by the Environment Agency.

Sampling tap water

4.4 The following sampling procedure should be followed:

- where possible, ensure that the tap is in good condition with no leaks. Mixer taps should be avoided if possible;
- remove any internal and external fittings such as hosing;

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- clean the end of the tap thoroughly with a clean disposable cloth (and detergent if necessary). Sterilise with sodium hypochlorite solution (sufficient to give 1% available chlorine) made up on the day of use, or chlorine dioxide foam. Sterilisation can be carried out by preparing a hypochlorite solution in a measuring jug and by suspending it under the tap such that the end of the tap is immersed in the solution for 2 - 3 minutes. Alternatively, use a wash bottle to spray hypochlorite solution onto the outside and inside of the tap spout. Leave for 2 - 3 minutes before rinsing;

Safety Note: Sodium hypochlorite is highly corrosive and should be handled with care. Nitrile gloves and goggles should be worn, and if contact with skin, eyes or clothes occurs, wash the affected area immediately with copious amounts of water. Contact with clothes may result in a bleaching effect.

- turn on the tap gently to avoid unnecessary aerosol production and run water to waste for two to three minutes;

Note: For initial system sampling take a Post-Flush sample (as defined in BS 7592: 2008) at sentinel points without disinfection. Where there is an initial concern with a particular outlet location – say, a combined system and outlet problem – a BS Pre-Flush sample should be taken. If concerns persist with an outlet location (typically, a known dead-leg issue or lack of, or low, water use, a further BS Pre-Flush sample should be taken followed by disinfection before a BS Post-Flush with disinfection sample. Water should be allowed to run hot for 1 minute and cold for 2 minutes by which sampling would be temperature calibrated.

- aseptically open a labelled sterile bottle (1 litre or 500ml bottle containing neutraliser; as paragraph 4.3), fill almost to the brim with water, replace and tighten the lid and shake the bottle to distribute the sodium thiosulphate;
- there is no prescriptive cooling method or temperatures but ideally, water samples should be transported as taken but stored at between 6ºC and 18ºC if a delay is anticipated prior to despatch to a (remote) laboratory. Samples should be transported out of the sun as outlined in BS6068 and ISO 11731. Most samples are transported in shopping trolleys or plastic trays as soon as possible. Guidelines do not require samples to be cooled down prior to transportation. However they should be submitted to the accredited laboratory to ensure that they can be examined promptly, ideally the same day, but always within 24 hours of collection. Where the accredited laboratory in on campus where the samples are drawn, the timescale from source to lab should be no greater than 2 hours. If there is a delay in sending samples to a laboratory, they should be stored at between 6ºC and 18ºC.

Sampling Shower or Mixer Tap Water

4.5 The following sampling procedure should be followed:

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- normally use a 1 litre sample which should be taken from each shower head/outlet;
- before turning on the shower/outlet, adjust the temperature setting to the midpoint for non-thermostatic taps and the normal use temperature (35°C to 43°C) for thermostatic taps;
- place a sterile plastic bag over the shower head/outlet and secure with a rubber band. Using sterile scissors cut off one of the bottom corners of the bag to form a funnel. Use this funnel to fill the bottle;
- replace and tighten the lid and shake the bottle to distribute the sodium thiosulphate;
- all water samples for *Legionella* analysis should be stored at an ambient temperature (approximately 20°C), in the dark, and returned to the accredited laboratory as soon as possible to ensure that they can be examined promptly, preferably the same day but at the latest so that processing can begin within 24 hours of taking the sample.

Sampling Swimming, Spa and Hydrotherapy Pool Water

4.6 The following sampling procedure should be followed from a number of sample points and from the balance tank (and swab samples from inside/behind any jets):

- outside shoes should be removed or plastic shoe coverings should be worn if entering swimming pool areas;
- wipe the outside of a sterile bottle (500ml sample bottle containing neutraliser as paragraph 4.3) with an alcohol wipe if not individually packed, and label with a waterproof marker or ball point pen;
- aseptically open the bottle;
- immerse the bottle, keeping the long axis approximately horizontal but with the neck pointing slightly upwards to avoid loss of the neutralising agent;
- once the bottle is immersed to about 200–400mm below the surface, tilt the bottle to allow it to fill, leaving a small headspace;
- on removal from the water, immediately replace the cap and shake the sample to disperse the neutralising agent;
- water samples should be stored between 2ºC and 8ºC, and submitted to the laboratory in a timely way to ensure that they are examined on the day of collection or at least within 24 hours of the collection;
- if both routine testing parameters and *Legionella* are required, then separate 1 litre and 500ml samples should be taken;
- it is also good practice to determine total and combined disinfectant levels and pH value from the same site as the microbiological sample. These should be determined in a separate sample collected in a bottle without any neutralising agent (e.g. a sterile plastic universal) and the tests carried out at the pool-side. These results together with information on the number of users in the pool at the time of sampling should accompany the sample to

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the laboratory. Also the number of bathers should be noted together with the type of disinfectant in use;

- identification information for each individual sample should be given to the accredited laboratory to confirm;
  - the specific sampling point;
  - the room/location of sampling point;
  - the premises, building block, floor etc.

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5. Results expected

General

5.1 Tests could take between 5 and 10 days to complete:

- an early warning can be requested by phone or email to confirm product failing to meet its specification prior to completion of testing;
- micro-organisms for which tests are to be carried out would include E coli, staphylococcus aureus and pseudomonas aeruginosa;
- written reports to be provided on completion via paper copies and email advising the number of bacteria, yeasts and moulds per gram of product;
- in smaller healthcare premises, depending on configuration of systems, it may be possible to continue functioning despite adverse readings by switching to bottled supplies for drinking water purposes.

Sampling Procedures

5.2 The Sampling and Leachate Testing should to be undertaken is detailed in SHTM 04-01 Part E.

5.3 As described in paragraph 4.4 sampling must follow that set out in BS7592: 2008 Code of Practice and BS EN ISO 5667-1: 2007 on Water Quality Sampling. Those organising sampling must make clear in advance which water quality technique is to be undertaken in order that systematic conclusion on risk can be drawn.

5.4 For initial water system sampling take a Post-Flush sample (as defined in BS7592: 2008) at sentinel points without disinfection. Where there is an initial concern with a particular outlet location – say, a combined system and outlet problem – a BS Pre-Flush sample should be taken. If concerns persist with an outlet location (typically, a known dead-leg issue or lack of, or low, water use, a further BS Pre-Flush sample should be taken followed by disinfection before a BS Post-Flush with disinfection sample. Water should be allowed to run hot for 1 minute and cold for 2 minutes by which sampling would be temperature calibrated.

Interpretation of results and further actions

5.5 Where water quality sampling in a water system confirmed (acceptable) *Legionella* results **less than 100 CFUs/Litre** – the Authorised Person (Water) would be informed and provided with copies of the samples in writing and associated record keeping. The Authorised Person (Water) would provide interpretation (with the Consultant Microbiologist when and where required) on the results and confirm if any actions are required.

5.6 Where water quality sampling in a water system confirmed *Legionella* results in **excess of 100, but less than 1,000 CFUs/Litre** – the Authorised Person

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(Water) and Consultant Microbiologist must be informed and provided with copies of the samples in writing. The Consultant Microbiologist would provide interpretation on the results and confirm the necessary actions prior to bringing the water system into use.

5.7 Where water quality sampling in a water system confirmed *Legionella* results in **excess of 1,000 CFUs/Litre** *immediate* action must be taken and the Consultant Microbiologist and Authorised Person (Water) must be informed and provided with copies of the samples in writing. They will immediately confirm the necessary actions prior to re-sampling and bringing the water system into use when (acceptable) *Legionella* results are reliably less than 100 CFUs/Litre.

Note: Where continued water system sampling is required, this would be undertaken on a weekly frequency.

5.8 Where the results of three consecutive weekly water system samples remained below 100 CFUs/Litre, the Authorised Person (Water) and Consultant Microbiologist would be informed and sampling would revert to a monthly sampling frequency.

5.9 Where the results of three consecutive monthly Water System samples remained below 100 CFUs/Litre, the Authorised Person (Water) and Consultant Microbiologist would be informed and sampling would revert to a 3-monthly sampling frequency.

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NHS National Services Scotland

Scottish Health Technical Memorandum 04-01:

The control of *Legionella*, hygiene, 'safe' hot water, cold water and drinking water systems

Part D: Disinfection of Domestic Water Systems

Health Facilities Scotland
Engineering and Environment

August 2011

Contents

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Preface

About Scottish Health Technical Memoranda

Engineering Scottish Health Technical Memoranda (SHTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of SHTM guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle: Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Scottish Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to repeat unnecessarily international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of eight subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

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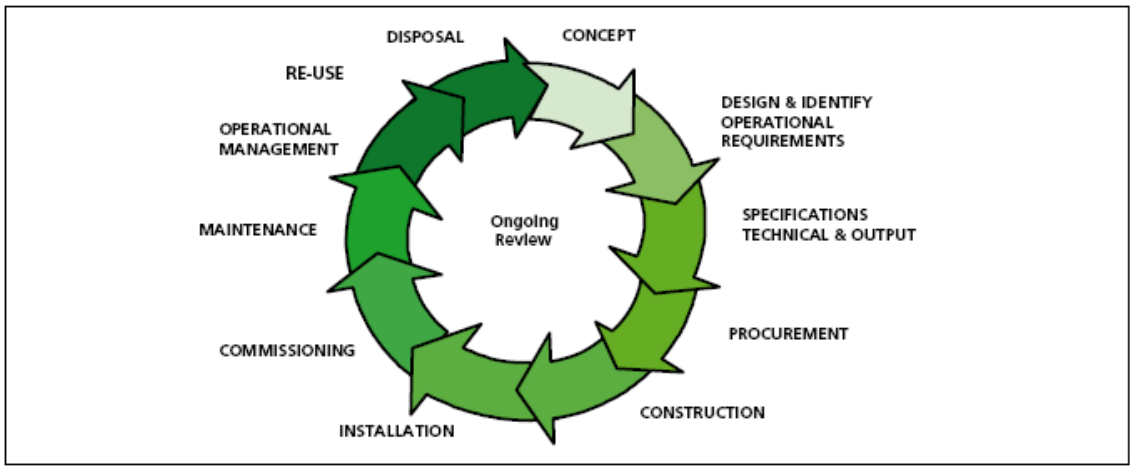

Healthcare building life-cycle

Structure of the Scottish Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of eight core subjects:

Scottish Health Technical Memorandum 00: Policies and principles (applicable to all Scottish Health Technical Memoranda in this series)

Scottish Health Technical Memorandum 01: Decontamination

Scottish Health Technical Memorandum 02: Medical gases

Scottish Health Technical Memorandum 03: Heating and ventilation systems

Scottish Health Technical Memorandum 04: Water systems

Scottish Health Technical Memorandum 05: Reserved for future use

Scottish Health Technical Memorandum 06: Electrical services

Scottish Health Technical Memorandum 07: Environment and sustainability

Scottish Health Technical Memorandum 08: Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Scottish Health Technical Memorandum 06-02 Part A will represent: Electrical safety guidance for low voltage systems. In a similar way Scottish Health Technical Memorandum 07-02 will simply represent: Environment and Sustainability – EnCO2de.

All Scottish Health Technical Memoranda are supported by the initial document Scottish Health Technical Memorandum 00 which embraces the management

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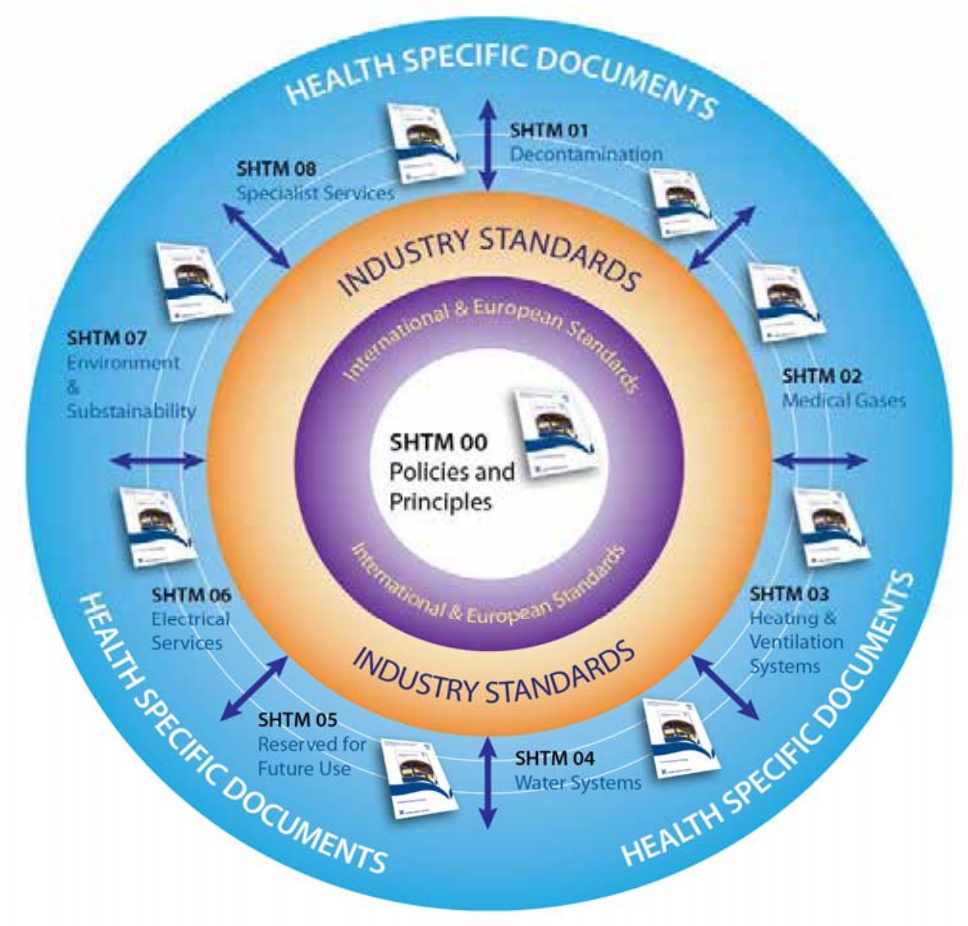
and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

Health Facilities Scotland wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.



Engineering guidance structure

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1. Introduction

Background information

1.1 Health Facilities Scotland (HFS) Scottish Engineering and Technology Advisory Group raised concerns regarding a lack of information and guidance on the addition of chemicals to water in healthcare premises. In response to this, a Short-Life Working Group was formed and this eventually became the **National Water Services Advisory Group**. Part of the remit of this Group was to review available literature not only on the chemical treatment of water but also on processes used to treat water.

1.2 The use of any chemical in the treatment of potable water carries a risk and estates staff will need to call an independent party to review all paperwork and risk assessments before a treatment is implemented. This is of particular relevance when campaign or continuous treatment is contemplated but should also be implemented when shock treatment is proposed.

Group Membership

1.3 The group consisted of these members:

Tom Foley (Chair) NHS Tayside

Jim Alderton NHS Forth Valley

Iain McInally NHS Ayrshire & Arran

David Bennett NHS Tayside

Kenneth Walker NHS Grampian

Ged Mather NHS Borders

Alistair Johnstone NHS Dumfries & Galloway

Daniel Egan Golden Jubilee Hospital

Edward McLaughlan HFS Scotland

Ian Stewart HFS Scotland

Geraldine O'Brien HFS Scotland

Purpose of the Report

1.4 The purpose of this report has been to draw together peer reviewed information on potable water disinfection methods, in order to analyse them and identify the pros and cons associated with the use of each method

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Report Layout

1.5 Supplementary to this report is a quick reference guide to each method, consisting of bullet points indicating the advantages, disadvantages and safety factors to be considered when using that method. This report will ultimately provide a review of published work on each of the disinfection systems available, how these chemicals/treatments affect NHSScotland estate and its occupants, and the main advantages and disadvantages associated with their uses, in order that the most appropriate system can be selected.

- Appendix 1 provides some case studies for further reading;
- Appendix 2 comprises a decision matrix, which has been arranged for use by estates staff during the decision-making process;
- Appendix 3 is provided to assess risks associated with the content/production of this document.

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2. Disinfection of water systems

General Warning Regarding Chemical Disinfection of Hospital Water:

It has been found that the renal water plants do not filter out hydrogen peroxide, copper-silver ions, chlorine, chloramines and ozone. These disinfection systems should not be used where water serves a haemodialysis treatment area (SAN HAZ (SC) 08/07, 2008). Due to the extremely sensitive nature of renal water plants, no chemicals should be added to the water going to these units. If possible these units should be kept on a separate mains supply, or at least isolated when any shock or campaign treatment is planned.

Introduction

2.1 Opportunistic pathogens colonise water systems and can cause pulmonary, wound and bloodstream infections in healthcare patients. This contributes to approximately 25% of all healthcare-acquired infections (Anaisse et al., 2002). Papers published on nosocomial outbreaks in healthcare facilities have provided evidence that the source of contamination often originates from pathogens in the water supply. Bacteria, for instance, have been implicated in an estimated 1,400 deaths each year as a result of waterborne nosocomial pneumonias caused by *Pseudomonas aeruginosa* (Anaisse *et al*., 2002). Mucoid strains of *Pseudomonas aeruginosa* have been shown to have increased resistance to chlorine as a result of being protected by a biofilm (Grobe *et al*., 2001). These strains have been found to persist in swimming pool PVC pipework.

2.2 Another example of opportunistic pathogens is mycobacteria, which can survive in potable water systems for several years due to having a moderate resistance to chlorine. These bacteria have been implicated in serious nosocomial outbreaks (Reyn et al. 1994), and *Mycobacteria avium* has been shown to be resistant to chloramination, chlorination, chlorine and ozone disinfectants (Taylor et al. 2000). Mycobacteria are common in the natural environment and can colonise water distribution systems (Wright et al., 1985). Taylor *et al*. (2000) state that *Mycobacterium avium* can be found in public water supply and can be the cause of infection in hospital patients. Some studies have shown mycobacteria colonizing only parts of hospital water systems (Fox et al., 1992; Fujita et al., 2002). This suggests that the source of the contamination in these cases is not necessarily the public supply. Fujita et al.'s (2002) results also show that the colonisation affected directly connected parts of the distribution system, suggesting that contamination can occur at a water outlet, and then travel throughout the system. Mycobacteria is one of the most common opportunistic infections in AIDS patients, and it has been reported that 20% to 40% are infected by mycobacteria (Horsburgh, 1991).

2.3 Other pathogens that may contaminate healthcare domestic water systems are Aeromonas, which are found in many types of water and have been shown to inhabit biofilms in distribution systems. Aeromonas symptoms include diarrhoea that can last a few days or weeks (Vila *et al*., 2003), and is generally not life

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threatening. However, high risk groups such as immuno-compromised, young, and old patients' lives may still be at risk from such an infection. Protozoa such as Cryptosporidium and Giardia can also be present in the domestic water system and although the main symptoms again include diarrhoea, they can present a more serious threat to patients (Freije, 2005).

2.3 A paper produced by Yu (2007), indicated that researchers have found 70 percent of hospital water systems tested in the US to be positive for *Legionella* species. Many of the standard hospital disinfection methods involve the use of chlorine, however Kuchta (1983) states that *Legionella* can survive low levels of chlorine for relatively long periods of time. Another factor that may promote the growth of *Legionella* is the temperature of the system, although Scottish guidance - SHTM 04-01 Part A, (2011) - specifies the flow and return temperature of a domestic hot water system in a healthcare environment should be no less than 60°C at the calorifiers with a return temperature of 55ºC, the minimum allowable return temperature is 50ºC. This temperature of 50ºC should not be designed for as it will not kill off, only inhibit *Legionella* growth. The optimum temperature for multiplication of *Legionella* strains in culture media is approximately 37°C (Kramer and Ford, 1994); this temperature should never be reached in a system unless there is a malfunction. However, contrary to common belief a healthcare institution's cold water supply may also be contaminated with *Legionella* (Hoebe 1998). Colbourne & Trew (1986) maintain that *Legionella* occurs in 52 to 54% of domestic and cooling water inside commercial, industrial and health care buildings, these types of water systems are now regarded as a normal habitat for *Legionella. Legionella* is commonly found in the public water supply, the public is not aware that *Legionella* is a common inhabitant of man-made water distribution systems (Stout and Yu, 2001).

2.4 The reason treated water systems continue to be colonised by these pathogens, is due to an inappropriate treatment regime. *Legionella* is ubiquitous in water systems unless treated, however, Zhang *et al*., (2009) states that infection can be prevented through using an appropriate water disinfection system. Chlorination, the traditional method, as mentioned above may not be the most efficient technique and, following growing evidence of a link between chlorination and mutagens in drinking water (Gopala *et al*., 2007), alternative disinfectants continue to be investigated. There are many disinfection systems currently available, examples of which include

- heat and flush;
- continuous chlorination;
- chlorine dioxide;
- Ultra Violet light (UV);
- copper silver ionisation;
- silver catalysed hydrogen peroxide;
- ozone and chloramines.

All of these decontamination processes have advantages and disadvantages and work at their optimal performance within different parameters. The main

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aim of this report is to investigate the different methods, analyse their advantages and disadvantages and determine the factors needed to ensure optimal results when using each system.

Physical Parameters

2.5 When considering the most suitable method of disinfection for a healthcare facility a number of parameters have to be taken into consideration, factors to be considered include the condition of estate, the health of the occupants, the quality of the public water supply, finance, and the availability of resources to implement a particular regime.

Parameters of Incoming Water

2.6 There are many factors concerning the incoming water supply that should be taken into consideration when selecting the most suitable disinfection method. These include aspects such as:

- pH - has no effect on Ozone or UV, however the disinfection power is reduced with a higher pH than 8 for continuous chlorination (See Appendix 2 for more details);
- temperature – has no effect on Ozone or UV, however the residual effect decreases for continuous chlorination and chlorine dioxide when temperature increases;
- taste and odour – if this is already a problem, chlorine dioxide can neutralise these odours. However some disinfectants may contribute to taste and odour, such as chlorination if used at a high dose (See Appendix 2 for more details);
- if systems or parts of systems are unused for long periods of time then it is essential that a full flushing regime is instigated. If the water is not used on a regular basis then a residual disinfectant will be required, the volume and pipework design should also be considered as this may also determine if a residual effect is required. Disinfectants such as UV and Ozone have no residual effect, whereas chlorine dioxide, copper – silver ionisation and silver catalysed hydrogen peroxide have a long-lasting residual effect.

Heat and Flush

2.7 This process is one similar to pasteurisation and is distinct from normal temperature control applied to DHWS; this is used as a means of disinfection causing the destruction of disease-causing microorganisms. Increasing the temperature of hot water was the first method used to control *Legionella* in a hospital distribution system (Fisher *et al*., 1981). This chemical-free method requires no additional equipment and is commonly used, particularly as an emergency decontamination procedure in hospital outbreak scenarios.

Method

2.8 As stated in L8, and SHTM 04-01 Part A this disinfection is carried out through raising the temperature of the entire contents of the calorifier, or hot water

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heater, followed by circulating the water throughout the system for at least an hour at 75ºC. The calorifier/heater temperature must be sufficiently high to ensure that the temperature in all parts of the circulating system, and at the return connection, do not fall below 75 C (Zacheus and Martikainen, 1996). This can be used as a continuous process in a hot water system only but has a significant cost to sustain the high temperatures required. This form of disinfection can only be used as a shock treatment for an outbreak in a cold water system; therefore, it is not suitable for continuous disinfection. It must also be noted that when utilising this method for a cold water system particular attention must be made to the thermal expansion of the system and this must be accounted for.

Advantages

2.10 The main advantages to this form of disinfection are that it requires no specialist equipment and therefore can be implemented immediately after an outbreak has been detected. If also used to disinfect the cold water system an additional connection from the calorifier is required, this must be disconnected after flushing and any branch connections must *not* result in extended dead legs being formed.

Disadvantages

2.11 One of the main disadvantages to using this method of disinfection for treatment of a water distribution system is that disinfection may not eradicate *Legionella* fully and recolonisation may occur. This disinfection method is also labour intensive and numerous personnel are required to monitor water temperatures and flushing times. It can also prove ineffective for long-term *Legionella* infestation management (Zhang et al., 2009). Furthermore, the energy costs of maintaining a hospital hot water system above 60ºC are substantial and may not reliably prevent persistence at parts of the system where there is infrequent use and a lower temperature (Farr *et al*., 1998).

(See Appendix 1 on Case Studies for further information)

Continuous chlorination

2.12 Chlorination was the primary method of disinfection for drinking water from the early 1900s, however in the 1970s, it was discovered that chlorination caused a number of disinfection by-products that are known to be hazardous to human health (Moudgal *et al*. 2000). Also due to the risks inherent in the handling of chemicals to producing chlorine gas it is no longer as prominent in systems within UK healthcare facilities and has been replaced with Chlorine Dioxide.

Method

2.13 Chlorination is the process of adding chlorine to water as a means of water purification. This is accomplished by continuous injection through calcium hypochlorite, sodium hypochlorite, or gas chlorination. The effectiveness of chlorine as a disinfectant is determined by the chlorine concentration, contact time, the pH level, temperature, the concentration of organic matter, and the number and types of microorganisms in the water.

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Advantages

2.14 Continuous chlorination provides a residual disinfectant concentration throughout the entire distribution system (Fass et al., 1998). Nearly 100 years of chlorination for the disinfection of drinking water has demonstrated the effectiveness of this process for the inactivation of microbial pathogens, with the notable exception of *Cryptosporidium* where very high concentrations of chlorine are required (Korich *et al*., 1990).

Disadvantages

2.15 There are several disadvantages to using chlorine as a disinfectant:

- it is highly corrosive and causes damage to pipework (Lin *et al*., 1998);
- needs monitoring due to the fact that once added and circulating freely within the water the chlorine combines with organic compounds and produces carcinogenic chloroform and carbon tetrachloride. It is the combination of chlorine and organic materials already in the water that produces cancer-causing by products. The more organic matter in the water, the greater is the accumulation of Trihalomethanes (THMs) (Waller *et al*., 1998). Also studies in Belgium have related development of malignant melanoma to consumption of chlorinated water (Douglass, 1994). The residual chlorine levels should be below 5 mg/litre as stated in the drinking water quality guideline (WHO Drinking Water Guidelines, 2004);
- Chlorine may only suppress *Legionella* and not kill it and rarely can *Legionella* be eradicated from a system using this method alone. Moreover, the inactivation of *Cryptosporidium* requires high chlorine dosages, thereby resulting in higher by-product concentrations and increased rates of corrosion. One of the main side effects to using chlorination as a disinfectant is that it reacts with natural organic matter to produce halogenated disinfection by-products i.e. THMs;
- Chlorine reacts with organic materials and creates carcinogenic by-products called (THMs), and numerous studies have linked the consumption of chlorinated water with cancer (Lin *et al*., 1998). This in turn has led to guidelines by international organisations such as the World Health Organisation to be revised to lower the THMs in drinking water;
- Chlorine has no detergent cleansing powers; therefore it is essential that slime and debris are removed by thoroughly cleansing before chlorine is used. However, chlorine should not be used with some other biocides, since they may neutralise each other unless they are known to be compatible. Such as ammonia which reacts with chlorine to form harmful THMs.

Chlorine Dioxide (ClO_2)

2.16 Chlorine dioxide must be manufactured on site because it decomposes readily and presents toxicity hazards when stored (Kim *et al*., 2002).

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Method

2.17 The chemical is a gas that is generated mechanically or electrolytically from a sodium chlorite solution which is then introduced into the water distribution system.

Advantages

2.18 Chlorine dioxide is a very selective oxide, allowing lower dosages to be used to obtain the same results as chlorine or ozone (Gates, 1998). Radziminski et al. (2002) state that chlorine dioxide is superior to chlorine in the destruction of spores, bacteria, viruses, protozoan cysts, biofilm, and waterborne pathogens. There are also only minimal corrosion issues associated with using chlorine dioxide, and although biofilm in the pipework can protect *Legionella* from disinfection system such as heat and flush and chlorine, chlorine dioxide can remove biofilm and kill these bacteria, spores and viruses. ClO_2 is also an effective biocide over a wide pH range and is useful for removing iron and manganese to control taste and odour (Zhang *et al*., 2009). However taste problems can become an issue from chlorine dioxide at high dosage levels.

Disadvantages

2.19 There are some dangers to using this disinfectant in potable water, as chlorine dioxide and its by-products, (THMs), chlorate and chlorite ions, do have toxic properties and pose health risks to consumers (Zhang et al., 2009). Chlorine dioxide generally forms less THMs, haloacetic acids (HAAs), and total organic halogen (TOX) than free chlorine. However, chlorine dioxide forms more iodinated DBPs when iodide is present in the source water. The WHO's recommended guideline for chlorite in drinking water is less than 0.2 mg/litre, while the Secretary of State for the Environment's legal requirement is that the combined concentration of chlorine dioxide, chlorite and chlorate should not exceed 0.5 ppm.

(See Appendix 1 on Case Studies for further information).

UV light

2.20 Disinfection using UV light differs considerably from chemical disinfectants such as chlorine and ozone, which inactivate microorganisms by destroying or damaging cellular structures, interfering with metabolism, and hindering biosynthesis and growth (Snowball and Hornsey, 1988). UV on the other hand, inactivates microorganisms by damaging their nucleic acid, thereby preventing the microorganism from replicating.

Method

2.21 This disinfection method involves exposing contaminated water to radiation from UV light. The most efficient and widely used device for this purpose is the mercury arc lamp, as approximately 85% of its energy output is of the 253.7 nm wavelength, which is within the optimum germicidal range of 250–270 nm (Chen *et al*., 2006). This can be used at the entry to the domestic water system where all of the water is disinfected or can be used as a point of use system which Kim

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et al. (2000) suggest is the most effective use of this type of filtration system. The use of a point of use system may not be feasible in a healthcare setting as this would not be economical on a large scale system.

Advantages

2.22 UV light can inactivate pathogenic microorganisms without forming the by-products that other chemical treatments create, and it has proven effective against some pathogens, such as *Cryptosporidium*, that are resistant to commonly used disinfectants like chlorine (USEPA, 2003). In particular, several studies have confirmed the efficacy of UV light for disinfecting *Legionella* in laboratory water settings (Muraca *et al*., 1987).

2.23 Some other advantages of ultraviolet light include its easy installation, and its lack of adverse effects on water or plumbing systems. Studies suggest that the efficacy of UV light is only minimally affected by high water temperature (Severin *et al*., 1983; Malley, 2000). Studies also indicate that UV disinfection at doses of up to 200 mJ/cm^2 do not change the pH, turbidity, dissolved organic carbon level, UV transmittance (UVT), colour, nitrate, nitrite, bromide, iron, or manganese of the water being treated (Malley *et al*., 1995).

2.24 Lin *et al.* (1998) state that if UV light is used to disinfect an entire system, as it is only effective immediately after disinfection, and it should be combined with another systemic disinfection method such as hyperchlorination or thermal eradication. Filters are also required prior to UV filtration to remove particles from the water system (Kim *et al*., 2002). The recommended pre-filter for each UV model depends on the turbidity of the local water supply this filter size can range from 20-5 microns.

Disadvantages

2.25 The main disadvantage to this form of disinfection is its lack of residual protection. If used at the point of entry to a domestic water system, levels of contamination would have to be measured at outlets, as *Legionella* re-growth in the biofilm layers of scale and accumulated debris still allows for recolonisation. Maintenance of the water system is necessary and important to reduce this biofilm formation and *Legionella* recolonisation (Franzin *et al*., 2002).

2.26 As discussed above, another way UV treatment can be utilised is as a point of use system. Although this system seems to be effective, in the case of a large hospital it would be uneconomical as there are many points of use. Another possible drawback to using UV light as a disinfectant is that some of the microorganism cells damaged by the UV light can be repaired, either in the presence of light, termed ‘photoreactivation’, or through a ‘dark repair’ in the absence of light (Jagger, 1967). As a result, the strategy in UV disinfection has been to provide a sufficiently high dosage to ensure that nucleic acid is damaged beyond repair. UV disinfection costs will vary depending on size and difficulty of installation. The Water Research Foundation carried out a case study on a water treatment works in Arizona, and found that running costs were $0.004 per 1,000 gallons. (http://www.waterresearchfoundation.org/research/TopicsandProjects/Resource

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s/caseStudies/caseStudyFlagStaff.aspx. It is impossible to convert this into a UK equivalent figure, but this illustrates the relatively low cost of treatment by volume. Small scale systems are available from several manufacturers. One example of these is a 430 litres/minute system costing £4,499, with lower priced systems for lower water demand, going down to 40 litres/minute (http://www.eastmidlandswater.com/products2.asp?CategoryID=18&SubcategoryID=30).

The intensity of the lamps declines over time; therefore they need to be replaced in most units every 8,000 to 9,000 hours for optimum unit performance (Srikanth, 1995).

Copper-Silver Ionisation

2.27 Metals such as copper and silver ions are known as bactericidal agents. Most studies on the use of copper-silver ionisation as a disinfection method have suggested good efficacy for *Legionella* control in water systems (Liu *et al*., 1994). A laboratory study by Huang *et al*. (2008) of copper and silver ions in combination provided evidence to suggest that bactericidal efficiencies are greater than 99.99% against the most significant clinical waterborne microbes; *P. aeruginosa*, *Acinetobacter baumannii*, and *S. maltophilia*, including *Legionella*. Silvestry-Rodriguez et al. (2007) summarises the disinfectant properties of copper-silver ionisation for large building water distribution systems, stating that this method has an appreciable impact on levels of coliform bacteria, iron-related bacteria, sulphate-reducing bacteria and slime producing bacteria. This has led to the conclusion that copper–silver ionisation may have the potential to eradicate major waterborne pathogens in hospital distribution systems. However the eradication efficacy of ionisation under field conditions in UK institutional water systems and its significance in reducing hospital-acquired infections are still to be determined. Studies in the United States have shown copper-silver ionisation to be effective at controlling *Legionella* in hospitals (Lin *et al*., 1998; Stout *et al*., 1998).

Method

2.28 This disinfection method is brought about by electrolysis, positive copper and silver ions are created from electrodes made of copper and silver, these ions are then distributed throughout water systems to eradicate bacteria. Copper ions penetrate the cell wall and as a result they will create an entrance for silver ions. Silver ions bond to various parts of the cell, such as the DNA and RNA, causing all life support systems in the cell to be immobilized. The ions remain active until they are absorbed by a microorganism.

Advantages

2.29 Copper-silver ionisation systems have many advantages in that they are easily installed and maintained, and their efficacy is not affected by high water temperature, unlike chlorine and ultra-violet light (Lin Yu *et al*., 1998). Additionally, *Legionella* is killed through this disinfection method rather than suppressed, which minimises the possibility of recolonisation (Lin *et al*., 1996). This was demonstrated in Liu Z *et al*'s study in 1994 where recolonisation was

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delayed by six to twelve weeks, even after the ionisation was shut down in one hospital. This factor provides a safety margin if the system malfunctions, unlike chlorination through which *Legionella* can rapidly re-appear.

Disadvantages

2.30 Some of the disadvantages to copper-silver ionisation are that silver ions react easily with chlorines and nitrates that are present in the water, causing them to no longer be effective, therefore to ascertain the level of ionization required the levels of chlorines and nitrates present in the water must be established. This may cause a problem if the water has very high levels of chlorines and nitrates as a very high level of copper and silver ions would be required to disinfect the entire system properly. Furthermore, some microorganisms can become resilient to silver and it is suggested that *Legionella* could develop resistance to copper and silver ions (Mietzner *et al*., 2005). This form of disinfection is also expensive to install, and the electrodes must be cleaned regularly to reduce scale build up, and replaced annually to give optimal performance. High concentrations of silver in the water can also stain porcelain (Lin *et al*., 1998). The only obvious sign of silver overload to humans is Argyria, a condition in which skin and hair are heavily discoloured by silver in the tissues. The amount of silver required to develop Argyria is estimated (by the EPA) to be 3.8 grams per day.

2.31 The pH of water is an important factor in the efficacy of copper and silver (Lin *et al*., 2002), as elevated pH levels (>8.0) reduce the effectiveness of copper ions against *Legionella*. Although pH has little effect on silver ions, a higher pH can alter the positively charged copper ions to become negatively charged, and therefore less effective at eradicating *Legionella*. Sensors would have to be provided in order to maintain accurate concentrations throughout the system. In terms of these concentrations in water, the European Union does not dictate any standards concerning silver. However copper has a maximum value of 0.02mg/litre (EU Drinking water directive, 98/83/EC1998).The WHO also does not dictate any standards; they believe the available data is insufficient for recommending a concentration limit (WHO Guidelines for Drinking Water Quality, 2004). The United States however, dictates a maximum value of 1 mg/litre for copper and a maximum value of 0.1 mg/litre for silver (EPA National Secondary Drinking Water regulations, 2002). Industry leaders who manufacture copper silver ionisation technology recommend a copper concentration of 0.4 to 0.8 mg/litre and a silver concentration at 40 to 60 µg/litre, to be compliant with EPA drinking water standards (Shields, 2002).

2.32 The Health and Safety Executive issued an Approved Code of Practice and guidance on the control of *Legionella* bacteria (L8, 2000) in water systems, below is the statement made in clause 176 of the document:

"The application of ionisation will need to be properly assessed, designed and maintained as part of an overall water treatment program. The Water Supply (Water Quality) Regulations and Private Supply Regulations prescribe a maximum value for the level of copper and silver ions in drinking water supplies. It is important that installers of ionisation systems are aware of the need to avoid any breach of these Regulations and maintain copper and silver levels

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below the maximum allowable concentration. The local water company may need to be consulted to check that the installation complies with the requirements of the Water Regulations. "

http://www.hse.gov.uk/pubns/priced/l8.pdf

2.33 The Scottish Government issued a formal document stating that silver is not to be used continuously as a disinfectant for a public water supply. Below is what the Drinking Water Quality Division - List of Approved Products, December 2007 states:

*"C*urrent approval for the use of products containing silver salts in relation to emergency disinfection of water intended for human consumption is subject to the following conditions of approval:

- the concentration of silver in the water does not exceed 80 µg/litre; and
- consumers are exposed to water containing silver for only as long as necessary to restore conventional treatment, and for no more than a total of 90 days in any period of a year.

These conditions ensure that there is only a limited exposure of the consumer to silver". http://www.scotland.gov.uk/Publications/2008/03/04152957/9

2.34 For a public water supply indicated by The Water Supply (Water Quality) (Scotland) Regulations (2001), the inclusion of silver is not contained in the document as no product has been approved for this application and would have to be assessed for this purpose.
http://www.opsi.gov.uk/legislation/scotland/ssi2001/20010207.htm

2.35 In contrast to this if a hospital has its own private water supply then, The Private Water Supplies (Scotland) Regulations (2006) should be adhered to, schedule 3 in these regulations state that:

"Silver may be used in some water treatment devices where it is used for disinfection purposes"

Table B part II states that a concentration of 10µg/litre is allowed and if used in a water treatment process, 10µg/litre may be substituted for 80µg/litre.

http://www.opsi.gov.uk/legislation/scotland/ssi2006/20060209.htm#4

2.36 The above Scottish regulations do not imply that silver is any safer to be used in a private supply than a public supply, only that silver is more likely to be used in a private water supply due to the smaller quantities involved, for public supplies the economics of using silver would not stand up against cheaper alternatives such as chlorine.

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Note: It can be concluded that there is no clear decision to be made on the use of silver in domestic water systems, however the Opinion of Counsel have put forward ANY form of treatment to domestic water systems that causes a change to the condition supplied by the Water Authority leaves the User of that Treatment open to legal challenge. Due to this, the Counsel recommends that an independent assessment is carried out of all Risk Assessment and Method Statement documentation prior to treatment being initiated. This documentation should be supplied to Scottish Water and to the Drinking Water Inspectorate.

Silver Catalysed Hydrogen Peroxide

2.37 There is very little research within the UK on the use of silver catalysed hydrogen peroxide as it is a relatively new form of decontamination and at present is only implemented in a small number of water distribution systems within the UK (it is widely used in Europe). Available research suggests that combined Sliver and Hydrogen Peroxide has a moderate bactericidal effect on *E. coli* and only a mild virucidal effect (Pedahzur *et al*., 2000).

Method

2.38 A silver catalysed hydrogen peroxide solution is added to a water system by injecting it directly into the water.

Advantages

2.39 In some instances, the combined bactericidal effects of silver and hydrogen peroxide are 1,000-fold higher than the sum of them being introduced on their own. Another benefit to using this disinfectant is that the biocidal action of silver catalysed hydrogen peroxide generally increases with rising temperature and pH levels (Pedahzur *et al*., 2000). In addition, the slow and moderate bactericidal effect, and the prolonged stability and efficacy at relatively low concentrations, point to its use as a secondary long-acting residual disinfectant for good quality drinking waters (Pedahzur *et al*., 2000).

Disadvantages

2.40 One area of concern is the level of silver contained in the water. As discussed previously in this document under the copper-silver ionisation section. There are Scottish Government guidelines indicating levels of silver allowed in a water supply, which should be adhered to in this instance. As also stated in the previous section on Copper/Silver ionisation, the Private Water Regulation Act (2006) allows the use of silver for disinfection. However there is no mention of Hydrogen peroxide in this document. The Drinking Water Quality Division - List of Approved Products, December 2007 states in relation to Hydrogen peroxide:

"Hydrogen peroxide containing silver or its compounds should not be used continuously as a disinfectant for public water supply".

http://www.scotland.gov.uk/Publications/2004/02/18931/33327

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Levels of silver must also adhere to the documents produced by Scottish water as stated in the previous section on copper-silver ionisation.

Ozone

2.41 Ozone is a similar disinfectant to UV light as it decomposes quickly in potable water and is therefore normally used as a secondary disinfectant at point of use. Ozone is an unstable compound and because of its instability, it cannot produce a persistent disinfectant residual in distribution systems (Singer, 1994).

Method

2.42 Ozone disinfects water by damaging the DNA of microorganisms (Kim et al., 2002). Ozone in aqueous solutions may react with microbes either by a direct reaction with molecular ozone or by an indirect reaction with the radical species formed when ozone decomposes.

Advantages

2.43 Ozone is one of the strongest and fastest acting disinfectants, and its high efficiency may have significant advantages in water treatment processes (Wojtenko, 2001). The bactericidal activity of ozone is much less prone to variation in pH and ammonia content than chlorine, and is more effective at low temperatures (Ingrams & Barnes, 1954), however ozone does react with ferrous and manganous salts to produce a scum that must be filtered off. The use of ozone in the removal of colour and odour has been well documented, and this use may be combined with the disinfection process (O'Donovan, 1965).

Disadvantages

2.44 One of the main disadvantages to using ozone as a disinfectant is that it has been shown that mutagenic and possibly carcinogenic by products may be produced under certain conditions of ozonation (Charmichael et al., 1982). Ozone is not a widely used disinfectant mainly due to its cost, and many hospitals choose to use chlorine, chloramines and chlorine dioxide which are cheaper to set up and run. Kim *et al*. (2002) state that one of the main reasons ozone on its own is not suitable as a disinfectant is that it has a very short life and carries no residual disinfectant into the water mains. This confirms previous reports in which ozone alone was found to be inefficient for controlling *Legionella* in water systems (Blanc *et al*., 2005). Charmichael *et al*. (1982) state that a more effective disinfection method would be to disinfect water by ozonation and then add small amounts of another disinfectant to give a residual effect in the piped supply. Chlorine would form (THMs) when combined with ozone which also carry risks; these are discussed in the section on Continuous Chlorination.

Chloramines

2.45 There has been an increasing interest in using chloramines as a secondary disinfectant to maintain a residual disinfectant effect throughout the distribution system (Seidel *et al*., 2005). Chloramines provide a similar protection to

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Chlorine and, although they have weaker bactericidal properties, they are more persistent in the water supply, lasting from 10 – 14 days.

Method

2.46 Adding ammonia to water containing free chlorine, hypochlorous acid (HOCl) and hypochlorite ions (OCl-), can, depending on the pH, produce chloramines. The ideal pH value for this reaction is 8.4, at which point the water is slightly alkaline.

Advantages

2.47 There are advantages to using this form of disinfectant. Primarily, chloramine technology is easily installed and maintained and it is among the less expensive disinfectant alternatives to chlorine that has a residual effect (USEPA, 2007). Chloramine is also not as reactive as chlorine, and forms fewer disinfection by-products, which, as discussed previously (Continuous Chlorination), may be harmful to humans (Hua, 2007). However, it should be noted that chloramines form more iodinated DBPs when iodide is present in the source water (Hua, 2007). In addition, as chloramine is more stable and longer lasting than chlorine, and provides better protection against bacterial re-growth. Chloramine is also effective in controlling biofilm, as shown by a study conducted by LeChevallier (1988) in which chloramines were more effective at inactivating biofilm organisms than free chlorine.

Disadvantages

2.48 There are some drawbacks to using chloramines, mainly because it can lead to the production of excess ammonia present in the water and leads to taste and odour problems. This can however be prevented by maintaining a pH level above seven which must be tested for prior to implementation for this disinfection system to be deemed suitable, and keeping the chlorine to ammonia ratio at 5:1 (USEPA Water Disinfection, 2007) these levels must be continually observed and the dose rate must be constantly adapted to maintain the specified ratio. Additionally, there are some potential problems with chloramines in relation to the corrosion of copper pipes and elastomer gaskets (USEPA Water Disinfection, 2007). Estates staff have also found that in the UK and the rest of Europe, this disinfection system is only available on large scale installations and at present it is not accessible to most NHSScotland healthcare settings.

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3. Disinfecting agents: Pros and cons

Chlorine

H&S: Chlorine gas - Very dangerous

Hypochlorite liquid, etc - Dangerous/Moderate

Chlorine release tablets - OK

Cost: Low

Advantages: Well-established technology.

Readily available as gas, liquid or powder.

Inexpensive.

Relatively simple and flexible dosing control.

Well-known taste, if present.

Can eliminate certain noxious odours during disinfection.

Liquid chemical can be prepared off or on site.

Available as tablets for ease of handling.

Can be generated from salt and electricity.

More cost-effective than either UV or ozone disinfection.

The residual that remains in the water can prolong disinfection even after initial treatment and can be measured to evaluate the effectiveness.

Reliable and effective against a wide spectrum of pathogenic organisms.

Effective in oxidising certain organic and inorganic compounds.

Toxic to most microorganisms.

Disadvantages: May dissipate quite rapidly (12 to 24h), especially in distribution due to reacting with organic matter and other oxidizable contaminants. For this reason it may not reach the end of the water system, even if high doses applied.

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Dosing equipment requires regular maintenance.

Can create taste and odour problems in poor quality water.

Can create carcinogenic compounds Trihalomethanes (THMs) in poor quality water. When considering the water from the utility provider, although it is of a potable standard there is still organic matter in the water that reacts with Chlorine to create THMs.

Simple neutralisation may be required before discharge to the environment. Any chemical discharge to a drain needs to be sanctioned by the Water Authority, who may then impose conditions on the discharge.

Long-term effects of discharging dechlorinated compounds into the environment are unknown.

Does not penetrate into centre of established biofilms.

All forms of chlorine are highly corrosive and toxic. Thus, storage, shipping, and handling pose a risk, requiring increased safety regulations.

Some parasitic species have shown resistance to low doses of chlorine, including oocysts of *Cryptosporidium parvum*, cysts, of *Endamoeba histolytica* and *Giardia lamblia*, and eggs of parasitic worms.

Potentially dangerous in case of a leak of chlorine gas.

System corrosion causes pipe leaks.

Workers must have access to a wash down hose, chemical eyewash, and shower. Operators must also wear the proper safety equipment, including carrying an Acid Gas escape respirator.

Must be removed from water prior to dialysis.

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Chloramine (monochloramine)

H&S: Chlorine: Gas - Very dangerous

Liquid - Dangerous/Moderate

Tablets - OK

Ammonia: Gas - Very dangerous

Solutions - OK

Cost: Low

Advantages: Less potent disinfectant, but more persistent (residual can last 10 to 14 days).

Less prone to creating taste or odour problems, if correctly applied.

Low residuals can be effective.

Will generally not create carcinogenic compounds (THMs).

Some effect on biofilms.

Chloramines may provide a less obnoxious taste and smell than chlorine.

Few disinfection by-products are formed.

Chloramines remain active for a long time, longer than chlorine.

Disadvantages: Weak disinfectant and oxidation agent compared to chlorine. Ineffective against viruses and cysts (*Giardia, Cryptosporidium*).

High dosage and prolonged contact time required in comparison to the other disinfectants. Must be removed from water prior to dialysis.

Requires careful, precise mixing and dosing regime. Can create bad tastes, due to creation of dichloramine or trichloramine, if dosing is inaccurate or if pH unsuitable.

Has to be mixed and dosed on site. Not available as package plant. Dosing equipment requires regular maintenance. More difficult to remove from water than chlorine or chlorine

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dioxide, needs to be removed using active carbon. May not penetrate into biofilm. Can cause corrosion to copper. Workers must have access to a wash down hose, chemical

eyewash, and shower. Operators must also wear the proper safety equipment, including carrying an Acid Gas escape respirator.

Must not be used in water systems supplying dialysis machines.

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Chlorine Dioxide

H&S: Dangerous - When chlorine dioxide concentrations reach 10% or more in air, chlorine dioxide becomes explosive.

Cost: Moderate

Advantages: Chlorine dioxide is more effective than chlorine and chloramines for inactivation of viruses, *Cryptosporidium* and *Giardia*.

Required contact time and concentration is low.

Generally good at controlling bad tastes and odours.

Available as package plant.

More effective at a high pH level.

Will remove biofilm, over a period of time.

Oxidizes iron, manganese, and sulphides.

May enhance the clarification process.

Is easy to generate. Provides residuals.

No formation of bromides from bromates.

At the concentrations required for disinfection, chlorine dioxide is not corrosive.

Must not be used in water systems supplying dialysis machines.

Disadvantages: Unstable, generally must be dosed immediately after manufacture - has to be made on site.

Requires careful, precise mixing and dosing regime, low pH needed.

May cause precipitation of iron and manganese.

Dosing equipment requires regular maintenance.

Can lead to production of noxious odours in some systems, may need to be neutralised before discharge to the environment. Any chemical discharge to a drain needs to be sanctioned by the Water Authority, who may then impose conditions on the discharge.

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The chlorine dioxide process forms the specific by-products chlorite and chlorate.

Costs associated with training, sampling, and laboratory testing for chlorite and chlorate are high.

Cost of the sodium chlorite is high.

Chlorine dioxide decomposes in sunlight.

Workers must have access to a wash down hose, chemical eyewash, and shower. Operators must also wear the proper safety equipment, including carrying an Acid Gas escape respirator.

Chlorine dioxide is generally effective for the deactivation of pathogenic microorganisms. It is less effective for the deactivation of rotaviruses and E. coli bacteria.

5 to 10 times more expensive that chlorine.

Can form THMs at lower levels than chlorine, forms more iodinated DBPs in relation to the other disinfection methods when iodide is present in the source water.

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Ozone

H&S: Dangerous

Cost: High

Advantages:

Rapid and strong disinfectant and oxidation agent.

Been used for several decades for disinfection, colour elimination, taste and odour control.

Does not form Trihalomethanes (THMs).

Very effective against Giardia, Cryptosporidium and any other pathogenic microflora.

Facilitates removal of turbidity from water.

Can improve the palatability of the water.

Package plants are available.

Disadvantages:

Disinfects only at the point of injection.

Specialised equipment required to generate ozone.

Decomposes quickly.

Hard to hold effective concentration.

Ground level ozone is an air pollutant with harmful effects on lung function.

Bromite mutagenic and carcinogenic by-products may be produced under certain conditions.

Must use biologically active filters to remove by products.

No residual disinfection.

Expensive for initial equipment.

May cause precipitation of iron.

Plant and equipment require regular maintenance.

When reacting with organic compounds, ozone disintegrates them into smaller components, which could become a feeding media for microorganisms growth in water distribution systems.

Requires high voltage equipment.

Training and installation support required.

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Silver Catalysed Hydrogen Peroxide

H&S: Dangerous

Cost: Moderate

Advantages: Hydrogen peroxide is catalysed with silver for increased activity.

Rapid and effective disinfectant.

Will remove biofilm.

Works in all temperatures.

Silver has curative properties against disease.

Disinfects drinking water for long periods of time.

Will not corrode pipes.

Easy to install and maintain.

Disadvantages: Residual Silver may need to be neutralised before discharge to the environment. Any chemical discharge to a drain needs to be sanctioned by the Water Authority, who may then impose conditions on the discharge. Expensive chemicals but overall system is cost effective. Not approved for continuous dosing, except in emergencies. See http://www.scotland.gov.uk/Publications/2008/03/04152957/9

Maintenance of plant is simple and straightforward but there is a need to maintain close control over the sensor used to monitor dosage rates.

Requires the inclusion of a filter on the inlet to the sensor and regular inspection of it to ensure a clean sensor electrode.

Biocidal efficacy of silver may be compromised by high concentrations of chloride.

High pH may affect efficacy.

Not equally effective for all pathogens.

Must not be used in water systems supplying dialysis machines.

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Silver/copper ionisation

H&S: Can be dangerous to dialysis patients

Cost: Low

Advantages: Works in all temperatures. High doses will remove biofilm. Silver has curative properties against disease. Disinfects drinking water for long periods of time. Will not corrode pipes. Easy to install and maintain.

Disadvantages: Monitoring the silver levels is difficult and expensive. Can stain porcelain. May need to be neutralised before discharge to the environment. Any chemical discharge to a drain needs to be sanctioned by the Water Authority, who may then impose conditions on the discharge.

High pH may affect efficacy.

Biocidal efficacy of silver may be compromised by high concentrations of chloride. Level of silver required for effectiveness is eight times greater than for silver catalysed hydrogen peroxide. Not equally effective for all pathogens. Must not be used in water systems supplying dialysis machines.

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Ultra Violet

H&S: UV radiation is not suitable for water with high levels of suspended solids, turbidity, colour, or soluble organic matter. UV light can cause serious damage to the retina if viewed directly through the viewing port.

Cost: High

Advantages: Requires no chemical handling. Effective in clean, low turbidity waters. No special requirements for storage and transportation. No formation of by-products. Not effected by pH or temperature.

Disadvantages: Only works at point of entry. Leaves no residual disinfectant in the water. Can be ineffective in turbid waters. Expensive in equipment and maintenance. Actually, the UV generator is quite inexpensive, relatively speaking. The cost increases, though, when serious filtration is needed to allow the process to work.

Power supply deviations effect wavelength. Requires pre filtration. May require frequent cleaning of tubes and chamber. Water velocity is critical so may require special chamber to provide appropriate dwell time. Poor penetrating power of UV light in established biofilms. Turbidity makes it difficult for radiation to penetrate water. These materials can react with UV radiation, and reduce disinfection performance.

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Appendix 1

Case Studies

Heat and Flush

Colville *et al* (1993) stated that following a heat and flush treatment at Nottingham University Hospital, new cases of hospital-acquired Legionnaires' disease were reported. Chen *et al*., (2005) also reported recolonisation in a Taiwanese hospital where heat and flush was used for the treatment of Legionella. It should be noted that when adhering to the recommendations of two authoritative bodies, namely the Centers for Disease Control and Prevention (CDC) and the American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE), the heat and flush method was shown to be ineffective in eradicating *Legionella* from this hospital's water system. The paper puts forward that this failure may have been due to the flush time, which is recommended by ASHRAE to be greater than five minutes. The author suggests that a flush time of thirty minutes would have been required to eliminate Legionella in this system. Zhang *et al*. (2009) maintains that the heat and flush method is labour intensive and numerous personnel are required to monitor water temperatures and flushing times and can prove ineffective for long-term Legionella infestation management.

Chlorine Dioxide

Pavey and Roper (1997) have published results indicating that chlorine dioxide concentrations of 0.1 ppm to 0.2 ppm were shown to be effective in decontaminating a cold water system, whilst higher concentrations up to 0.35 ppm were needed for the hot water system.

Other studies have shown that temperature and high levels of total organic carbon in drinking water would cause deterioration of the chlorine dioxide levels in the water, therefore affecting the efficiency to control contaminants (Zhang *et al*., 2008). Maintaining a sufficient residual level of chlorine dioxide in the hot water system is a difficult task as an elevated water temperature accelerates the conversion of chlorine dioxide to chlorite, through reactions with organic compounds in the water distribution system. This finding is consistent with Zhang et *al*'s. (2007) study observation where the mean chlorite concentration in hot water was higher than that in cold water. Additionally, results from Pavey and Roper's (1997) study showed that more chlorine dioxide was used in the soft water than hard water systems to achieve the same concentration.

Zhang *et al*'s. (2007) study also showed that chlorine dioxide did not completely eliminate Legionella organisms from a hospital's hot and cold water system, given a target feed concentration of 0.5-0.7 mg/litre in the cold water.

UV

Abbaszadegan *et al*. (1997) completed an experiment to evaluate the microbial disinfection efficacy of a point-of-use water treatment system comprised of a

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pressed activated carbon block filter followed by an ultraviolet (UV) light reactor. This method of filtration was found to effectively remove and/or inactivate more than 99.9999% of the bacterial pathogens, more than 99.99% of the viruses and more than 99.9% of the protozoan cysts and oocysts, tested to 150% of the water treatment capacity of the point of use water treatment system. These findings suggest that a properly designed and operated point of use water treatment may be adopted as an approach to removing microbiological waterborne pathogens from potable water (Abbaszadegan *et al*., 1997). This system would probably not be considered on a large scale as it has a high capital and revenue costs compared to other disinfectant methods as many disinfection points would be required as UV has no residual effect. Also there may be problems in retro fitting a UV system if there is limited space.

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Appendix 2

Traditional forms of water treatment for the disinfection of potable water systems in healthcare premises

Biocide comparison chart

Parameters	Heat and flush	Continuous chlorination	Chlorine dioxide	Ultra violet light (U.V.)	Copper – silver ionisation	Silver catalysed hydrogen peroxide	Ozone	Chloramines
Concentration required at outlets during continuous use	Continuously above 55°C	2-4 mg/l as free chlorine (Zhang, 2007)	0.5 mg/l as CL02 (Zhang, 2007)	300 nm (Chen *et al*., 2006)	Cu=0.2-0.4 mg/l	H202=15 mg/l	0.1 to 5.0 mg/l over a contact time ranging from 5 minutes to 15 minutes	WHO maximum allowable concentration is 3.0 mg/l based on the NOAEL level
	70-80°C for 30 min (Zacheus and Martikainen, 1996)				Ag=0.02-0.04 mg/l (Kim *et al*., 2002)	Ag=0.008 mg/l (Pedahzur *et al*., 2000)	(Kim *et al*., 2002)	1.0 mg/l for design purposes (Kim, 2002)
On-site efficacy documented in literature	Yes (Zacheus and Martikainen, 1996)	Yes (Korich et al., 1990)	Yes (Gates, 1998)	Yes (Maraca *et al*., 1987)	Yes (Blanc, 2005)	Yes (Kim *et al*., 2002)	Yes (Kim *et al*., 2002)	Yes (Kim *et al*., 2002)
Residual effect	No	Yes (WHO, 2004)	Yes (Thomas, 2004)	No (Chen et al., 2006)	Yes (Blanc, 2005)	Yes (Kim et al., 2002)	No (Kim et al., 2002)	Yes (Kim et al., 2002)
Time to re-colonisation after treatment stopped	Varies but usually a few months (Zacheus and Martikainen, 1996)	1-2 Weeks (Fiehn & Henriksen, 1988)	Some residual protection until biofilm is re-established (Gates, 1998)	Only works at point of entry (Maraca *et al*., 1987)	6-12 weeks (Liu *et al*., 2004)	Long lasting residual effect in water (Pedahzur *et al*., 2000)	No residual disinfectant (Kim *et al*., 2002)	A few days, far less effective than chlorine (Kim et al., 2002)
Temperature	N/A	Residuals decrease as temperature increases (Kim *et al*., 2002)	Residuals decrease as temperature increases. Bacterial kill rate increases with increase in water temperature (Kim *et al*., 2002)	Temperature effects are minimal (Mally, 2000)	Residuals unaffected by high temperature (Lin *et al*., 1996)	No reported degradation at up to 90 degrees, centigrade. Poor disinfectant below 10 degrees (Pedahzur *et al*., 2000)	Unaffected by temperature (Kim *et al*., 2002)	Unaffected by temperature (Hua, 2007)
PH	No effect (Neurener, 2002)	PH>8 Disinfection power is reduced (Neurener, 2002)	Effective over normal range of PH values for drinking water below pH of 10 (Kim *et al*., 2002)	No effect (Mally, 1995)	Elevated pH (>8) may effect efficacy (Blanc, 2005)	Biocidal action generally increased with increased pH (Pedahzur *et al*., 2000)	No effect (Kim *et al*., 2002)	Quantities of ammonia and chlorine depend on the acidity of the water (USEPA, 2007)
Disinfection by-product	None (Neurener, 2002)	Trihalomethane (THMs) (Hua, 2007)	Can form (THMs) lower levels than chlorine. Forms more iodinated DBPs when iodide is present in the source water (Hua, 2007)	Ozone (Jeong, 2005)	None known but residual levels of Cu and Ag (Neurener, 2002)	Residual levels of Ag. Primary compound breaks down into water and oxygen (Pedahzur *et al*., 2000)	Bromite mutagenic and carcinogenic by-products may be produced under certain conditions (Charmichel *et al*., 1982)	Can form (THMs) lower levels than chlorine. Forms more iodinated DBPs when iodide is present in the source water (Hua, 2007)

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Parameters	Heat and flush	Continuous chlorination	Chlorine dioxide	Ultra violet light (U.V.)	Copper – silver ionisation	Silver catalysed hydrogen peroxide	Ozone	Chloramines
Taste and odours at nmo	No (Neurener, 2002)	Yes taste and odour problems (Kim *et al*., 2002)	Minimal at high concentrations, Neutralises odours (Kim *et al*., 2002)	Only if High intensity, ozone lamps are used (Froese *et al*,m 1999)	None (Lin *et al*,m 1998)	None (Pedahzur *et al*., 2000)	Could allow formation of odorous, aldehydes (Frose *et al*., 1999)	Depends on acidity of the water or ratio of ammonia (USEPA, 2007)
Pipe corrosion	Old pipes may be affected (Neurener, 2002)	Highly corrosive (Lin *et al*., 1998)	Minimal potential of corrosion problems (Sinnivasan *et al*., 2003)	Potential corrosion problems if high intensity ozone lamps are used (USEPA, 2007)	Copper concentrations above 1 mg/l can corrode iron and steel (HTM 04-01)	None observed at normal concentrations (O'Donnell, 2007)	Corrosive for specific materials and in certain circumstances. Particularly attacks rubber products and causes degradation of metals (USEPA, 2007)	Corrosive for specific materials and in certain circumstances. Particularly attacks rubber and Elastomeric products (USEPA. 2007)
Maintenance issues		COSHH applies	COSHH applies		COSHH applies	COSHH applies	COSHH applies	
	Scalding possible	Concentration control and monitoring	Concentration control and monitoring (Neurener, 2002)	Must be proceeded by filtration, which required replacement.	Routine ion monitoring	Routine monitoring of Ag content	System required to be filtered to remove metallic components precipitated out	Routine monitoring of chlorine and ammonia levels
			Chlorine dioxide must be handled with great care, requires trained workers for operation and maintenance					
	Labour intensive (Neurener, 2002)	Corrosion control (Lin *et al*., 1998)	Corrosion control (USEPA, 2007)	Routine cleaning (USEPA, 2007)	Routine inspection of electrodes (Neurener, 2002)	Routine inspection of electrodes (Kim, 2002)	(Odonovan, 1965)	(USEPA, 2007)
Maintenance issues	Does not penetrate biofilm (Chen *et al*., 2005)	Does not penetrate biofilm (Kim *et al*., 2002)	Presents toxicity hazards when stored (Kim *et al*., 2002)	Can only be effective at point of entry (Mally *et al*., 2002)	Electrodes must be replaced annually (Kim *et al*., 2002)	Can be lethal to dialysis patients if the hydrogen peroxide is not filtered out properly (SAN, HAZ(SC) 08/07)	None identified (Kim *et al*., 2002)	Chloramines can remain in the water for a long period of time posing problems for dialysis patients (USEPA, 2007)
Efficacy issues	*Legionella* bacteria only lie dormant below 20°C and are killed above 60°C	Loses efficacy at elevated pH. Decays at elevated temperature and over distance (SHTM 2040 Part 5)	Decays at elevated temperature and over distance	Particle filtration required	Can be lethal to dialysis patients if the silver is not filtered out properly (SAN, HAZ(SC) 08/07)			Filtration to remove chloramine is expensive and complex (USEPA, 2007)
	Time dependent (Chen *et al*., 2005)		Efficacy reduces with an increase in the organic content of the water	Does not work with shadows (Abbaszadegan, 1997)				
			Decays when in contact with corrosion products deposited in iron and copper pipe work (USEPA, 2007)					

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Parameters	Heat and flush	Continuous chlorination	Chlorine dioxide	Ultra violet light (U.V.)	Copper – silver ionisation	Silver catalysed hydrogen peroxide	Ozone	Chloramines
Other issues		Concerns raised about long-term health implications from by-products (Frose 1989)	Concerns raised about long-term health implications from by-products (Vischetti 2004)	Concerns raised about chemical degradation arising out of some UV treatments (Corin *et al*., 1996)	Argyria possible from prolonged exposure to very high silver levels (typically 100 times the recommended dosing concentration) (Butkus 2005)	Argyria possible from prolonged exposure to very high silver levels (typically 1000 times the recommended dosing concentration) (Butkus 2005)	Suitable fro use in dialysis units but decomposition products include small quantities of hydrogen peroxide, which produces an adverse affect on renal patients (AAMI/ANSI 1992)	At high dosage rates (500mg/l), will degrade RO membranes (USEPA 2007)
		Adverse affect on neonates (Magnus 1999)	Adverse affect on neonates (Tuthill *et al*., 1982)	UV can form Nitrite (Sharpless *et al*., 2003)	Recommended silver concentration may lead to discolouration of sanitary ware, porcelain, etc. (lin et al., 1998)	Adverse affect on renal dialysis systems. Maximum allowable silver concentration of 0.005 mg/l (AAMI/ANSI 1992)	Low concentrations of ozone may produce mutagenicity in the water (0.5 to 1.5 mg/l) (Bourbigot *et al*., 1986)	Can cause nitrite levels in the water to rise, which may be harmful to children under 5 (Pintar & Slawson 2003)
			Adverse affect on renal dialysis systems (Zhang 1999)		For dialysis systems, maximum allowable concentration are copper at 0.1 mg/l and silver at 0.005 mg/l (AAMI/ANSI 1992)	Some microorganisms can become resilient to silver (Lin *et al*., 1998)		Monochloramine vapours released into the atmosphere may give rise to asthma attacks in susceptible individuals (Emanuel 1998)
			Adverse affect on renal water treatment plants (Zhang 1999)		Some microorganisms can become resilient to silver (Lin *et al*., 1998)			Must be filtered before dialysis (USEPA 2007)

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Appendix 3

Risk register

Ref No	Description of risk	Date and person raised	Issue owner	Resolution date	Impact	Probability	Rusk status based on 5*5 matrix	Comment: Progress: Resolution:
1	Risk of implementing a water management strategy that does not meet users requirements		Group		Major	10%	Low	The group are experienced and proficient in water systems. Outside consultation is also an option.
2	Financial risk		HFS		Low	10%	Low	The financial implications are currently low. This may increase if outside consultations sought
3	Resource risk		HFS		Low	10%	Low	Discussions are ongoing with regard to increasing the size of the group
4	The project becomes a data collection exercise and is not an effective management tool		Group		High	10%	Low	
5	Risk that the quality of data is not sufficient to enable a proper assessment of disinfection of water systems		HFS		High	10%	Low	A great deal of data has already been gathered and vetted
6	Non co-operation from Water Management companies with regard to access to test results		Group		Medium	30%	Medium	
7	Lack of specialist advice i.e. Medical/Microbiology		HFS		High	10%	Low	Advice is available at individual Board level

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Scottish Health Technical Memorandum 04-01

The control of *Legionella*, hygiene, 'safe' hot water, cold water and drinking water systems Part F: Chloramination of water supplies

Health Facilities Scotland
Engineering and Environment

December 2011

Health Facilities Scotland

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Contents

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Preface

About Scottish Health Technical Memoranda

Scottish Engineering Health Technical Memoranda (SHTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of SHTM guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle. Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Scottish Engineering Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to repeat unnecessarily international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of eight subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

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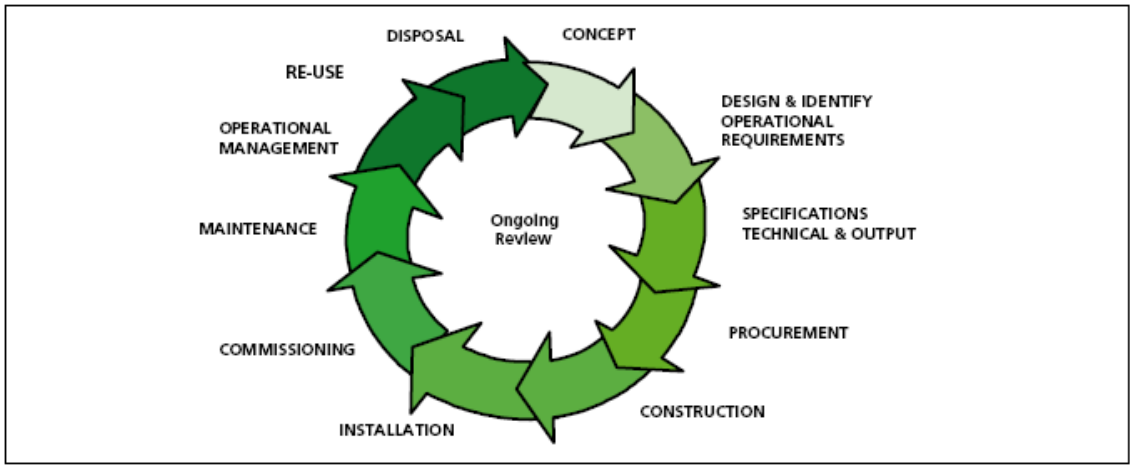

Healthcare building life-cycle

Structure of the Scottish Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of eight core subjects pending a re-assessment of Firecode SHTMs 81-86.

Scottish Health Technical Memorandum 00: Policies and principles (applicable to all Scottish Health Technical Memoranda in this series)

Scottish Health Technical Memorandum 01: Decontamination

Scottish Health Technical Memorandum 02: Medical gases

Scottish Health Technical Memorandum 03: Heating and ventilation systems

Scottish Health Technical Memorandum 04: Water systems

Scottish Health Technical Memorandum 05: Reserved for future use

Scottish Health Technical Memorandum 06: Electrical services

Scottish Health Technical Memorandum 07: Environment and sustainability

Scottish Health Technical Memorandum 08: Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Scottish Health Technical Memorandum 06-02 Part A will represent Electrical Services - Electrical safety guidance for low voltage systems.

In a similar way Scottish Health Technical Memorandum 07-02 will simply represent Environment and Sustainability – EnCO_2de.

All Scottish Health Technical Memoranda are supported by the initial document Scottish Health Technical Memorandum 00 which embraces the management

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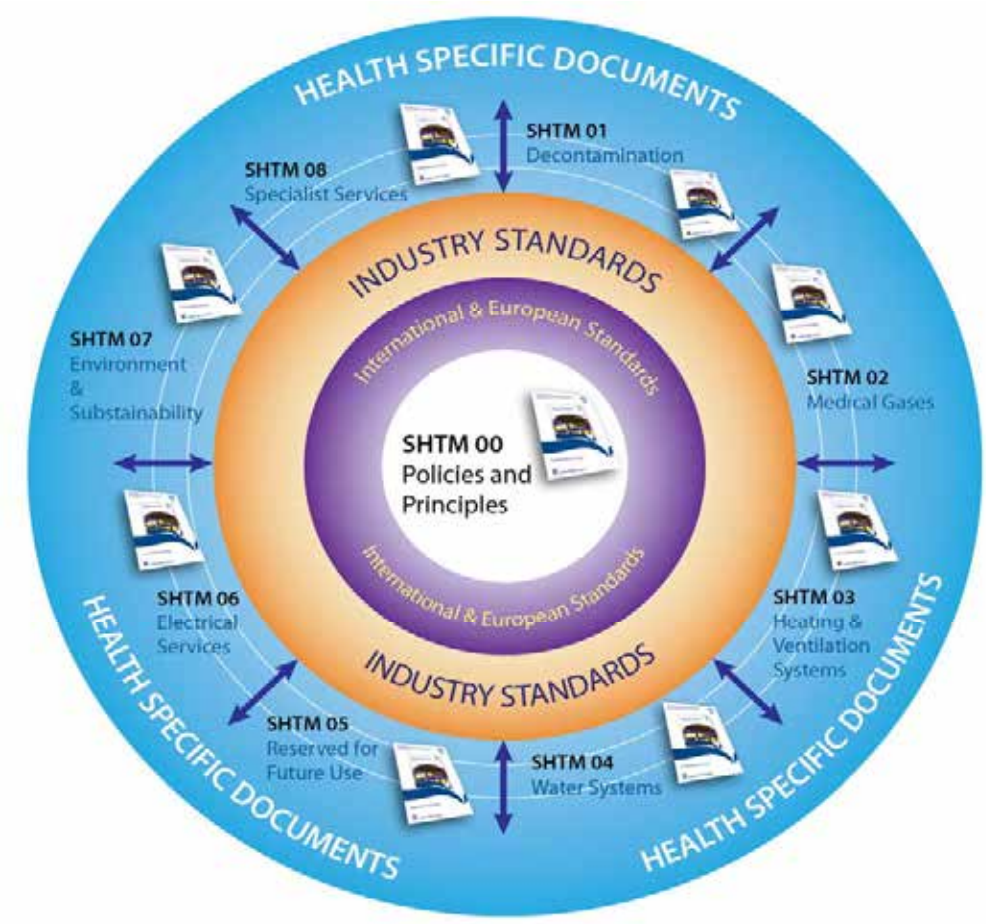
and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

Health Facilities Scotland wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.



Engineering guidance structure

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Executive summary

Background information

Chloramine is increasingly replacing chlorine as the secondary disinfectant in water treatment systems primarily because it produces fewer dangerous disinfection by-products. Chloraminated water is already being introduced within some regions of Scotland and it is envisaged that most NHS Boards in Scotland will soon confront a change in their water supply disinfection regime.

This guidance provides information on the likely impact of the change backed up by relevant case studies.

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1. Methodology

Aim of this SHTM

1.1 The aim of this SHTM is to assess the impact chloramination may have on patient safety and infrastructure within healthcare facilities provided by NHSScotland.

Factors examined

1.2 Following an outline of the relevant background detail, numerous factors have been examined including:

- those which will directly affect patients;
- those which may impinge upon the general populace;
- those which could concern estates staff.

Case studies undertaken

1.3 A series of case studies has been used to examine which lessons can be learned from water utilities which converted to chloramine disinfectant. The information contained within this SHTM was sourced from published technical papers and reports authorised by regulatory bodies in addition to material available online. The SHTM concludes with a series of observations and recommendations which have arisen from an appraisal of the relevant data and review of the literature.

Review questions

1.4 This SHTM seeks to verify if the introduction of chloramine into the common water supply enables a different maintenance regime to be developed in healthcare facilities without impacting on patient safety. Answers have been sourced to the following questions:

- what is chloramine?
- what is chloramination as it relates to water disinfection?
- what are the benefits and risks of using chloramine for water disinfection within a healthcare environment when compared with chlorine?
- are there any negative impacts that could occur when converting from chlorine to chloramine water disinfection and, if so, how can these be minimised?
- what has been the experience of other healthcare organisations which have changed to chloramine for their water disinfection needs? What can be learned from these past experiences?

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Abbreviations

1.5 The following abbreviations have been used throughout this SHTM:

AWWARF	American Water Works Association Research Foundation
DBP	disinfectant by-product
HAA	haloacetic acids
HPC	heterotrophic
MWUA	Maine Water Utilities Association
NDMA	N-nitrosodimethylamine
NWSAG	National Water Services Advisory Group
PEFEx	Property & Advisory Forum Executive (Predecessor of Health Facilities Scotland)
SEDWQU	Scottish Executive Drinking Water Quality Unit
SFPUC	San Francisco Public Utilities Commission
THM	trihalomethane
USEPA	United States Environmental Protection Agency
UWRAA	Urban Water Research Association of Australia

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2. Introduction

General

2.1 Reference is made in this SHTM to lead and copper pipework. It is believed that all lead pipework has been removed from NHS premises in Scotland and copper pipework is no longer routinely specified. Lead service pipes were phased out in the 1960s and proscribed in 1969, with lead-soldered joints being prohibited in 1987. Many existing installations still use copper pipework whereas some fittings may use alloys containing lead, therefore issues raised in case studies are still relevant.

2.2 Chloramination, whilst reducing the levels of *Legionella* in the water, may give rise to increased levels of other contaminants. Therefore, NHS Boards that are supplied with chloraminated water should be aware of the potential for incoming water to have increased levels of other contaminants; the types of contaminants likely to arise from this process are discussed within this document.

2.3 However, it should be noted that when water is supplied to Dialysis Units, Hydrotherapy Units and Manufacturing Pharmacies additional action should be taken at point of use. Further details on how to manage these areas are described in Parts A & B of this SHTM.

Secondary disinfection

2.4 The final step in water purification schemes within most developed countries involves the addition of disinfectant intended to persist within the distribution system. Known as 'secondary disinfection', this practice is intended to maintain water quality by inactivating pathogens or bacteria that may have entered the distribution network and is usually distinguished from a 'primary disinfection' stage which targets source water.

2.5 For many years chlorine was the most widely used secondary disinfectant, although other substances were viewed as suitable (and in some cases preferable) alternatives. In one such instance, water authorities in Australia concerned with controlling the prevalence of the pathogenic amoeba *Naegleria fowleri* realised that chloramine was much more effective as a counter-measure (Urban Water Research Association of Australia [UWRAA], 1990).

2.6 However, the discovery that natural organic matter in water could react with chlorine to produce hazardous compounds known as disinfection by-products (DBPs), prominent among which were trihalomethanes (THMs) and haloacetic acids (HAAs), constituted the principal motivation for the use of chloramine.

2.7 During the 1970s and 1980s concern grew in the United States that exposure to THMs at high concentrations might increase the risk of some cancers. As a result, the United States Environmental Protection Agency (USEPA) began regulating THMs and developed the Stage 1 Disinfectants and Disinfection By-Products Rule, lowering the permissible total THM concentration to 80 µg/litre in

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December 2001, with HAAs limited to 60 µg/litre (San Francisco Public Utilities Commission [SFPUC], 2004; Edwards *et al*., 2005).

2.8 It was known that using chloramine as an alternative to chlorine reduced the formation of these potentially carcinogenic THMs, ostensibly making the water safer for human consumption. Although chloramine had been used for disinfection in a small number of facilities within the US since the early 1900s, its popularity in recent years has soared, principally because it is a low-cost means of complying with the USEPA regulations (Edwards *et al*., 2005); 30% of water utilities in the US already used chloramine as a secondary disinfectant by 2004 (Flannery *et al*., 2006).

2.9 Notwithstanding Spain and Sweden's long established use of chloramine, European nations were generally slower to respond to the DBP issue (Lenntech, 2009). However, the number of water treatment plants in the EU using chloramine is expected to increase as utility companies seek to comply with more stringent regulatory requirements.

2.10 Scotland is bound to the EU Drinking Water Directive (98/83/EC) which limits total THM concentrations to100 µg/litre but does not specifically mention other DBPs. As part of its long term investment programme to improve water quality for customers, Scottish Water is gradually increasing the number of areas within Scotland that are supplied with chloraminated water (Scottish Water, 2010).

2.11 While chloramination appears to have several advantages in comparison with chlorination (these terms will be used henceforth to denote the relevant secondary disinfectant), its associated risks are still being determined. For example, a claim by Dr Michael J. Plewa of the University of Illinois that only 17% of DBPs associated with chloramination have been identified (see Barlow (2004)) has been given much publicity by campaign groups (such as 'Concerned Citizens about Chloramines') anxious about the purity of water supplies and companies which sell domestic purification equipment (exemplified by Aquavantage (see www.buyaquavantage.com/av-learnmore-epa.htm)).

Chloramination – possible risks?

2.12 Recent studies have found possible links between chloramination and blood lead levels (Miranda *et al*., 2007), nitrification, increased bacterial growth and the degradation or corrosion of pipe fittings (see, for example, Kirmeyer et al. (1993)). In addition, chloramine is known to be toxic in the bloodstream, thus posing significant risks for dialysis patients (Arrowsmith, 2002). Despite the well-known susceptibility of babies to nitrified water supplies (see, for example, Florida Department of Health, 2010), little detailed research work has focused on the impact chloramine might have on the healthcare environment and patient safety. In particular, there are no directly related literature surveys.

2.13 There exists a considerable body of literature that addresses chloramination from various other perspectives. A particularly comprehensive review of the topic was carried out by Kirmeyer et al. (1993) on behalf of the American Water Works Association Research Foundation (AWWARF) and this report draws heavily on the case studies contained therein. The AWWARF study was in fact

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supplemented more recently with the results of further research and practical experience of chloramination (Kirmeyer et al., 2004). Research focusing on some of the potential risks of chloramine is reasonably extensive (see, for example, Edwards *et al*. (2005), Miranda *et al*. (2007) and Weintraub et al. (2006)). While information on chloramine within a healthcare setting is sparse, Arrowsmith (2002) and Walker (2004) provide some foundation and several studies have associated chloramination with a *decreased* risk of Legionnaires' disease (Heffelfinger *et al*., 2003; Flannery et al., 2006; Kool *et al*., 1999). Additionally, there is anecdotal evidence that some NHSScotland Boards have had no reports of *Legionella* since their incoming water supplies were altered to being treated with chloramine.

Chloramination – advantages and disadvantages

2.14 This SHTM examines chloramination and discusses the various advantages and disadvantages of using chloramine as a disinfectant. It has also attempted to garner information from organisations that have converted from chlorine to chloramine and to determine the lessons that were learned in the process. Ultimately, it seeks to establish which problems Scotland's NHS Boards may encounter when faced with a changeover to a chloraminated water supply.

2.15 Following a detailed description of the chemical reactions and water treatment processes entailed, this SHTM discusses the advantages and disadvantages of chloramination. Attention subsequently focuses upon the main findings in respect of the impact chloramination may have, particularly with reference to patients and staff within NHSScotland healthcare facilities. The various issues involved are separated into

- those which have a direct impact on the NHS (dialysis, nitrification and the inactivation of pathogens);
- those which affect the populace, some of which may have a long-term impact upon the NHS (chloramine ingestion, cancer, disinfection by-products and aquatic life);
- those which will be primarily of concern to NHS estates staff (lead-leaching, metal corrosion and the degradation of rubber).

2.16 This SHTM proceeds to examine the experience of numerous water utilities following a conversion to chloraminated water. Finally, in light of the knowledge acquired in the literature survey, it concludes with a summary of the main observations and a list of recommended actions NHS Boards should consider.

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3. Preparation of this SHTM

Sources of information

3.1 The initial review was carried out primarily as a literature survey with as systematic an approach as possible adopted given time and resource constraints. Information was obtained both from online sources and books, journals and guides. The researchers aimed to gather a wide range of information from many different sources, mostly from outside the UK. However, the case studies were as representative as possible.

3.2 In order to determine the key organisations in this field and the main sources of information, searches were carried out via general search engines such as Google. Search terms used included:

> Chloramine, chloramination, monochloramine, … + potable water, … + drinking water, + risks, … + benefits, … + healthcare, … + hospitals, … + pathogens, … + DBPs, … + toxicity, … + corrosion, … + materials degradation, … + lead-leaching, … + dezincification + bacteria.

3.3 Journal papers and articles were obtained from NHS libraries and databases, either online or in hard copy. Databases searched included Science Direct, MEDLINE and Cochrane. Several books on the topic were also sought from the NHS Library.

3.4 Source material which was deemed acceptable fulfils one or more of the following criteria: peer-reviewed scientific papers and articles, reliable information from reputable organisations, work carried out by or on behalf of governments and comprehensive case studies. Information from unknown organisations or agenda-driven websites was excluded as were case studies with insufficient details.

3.5 In published form as this SHTM it is expected to be used by NHSScotland managers, facilities management providers, designers and decision-makers to assist them in determining how chloramination could affect healthcare procedures and patient safety and enable them to take the steps necessary to minimise any negative impacts.

Note: This would include those responsible for home dialysis equipment.

Risk of bias

3.6 The information used in this SHTM came from a variety of sources, although there was a clear bias towards those from the United States. This has been largely unavoidable because the US has led the world in chloramination and possesses most expertise and experience. Nevertheless, there is not necessarily a bias within the US *per se*, since a wide spectrum of perspectives is reflected in the literature.

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3.7 As chloramination becomes more widespread, particularly within United Kingdom, Europe and Australia, more case studies and information will become available. However, it will take time for lessons to be learned and shared. It is therefore anticipated that future updates of this SHTM will have a wider international slant.

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4. Chemistry of chloramination

Basic Chemistry

4.1 This section follows UWRAA (1990) in describing the chemical reactions involved in the formation of chloramine.

- when gaseous chlorine is added to water it is said to hydrolyse or disproportionate as shown below:

$$Cl_2 + H_2O \rightarrow HOCl + H+ + Cl- \quad (1)$$

- a dissociation of the relatively weak hypochlorous acid HOCl into hypochlorite and hydrogen ions follows:

$$HOCl \rightarrow ClO- + H+ \quad (2)$$

- the hypochlorite ion ClO- very rapidly establishes equilibrium with hypochlorous acid. The reaction between HOCl and ammonia NH_3 forms monochloramine NH_2Cl:

$$HOCl + NH_3 \rightarrow NH_2Cl + H_2O \quad (3)$$

- the reaction between monochloramine and hypochlorous acid forms dichloramine NHCl2:

$$HOCl + NH_2Cl \rightarrow NHCl_2 + H_2O \quad (4)$$

- while the reaction between dichloramine and hydrochlorous acid forms trichloramine NCl_3:

$$HOCl + NHCl_2 \rightarrow \quad NCl_3 + H_2O \quad (5)$$

Definitions

4.2 Monochloramine, dichloramine and trichloramine are sometimes collectively known as combined chlorine (or combined available chlorine). However, depending on whether the context involves water treatment or chemistry, the term 'chloramine' is used to denote both the compound monochloramine alone as well as the mixture of compounds, monochloramine, dichloramine and trichloramine. Monochloramine predominates at ratios of chlorine to ammonia-nitrogen of 3:1 to 5:1, while the formation of dichloramine and trichloramine are favoured by higher ratios (Hankin, 2001).

4.3 Collectively, Cl_2 (the chlorine molecule), HOCl (hydrochlorous acid) and the hypochlorite ion (ClO-) are known as free chlorine or freely available chlorine.

Chloramination – a Brief Summary

4.4 Chloramination is a water management practice that uses chloramine to treat and deliver public water supplies in compliance with water supply regulations

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(Flannery et al., 2006), while apparently producing fewer potentially dangerous DBPs than chlorine (SFPUC, 2004).

4.5 Municipal drinking water disinfection generally occurs in two phases, the first being an initial disinfection to kill organisms in the water, while a residual disinfection agent maintains biocidal activity throughout the water distribution system (Kool *et al*.,1999). Chloramination is known to provide a lasting residual disinfectant in the water system (Flannery *et al*., 2006) and, consequently, a typical chloramine water treatment plant uses chlorine for the initial disinfection and monochloramine for the residual disinfection (Kool *et al*., 1999).

4.6 The process of chloramination usually introduces chloramine at a concentration of 1.5 to 2.5 mg/litre, although it can be as low as 0.2 mg/litre and as high as 3.0 mg/litre based on World Health Organisation (WHO) recommendations (Hankin, 2001). It is known that because chloramine is a weaker agent a higher disinfectant residual will be needed to produce the same results as chlorine (MWUA, 2010). Therefore, a residual of 2.0 mg/litre of chloramine is relatively equivalent to a residual of 0.5 mg/litre of free chlorine.

4.7 Monochloramine is the most active chloramine compound and forms preferentially at the ratios of chlorine to ammonia-nitrogen defined above and at a pH value in the range 7.5 – 9.0 (Kim et al., 2002). At ratios of chlorine to ammonia-nitrogen between 5:1 and 7:1 and a pH ranging from 4 to 7 dichloramine tends to form, while the corresponding values favouring trichloramine are 7:1 and above and pH levels lower than 3.0.

4.8 Both trichloramine and dichloramine can cause taste and odour problems (Lenntech, 2009; Kool et al., 1999). It should be noted that the chloramine compounds can be broken down into free chlorine relatively easily and have a half-life ranging from one minute to 23 days (Lenntech, 2009). One major reaction leading to chloramine loss is initiated by the disproportionate of monochloramine, namely (see UWRAA (1990)):

$$NH_2Cl + NH_2Cl \rightarrow NHCl_2 + NH_3 \qquad (6)$$

The subsequent decomposition of dichloramine results in the loss of chloramine:

$$NHCl_2 + NH_2Cl \rightarrow N_2 + 3Cl^- + 3H^+ \qquad (7)$$

4.9 Although it will ultimately decay, chloramine is more stable than free chlorine and persists for longer periods, thereby enabling the disinfectant to reach more remote areas of a distribution system (SFPUC, 2004) and facilitating a potential reduction in costs (Kool et al., 1999). However, it is also a less effective (Kim et al., 2002), less reactive (American Society of Microbiology, 2007) and slower disinfectant (Kool et al., 1999) than chlorine and is weak at inactivating certain viruses (Hankin, 2001). Its slow reaction means that if there is contamination after water leaves a treatment plant, monochloramine may not be as effective as chlorine, since there is little control over its contact time with the contaminant (American Society of Microbiology, 2007). On the other hand, chloramines provide antibacterial activity with lower total chlorine (namely, the chlorine

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content of free chlorine and combined chlorine) levels (Arrowsmith, 2002) and seem to penetrate biofilm more thoroughly than free chlorine, enabling them to kill sessile biofilm bacteria (Kool *et al*., 1999). According to Walker (2010), a distinct benefit of chloramines in comparison with chlorine is that they have no significant odour or taste provided the levels of dichloramine and trichloramine are insignificant, which water utilities usually can ensure by the appropriate manipulation of variables such as pH and chlorine: ammonia-nitrogen ratios.

4.10 It is believed that monochloramine produces fewer dangerous DBPs (such as THMs and HAAs) since the contact time of the initial chlorine is shorter (Hankin, 2001) and this is the main factor driving the changeover in the US and elsewhere.

4.11 The USEPA states that THM reductions of 40-80% are usually experienced when a utility company switches from free chlorine to chloramines (Water Research Foundation, 1999). The THM by-products are chemical compounds that form when chlorine mixes with naturally occurring organics in source water. Many THMs are carcinogenic in laboratory animals and therefore expected to be so in humans (Kool et al., 1999). It is also suspected that they are associated with reproductive problems (Guay, Rodriguez & Serodes, 2004), although more research is needed to confirm this possible finding.

4.12 The EU currently has set a standard of 100 parts per billion as the safe level of THMs in drinking water although Scottish Water aims to reduce THM levels significantly lower. Since monochloramine produces fewer DBPs and is in contact with the water for a longer period, thereby shortening the time that free chlorine is in the system, it is believed that a chloramination regime poses less of a cancer risk than disinfection by free chlorine (Kool *et al*.,1999).

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5. Issues Arising from Chloramination

Factors Directly Affecting NHSScotland Healthcare Staff:

Dialysis (including home dialysis)

5.1 Chloramines are known to be particularly harmful when they directly enter the bloodstream and because they persist in a water system longer than chlorine they pose a particular danger during dialysis. However, dialysis patients can use chloraminated water for drinking, cooking and bathing (Hankin, 2001).

5.2 The Renal Association currently sets limits of 0.1 mg/litre for chloramine (and 0.5 mg/litre for total chlorine) in dialysis water because excess amounts can cause haemolysis in patients (Arrowsmith, 2002).

5.3 Many dialysis patients also suffer from anaemia or methaemoglobinaemia, since they lack the natural hormone erythropoietin (EPO) which stimulates bone marrow to produce red blood cells. In these patients EPO is not produced in sufficient quantities and although synthetic EPO can be provided it is accompanied by unpleasant side effects. When chlorine or chloramine exist in dialysis water the need for EPO increases and transfusions may be necessary in severe cases (Hankin, 2001). Consequently, it is important to ensure that all chlorine and chloramines are eliminated from water used for dialysis treatment in order to minimise required EPO dosages (Arrowsmith, 2002). Furthermore, during the dialysis process the water comes into contact with the blood through a permeable membrane. This membrane does not remove the chloramines but can be damaged by them and therefore the chloramines need to be removed before the water passes through any reverse osmosis membrane system (Hankin, 2001).

5.4 Chloramine removal can be achieved through several processes. One possibility is deionisation, although this practice is inconsistent. Another is chemical reduction by the use of ascorbic acid (Vitamin C); a concern in this case is the acid's toxicity for dialysis patients.

5.5 The most common solution is to use filters containing granular activated carbon (GAC) which is made mostly from bituminous coal. The resulting charcoal is pulverised and activated by exposure to superheated steam which increases its surface area for absorption and provides filtration down to 2 µm (Arrowsmith, 2002). In order that the life of the carbon filters is optimised, monitoring of the water is essential and sampling must be carried out using the DPD test or a simple drop test for total oxidant. Small photometers are also available as an alternative (Arrowsmith, 2002).

5.6 Currently, all NHS equipment used for renal care treatments is required to be modified with GAC filtration in compliance with SAN (SC) 03/10. The size of carbon filter required in chloraminated systems, however, is approximately 10 times that required for chlorine systems, implying an increase in cost. Although an economic solution might save on testing and monitoring costs by having a

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central facility serving the renal dialysis unit, this would conflict with NHS policy which encourages patients to dialyse at home (Scottish Executive Drinking Water Quality Unit [SEDWQU], 2002).

5.7 The main issue with respect to home dialysis equipment is 'chloramine-proofing' the units since a substantial number of carbon filters would be required and protocols introduced to ensure that patients test and monitor their own water. While it was proposed by NHSScotland that Scottish Water contributes to the cost of chloramine-proofing the units, there is currently no provision in the Scottish Water investment plan for this funding (SEDWQU, 2002). In order that the home dialysis units are monitored adequately, one solution would be a programme that includes routine visits to change carbon filters.

5.8 Arrowsmith (2002) suggests that dialysis filtration can be continued based on the assumption that the carbon filters can remove 1.0 mg/litre total chlorine (free chlorine or monochloramine). Levels of total chlorine in the water supply remain relatively constant aside from a small reduction in winter or during public water mains work where disinfection is carried out afterwards. It is essential therefore that the water authority is notified of dialysis patients in its area so that they can be included on the 'sensitive client' list and notified when chlorine or chloramine levels will be high. It is noted that this process is the NHS Boards' responsibility (Arrowsmith, 2002).

Nitrification

5.9 Another potential problem with the use of monochloramine is nitrification, which is caused by a reaction between ammonia-oxidising bacteria and excess ammonia from an incorrect dosing (MWUA, 2010) or from the decay of chloramine due to water ageing and temperature increases. The nitrifying bacteria can be found on the inside of water pipes, protected by biofilms, and nitrification can occur if there are low disinfectant residuals to combat it. Currently two-thirds of medium and large water distribution systems in the US that use chloramines experience nitrification to some degree (MWUA, 2010).

5.10 During the nitrification process, the bacteria oxidise the ammonia and produce nitrite, which is subsequently converted to nitrate and organic carbon in the form of biomass and soluble microbial products. The health concerns of excess nitrate in water relate to the capacity of blood to carry oxygen; short-term exposure to excessive levels of nitrate or nitrite can lead to potential problems, the most serious of which in a healthcare context is 'blue baby disease'.

5.11 Consequently, drinking water standards for nitrite and nitrate have been set within the United States at 1 mg/litre and 10 mg/litre, respectively (MWUA, 2010). In comparison, the permitted concentration values in Scotland are 0.5 mg/litre (nitrite) and 50 mg/litre (nitrate) in accordance with the EU Drinking Water Directive 98/83/EC.

5.12 There appear to be no studies that address the use of chloraminated water within maternity wards and as a result no definitive relevant conclusions or recommendations can be made within this survey. Nonetheless, it might be reasonable to suggest that caution should be the watch-word. The presence of

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nitrification in water is relatively straightforward to ascertain and several manufacturers sell test strips at low cost which can detect the relative level of both nitrates and nitrites.

5.13 With regard to chloramine, it must also be considered that the levels of organic carbon created by nitrifiers may be sufficient to support the growth of heterotrophic (HPC) bacteria. In one study (MWUA, 2010), the levels of HPC bacteria were 1,000 times more than they would have been had chlorine been used as the disinfectant. A significant advantage of chlorine is that it does not release nutrients for bacterial growth.

5.14 During nitrification, chloramine residuals are consumed faster than those of nitrate due to an increase in demand and a system with no chloramine residuals is vulnerable to future bacterial contamination. The numbers of nitrifying bacteria increase markedly during periods of accelerated chloramine decay, although the causality of this relationship is not fully clear (UWRAA, 1990).

5.15 Nitrification is also usually accompanied by a reduction in pH and dissolved oxygen; under certain conditions nitrifying bacteria can potentially accelerate lead and copper corrosion due to the release of nitric acid (Kirmeyer et al., 1993). It should be noted that Scottish Health Technical Memorandum (SHTM) 04-01 Part E 'Alternative materials and filtration' states copper is no longer routinely specified for use in NHSScotland premises (HFS 2011). This repeats the statement in the superseded Scottish Hospital Technical Note (SHTN) 2 (PEFEx, 1999). However, these publications have not gone as far as to state that existing copper within systems had to be removed. As a result some older healthcare premises still contain large amounts of copper pipework.

5.16 The Water Research Foundation (1999) states that nitrification and its methods of control depend on water quality factors:

- pH;
- temperature;
- chloramine residual;
- ammonia concentration;
- chlorine-to-ammonia ratio;
- concentrations of organic compounds and distribution factors;
- detention time;
- reservoir design and operation;
- sediment;
- tuberculation in piping;
- biofilm;
- the absence of sunlight.

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5.17 There is no consensus within the literature concerning the relative significance of nitrification in relation to chloramination. According to MWUA (2010), nitrification alone may negate the benefits of using chloramine, although full consideration of its suitability should include the source water type and quality and the overall treatment process required to produce potable water.

5.18 The UWRAA (1990) report into chloramination asserts that nitrification is the major problem facing operators of chloraminated systems. On the other hand, SFPUC (2004) states:

'nitrification is more of a nuisance and operational a health issue since nitrification is due to metabolism and growth of harmless non-pathogenic nitrifying bacteria that are ubiquitous in soils and water'.

5.19 To minimise nitrification, treatment plants must ensure that sufficient disinfection residual is maintained at all times and particularly during the winter months. Additionally, free ammonia entering the system should be limited and the distribution network flushed periodically to prevent water ageing in areas of low circulation. In the US, several utilities have rid their systems of nitrifying bacteria by temporarily converting to chlorine (Kirmeyer *et al*., 2004). Lastly, booster stations should be established and supplemental treatment applied at storage and pumping stations to increase monocholoramine concentrations (MWUA, 2010).

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Note:

Piping Materials

Feedback obtained during the preparation of this SHTM raised the topic of the effect different piping materials might have on biofilm formation and thereby nitrification. There is thus a link other than corrosion between the issues of chloramination and piping material, albeit indirectly.

Kerr *et al*.(1999) carried out a lengthy experiment which examined the relative resistance of cast iron, Thermanox (a trademark name for a polymer widely used in laboratory equipment), medium-density polyethylene (MDPE) and unplasticised polyvinyl chloride (PVC-U) to biofilm accumulation. Potable water was pumped at a rate of 3 ml/minute past specimens of the various materials and measurements taken of the numbers of viable heterotrophs (organisms that cannot fix carbon and use organic carbon for growth). Bacteria built up exponentially during an initial phase of 2-3 weeks and then tended to level off, with the exception of cast iron which showed a slower, but steady, increase. A year or so later, it was apparent that the plastics resisted biofilm formation to a much greater extent than cast iron, with both MDPE and PVC-U superior to Thermanox in this regard. Park et al. (2007) performed a similar experiment and discovered little difference between stainless steel, galvanised steel and PVC in resisting biofilm formation.

Yu *et al*. (2010) analysed the capability of 6 different piping materials (copper, chlorinated PVC, (PVC-C), polybutylene (PB), polyethylene (PE), stainless steel and zinc-coated steel) in resisting biofilm formation in drinking water, a mix between drinking water and river water and drinking water inoculated with *E. coli.* This experiment differed from those above in not simulating water flow. The material which exhibited the most resistance to bacteria formation was copper with the steels faring worst while the plastics were fairly indistinguishable. Silhan et al. (2006) was concerned with the formation of biofilm in galvanised steel, PEX (cross-linked polyethylene), MDPE and copper. These researchers were also looking at the survival of *E. coli* in both biofilm and water within each of these piping materials. Once again, steel fared less well with copper being most resistant to biofilm formation. *E. coli* was not detected within biofilm on any material. It was noted that biofilm formation was very significantly increased at very warm temperatures (35ºC) in the plastics but relatively unaffected in the metals.

There are some discrepancies between results within the literature and the papers referred to above only report a series of experiments. The general picture appears to be that plastic piping is increasingly favoured by water utilities which view the rough surfaces of old cast iron pipes as encouraging biofilm growth (Water Quality and Health Council).

5.20 Recent research has investigated the role nitrification may have in the corrosion of plumbing systems (Zhang *et al*., 2008). The research group concerned has also been examining whether pipe corrosion may induce or exacerbate nitrification. This work was motivated by fears of copper and lead dissolution

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caused by nitrification, the risk of which is considered likely to increase with a chloraminated water supply. It is important to note that the experiment was laboratory-based and no recommendations were made with respect to piping materials.

Inactivation of Pathogens

5.21 Chloramine is a less effective biocide than agents such as hypochlorous acid, hypochlorite, ozone or chlorine dioxide. This was verified in Kirmeyer *at al*. (1993) which tabulated research by Olivieri *et al*. (1985) recording CT values (dosage concentration x time taken to inactivate various percentages of pathogens present) for a variety of biocides in relation to *E. coli* and Poliovirus1. The same source also records data obtained by the USEPA that established the CT values of chloramine and other agents for various inactivation levels of *Giardia lamblia* and what were known generically as 'viruses'; again, the values associated with chloramine are very much larger than those of other agents, including chlorine. It is also known that chloramine is ineffective in removing *Cryptosporidium parvum*, although this applies to chlorine too.

5.22 Nonetheless, it is important to note that chloramine is intended to be a secondary disinfectant and its comparatively large related CT values should not preclude it from this role. The Australian experience of a changeover from chlorine to chloramine (UWRAA, 1990) was positive in terms of microbiological quality. One paramount concern was to control the growth of *Naegleria fowleri*, the causative agent of an invariably fatal disease which attacks the central nervous system.

5.23 In this regard, chloramination was found to be highly successful, with only 1 sample out of a total of 580 containing this amoeba after chloramination – the corresponding figure before the changeover was 40 positive samples from a total of 701. The Australian authorities also carried out surveys at various locations to ascertain the impact on the traditional indicators of microbiological quality: total coliforms, *E. coli* and plate count organisms; HPC iron bacteria, *Aeromonas* spp. and fungi were also examined.

5.24 UWRAA (1990) reports that by each of the aforementioned criteria, chloramination of a previously chlorinated supply improved microbiological quality. For example, in two river systems the frequency of isolation of total coliforms was reduced from values of 45.9% and 32.3% to 1.7% and 4.8% respectively. Kirmeyer *et al*. (1993) confirms that chloramine has been very successful in practice in terms of reducing coliform organisms. Moreover, as mentioned previously, chloramine also seems to be more effective than chlorine for controlling biofilm in pipes (LeChevallier et al. as cited in Kirmeyer et al. (1993)). While chloramine's mechanism of action make it a weak primary disinfectant, Kirmeyer *et al*. (1993) describes research suggesting that the very same properties may account for its ability to penetrate biofilm. A detailed discussion of the processes involved is beyond the scope of this SHTM.

5.25 One key advantage of chloramination in a healthcare context may be a reduced risk of the outbreak of Legionnaires' disease, a community-acquired and nosocomial type of pneumonia caused by the inhalation of aerosols or the

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microaspiration of water containing *Legionella* bacteria (see, for example, Flannery *et al*. (2006) and Heffelfinger *et al*. (2003)). Each year in the US there are 8,000 to 18,000 cases of Legionnaires' disease, of which 10-20% occur from outbreaks (Kool *et al*., 1999).

5.26 Prevention of this disease currently focuses mainly on preventing or limiting the colonisation of *Legionella* bacteria in water pipe systems by increasing temperature in hot water pipes and employing 'heat and flush' to cold water pipes or supplementing with extra chlorine. However, both of these treatments are generally unsuitable, due to practical constraints in the former instances while extra chlorine may quicken the development of corrosion and leaks in plumbing systems (Heffelfinger *et al*., 2003).

5.27 In one study (Flannery *et al*., 2006), a two-year trial during which water and biofilm were collected from 53 buildings during six intervals, it was found that *Legionella* colonized 60% of the hot water systems before chloramine was introduced, at which point colonization decreased to only 4%. These authors therefore concluded that "increasing use of monochloramine in water supplies throughout the United States may reduce *Legionella* transmission and incidence of Legionnaires' disease".

5.28 Another study (Heffelfinger *et al*., 2003) was conducted through a survey of 459 members of the Society for Healthcare Epidemiology of America that addressed hospital features, endemic- and outbreak-related, hospital-acquired Legionnaires' disease, water supply sources and methods of disinfection used by the hospitals and water treatment plants. Results from the 166 hospitals that responded found that hospitals supplied with drinking water disinfected with chloramine were less likely to have sporadic cases or outbreaks of hospital-acquired Legionnaires' disease.

5.29 Kool *et al*. (1999) also discovered that hospitals supplied with drinking water containing free chlorine were more likely to have a reported outbreak of Legionnaires' disease than those which used chloraminated water. In Kool's study, 32 hospitals that had experienced outbreaks of Legionnaires' disease were compared with 48 control hospitals selected for their hospital characteristics and water treatment factors. It was suggested that 90% of the outbreaks associated with drinking water may not have occurred had chloramine been used for disinfection rather than free chlorine, although these authors recommended that further studies be conducted to confirm this finding.

5.30 In addition to research in the form of case studies, an in vitro experiment that measured the effect of disinfectants on *Legionella* growth showed monochloramine to be more effective at killing the bacteria in biofilm than chlorine (Donlan *et al*. as cited in Heffelfinger *et al*., 2003).

5.31 Finally, another study of a hospital's water system indicated that monochloramine generated on site and used as a supplemental disinfectant could lead to the rapid and sustained reduction of *Legionella* growth (Shelton et al., as cited in Heffelfinger et al. 2003). The relative ability of monochloramine to inactivate *Legionella* bacteria is thought to arise from its property of penetrating biofilm more aggressively than free chlorine. Nevertheless,

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although these studies suggest that monochloramine reduces the risk of Legionnaires' disease, it cannot be concluded that monochloramine will kill *Legionella* bacteria in all instances.

Factors Indirectly Affecting NHSScotland:

Chloramine Ingestion

5.32 Surprisingly little data exist on the health effects of monochloramine ingestion despite its long history in water disinfection. According to Hankin (2001), ingested monochloramine would reach the stomach intact and rapidly decay in stomach acid. No studies were found that suggest chloramines could have any negative impact in respect of stomach ulcers, although this is an area that warrants more research. It can be only tentatively suggested that chloramine is not expected to enter the systemic circulation intact.

5.33 In one past study, the short-term exposure to a maximum of 24 mg/litre of monochloramine in drinking water did not produce any adverse effects (Lubbers *et al*., 1981). International guidelines for drinking water quality suggest that no short-term or long-term health effects have been associated with chloramines in water (Hankin, 2001).

Cancer

5.34 Hankin (2001) states that to date the International Agency for Research on Cancer has not fully evaluated the cancer-causing potential of chloramines. Although a number of studies have found chlorinated drinking water to be associated with bladder and colon cancer, few of these involved chloraminated drinking water. In research conducted by Zierler *et al*. (as cited in Health Canada, 1995), it was found that the incidence rate of pneumonia and influenza leading to deaths in a Massachusetts community was slightly higher among those who had their water disinfected with chloramine rather than chlorine. On the other hand, the bladder cancer mortality rate was more excessive among residents using chlorinated water in comparison with those supplied with chloraminated water.

5.35 There is little other information available indicating any link between cancer and chloramine. The USEPA (1992)) has not classified chloramine/monochloramine as carcinogenic because there are inconclusive human data and equivocal evidence from laboratory animal assays. However, Edwards *et al*. (2005) states that '*the switch to chloramine immediately reduces the concentration of potentially carcinogenic disinfectant by-products in water*' (p.2). Bull and Kopfler (as cited in Kirmeyer *et al*. (1993)) believe this reduction in cancer risk could be as much as 80%, assuming that the chloramine used produces similar by-products to chlorine, but rather at lower levels. In conclusion, further research is needed to determine if any associations may exist between chloramine and cancer.

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Disinfection By-Products

5.36 As stated previously, chloramine is known to produce fewer dangerous DBPs in comparison with chlorine, (see, for example, SFPUC (2004)). However, there are two particular DBPs produced to a greater degree during chloramination than chlorination which give cause for concern: cyanogen chloride and N-nitrosodimethylamine (NDMA). NDMA in particular can develop at higher concentrations in areas where precursor amines exist in the water from man-made sources, thereby necessitating enhanced monitoring and controlling of existing amines. Further research is being conducted on this by-product and progress has been made within the United States to limit its formation.

5.37 In 2004, there was another worrying development when iodoacid, the most toxic and DNA-damaging to mammalian cells of DBPs discovered to date, was discovered in chloraminated water within Texas. This may have been a rare occurrence due to the area's high levels of bromide and iodide (Barlow, 2004). It has been claimed that scientists currently have only been able to identify 50% of the DBPs in chlorine-treated water and only 17% of those in chloramine-treated water. In addition, the Water Research Foundation (1999) states that DBP formation decreases as the pH increases and the chlorine-to-ammonia ratio decreases and that a change in either of these variables can significantly impact DBP formation, suggesting that there is still a long way to go in determining the full effects and impacts of chloramination (Hankin, 2001).

Factors Affecting NHSScotland Estates Staff:

Lead-Leaching and Corrosion

5.38 Some research has revealed that the conversion from chlorine to chloramine can cause an increase in blood lead levels due to corrosion, a new and unexpected finding both for regulators and the water industry (SFPUC, 2004). In general, most childhood lead uptake occurs from exposure to degrading lead paint, although 14-20% of childhood lead exposure in the United States is estimated to originate from drinking water (USEPA, as cited in Miranda et al., 2007). Surprisingly, Edwards et al. (as cited in Edwards *et al*., 2005) state that there are no maximum contaminant levels enforced 'at the tap' in the United States, although an 'action level' of lead concentration is given as 15 µg/litre. In comparison, in accordance with the EU Drinking Water Directive (98/83/EC) Scotland imposes an upper limit on lead concentration of 10 µg/litre.

5.39 Several studies have proved that the introduction of chloramines to water systems containing lead-based pipes, fixtures or solder may increase the amount of lead in the water due to changes in the resulting water chemistry (Edwards & Dudi; Mass *et al*.; Schock; Shock *et al*.; Switzeret *et al*.; as cited in Miranda *et al*. (2007)).

5.40 Miranda *et al*., (2007) also discovered that a change to chloramine disinfection in the Goldsboro Water System in North Carolina was associated with an increase in children's blood lead levels. However, this particular study noted that the impact of the change was progressively mitigated in newer housing and in houses built after 1950, with the age of the house constituting a stronger

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influence on blood lead than the use of chloramines as a disinfectant (Miranda *et al*., 2007).

5.41 Variables such as the location of a potential lead source, the timing of sample collection and small changes in water chemistry can affect measured water lead levels considerably. In addition '*numerous factors can contribute to metal corrosion including water quality, biofilms, the pipe manufacturing process, and the design and installation methods of piping systems*' (SFPUC, 2004, p.15). In two studies (North Carolina and Washington, DC) this unpredictability caused the increased levels of lead as a result of chloramination to remain undetected until almost a year after the conversion had taken place (Miranda *et al*., 2007). It has been suggested that the dissolving of lead from pipes into water following chloramination may only be a transient process as a new film may subsequently develop inside the pipe, thereby creating a barrier between the water and lead source (Miranda *et al*., 2007). Evidently, there is still much to learn about the association between chloramine and lead-leaching.

5.42 Lead piping within Scottish houses and infrastructure is highly unusual nowadays and the main problem is likely to stem from lead-tin solder or degradation of brass fittings. Brass components can also experience dezincification, although the correlation between this phenomenon and chloramination is as yet unclear. Ideally, brass in taps and other appurtenances should be of a composition that is dezincification-resistant (DZR) and relatively immune to the leaching of copper (and lead, if present at all).

5.43 Miranda et al. (2007) summarised the current state of knowledge on general metal corrosion from chloramine by stating that 'the details of all the related environmental chemistry are not fully understood and are highly dependent on the particular chemical interactions found in each water treatment and distribution system'. The most comprehensive field study covering the impact of chloramination and materials deterioration is contained within Kirmeyer et al. (2004). This report confirms that both chlorine and chloramine can increase water's corrosiveness towards copper and its alloys (brass, bronze, cupronickel, etc), especially at low pH levels. There are two distinct manifestations of copper corrosion: a uniform, gradual thinning and a more destructive form, known as 'pitting'. Kirmeyer et al. (2004) details a survey of 31 utilities which converted from chlorination to chloramination after 1980. 13 of the respondents found there had been no increase in pipe erosion, 17 did not know and only 1 thought there had been an increase in the corrosion of galvanised pipes. Biocorrosion of copper piping was mentioned by Kirmeyer et al. (2004), although an evaluation of the influence of water disinfectant in controlling it requires further investigation.

5.44 There is little available data on the relative degradation of plastic piping fittings and associated equipment by chlorinated and chloraminated water. Kirmeyer et al. (2004) reports only one issue related to the possible impact of chloramination on plastic components, namely, hot water propylene dip tube heaters in Chesterfield, Virginia, and does not confirm that this was a result of the changeover. Chung *et al*., (2006) carried out a series of tests on ½" standard SDR-9 PEX tubing and found no discernible difference between the

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degradation induced by water containing representative concentrations of chlorine, chloramine and chlorine dioxide.

5.45 Carrying out research for the Urban Water Research Association of Australia (UWRAA), Moore (1998) concluded that the long term testing of a variety of materials at chloramination levels of 4 mg/litre and lower indicated:

- increased de-alloying of copper-based alloys, particularly in non-DZR materials (DZR alloys showed some corrosion but well within limits);
- increased corrosion of copper;
- negligible effect on stainless steel and plastic materials.

Moore (1998) accordingly recommended that the use of DZR materials in Australian water supplies should be mandatory.

Effect on Rubber

5.46 According to SFPUC (2004), the use of chloramine in a water system can have deleterious effects on distribution system plumbing fixtures, particularly natural rubber products and their derivatives commonly used in household appliances. Indeed, Kirmeyer et al. (2004) places this factor (after concerns about dialysis patients and aquaculture and ahead of those related to nitrification) as the second most serious hazard related to chloramination.

5.47 Practical experience has revealed that the severity of the effect of chloramine exposure on rubber has varied widely and is dependent on the material used, the amount of chloramine present and the temperature of the operating environment (Kirmeyer et al., 2004; Ashtabula Rubber Co., 2010). For example, one study found that 23% of utilities surveyed experienced an increase in the materials degraded after chloramination. In another case, after Austin, Texas, converted a portion of its water system to chloramine a number of complaints were received from customers concerning black specks in the water which were the result of the degradation of nitrile rubber material within the system (SFPUC, 2004). Moore (1998) stated that both natural rubber and neoprene suffered from significant attack in chloraminated water.

5.48 To examine the impact of chloramine on rubber products, the American Water Works Association Research Foundation (AWWARF) – see Kirmeyer et al. (1993) – studied seven elastomer formulations including natural rubber, nitrile, Styrene Butadiene Rubber (SBR), Neoprene, Ethylene propylene butadiene Monsoner (EPDM), silicone, and fluorocarbon and subjected them to a number of tests to determine their life cycle when exposed to chloramine. It was found that natural rubber subjected to chloramine exposure tended to crack, exhibit severe swelling and lose elasticity and tensile strength; chloramine attacked the polymers which significantly degraded rubber's physical properties. Furthermore, it was verified that the rate of decay was positively associated with increased temperatures.

5.49 Nitrile, SBR, neoprene and EPDM fared better in these tests but still showed significant degradation, whereas the considerably more expensive options

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silicone and fluorocarbon performed well. Custom, chloramine-resistant EPDM and nitrile materials are now available and are increasingly being used within the US potable water industry (Ashtabula Rubber Co., 2010). NHSScotland should therefore ensure that any rubber components within their facilities, which can be found in kitchen fixtures, bathroom shower heads and taps, bathroom toilets, drinking fountains, irrigation, systems, ice makers, fire suppression systems, sprinklers, water pipes and water meters contain chloramine-resistant components.

Notes:

Safety Action Notice:

A Safety Action Notice published by Health Facilities Scotland in 2009 looked at the risk of flexible hoses harbouring Legionella and other potentially harmful micro-organisms, it stated that HFS had received reports that high levels of Pseudomonas and *Legionella* bacteria had been found in water samples taken from water outlets fed by flexible hoses, this was confirmed by testing of the hoses which revealed colonisation of the lining. The lining material in these reports was EPDM. However, it is possible that other lining materials (and washers within the couplings) could have been similarly affected. Due to this, in situations where flexible hoses must be used they should be lined with an alternative to EPDM and be WRAS approved.

Aquatic Life:

Chloramines are harmful to fresh and saltwater fish and aquatic reptiles and amphibians, easily passing through the gills and directly entering the bloodstream (SFPUC, 2004). Here the compounds bind to iron in red blood cell haemoglobin and reduce each cell's capacity to carry oxygen. Care must therefore be taken to ensure that water courses are discharged neutrally or water-conditioning agents are added to remove the ammonia and chlorine (Walker, 2010). Specifically, SFPUC (2004) suggests that to remove or neutralise chloramine, a GAC filtration system or an additive that contains a dechloraminating chemical for both ammonia and chlorine, should be used. In addition, water tests should be completed frequently to ensure that chloramine has been sufficiently reduced (SFPUC, 2003). Consultation with the Water Authority may be required to ensure that any WRAS arising from processes introduced by them are not unreasonably borne by the consumer as they can be underwritten by savings achieved by the utility company.

Conversion from Chlorination to Chloramination

5.50 An appreciable body of information has now been established documenting the experiences of water authorities which have converted from chlorine to chloramine disinfection. A study conducted by Flannery *et al*. (2006) in California showed that the conversion to a monochloramine disinfection system resulted in higher concentrations of total chlorine and lower concentrations of THM components. While the average temperature and pH measured in building water samples remained relatively constant, the conversion resulted in a 10-fold increase in total chlorine concentrations in the hot-water systems.

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5.51 As a result, it was concluded that monochloramine in drinking water provides better control of Legionella growth in building plumbing systems than free chlorine, although the Group also state that the potential use of supplemental monochloramine in hospitals to prevent Legionnaires' disease still needs to be evaluated. In addition, the increased stability of monochloramine ensured higher disinfectant concentrations in potable hot water systems, since chlorine dissipates rapidly at higher temperatures.

5.52 Another conversion from chlorine to chloramine, completed by the Regional Municipality of Ottawa-Carleton in Canada in 1992, resulted in an average chloramine concentration of 0.92 mg/litre (95% of which was monochloramine) leaving the plant and 0.71 mg/litre in the distribution system. The changeover to chloramine produced no observable changes in the bacteriological quality of the drinking water (Health Canada, 1995), although the municipality has increased its average concentration to 1.0 mg/litre in order to achieve higher residual amounts at the end of the distribution system. According to SFPUC (2004), many water agencies that have converted to chloramine from chlorine have reported that customers note an improvement to taste and odour of the water.

Scottish experience

5.53 In a Scottish context, NHS Dumfries & Galloway recently completed a pilot scheme to measure and assess the impact of the changeover to chloramine, and noted no observable changes during or after the process, although it did start with a 'clean' water system in a new facility. NHS Lothian has also converted and likewise reported little noticeable change to water quality and operational maintenance (Walker, 2010). However, NHS Grampian, which has been supplied with chloraminated water for 7 years, noticed a considerable improvement in quality much cleaner water pipework and tank systems. Moreover, laboratory personnel who have been unable to culture Legionellae in supply and secondary system samples suggest that chloramination has the potential to reduce operational maintenance requirements.

5.54 On the other hand, NHS Grampian observed that the conversion introduced manganese in granular form, most likely originating from leaching of Scottish Water pipework (Walker, 2010). Anecdotally it has been suggested that differing distances from the reservoir to the point of use may account for differences in quality of water, this has not been proven.

Findings from the Case Studies

5.55 The case studies reviewed for this report are restricted to North America. Nevertheless, the experiences they provide are diverse and, as such, they still represent a valid basis for determining the possible effects of chloramine disinfection in other situations. The key point emerging from the case studies is that the impact of chloramination depends very much on the raw water quality, surrounding soil, pipe fittings and combinations of other chemicals.

5.56 Most of the case study organisations experienced one or more of the negative characteristics associated with chloraminated water and, consequently, the

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successful implementation of chloramination may rely heavily on the experimental abilities of individual water treatment plants to manipulate variables such as pH levels or the ratio of chlorine to ammonia-nitrogen appropriately.

5.57 However, bearing in mind the strict requirements of healthcare facilities, the risks already highlighted in this report warrant a degree of caution before chloramine can be recommended as a completely safe choice for NHSScotland and its patients. Some thoughts with regards to these case studies, in conjunction with relevant findings from the literature, are given below:

- the theoretically-oriented literature states that, being a more stable and persistent disinfectant than chlorine, chloramine has associated cost reductions. This principle was borne out by the case studies, with Brown Deer finding chloramine to be the best cost/benefit option and Massachusetts being able to eliminate booster stations by using a 5:1 chloramine to ammonia-nitrogen ratio, thereby saving $100,000 each year. However, when used, chloramine booster stations decreased service pipe failures for Brown Deer;
- a decrease in DBPs after switching to chloramine was observed by Gulf Coast, Massachusetts, Ann Arbor, Hackensack and Tampa Water Departments, indicating that this is also a reliable benefit of chloramine use. Moreover, the use of chloramine provided increased residual in water distribution systems for Brown Deer, Massachusetts, Vancouver and Tampa, thereby helping to decrease HPC and coliform bacteria levels. In Ann Arbor, however, where a decreased residual resulted in increased HPC levels in dead-end areas, free chlorination was used for control measures before re-conversion to chloramination;
- taste and odour results were more mixed: Philadelphia found chloramine to decrease taste and odour effects, whereas Vancouver found the opposite occurred. Vancouver attributes this result to chloramine residual being more widespread within the test area and its presence more detectable to customers than the chlorine previously used;
- of the 14 case studies, lead corrosion from chloramine was evident in Brown Deer, North Carolina, Washington and Maui, while in Massachusetts chloramination actually helped to decrease iron corrosion. Affecting 29% of the case studies in this report, lead-leaching is a dangerous characteristic and its possible link with chloramine requires substantial future analysis;
- Nitrification is described alternatively as ‘more of a nuisance and operational problem than a health issue’ (SFPUC, 2004, p.8) and a factor that may negate the benefits of using chloramine (MWUA, 2010). Reports of nitrification in the case studies were not very common although when they did occur they were dealt with by experimenting with different solutions. Ann Arbor, for instance, managed to decrease nitrification by changing its ratio of chlorine to ammonia-nitrogen and increasing pH before temporarily switching to free chlorine. Portland, however, employed the use of booster stations to decrease its nitrification;

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- although chloramine is known to have increased residuals and reached outer-most areas of their distribution systems, Washington and Maui both noticed that during stagnation periods there was an increase in bacteria levels. In Maui's case, the chloramine was being mixed with phosphate and causing a slime-forming bacteria at a pH of 7.7;
- nitrification falls within the remit of water utility organisations and NHSScotland has little leeway in controlling the amounts of excess ammonia within a water distribution system. As noted in the recommendations, however, it is possible to take action to minimise the formation of nitrification within NHS facility water systems by ensuring through the regular flushing of pipes and the avoidance of dead-legs that no stagnation of water occurs. Provided UK and NHS regulations and procedures concerning these practices are complied with, stagnation and its possible associated bacterial growth should not prove a significant issue within Scottish healthcare premises;
- the link between chloramine use and general health is still not known with absolute confidence. North Carolina experienced a number of health complaints after conversion to chloramine, although none of the skin disorders discovered was found after investigation to be fully attributable to chloramine;
- several of the case studies, including Vancouver and Tampa, noted the importance of a public education and notification programme when implementing chloramine treatment. Philadelphia in particular worked to understand customer perceptions and sensitivities with regard to chloraminated water and realised that direct communication with the public was the best option. Through its education programme, the organisation also attempted to develop a link between chloramine and safe, clean water, so that if the public detected a change in the taste of their water when the system converted from chlorination to chloramination, they would make this educated association rather than complain or panic. The water department noted that a public survey was a useful tool for gathering the required information and the populace can provide reliable information on water-related concerns;
- the Hackensack Water Authority initially avoided the public notification and education stage, believing that since it had already used chloramine in the (relatively distant) past the changeover would be trouble-free. However, the conversion caused substantial problems with aquatic life and several dialysis patients required transfusions. The conversion to chloramine was conducted successfully four years later following the launch of a proper information campaign;
- in the case of Scotland, an educational program on chloramination would generally be the responsibility of Scottish Water. However, if needed, a smaller campaign could be developed by the NHS Boards in Scotland to inform staff about the changeover;
- a monitoring programme before, during and after a change to a chloramine system is an important component for success. In particular, Portland states that an understanding of chloramine chemistry is vital for a monitoring strategy to be useful. It continued a monitoring programme with

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the objective of limiting free ammonia and ensuring high residuals in their system;

- several of the organisations in the case studies reported the use of chlorine to treat particularly difficult cases of bacteria, even though they may have implemented a chloraminated system; these include Ann Arbor and Maui. (Gulf Coast successfully combined chloramine with chlorine dioxide.) In all cases, the use of chlorine was successful, whether the aim was to decrease lead concentration, bacteria or nitrification. However, in Maui the chlorine residual decayed significantly while in Ann Arbor, there was an increase in HPC, coliform bacteria and THMs. The eventual outcome was that chloramine remained the preferred choice for these organisations, with chlorine simply on hand in future if needed for temporary treatments. Ann Arbor stated that future chlorination treatments would need to be accompanied by improved measures to minimise any negative effects.

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6. Conclusions and Implications

6.1 This SHTM has investigated the advantages and disadvantages entailed in a changeover from chlorinated to chloraminated water supplies, with particular focus on the bearing this might have on healthcare facilities. Chloramination is being adopted by water utility companies primarily because of the requirement to find a cost-effective means of complying with increasingly stringent regulations covering quality.

6.2 There are certainly advantages associated with using chloramine as a disinfectant, especially in terms of its long-lasting presence within the supply network and its generation of fewer dangerous by-products. Nevertheless, it is clear that the addition of chloramine to water is not entirely risk-free and, given the American experience, there are concerns over possible nitrification and materials degradation.

6.3 Scottish Water supplies the vast majority of Scotland's healthcare facilities, although a small number have their own private water source. Consequently, most NHS Boards have little control over the water within their domains and must adopt a reactive policy based on planning and monitoring. This review has identified the chief areas of concern in a medical context to be the safety of dialysis patients and small babies, while materials degradation in water distribution systems may become a problem in respect of physical infrastructure. It is important that these issues are addressed and there are some steps that can be taken by NHS Boards in regions of Scotland where chloramination is envisaged.

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7. Recommendations

Communication

7.1 Direct communication should be developed between NHSScotland Health Boards, healthcare and estates staff and Scottish Water (or the relevant water treatment organisation) to ensure all are fully briefed on issues concerning chloramination and aware of the actions needed from their side to ensure a successful change and the maintenance of patient safety. It is essential that unilateral changes from chlorination to chloramination of incoming water supplies do not occur without consultation. This has happened in the past.

Monitoring Water

7.2 NHSScotland Health Boards must give serious consideration to monitoring for possible nitrification the water supplied to wards with young babies and relatively inexpensive testing kits are available for this purpose. NHS Boards should also have an action plan in place to account for any sudden increase in nitrate levels. Additionally, a line of communication must be established between Scottish Water and NHSScotland Health Boards which would raise an early alarm in the event of a problem arising in the water supply. This will also help to ensure that unilateral decisions are not taken (see paragraph 7.1, above).

Dialysis Equipment

7.3 In advance of chloramination, NHS healthcare and estates staff must ensure that provision is made for the supply, installation and regular replacement of the appropriate granulated activated carbon (GAC) filters for dialysis machines. Previously, Safety Action Notice (SAN) (SC) 03/10 recommended that a notice of 12 months was required before changeover.

Distribution Infrastructure

7.4 The estates staff responsible for overseeing water networks within healthcare facilities must be informed as to the possible impact of chloramination on pipes and appurtenances. In particular, components containing rubber or vulnerable elastomers should be replaced when necessary by equivalents which are chloramine-resistant. In certain cases, it may be necessary to effect these changes in advance of chloramination.

7.5 Additionally, when pipes and fittings are being replaced they should be inspected for corrosion and other problems. Brass fittings should be dezincification-resistant (DZR). Due attention must be given to the need to avoid stagnation and dead-ends, although this is standard practice.

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Education and Notification

7.6 All staff should be informed of the changeover to chloraminated water beforehand. This will hopefully prevent any unnecessary alarms over unfamiliar tastes and odours and encourage vigilance.

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Introduction

Submission Reference:

SECTION 3.1: ARCHITECTURAL DESIGN STRATEGY 3.1

Submission Response:

The following is an illustrated narrative which explains the key aspects that have informed the architectural, masterplanning and landscaping proposals. This narrative should also be read in conjunction with the relevant Wayfinding (Volume 3 Section 3.2) and Arts strategy (Volume 3, Section 3.3) proposals.

Introduction

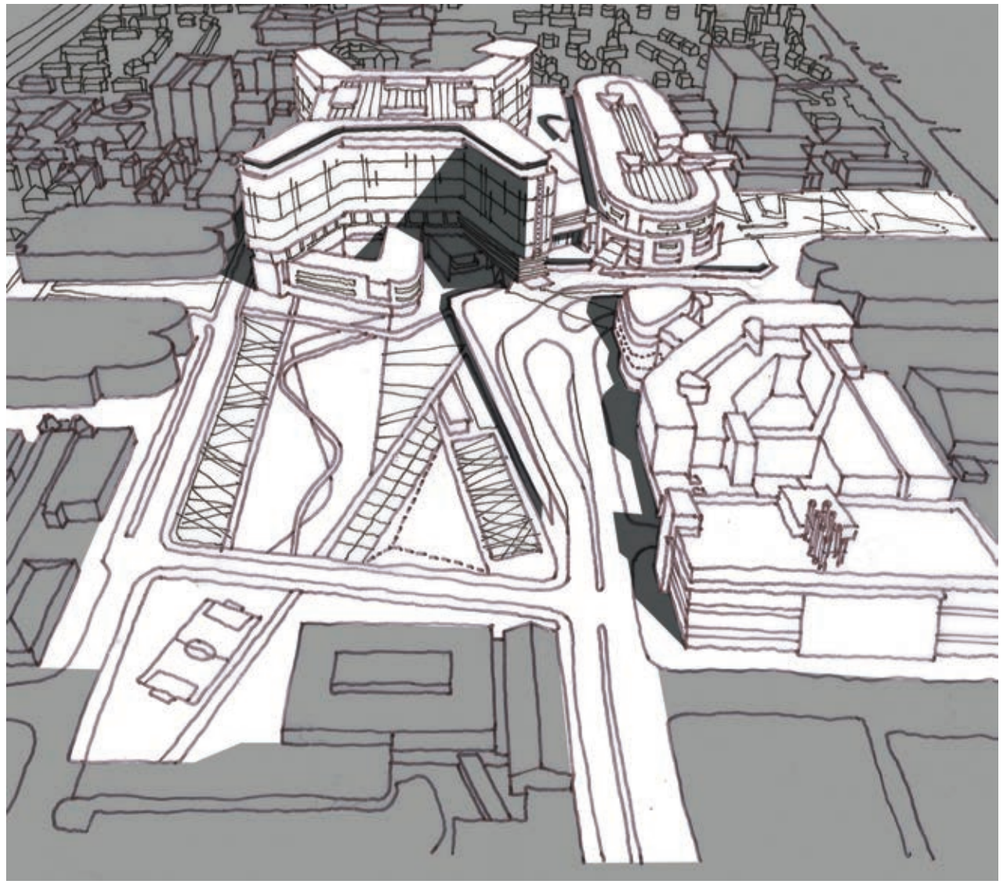
We have pursued an integrated approach to our masterplanning, design and clinical planning for all elements of the new hospital. This has influenced the way we have structured our team, our working methods and engagement with the Board over the past few months. Our goal is a hospital that is a fine piece of architecture - an elegant simple solution to a complex problem.

Hospitals are by virtue of their arrangement and multiplicity of services complex buildings. The big challenge to designers is to create a positive patient environment that also helps staff deliver complex clinical processes in a non-institutional environment. Our answer is simplicity - a building that can be easily understood by all of its users- both in its form and layout.

We have also sought to create an appropriate building for Glasgow with a sense of ‘wow’. We have done this through a process of honing and refinement of form and finishes, with some carefully considered grand gestures - the curved Children’s building, the two storey main entrance space and the central atria. These buildings will be a place of wonder and discovery for patients and visitors. A well designed hospital will improve staff retention and recruitment. Staff will want to work in this new hospital, feeling that it is a supportive environment in which they can pursue and develop their particular vocation or speciality.

We have endeavoured to capture and make real the aspirations of the Board, reflecting the heritage of Glasgow whilst rising to the challenge of current and future demands in a changing healthcare culture. We are confident that our proposals, informed by dialogue with the Board and its advisors, offer a simple elegant solution to a complex challenge, one that has enduring qualities that will stand the test of time.

This design statement is arranged in two sections in order to explain the key aspects of the scheme: Masterplan and Architecture.



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Masterplan

The Masterplan for the New South Glasgow Hospitals presents a cohesive design based upon function, clarity and the creation of an approachable environment of high quality. The masterplan has sought to make the best possible use of the site and the opportunities presented by the requirements of the brief. The arrangement of the buildings, routes and public spaces has been defined to create a user-friendly setting for this significant new landmark healthcare development for Glasgow. The design and layout of the site seeks to underpin very positive experiences of a high quality site for patients, staff and visitors. The masterplan is based upon the establishment of a durable parkland character which will enable the campus to evolve and grow over time in response to healthcare demands and opportunities for redevelopment of particular areas of the existing NHS estate. The masterplan provides the platform and a robust identity for the future.

Key Opportunities

Some of the key opportunities explored during the early stages of the masterplanning were as follows:

- Excellent legibility of main entrances upon arrival, through the definition of effective sight lines to aid orientation
- Definition of a very clear and unobstructed blue light route to A&E
- The creation of an expansive and influential green setting for the campus, which extends into and sets the scene for the hospital buildings
- The definition of a high quality arrival plaza as a significant new public space, to create a setting for the three main entrances
- The clear distribution of pick up and drop off facilities for specific modes of transport, to enable efficient and safe use of the public spaces to be defined for all
- The creation of a range of clear, safe and effective pedestrian routes into, through and around the site
- Realignment of the western car park to create enhanced space for a new Children's park and to enable disabled parking to be moved closer to the main entrance
- The establishment of distinct identities and high quality landscape settings for the Adult & Children's hospital buildings
- A sensitive and appropriate response to the listed buildings and the existing areas of the site which are to be retained
- The definition of a site structure based upon approachable public spaces as a setting for the new healthcare campus
- The continuation of the public spaces well into the internal areas of the buildings, which share a similarly approachable design ethos

The existing campus of the Southern General site in context

Design concept sketches to illustrate an expansive green character and early exploration of opportunities

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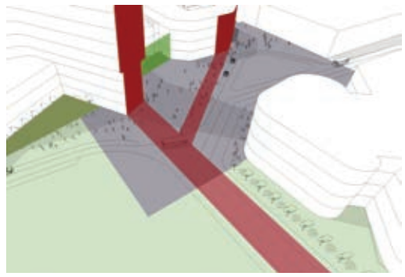
Masterplan Development

The Masterplan has been developed with flexibility in mind, creating spaces which can be easily added to or altered in the future without compromising the overall integrity and design of the landscape. Careful consideration has been given to the placement of buildings to create appropriately scaled spaces and ensure that routes between buildings are clear, safe and approachable. The various areas of the site are well connected and served by a range of routes for pedestrians, cyclists and vehicles. A transport hub is located at the heart of the site as a clear and logical point of arrival. Entrances are positioned around this large public arrival space and there is direct access for pedestrians from the drop off points from cars, taxis or buses.

Key

1 Arrival Square
2 Central Park
3 Children's Park
4 Entrance Boulevard
5 A&E Entrance
6 'Lollipop Lane'
7 Car-park setting
8 Blue-Light Boulevard

Green character & identity



Design concept sketch
– establishment of clear lines of site

Early masterplan structure

Design Concept Sketch – clear view to main entrance

Site Masterplan

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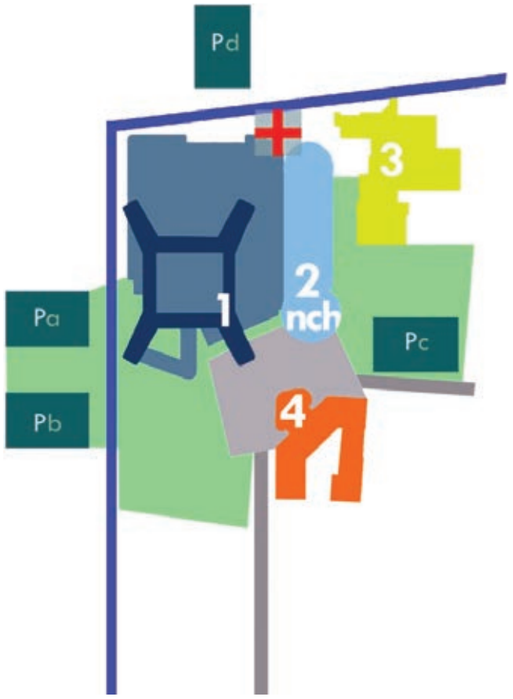
Public Space & Landscape Design

The new campus masterplan offers extensive grounds, delivering abundant green space for patients, staff and visitors throughout the day and night. The central park provides the setting for the Adult hospital. The Children's park provides the setting for the Children's hospital. The main entrances to both are located within the arrival space, which connects the two parks. Secondary entrances connect the buildings to the surrounding public areas and parks. The landscape can be easily read, is visually appealing and appropriately scaled to complement the architecture, with a clear hierarchy of external environments. Vehicular drop-off points are clearly located close to the main building, with parking set further away to promote pedestrian circulation as the dominant means of traversing the campus. Pedestrian facilities will ensure access for all through minimal level changes and high quality surface materials that reinforce movement towards the entrances. Vehicular speed will be controlled via traffic calming elements and pedestrian crossings, creating a more comfortable environment for pedestrians. The transport hub is centrally located, allowing for easy connections with public transport systems and designated cycle routes and shelters further promote the use of sustainable transport.

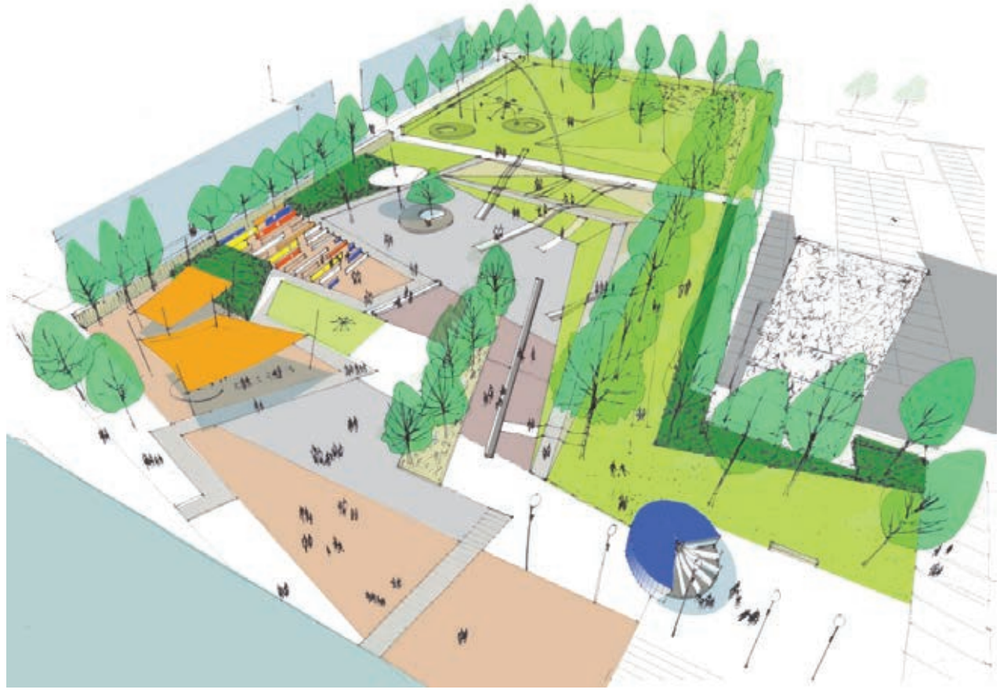
Colorful hand prints from hand painting on white background

An attractive & colourful surrounding for children & young people



Site identity and wayfinding map

Strong identity for adult and children's hospital



Design Concept Sketch for Children's Park

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Public Space & Landscape Design

The new campus masterplan offers extensive grounds, delivering abundant green space for patients, staff and visitors throughout the day and night. The central park provides the setting for the Adult hospital. The Children's park provides the setting for the Children's hospital. The main entrances to both are located within the arrival space, which connects the two parks. Secondary entrances connect the buildings to the surrounding public areas and parks. The landscape can be easily read, is visually appealing and appropriately scaled to complement the architecture, with a clear hierarchy of external environments. Vehicular drop-off points are clearly located close to the main building, with parking set further away to promote pedestrian circulation as the dominant means of traversing the campus. Pedestrian facilities will ensure access for all through minimal level changes and high quality surface materials that reinforce movement towards the entrances. Vehicular speed will be controlled via traffic calming elements and pedestrian crossings, creating a more comfortable environment for pedestrians. The transport hub is centrally located, allowing for easy connections with public transport systems and designated cycle routes and shelters further promote the use of sustainable transport.

Key Spaces and Places

The Central Park within the campus provides a functional retreat for patients, visitors and staff. The masterplan extends the soft landscape from ground level up the buildings, through the external courtyards and on to the roof, creating physical links between the hospital buildings and the surrounding landscape. These courtyard gardens provide therapeutic retreats for recovering patients, utilising level changes for rehabilitation where appropriate. The roof areas provide amenity whilst also supporting a wide range of vegetation types from sedum mats to shrubs and trees, reflecting the native species found at ground level for continuity.

The Masterplan recognises the opportunity presented by the expansive greenspace to optimise the use of the landscape, not only for the enjoyment of patients but also those who use the space on a regular basis, providing a focus for passive and active recreation, including the prposed 5-a-side pitch and an informal running track within close proximity to the hospital buildings. Informal lawns and a meandering path provide for use of the park as a thoroughfare as well as a place to relax, whilst the wildflower meadow and woodland vegetation establish a wildlife fringe with great habitat potential, increasing the overall campus biodiversity.

Children's Park

The New Children's Hospital will dock with the main building connecting the two whilst retaining a feeling of separation. The external environment for this hospital is focused towards delivering a stimulating space with low key play for a variety of age groups. The Children's Park and interactive play area is delivered with a playful use of colour, texture and creative design, easily accessed by all.

Hard and Soft Landscape

The campus-wide soft landscape strategy has been carefully considered through study of the supporting ecological reports and BREEAM requirements as well as a study of local flora and complementary 'exotic' species, which have been chosen for their low maintenance requirements. The softscape palette delivers year round visual interest, which achieves an appropriate sense of scale, softening the architecture rather than competing with it. The design remains mindful of the variable local climate, building aspect and success of desirable local flora. Such consideration is particularly important for the roof garden, which may be subject to extreme climate conditions. Widespread use of locally sourced native and exotic species will further the chances for successful plant establishment and will also create more habitats for local fauna.

Vegetation is used creatively to both screen undesirable views and frame important ones, whilst also acting to reinforce the wayfinding strategy for creating spatial hierarchy. Larger trees line the avenues and main access routes, whereas squares and gathering points are complemented by more intimate vegetation, formally arranged at a lower level, providing variety through foliage color, scent and flowers. Informal arrangements of wildflower meadows will provide an annual profusion of color across the Central Park, linking back to the main buildings and extending to the roof terrace, strengthening the green corridor. Such species will survive on poor quality soil and require minimal maintenance.

The development will result in a loss of protected tree species, which cannot be avoided. The Masterplan looks to replace any vegetation lost with suitable native alternatives and seeks wherever possible to further the variety of the naturalistic environment.

The palette of hard landscape material will create a cohesive and legible public realm to facilitate circulation. It will achieve this through the use of a range of surfacing materials which reinforce the character of particular areas. Hardscape treatment will act to differentiate as well as unify destination hubs and transition zones, responding to the environmental conditions, be it by providing pedestrian, shared or vehicular surfaces. Variety is desirable and will ensure visual interest and richness as well as providing a clear hierarchy of spaces. Hardscape materials will remain consistent within defined areas, providing a clear transition from one space to another whilst creating a sense of arrival. Level transitions, pedestrian ramps and service covers are carefully considered to avoid clumsy transitions between surfaces.

The hardscape environment has been designed to minimise the environmental impact. Permeable gravel surfaces permit surface water infiltration, whilst granite and paving slabs help to reduce the carbon expended on supply. Hard wearing surfaces delay the need for replacement materials and are used where the greatest level of activity is anticipated. Sustainable drainage systems are accommodated with surface run off being directed towards surface level drainage which is filtrated through a reed bed system. All materials will accord with the relevant British Standards and will meet BREEAM standards for 'Excellence'.

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Furniture Strategy

The furniture strategy is designed to respond to the variety of environments experienced across the campus, to provide robust, practical, comfortable and attractive features. Some seating is to be constructed on site, in the form of low seating walls faced with reclaimed dressed stone from site demolition, and other elements supplied as individual pieces of furniture. Design will vary according to the locality but quality will not be compromised. A complementary palette of bins, bollards, railings and cycle stands all add to the character and identify of the space.

Illuminating the Campus

Lighting within the hospital campus will create an environment which is as welcoming and accessible during the night as it is by day. Functional lighting to routes is to be used in conjunction with feature lighting in key areas. The lighting strategy will help to identify the New South Glasgow Hospitals as a unique location whist also delivering seamless integration with the surrounding environment. The scheme will allow for the use of power efficient luminaires with appropriately low maintenance requirements. Fittings will limit light pollution by providing a variety of light levels appropriate to the locality. Stronger lights affixed on lamp posts will delineate the primary routes and entrances where high visibility is of greatest importance. Subtle use of lower intensity light fixtures, uplighters and illuminated bollards will create a more intimate and relaxed environment for secondary pedestrian destinations, whilst still providing sufficient light to permit ease of use and without disturbing wildlife which may inhabit the area.

Sketch View through the central park

Design Sketch to illustrate visibility & entrance from boulevard

Sketch View of Path from Car Park to Entrance

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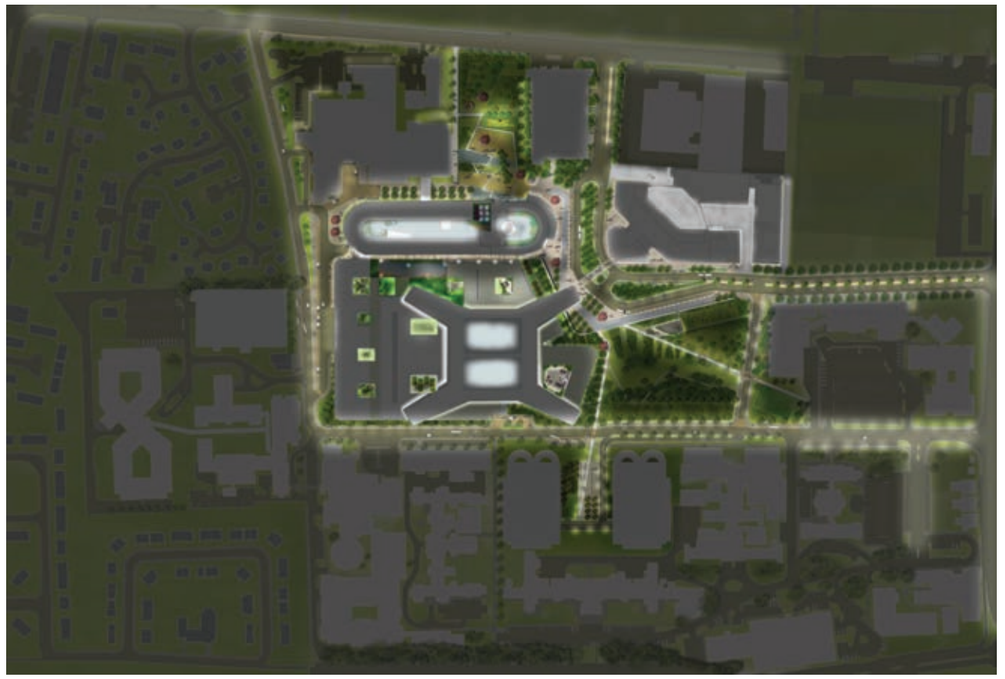

Illustrative plan view of the campus by night

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Architecture

Overview

The challenge for this development has been the provision of two different hospitals together on one campus, both requiring a different approach architecturally whilst maintaining both legibility and identity as a whole. The solution is the formal composition of the building as an expression of its principal functional parts, the wards, the Children's hospital and the podium levels (comprising the diagnostic and treatment services). These three elements each have their own specific character, albeit derived from a unified concept for the whole building. The façade treatment of each piece has been informed by material selection and detail with the design responding to aspect, functional content, as well as life-cycle and maintenance considerations.

Internally the challenge has been to maximise clinical adjacency whilst minimising circulation and maintaining a simple and robust wayfinding strategy. We believe we have achieved this as well as a strong robust, iconic architectural design.

References and Inspiration

We believe that the redevelopment of the Glasgow Southern General Hospital site should recognise and reference the importance of the history of the city. The Clyde as it meanders through the city with history steeped in shipbuilding offers ample opportunities for reference to materials, scale and form.

The building is large, yet it is evident that this scale when set within the surrounding shipyards along the Clyde is not only appropriate but necessary to relate to such imposing structures.

The Children's hospital takes its inspiration directly from the ships that once and still do glide down the Clyde. Rounded at both ends, with funnels references on the lift cores, the building reflects the shape and form of a ship. Further reference to the Clyde's history is evident in the roof gardens whose canopied play areas make reference to the decks on the majestic liners that once cruised the nearby river.

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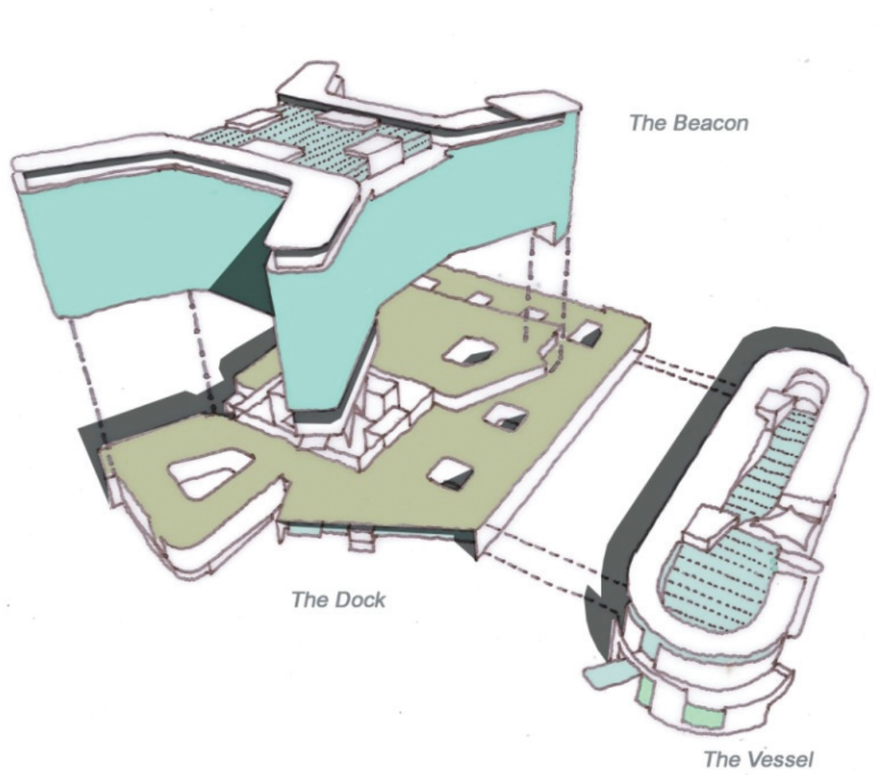
Building Architecture

Three blocks of accommodation of strikingly different geometry come together around the podium. The three principal elements are the ‘Beacon’ (Ward Tower), the ‘Dock’ (Podium) and the ‘Vessel’ (Children’s Hospital)



1. The Beacon (Tower)

The ward tower comprises 8 floors of ward accommodation with plant space in an interstitial layer and at roof level. Designed as a continuous free-flowing plan formation around a central atrium, maximum views and flexibility for all inpatients without overlooking any other patients is ensured.

The external expression of the ward tower remains consistent with this continuous planning approach and embraces and emphasises this free-flowing aspect through a distinct horizontal emphasis. This approach assists in mitigating height and any potential over-bearing effects.

Other subtle details are employed to vary the expression and respond to aspect and scale. A horizontal emphasis is proposed for alternate floors thus reducing the perceived height of the development whilst embracing the horizontal planning approach of the wards. On the longer east and west elevations, this horizontality is broken down in the central area of the elevation through the application of regularly spaced vertical aluminium fins which as well as providing some relief from oblique solar gain also allow a subtle hierarchy to be introduced. These fins are also proposed to be added to the tower ‘wings’ as a device to add subtle colour and relief from the smooth free-flowing skin of the

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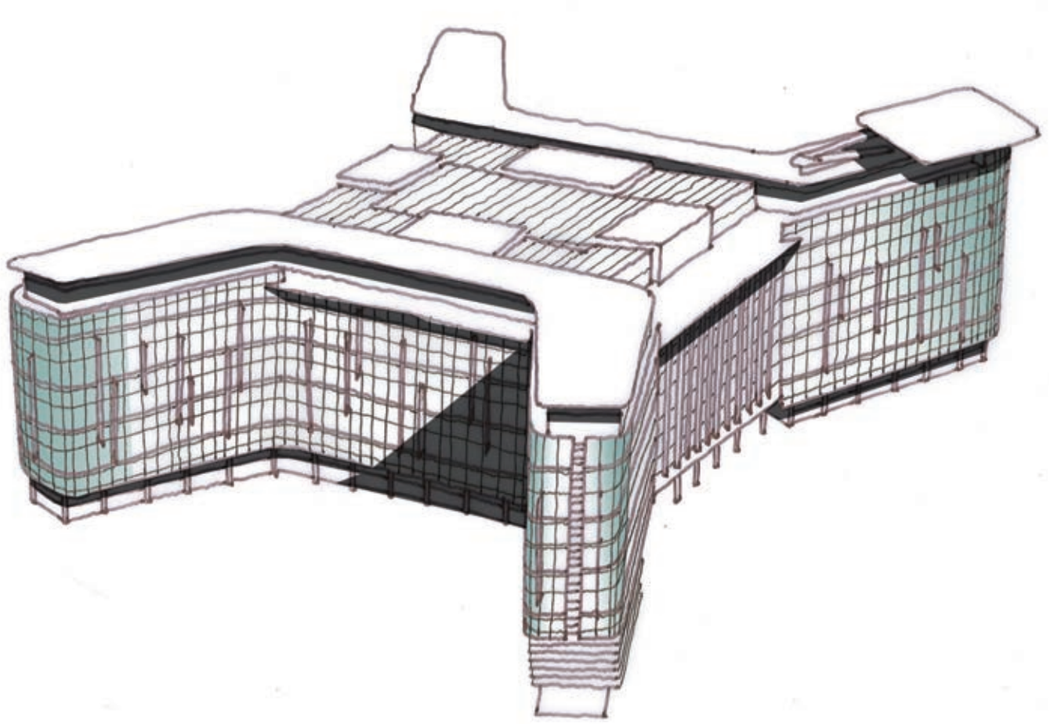
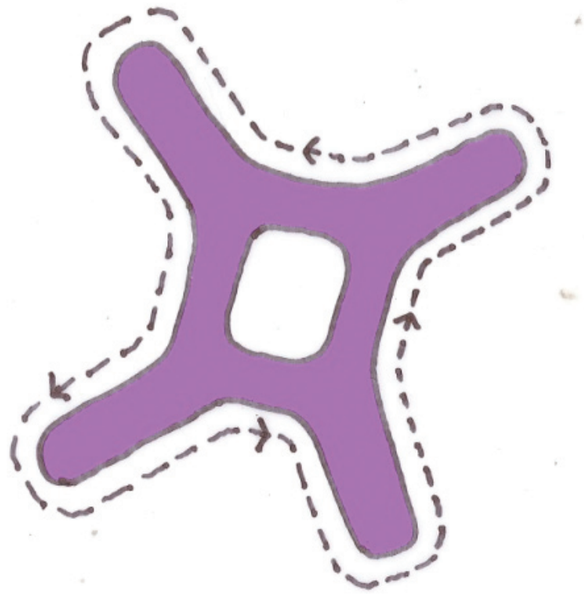
2. The Dock (Podium)

The podium varies in height between three and four storeys, responding to the varying scales of existing facilities around the perimeter of the site. It also accepts and exploits the difficulties often presented in attempting to adopt a legible compositional strategy that can respond to a myriad of small cellular spaces within. Our strategy is designed to deal with this and also to allow flexibility during the detail design phase, where the inevitable development of functional content requirements will impose change. Ensuring that the internal clinical plan is not compromised through a desire to achieve an external aesthetic/ compositional effect is critical in our view and our strategy is designed to prevent this



Sketch View of Tower



Free-form ward tower arrangement

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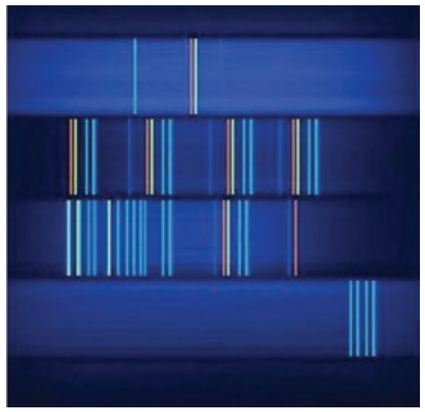
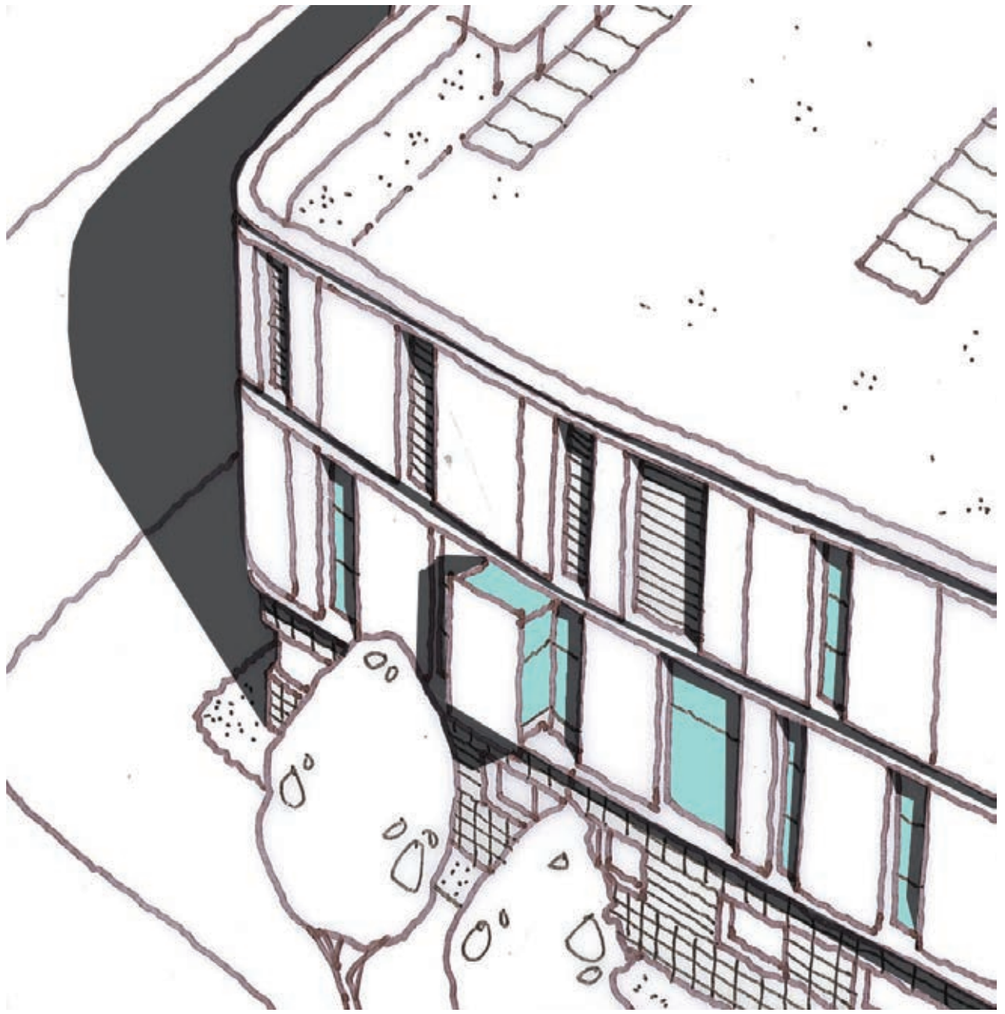
The podium takes its visual references from medical imagery and in particular the DNA strand. The strategy for fenestration and modular panel systems follows the principle of a DNA strand with the placing of varying width full-height solid or transparent panels, in a seemingly random manner. The perceived height of the podium is also mitigated by a horizontal emphasis, highlighted through the use of a separating floor level steel channel. Horizontality and a dynamic expression of the individual floor plates is also emphasised through the curving of corners, which allow views to continue around corners rather than terminate.





Sketch View of Podium

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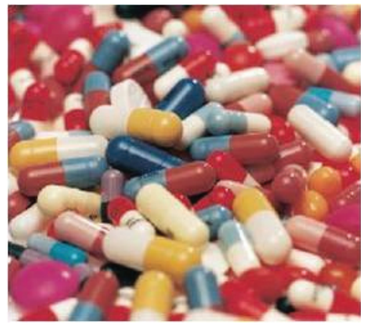
3. The Vessel (Children's Hospital)

The Children's hospital has been designed to reflect the patient group it is dealing with, who are generally very nervous about attending hospitals. With this in mind we have tried to make the building feel playful and colourful as well as light and airy. The theme of a vessel mooring alongside the dock, in this case the podium has been taken. The curved form of the building and the internal lift towers rising up to roof level providing expression as ship 'funnels' further add to this theme. The idea of the Children's hospital 'docking' with the Adult hospital providing support and security is an integral part of the overall composition. As such, the Children's hospital is treated as a more transient form which takes some cues from the acute building, in order to ensure an integrated approach, but also is treated as an individual piece with its own strong identity.

To further enhance the Children's hospital's identity and to ensure an appropriate response to human scale, the front of the building fragments to form an expressed screen/'arch' which assists in breaking down the mass and scale of the five storeys of accommodation. The 'arch' structure also encloses and protects a second floor terrace/play-deck, accessed from the Schiehallion ward and also provides a springing point for the main entrance canopy.

Sketch View of Children's Hospital from Children's Park



Further references have been considered to reduce any potential institutional effects whilst being mindful not to ignore other users. As well as maritime references, other sources of inspiration have been introduced in order to assist the external compositional strategy, to reinforce the building's individual identity and, above all, to engender a feeling of fun and relaxation. Accordingly, the use of colour through a study of imagery from areas ranging from medical (tablets, pills etc.) to confection (jelly beans, sweets, etc.) is proposed.
The building fenestration employs a simple strategy which groups pairs of windows with coloured panels. This grouping is then offset between adjacent floors, introducing a sense of random playfulness which mitigates formality and institutional feelings.

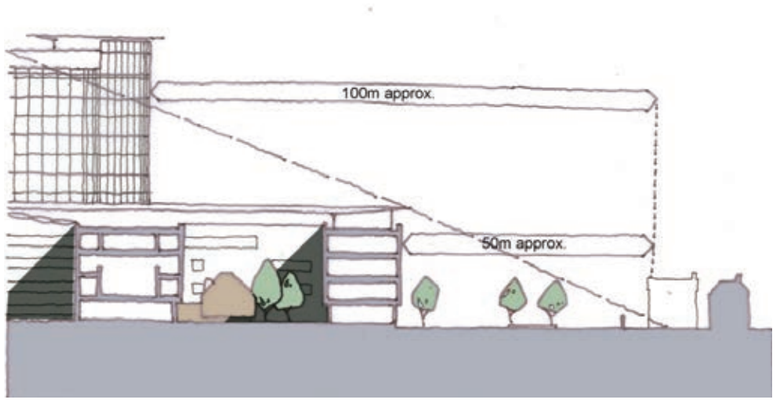
Entrances and Building Approach

The hospital has three significant entrances. The main entrance for both the Children's and the Adult facility are expressed such that as people arrive at the site, they are guided intuitively to the entry points, and are not dependant upon detailed signage. Both entrances overlook the central square and vehicular drop zones. It is the scale and presence of the building that gives our proposals a truly civic impression. The entrance canopies have been ideally placed to create both civic impact and to clearly present themselves to visitors approaching along the main boulevard. The third entrance, to the rear of the building, serves only as an entrance for the Adult and Children's Emergency Centre. This is not a grand entrance but no less important. It is necessarily functional and will be obvious due to the canopied drop areas along the length of this façade.

Scale

The overall scale of the building is the result of compact planning together with a desire to offer the potential to create landmark views for patients, staff and visitors over the surrounding hills as part of the healing environment. The tower will also act as a wayfinding beacon and landmark for the population of Glasgow. The placement of the building concentrates the mass and height to the centre of the site away from the adjacent terraced houses and smaller scale hospital facilities avoiding an over bearing building mass. The podium fixed at either 3 or 4 stories is a scale felt appropriate for the surroundings and includes a floor of plant accommodation which is set back where possible to further reduce its impact.

The scale of the courtyards allows sufficient daylight into the spaces between the 3 – 4 storeys of the podium or the Children's hospital. These courtyards will support a variety of therapies as well as contemplation and repose.



Schematic Section at Southern Perimeter of Site

Perspective View towards Main Entrance

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Permeability/Views

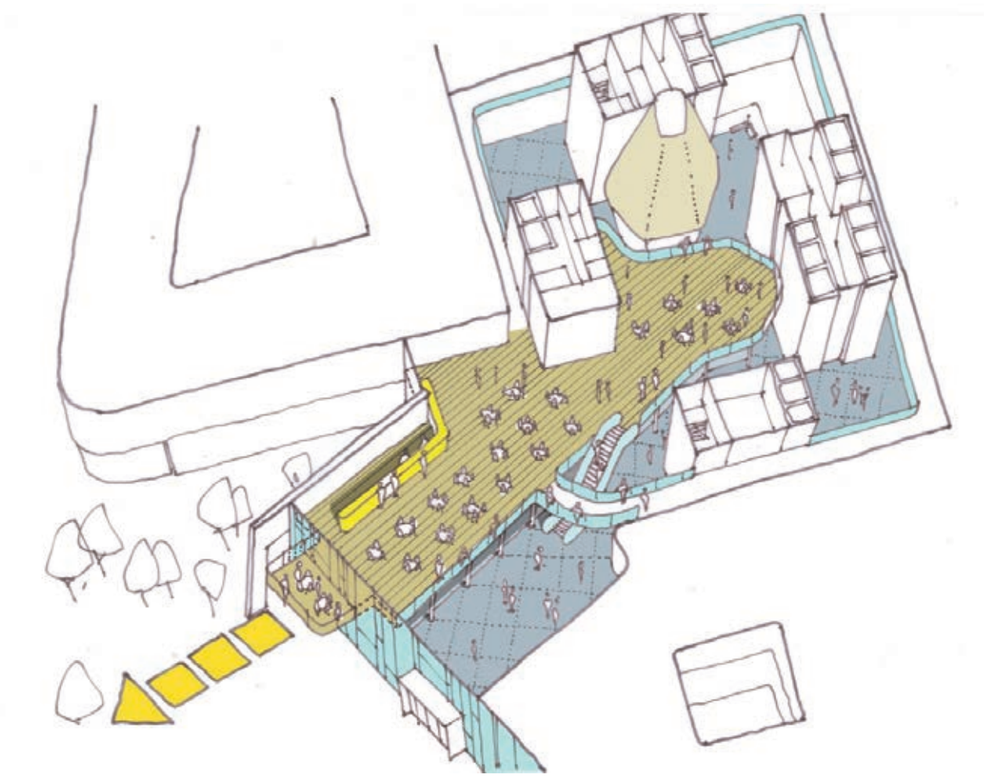
The importance of the building connecting with the surrounding landscape and the inside/outside functionality has been fundamental to the basic concept of this scheme. Maximising natural light and views to and from the hospital are not only important for orientation and the therapeutic recovery of the patients but also staff moral and easy wayfinding. To that end we have sought to ensure where possible there are strong links with the external environment.

The main entrances do not build barriers between the inside and outside rather they encourage you into them with continuity of floorscape, scale and permeability and use of materials. The Children's hospital maintains the link to the outside further by opening up the ground and first floor areas with a glass wall overlooking the proposed Children's park. This along with the 4 storey atrium will provide light and views over the park providing an exciting entrance space for children and visitors reducing stress for all.

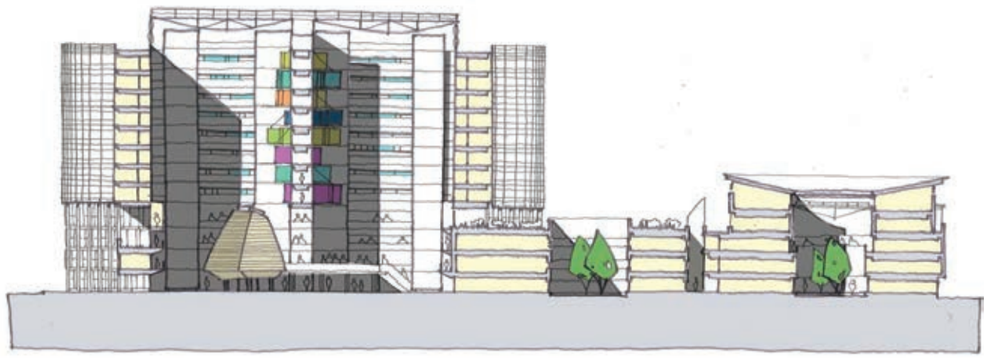
On the Adult hospital both the café and restaurant are located to ensure they maximise the benefit of the therapeutic nature of the landscape park. Set at the front of the building on two floors behind floor/ceiling glass they will not only provide a visual link for people as they approach but also relaxing zones with access outside should weather permit.

The main atria to the Adult hospital within the ward tower has been designed not simply as a top lit space, but rather as a space which maximises opportunities throughout its vertical height to gain light and views over the surrounding city. The central space breaks through to the outside at the ground floor and levels 3 and four on both the East and West facades to ensure natural daylight permeates the entire height of the space whilst allowing patients and visitors the opportunity to orientate themselves with their surroundings.

We have created an environment that will be perceived as a destination for the local community and people of Glasgow, one that is non-institutional, innovative and breaks down the common perception of healthcare environments.



3D Cutaway Sketch of Main Restaurant



Sketch Section through Adult Atrium

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Hierarchy of Space; Therapeutic Approach to Design

Although clinical adjacency issues are key to a successful hospital which are evident in our 1:200 drawings, we believe that by using a truly 'evidence based design' approach to the hospital as a whole can bring wider ranging benefits, including staff moral and retention, reduced patient treatment times by 14-21%. The evidence based approach is based on the concept of a health building as a hierarchy of spaces from public to social to private emphasis with different character as well as function. A number of simple principals are evident in this approach to design.

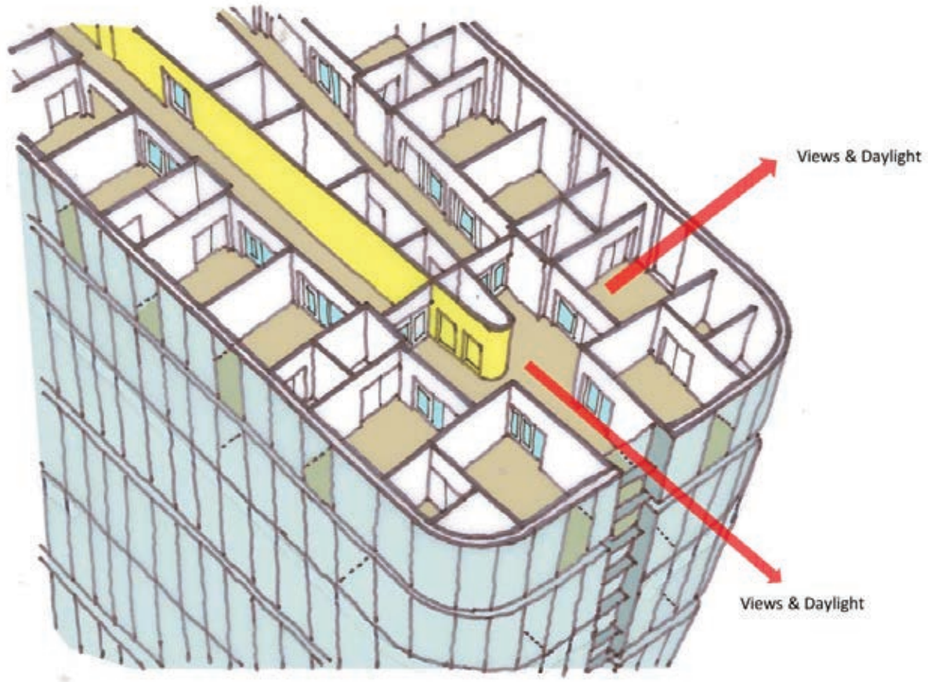
- Give patients privacy and dignity.
- Design to give patients, staff and visitors views within and from the building.
- Create spaces that have spatial legibility. Design so that there is a hierarchy of space, clearly demarking public / private with entrances clearly evident.
- Use art to define spaces but also to distract the patient / visitor.

Our design has used these design principles to produce what we believe is a truly holistic approach to the final design proposal. Firstly we have approached the Board's schedule of accommodation to create a space hierarchy within all departments which range from:

- Public space
- Social space
- Private space
- Intimate space

Our proposals encompass this approach across both hospitals with their differing levels of both private and intimate spaces readily accessible from the more lively public / social areas of the atria and main circulation cores.

We have attempted to create a sense of place rather than simply achieve functional requirements. All spaces make the best use of orientation, daylight, views, providing visual stimulus and spatial variety. Some spaces provide a sense of wonder such as the Adult hospital atria and the Children's central concourse with views out to the park, Radio Lollipop and the circular medi-cinema. Whilst others such as the multi faith centres and the consult / interview areas respect the privacy and dignity of patients and visitors.



Bedrooms areas in the Children's and Adult hospitals are designed to have all bedrooms outward looking over the landscaped parks and the wider views of Glasgow. Due to this clear design strategy there are no instances where a bedroom overlooks another bedroom. The use of interstitial bathrooms helps provide a shallow plan and regular shaped rooms but as each room has a window and glazed screens for observation it also ensures that light and views through into the corridors is maximised. Nurse bases are areas where natural light is further maximised for the benefit of patients and staff and on the Adult ward tower a connection with the inside and outside is continued with floor/ceiling glazing at the end of the ward corridor

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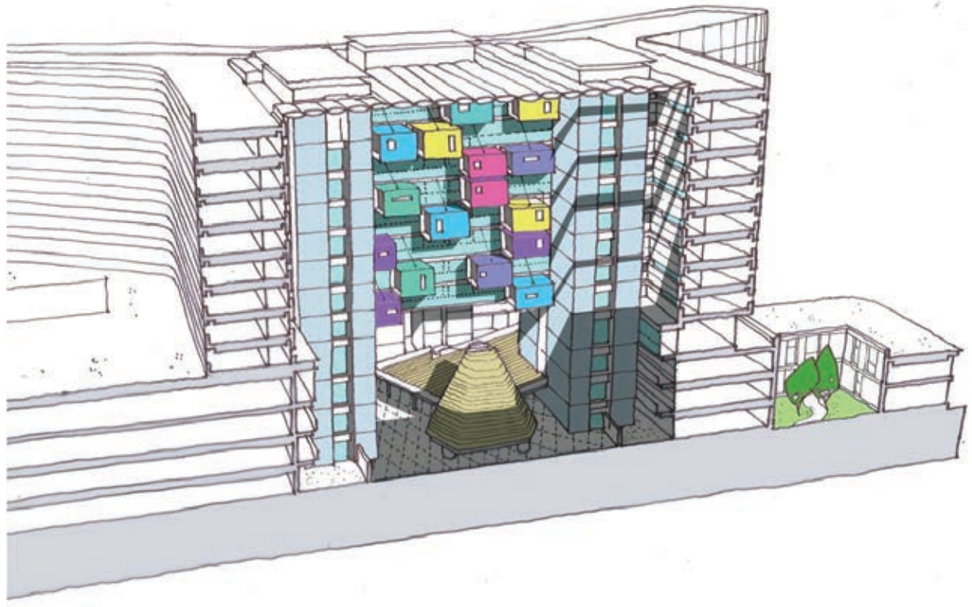
Entrances

Adult Hospital Atrium

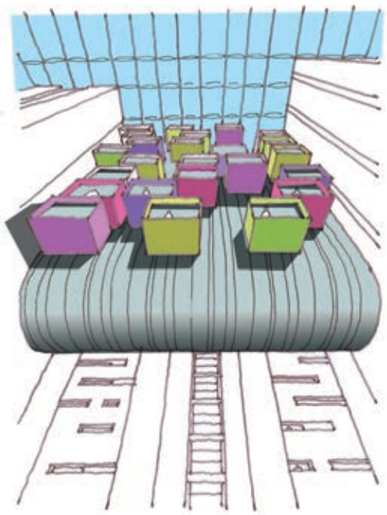
The entrance may be the starting point for your journey but the atrium is the place where you really start to orientate yourself, to contemplate, to experience a sense of wonder. The atrium is the centre of the Adult hospital. Its internal form not only provides the primary circulation routes for patients and visitors but in its style and form act as the canvas for the interior design strategy which with the use of specialist lighting will change throughout the day and seasons. At the lower levels the area will act as a hub providing routes to and from departments or circulation cores as well as areas for retail and dining. We have designed different levels of social space with both interactive and quiet spaces. If it is dull outside it will never be dull inside and it provides the perfect opportunity for exhibitions, community events and generating a sense of occasion.

Children's Concourse / Atrium

This is designed as an internal street linking both the inside and outside and the vertical circulation cores. Think of it more as the yellow brick road rather than a clinical street. Three-four storeys in height and top lit throughout its length it terminates at the second core opening out into the central courtyard. At a minimum of 15m wide the ground floor space is kept interactive by integrating the OPD waiting spaces. The floor plates above are curved to provide interest and will be coloured along their leading edges either with physical colour or imaginative lighting which, like the Adult atrium, can change with the time and seasons. Flooded with light and artwork on different plains this will be a magical space for visitors and children to recuperate.



3D Cutaway of Adult Atrium



Sketch of Adult Atrium

3D sketch of Children's Atrium

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Finishes - Building Envelope

The materials for the external envelope of the hospital have been chosen for their looks and contribution to the whole, for durability and for the ability to maintain a high quality of appearance with very low maintenance for the desired lifespan of the building. The design team have investigated several alternatives for elevational materials. As the design has developed it was clear it was not necessary to generate overt animation and interest in the facade rather a less is more approach. A carefully chosen palette of high quality, familiar materials will provide a calm, sophisticated supporting texture to the building forms.

The proposals are divided into three distinct elements, as already stated and as such, the material strategy varies for each as follows:

The tower is conceived as a glazed element, with a smooth continuous 'skin'. This approach is consistent with the continuous ribbon-like layout of the ward templates and also ensures that varying lighting/daylight/weather conditions can be exploited. A unitised curtain walling system is proposed offering advantages in construction and programme but also in consistency of detail.

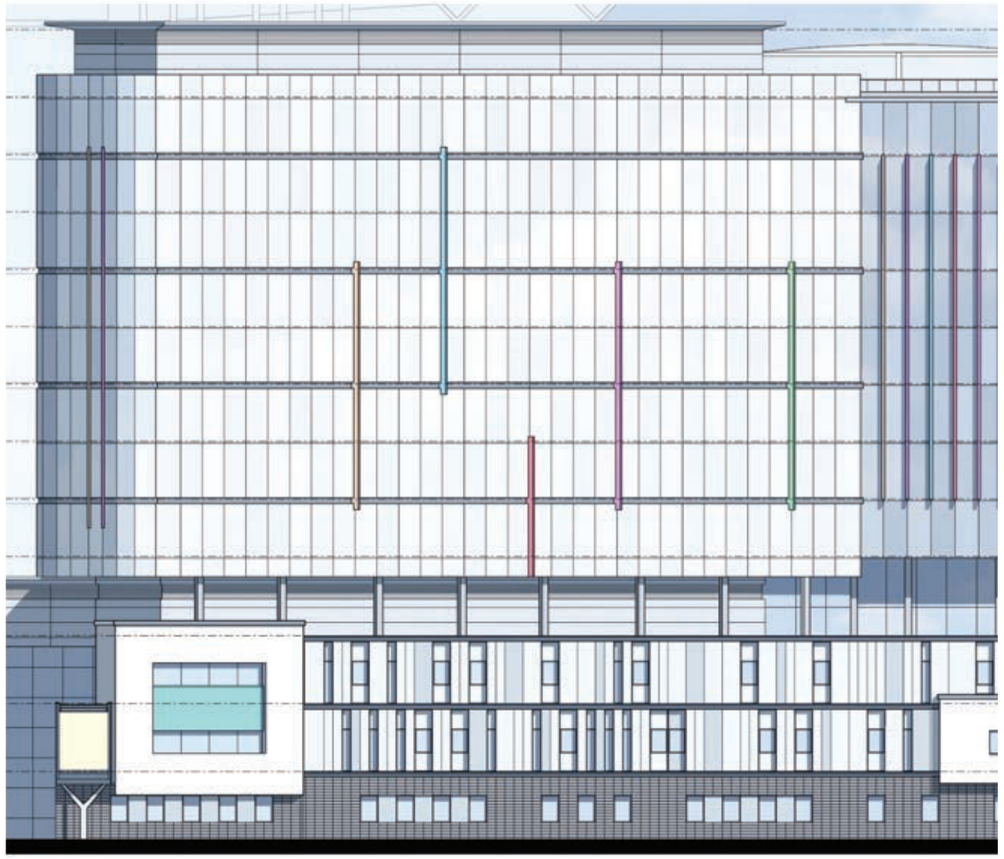
The podium is conceived as a vertically layered form consisting of a lightweight, panelled upper section sitting upon a solid, robust masonry plinth. The plinth is treated in a manner that will accept a higher degree of public contact and interaction and allow ease of maintenance. The upper floors shall be either full height high pressure laminate panels or full height double glazed units (obscured with opaque glazing where necessary). Floor/roof parapet steel channels separate the floors and reinforce the horizontal emphasis. Interest and variety is introduced by occasional small bay projections and expression of plant/ ventilation elements.

Given it will be viewed by the majority of the occupants of the Adult ward tower, the expression of the podium roof is critical. Large areas of roof planting is proposed – either as sedum or as a more fully landscaped, accessible roof terrace adjacent to the Children's hospital (third floor), providing a dedicated therapeutic amenity space. Other roof areas will consist of high-performance single-ply membranes, ballasted/paved as necessary.

The drive to ensure a separate identity for the Children's hospital suggests a similar approach to material selection. The Children's hospital is conceived as either a large, white vessel or a giant piece of confectionary. Accordingly, the simple use of white through-colour render is suggested as appropriate. A more robust masonry element is proposed for the base with a range of window sizes and heights introduced offering views for all age ranges of building users.

The roof of the Children's hospital will also be visible from the tower. The intention is not to introduce over-elaboration to the roof purely for aesthetic purposes and hence it is treated as a simple continuous form. Ribbed single ply membrane in a subtle colour, plus the expression of lift cores and ventilation cowls mentioned previously, will provide adequate rhythm, pattern and interest when viewed from above.

Courtyards are also proposed as simple, white rendered spaces in order to maximise the potential for reflected daylight. Careful detailing and consideration of aspect and wind direction will ensure that the potential for staining to render is eradicated.



Partial Elevation of Tower/podium

The glazing is proposed to extend past the uppermost roof level and the soffit of the lowest tower floor, forming a balustrade at roof level and reinforcing the impression of cladding as 'skin' at lower interstitial level. This detail stops at the junction of the tower wings with the main body where at roof level a small eaves is introduced. These measures help to sub-divide the form and scale of the tower, introducing a hierarchy whilst remaining consistent with the concept of a continuous horizontal ward-planning approach.

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Infection Control

Research and investigation have consistently confirmed that the healthcare environment is a secondary reservoir for organisms with the potential to infect patients. As such we have ensured that infection control principles are incorporated in our design, drawing on national guidance – particularly 'infection control in the built environment: design and planning (HFN30).

The key control of infection features of our scheme are outlined below:

Sizing, Space and Innovation

- Bed spaces of at least 3.6m in multi bed bays (our cruciform beds have minimum 6m spaces), with a maximum of 4 beds per multi bed bay.
- Provision of 100% single beds in the Adult Hospital including critical care and assessment wards.
- Provision of adequate sanitary facilities. En-suite shower/wc/wash per single bedroom: separate en suite facilities per multi bed bay.
- Single bedrooms are sized to ensure a variety of treatments can be undertaken at the bedside and these rooms and wards are generic so that patients movement is not required other than if critical care facilities are needed.

Partial Elevation of Children's Hospital

Isolation Rooms, Single Rooms

- Provision of a high proportion of ensuite single bedrooms as identified above.
- Provision of isolation rooms within each ward.
- Isolation rooms have lobbies with integral clinical hand wash facilities.
- The design of isolation lobbies complies with the latest HBN04 (supplement 1), eliminating the need for positive and negative pressure switching.

Sanitary Facilities, Clinical Sinks, Hand Cleanliness

- Quantities of clinical handwash basins complies with HFN30 (one per single bedroom, two per four-bed bay, one per critical care bedroom, one per consult exam.
- Procedure rooms as a rule have, as a minimum, a clinical handwash basin, or- where appropriate a scrub trough.
- Clinical wash basins are equipped with thermostatically controlled, single lever action taps; spray taps are not to be used.
- All areas where clinical activity are undertaken are provided with hand rub solutions, positioned at the point of care and within all staff utility rooms.
- Glove and apron and antibacterial solution dispensers will be provided outside any room which accommodates a patient bed, trolley or reclining chair.
- Clinical hand wash basins located so they are clearly visible when entering a room.
- Provision of clinical hand wash basins at entrance to each ward.
- All doors used by visitors and patients for personal hygiene are provided with doors capable of release from outside in case of collapse behind the door.

View of Adult Acute Single Bedroom

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Ancillary Areas

- Separation of clean and dirty processes within clinical areas.
- Ledges and ridges will be minimised in the design to avoid dust traps.
- All hot water will be delivered within safe working temperatures (i.e. Maximum of 43 degrees centigrade), and complies with ‘safe’ hot water and surface temperature guidance.
- All generic sanitary ware will utilise pre plumbed units.
- Theatres are designed with ultra clean ventilation and engineered to ensure air pressures are managed to minimise the risk of airborne contamination.

Storage

- Patient bedrooms are provided with locker and wardrobe space.
- Domestic cleaning equipment, laundry and clinical waste is always stored in purpose-built spaces to prevent cross contamination.

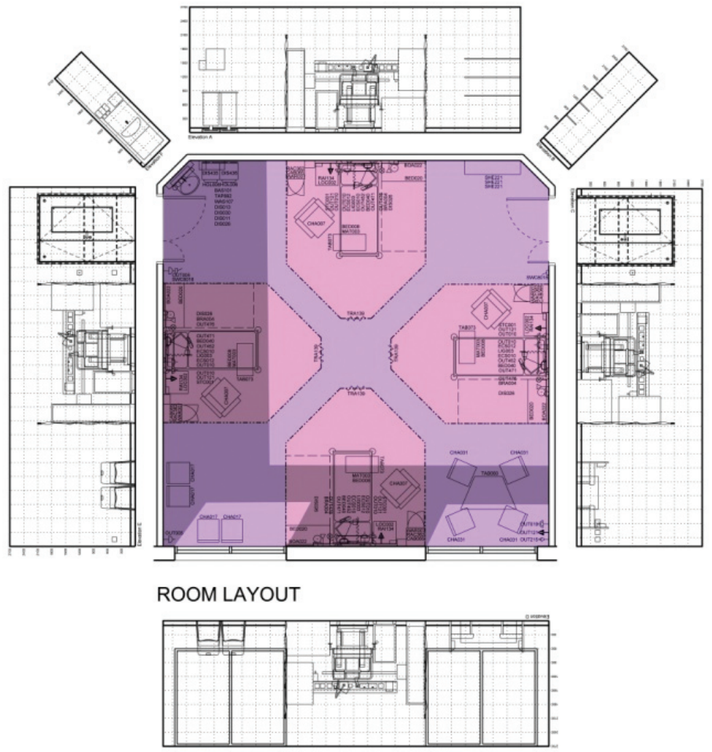
Finishes

- Finishes comply with HTM56 guidance and facilitate easy cleaning. In clinical areas, all finishes are seamless and impervious. In areas where joints are permitted, these are sealed/welded to prevent water egress, skirting boards are sealed.
- Where appropriate all details and fixtures and fittings will be designed and reviewed to ensure dust traps are kept to a minimum.

The Board’s brief has encouraged an innovative approach to the design of the new hospital. We believe we have responded to this by including many innovative design features covering a wide spectrum of disciplines.

Inpatient Wards

- The inpatient block epitomises the innovative approach to the hospital design. Each ward is built around the fact all bedrooms for Adults are single with interstitial bathrooms all outward looking giving the following benefits:
- Regular shaped room for maximum efficiency and the ability to incorporate ‘H’ shaped ceiling mounted patient hoists if required
- Excellent observation from corridors through glazing, plus optimised views and natural daylight.
- Short travel distance from bed to bathroom with access via double doors to aid patient access in any difficulty.
- Flexibility, all wards can be flexed in terms of size upwards or down from 28 beds as required as each ward abuts an adjacent ward with nothing in between.



Plan of 4-bed bay

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4 Bed Bays to the Children's Centre – an Innovative Approach

- Off set bays for improved privacy.
- A separate Ensuite adjacent to the ward providing privacy.
- Good staff observation into the bedroom.
- Maximum bedhead separation well in excess of the HTM for control of clinical infection.
- The cruciform arrangement allows for inclusion or privacy for all patients should they desire.
- Integral day spaces for teaching or rest periods.

Facilities Management

Our proposals have been designed for optimum functionality across a range of conventional and more innovatory systems for distribution and disposal, giving the Board a high degree of flexibility in the delivery of FM support. Automated Guided Vehicles will be used to deliver and collect various items to predetermined locations throughout the development. Whilst AGV technology is not new it has rarely if ever been used in UK hospitals. Requiring no fixed track and fitted with collision detection systems the AGV systems can be easily expanded if the Board deem them beneficial.

Perspective View of 4-bed bay

Automated Guided Vehicle

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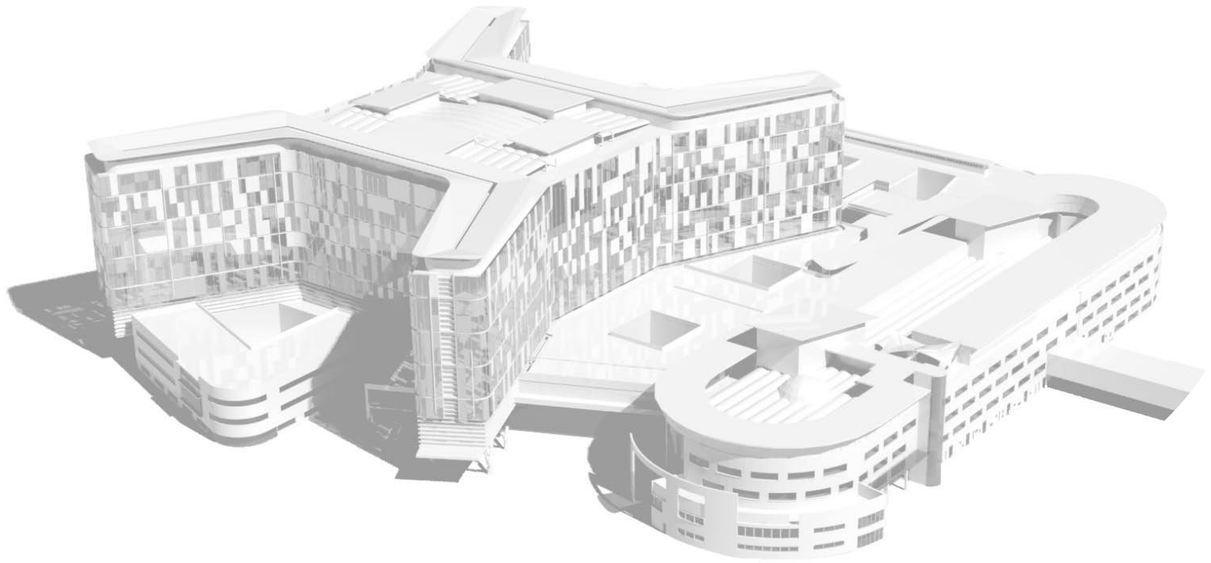
Summary

The resolution of our proposals has only been possible through the dialogue and engagement that has been offered to us by the Board. We have listened, we have understood and we have responded. Such close dialogue is critical in the success of any project and in this case has been instrumental in our ability to arrive at the solutions presented. We thrive on such dialogue and see this as an ongoing activity through the life of the design phases to come. There are many opportunities to enhance the already successful features of the design proposals and we would relish further engagement.

The conception of our design is based on a simple approach: a strong master-plan upon which a simple architectural proposition is imposed. We have designed from the inside out. Clinical effectiveness, flexibility and innovation is married with, but not dominated by architectural flare and expression.

This perfectly balanced building will deliver exemplary healthcare facilities, enhance the Board's profile and provide a lasting legacy of which the whole community and Glasgow can be proud for many years to come.

WAYFINDING STRATEGY



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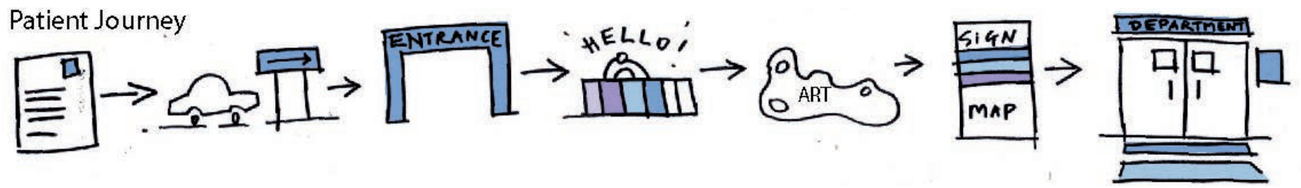
Introduction to Wayfinding



The design proposal for the New South Glasgow Hospitals is underpinned by the need for effective wayfinding to facilitate the diverse functions of the new facilities. The design process has been tested at each stage to ensure that design decisions support operational demands. Wayfinding refers to the movements around the hospital which will be made by staff, patients, visitors and for servicing and equipment.

The goal of the design process is to deliver a high quality healthcare environment which is as user-friendly as possible for people to use, whether for the first time or all the time. This means that journeys to particular parts of the hospital should be as easy to understand as possible and that regular journeys should involve the shortest practical distances for travel. The wayfinding strategy addresses orientation and movement at a variety of scales and ensures that movements can be based upon logical but ultimately intuitive decisions. Clear wayfinding has underpinned the design process in order to make the design as clear and robust as possible.

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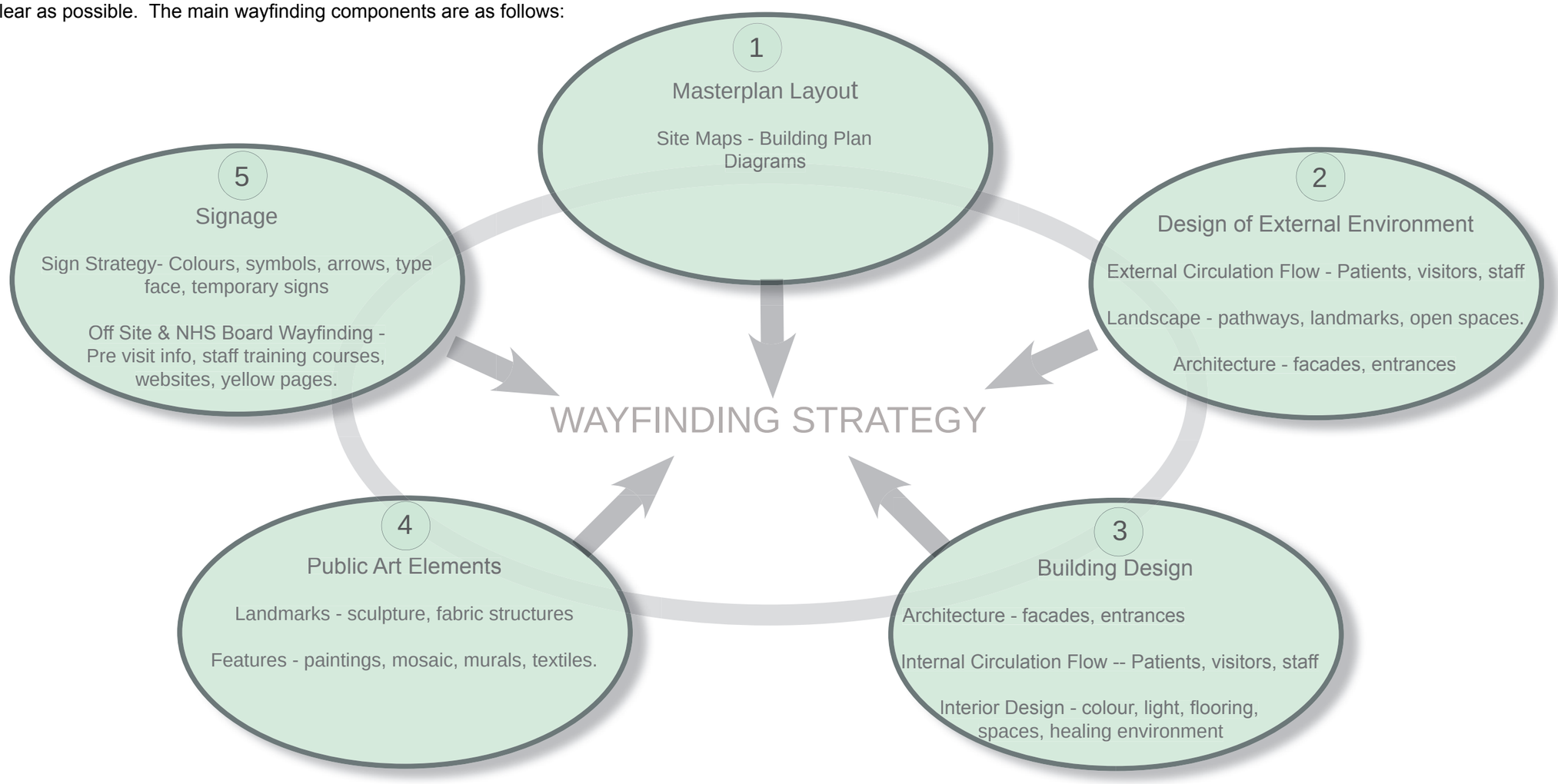
Principle Components & Hierarchy of Wayfinding

Wayfinding within the new hospital environment has been considered in response to a recognised hierarchy of movements and orientation decisions. It is the effectiveness of the decisions made by visitors (or other hospital users) during their journey(s) which will determine the success of the wayfinding. Wayfinding decisions are related to the following hierarchy, which captures the key decision points in hospital visits:

- Sub-regional location, profile and identity
- Access to location from within the city & local environment
- Site entrances
- Access to the various building entrances
- Site circulation
- Orientation within buildings
- Departmental orientation

A number of elements within the design process influence the effectiveness of the wayfinding and many of these overlap in the ways in which they strengthen the legibility of primary routes and make destinations as clear as possible. The main wayfinding components are as follows:



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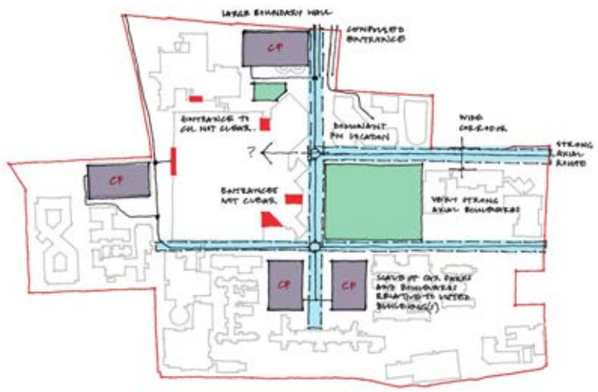
(1) Masterplanning

The masterplanning process has defined the layout of the site and established the position of the various buildings and the routes between them.
The position of the building entrances has been defined in response to the main approach along the entrance boulevard from Govan Road.

This means that the position of the entrances is clear as soon as possible within the site. Cars, buses, taxis, cyclists and pedestrians all have simple and direct access to the entrances.
The design of the entrances to each building makes them clearly identifiable and user-friendly.

The masterplan has also defined clear routes to entrances from car parks and other buildings. With the exception of accident and emergency, the building entrances for the new hospital are all sited within a new arrival square. This provides a clear and distinctive point of arrival which is clearly identifiable and is different from the approach roads. The masterplan has defined a clear separate route to the dedicated entrance for accident and emergency.

1. Exemplar Design



2. Site - Exemplar Evaluation & Critique

3. Re-Massing for better masterplanning & Wayfinding

4. Circulation & Spatial Analysis & Refinement

5. Urban Design, Green Space Potential

6. Masterplan Defined

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(2) Design of the External Environment

The core wayfinding principles which underpin the definition of the site layout (the masterplanning) are robustly supported by the design objectives for the external environment.

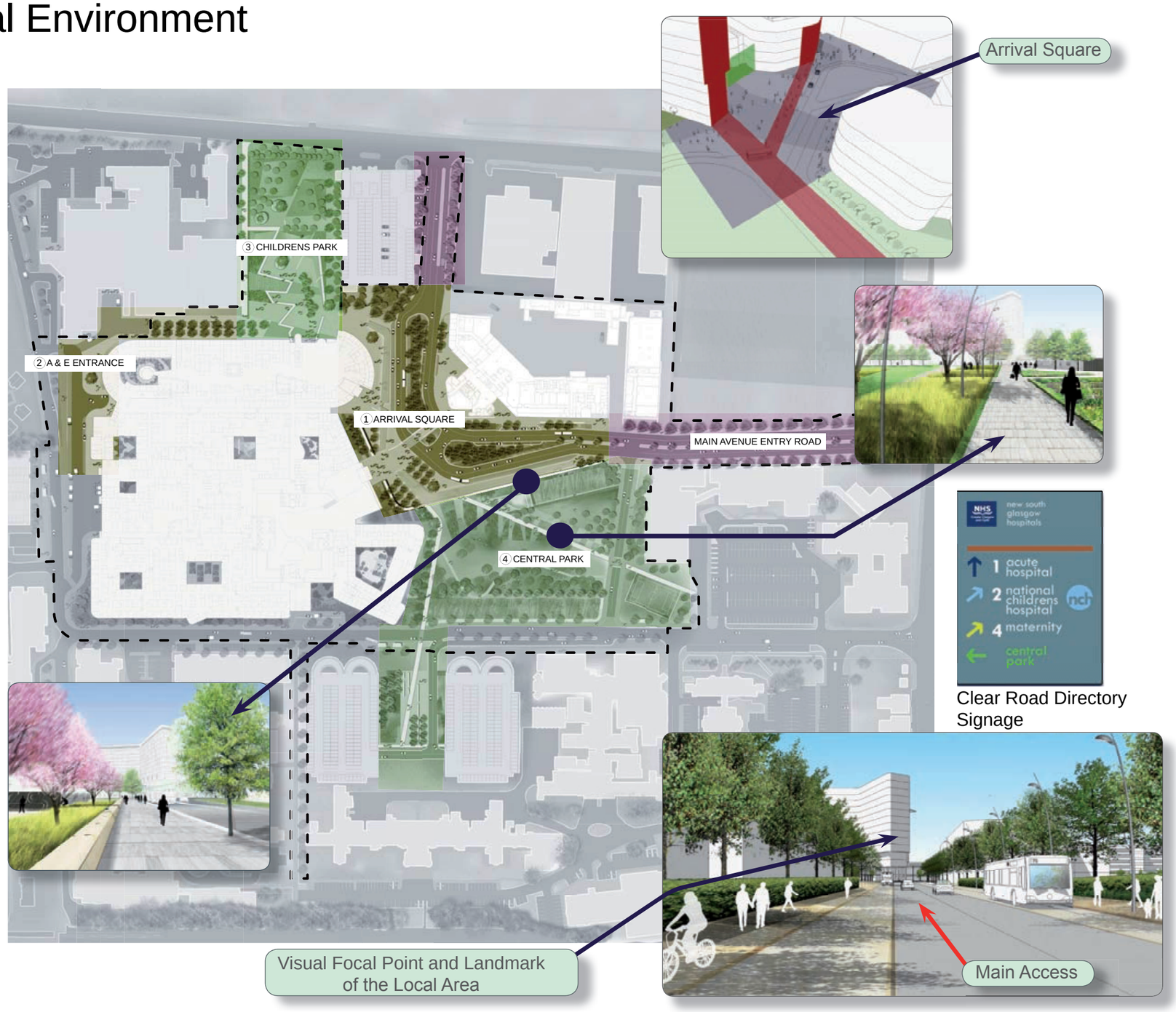
The masterplan structure is represented in the design of the external spaces as a clear hierarchy of open spaces. These include the arrival square, central park, children's park and main boulevard.

The core objectives of the public space design are the creation of a cohesive high quality green campus environment for the new hospital facilities and definition of a diverse range of well considered public spaces to establish an approachable and identifiable high quality character for this significant civic resource.

The new parkland campus environment is arranged around the hub of the arrival square, with clear and legible connections provided to all areas from this logical point of arrival.

This square functions as a transport hub as well as being a designed heart to the campus.

Within a short distance of the arrival point there is access to primary entrances, car parking, park and play areas, seating areas, the external cafe and public transport.



Clear Road Directory Signage

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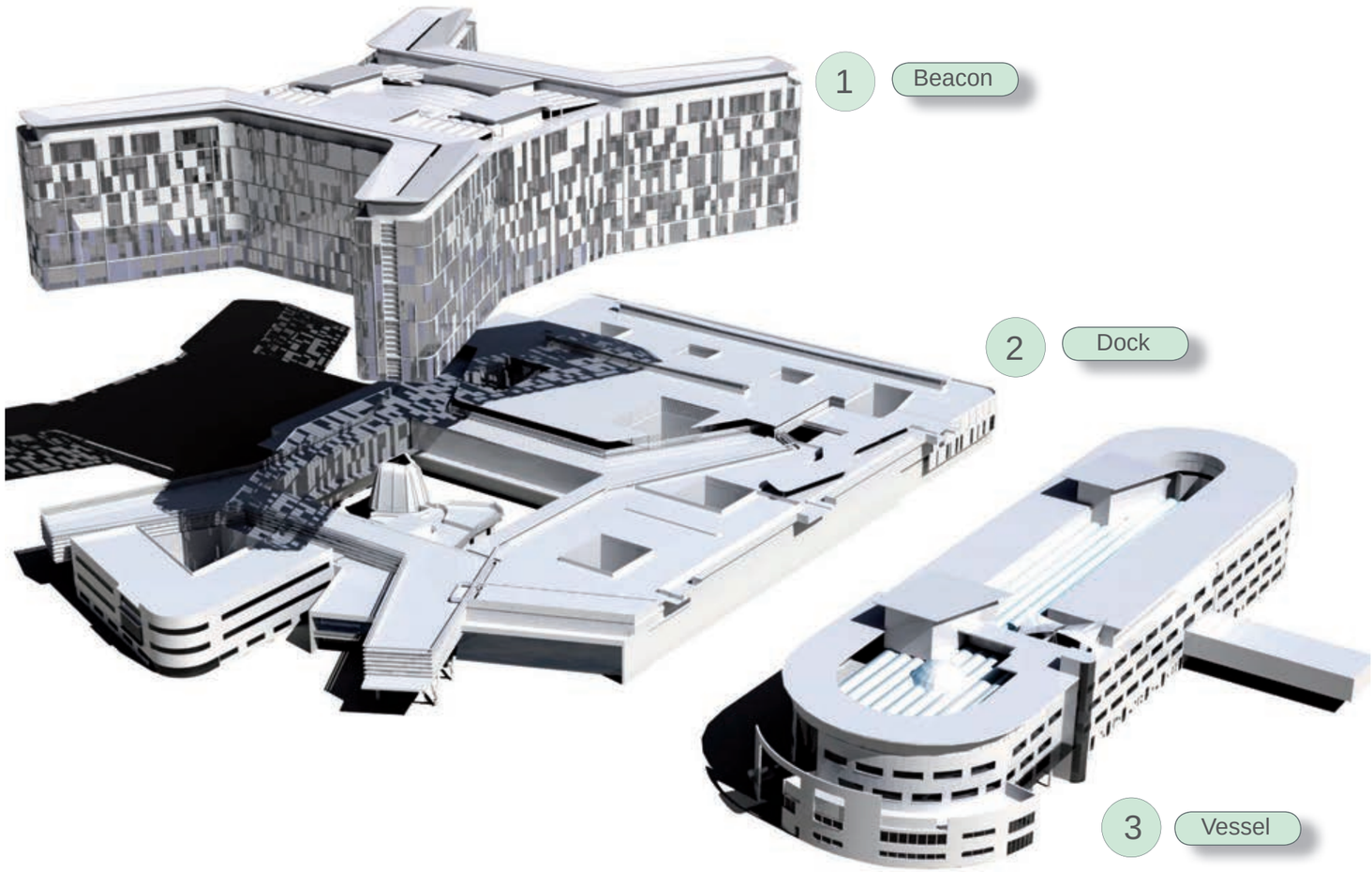
(3) Building Design & Central Theme

The design of the form of the buildings is a significant tool to aid wayfinding and make orientation as intuitive as possible.
The beacon character of the ward tower will create a local landmark. The form of the tower and its relationship with the arrival square provides a clear link between the form of the building seen from beyond the site and the journey to the main entrance.

The design of the New Children's Hospital is based upon the creation of a distinctive building within the site. The design provides this building with a unique identity and an appropriate character and this supports effective wayfinding. Elements of the building design, in the form of materials, colours and motifs are also to be used within the external environment and as a key to internal wayfinding.

The effectiveness of internal wayfinding is a driver for the design of the buildings and a wide range of operational movements are supported by the layout of the public and clinical areas and their relationships. Internal wayfinding is supported by a range of public art interventions which create a sense of place and identity within the buildings.



The Beacon or tower is reminiscent of a wharf building. The tower design also references the propeller of a boat.

The Podium, whilst taking visual cues from medical sources such as DNA also makes reference to the many fine Glasgow parks with its sensitive use of green & landscapes roofs and pockets of naturally lit courtyards.

The Childrens Hospital can be related to a vessel hugging the dock. It is treated as an independent form and references a range of influences including maritime, medical and even confectionary.

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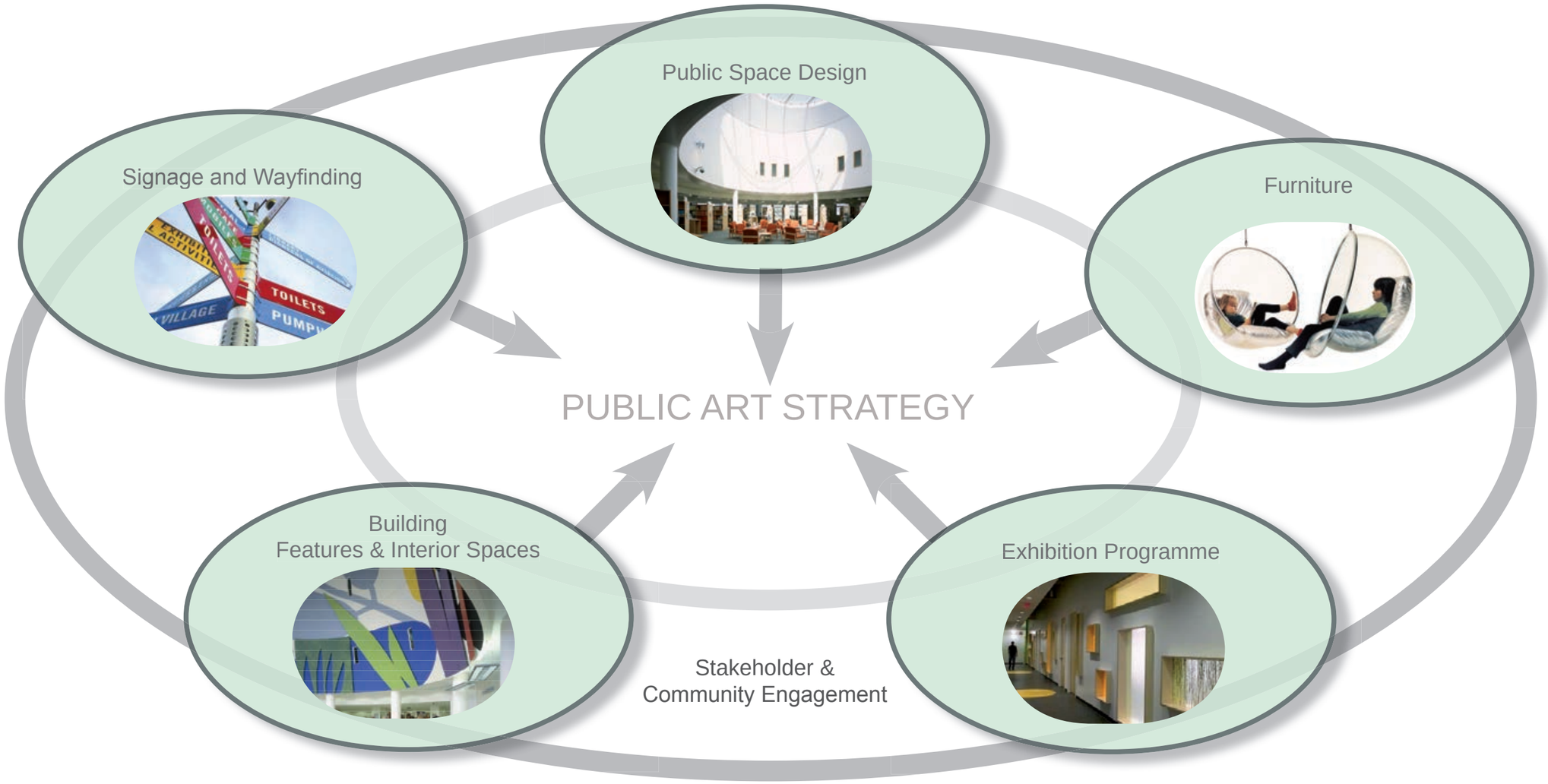
(4) Public Art

Public art will play a significant part in defining a distinctive character for the hospital and in creating an approachable centre of excellence. Creative expression is an established part of the design process which has already influenced the masterplan and the design of the external spaces. Creativity will add richness, colour and fun to the wayfinding process through the use of themes and motifs derived from community engagement.

The distinctive character of the New Children's Hospital offers particular opportunities for engagement with specific user groups and local schools to define a unique place with functional wayfinding elements developed as creative elements. Creative expressions within the design of the building fabric will create distinctive features which in turn are recognisable and create landmarks to aid orientation. Some examples which have been proposed include the main reception desks, structural elements and canopies within the building entrances, elevated coloured pods and lighting within the main atrium, creative design touches embedded within the design of ward rooms, external furniture and the design of internal walls. Signage will also be treated creatively and is intended to be defined with community input. Many of these proposals will be developed further during stage 2 when firm community engagement can be developed.



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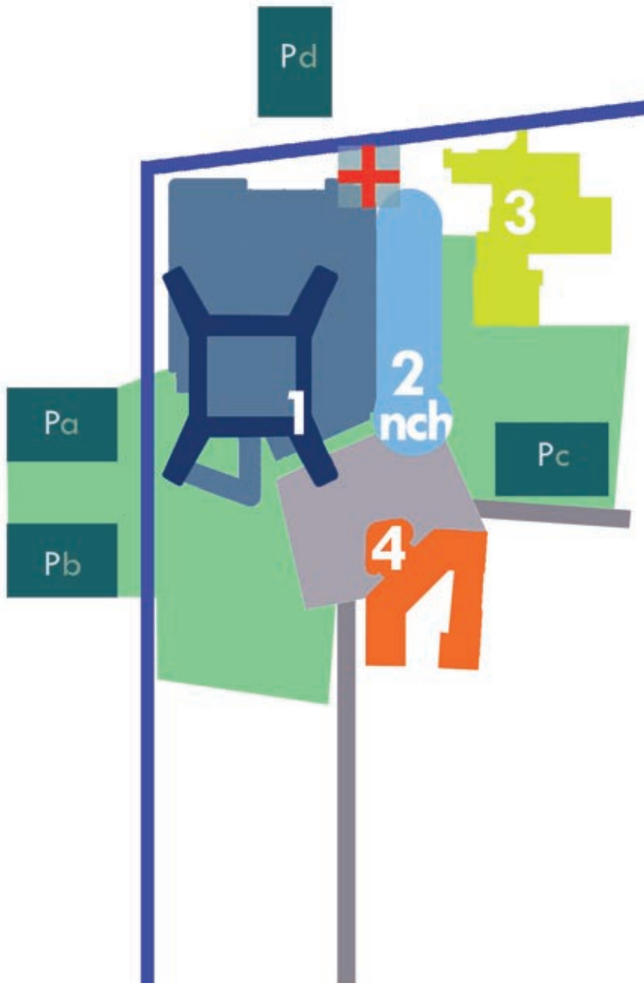
(5) Signage

There is a considerable overlap between public art and signage, but effective functional signage will also be provided to support the core functions of the hospital facilities.
This functional information will be supported by the creative use of colours, forms and imagery internally and externally and with specific regard to differentiating between different areas and moderating the significant scale of the hospital buildings.

The character of the wayfinding components has a big impact upon the quality and the feel of the environment. A legible place is much easier to use and this creates a better and more successful environment for staff and for visitors. The setting of the buildings, the use of colours and familiar forms communicates a favourable character for the hospital.

Example of Branding and Identity



Example of External Building Location Map

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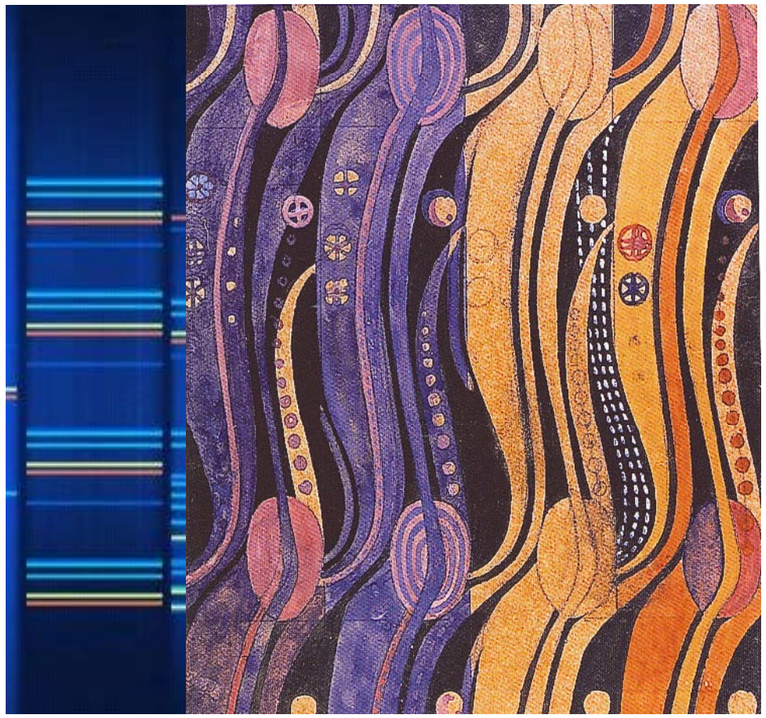
Design Inspiration For Wayfinding

The aim of the wayfinding and interior design strategy is to create a positive and therapeutic environment for patients, visitors and staff. This is achieved through careful consideration of materials, lighting, colours, art, views and space.

- **Materials** will be chosen carefully to offer a range of textures and hues to help create subtle back drops and a strong identity to each level and/ or department.
- **Lighting** not only provides general illumination to assist way finding and security but also highlights features and art.
- **Colour** is one of the key aspects used in the way finding strategy. Colour will also be used to help evoke feelings of calmness, tranquility, energy and healing in the appropriate spaces.
- **Views** link the inside of the building to the outside landscaping and surrounding area. A view from inside a room promotes wellbeing, helps locate people and brings in natural light. Views also provide wayfinding by informing people of their location relative to natural light via atrium space, courtyards and lightwells which occur in hospital streets and public spaces.
- **Spaces.** Throughout the building spaces range from intimately scaled rooms and zones to large public areas. Courtyards and large atrium spaces punctuate the main body of the building and draw daylight into key patient rooms and corridors.



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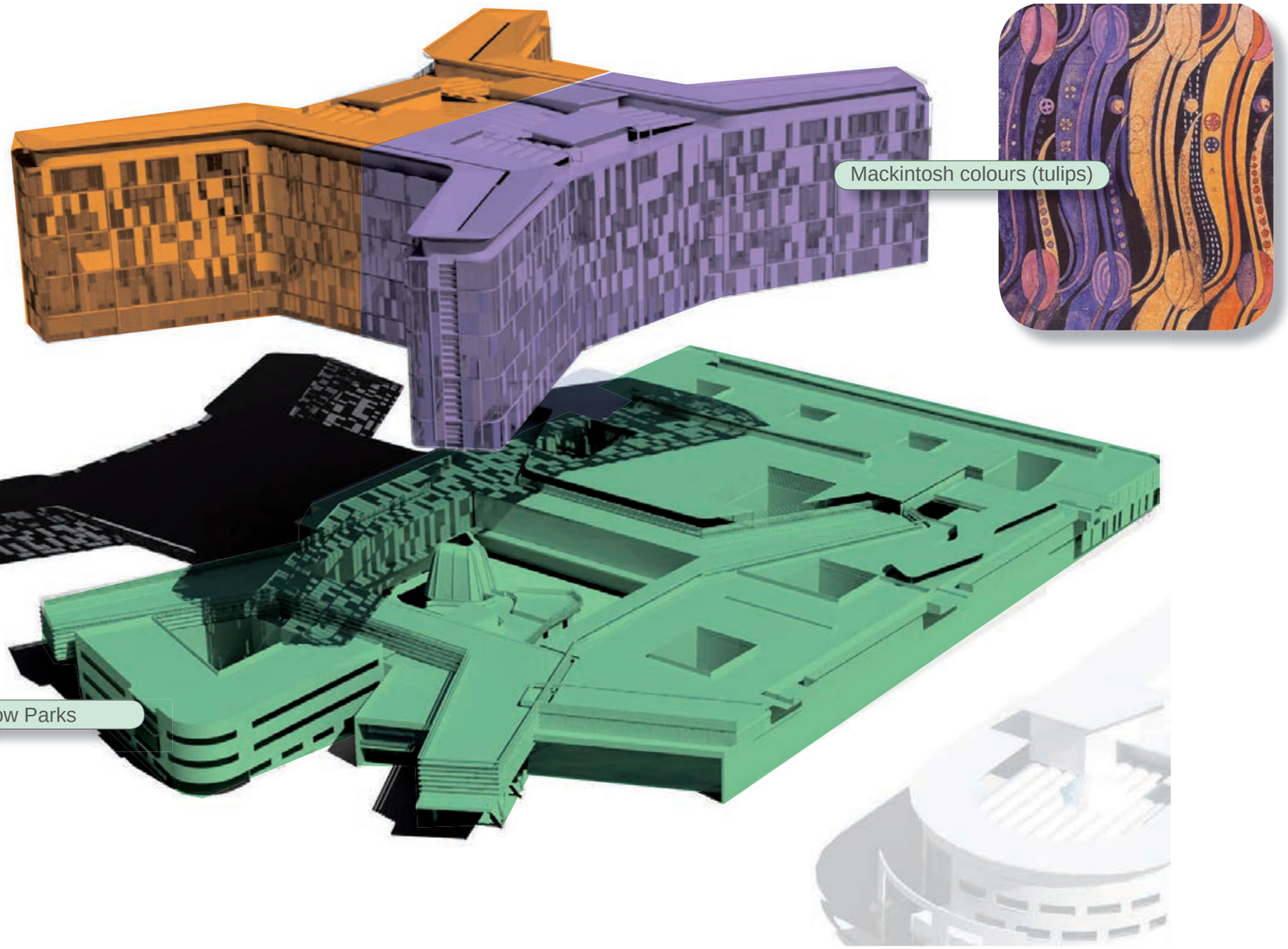
Internal Colour & themes - Adults

The Adult Acute Hospital based on the large dock buildings and the plan of the city and it's parks.

The colours that have been chosen for the internal zoning of the tower reflect those of Mackintosh's Tulips.
The colours for the Podium reflect that of the parks and landscapes of Glasgow.

The colours are carried out throughout each zone via interior design and wayfinding. The colours are also used externally drawing the outside into the building and form part of the way finding strategy.

Each inner public core of the building has it's own colour which can be easily identified. One orange core and one purple core.



Mackintosh colours (tulips)

Glasgow Parks

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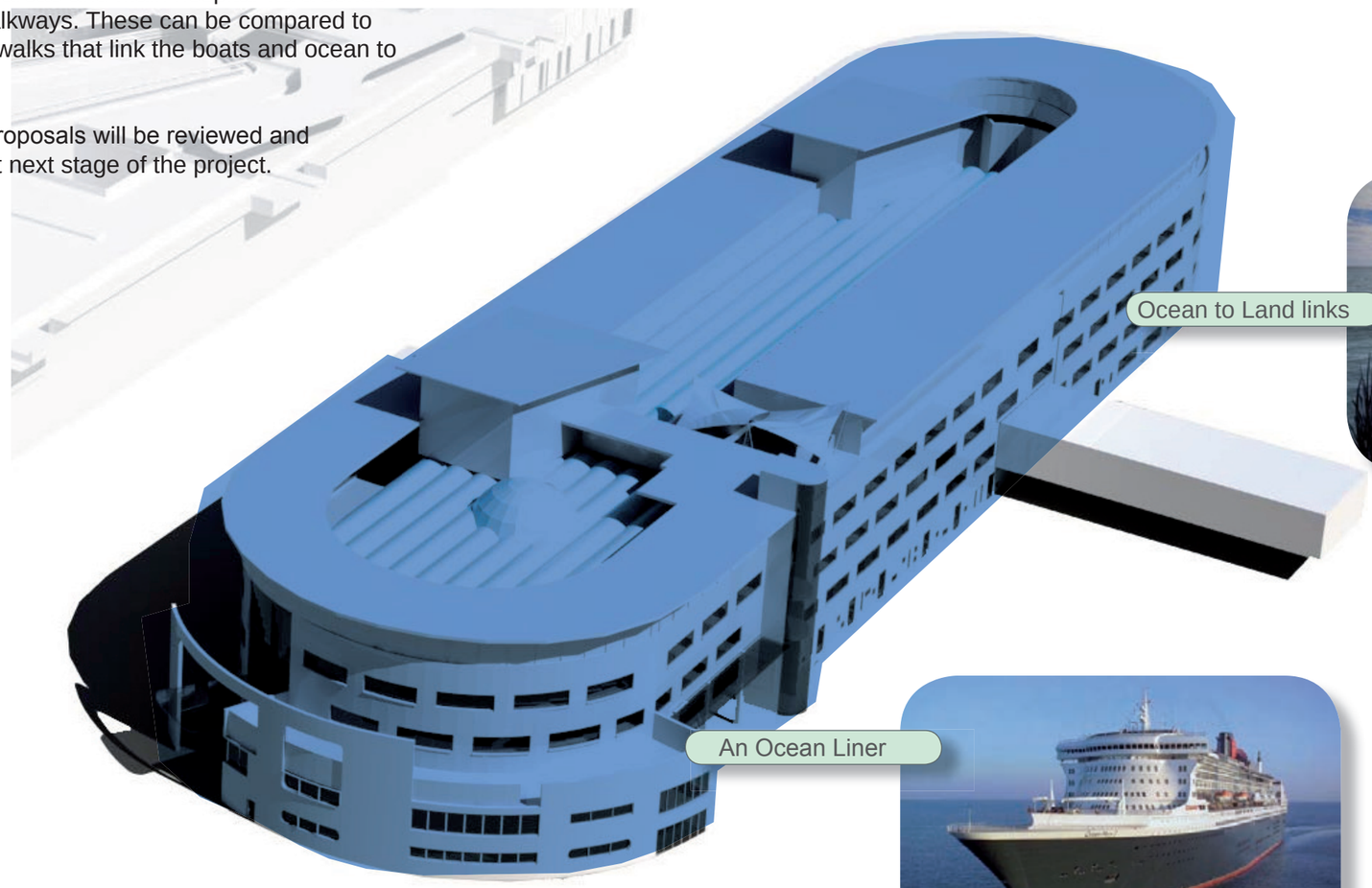
Internal Colour & themes - Childrens

The theme of the ocean, boats & Glasgow ship industries are carried through the interior of the building via the wayfinding colours: blues, whites and greys.

The childrens hospital is linked to the surrounding spaces eg. carparks, green areas and main hospital via a series link bridges and walkways. These can be compared to the piers and boardwalks that link the boats and ocean to the land.

These wayfinding proposals will be reviewed and developed further at next stage of the project.



Ocean to Land links

An Ocean Liner

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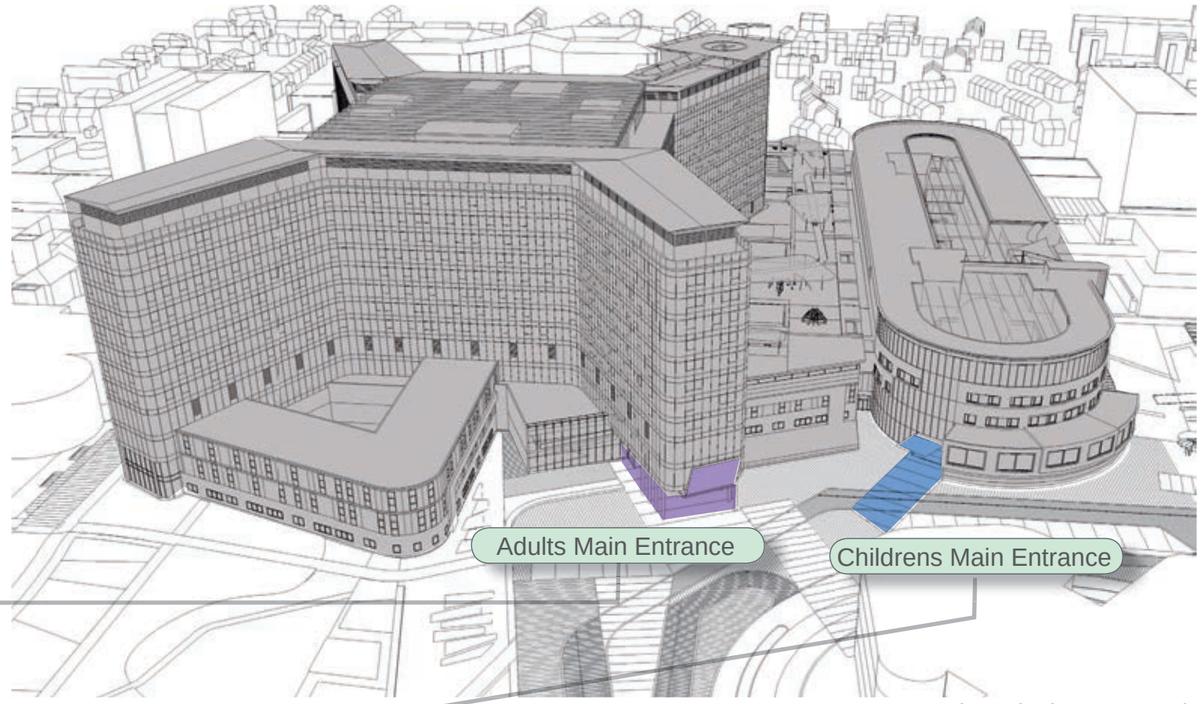
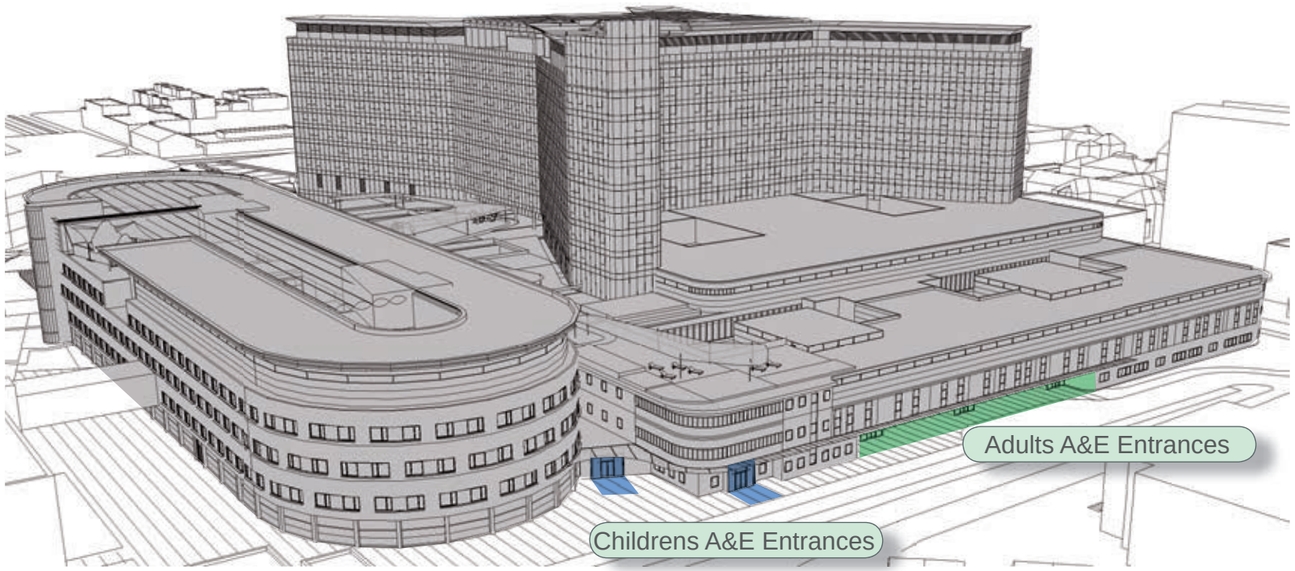
Building Entrances

There are 3 entrances to the building, the main adult hospital entrance, the main children's hospital entrance and the emergency centres entrance.

Each entrance has its own identity and will have clearly marked signage throughout the hospitals campus and on all main vehicle routes to the hospital.



Main Arrival Axonometric



Rear Emergency Access Axonometric

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Patient Journey - Generic

I need to visit the hospital. I have not been before.
What time do I need to arrive?
Which mode of transport shall I use to get there?
How long will each one take?
How much time should I allow for the journey?

I am unwell, so will be taken by a friend.
I have decided to travel by car. I know I can park at the hospital, but as I have not been before I do not know where to park.

I can see the hospital from a distance as it is a recognisable and distinctive landmark.
I can see the hospital from a distance as it is a recognisable and distinctive landmark. I can also follow the road signs.
Where is the entrance to the site? I follow the signs and the entrance is easy to find.
The hospital entrance is clearly visible from the entrance road. My friend follows signs to the entrance to drop me off at the front door.

We drive beside a park and the road is lined with lovely trees. Shadows flicker over the car. I enter through the adult hospital entrance.
I have noticed that buses also come to the front door, so I may come by bus next time.

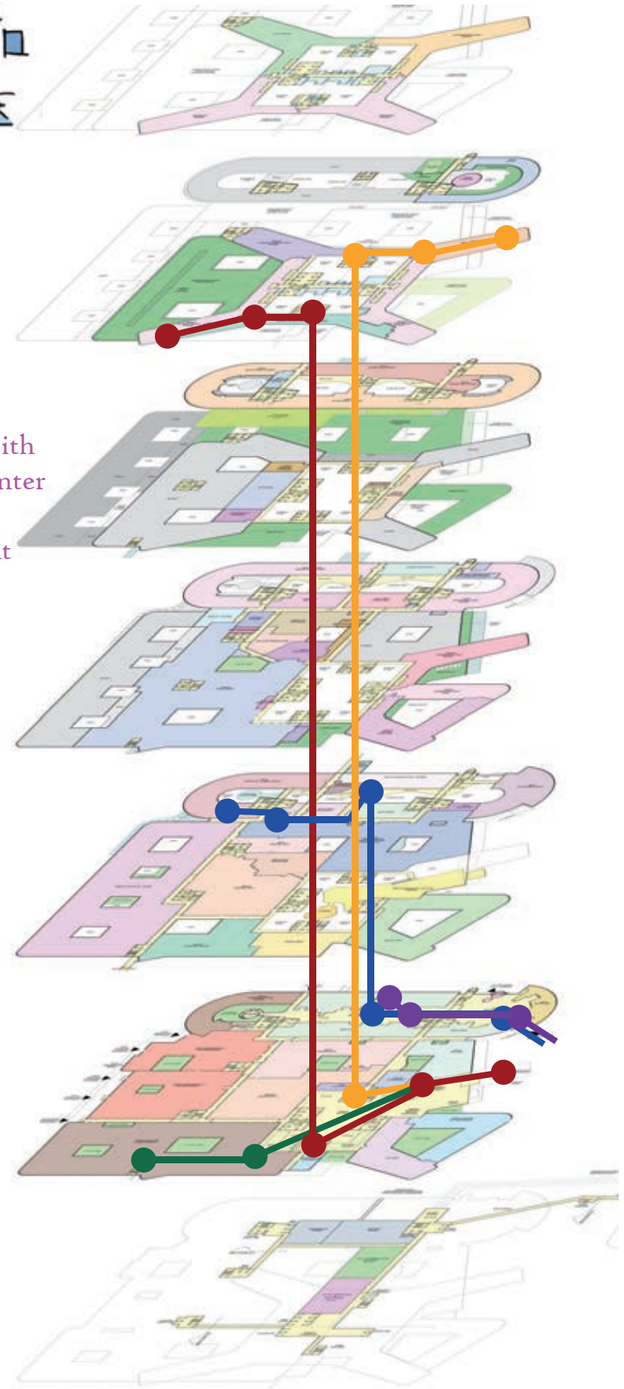
Inside the entrance there is a big reception desk and also signs to some of the main areas. The lifts are nice. They are different colours and the music is relaxing.

The hospital is a huge building. I have no idea what happens in all those rooms. The part that I am familiar with is a friendly place, with really colourful walls. There is always something different to look at on the walls.

After my treatment I am due to meet my friend in the café in the park (which we passed on the way to the main entrance). If it is raining we will meet in the café in the entrance area (the one in the big space with the coloured pods and interesting lights). I can look out of the window and watch people walking through the park.

I have dropped my friend at the front entrance to the hospital. In have helped her inside and I am now going to park my car. I can see the car park signs and the walking route from the car park to meet her goes through the park. I will wait for her in the café as I can see the new pictures from the local primary school. A couple of months ago my grandson painted a picture of me and it was displayed here for a while. I also prefer to wait here and enjoy the park on a nice day.

I need to visit A&E. There is a clear entrance for this and I can drive straight to the door. I can then park my car. I can see the signs to direct me to accident and emergency



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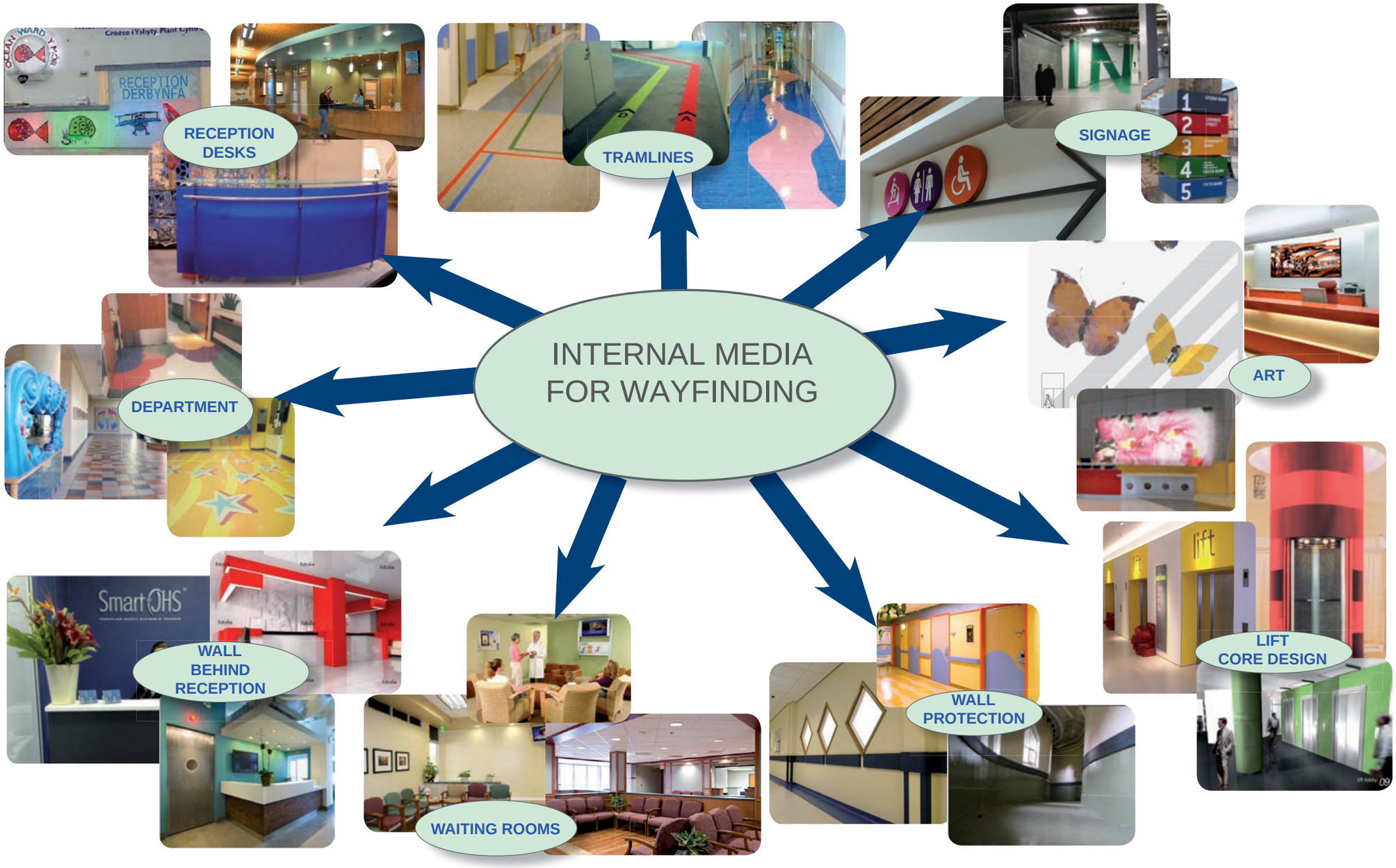
How Art, Interior Design and Signage is incorporated in Wayfinding



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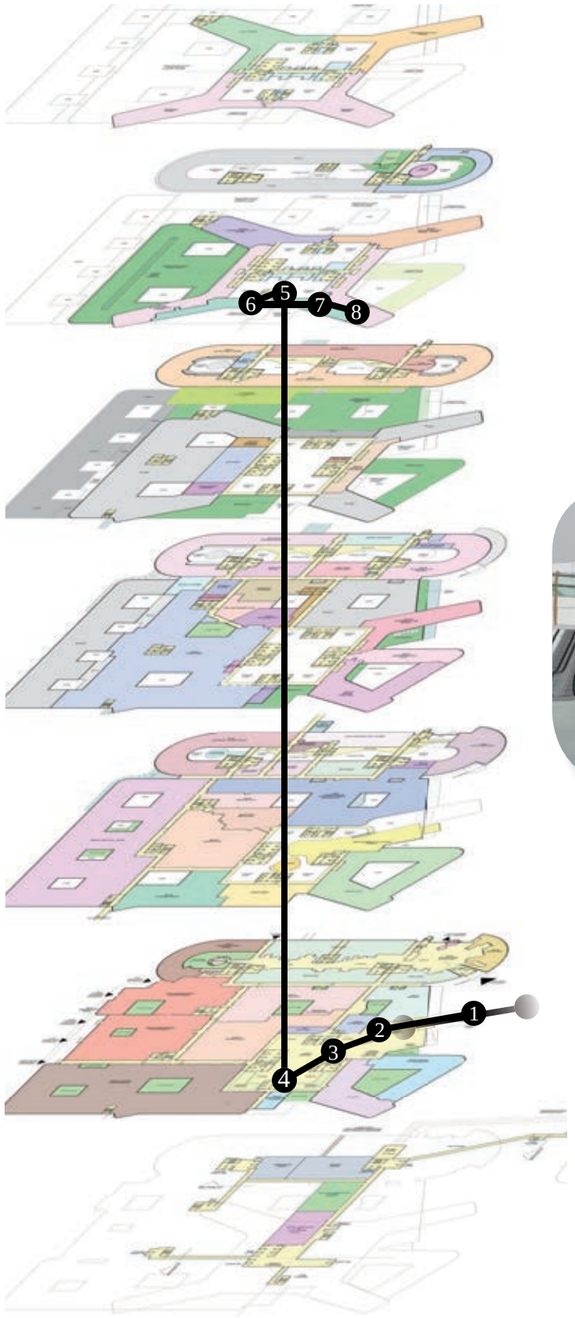
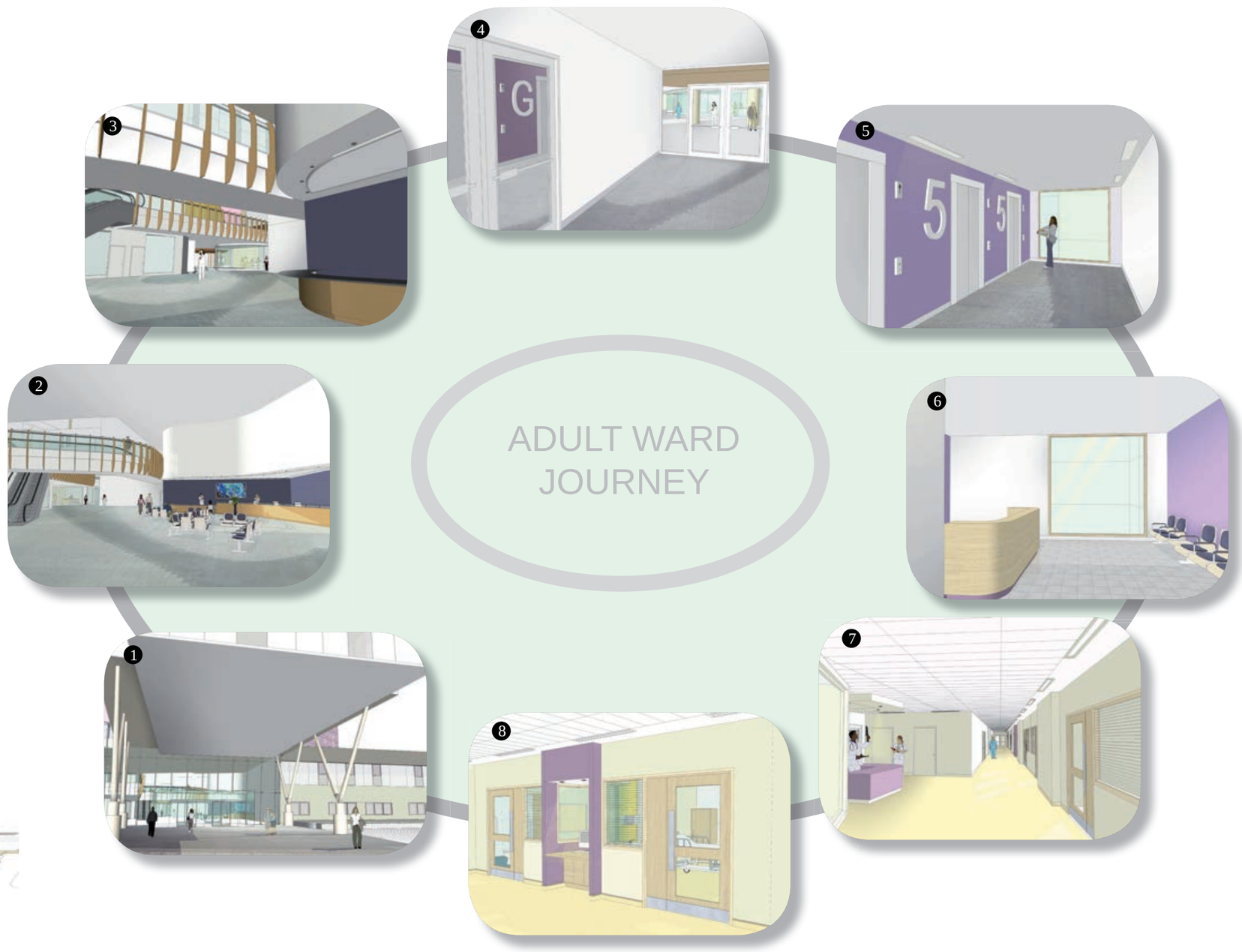
Patient Journey 1 - Adult Ward





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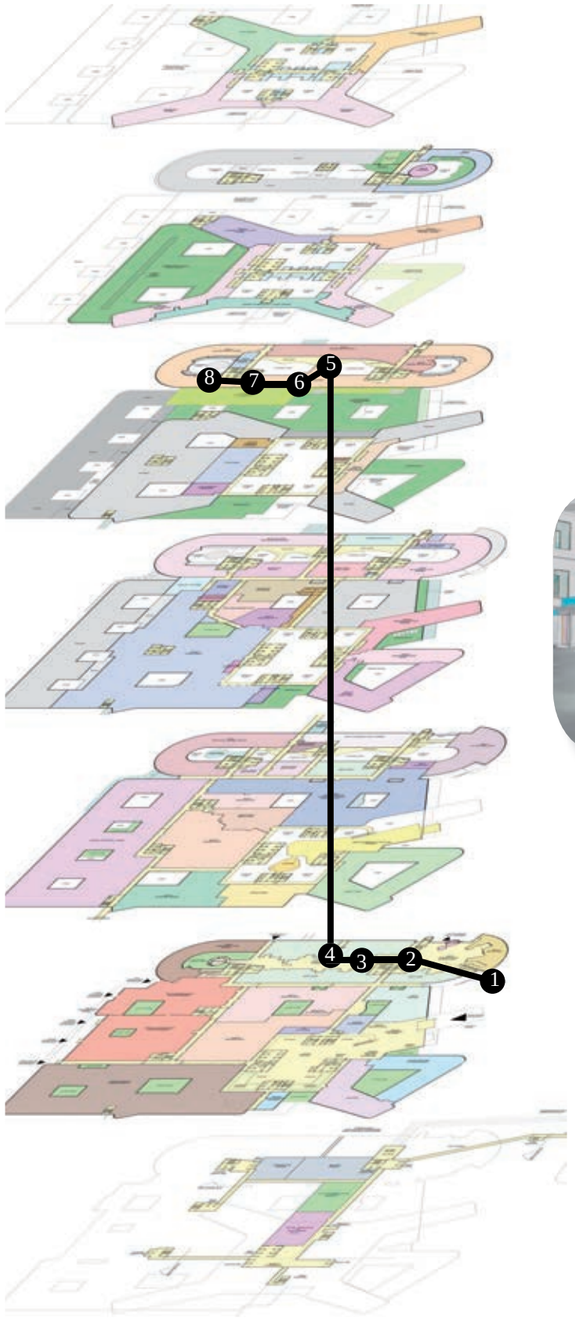
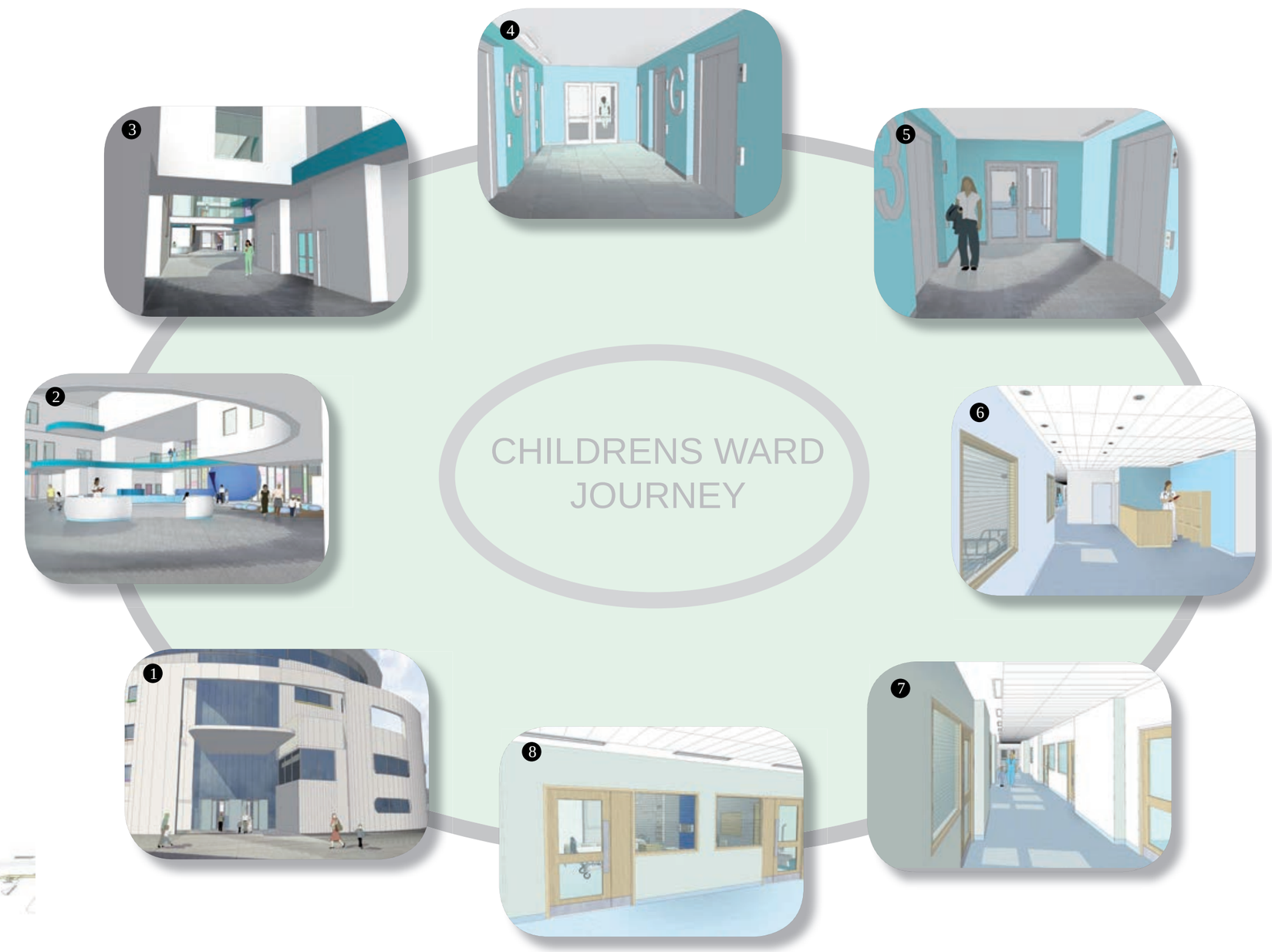
Patient Journey 2 - Childrens Ward





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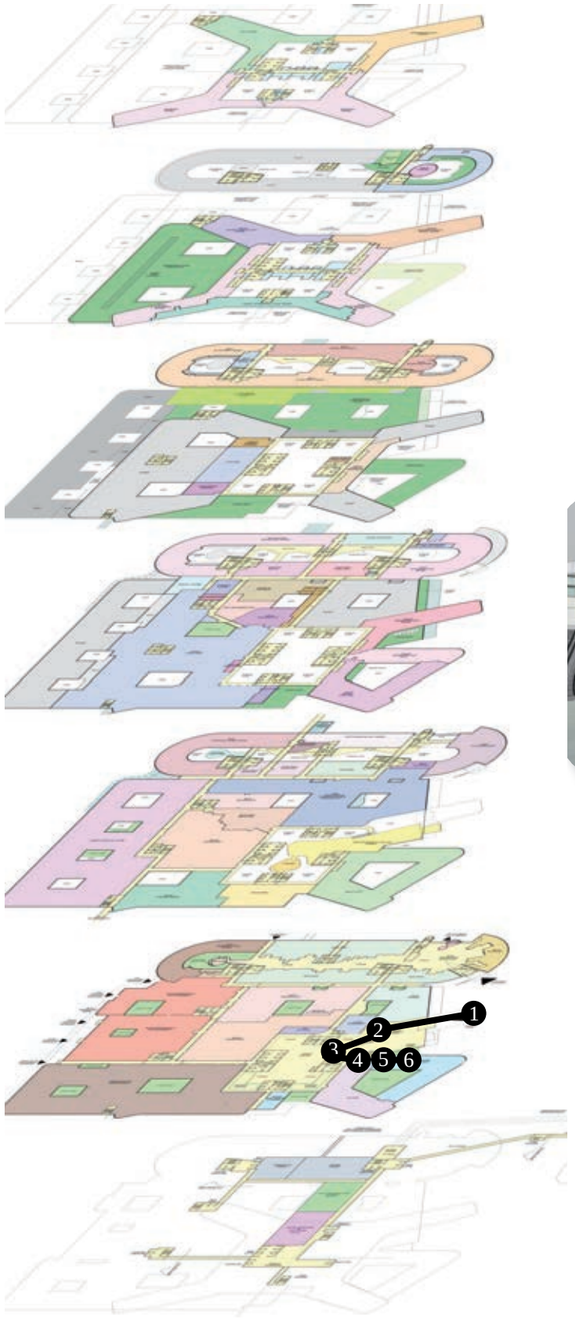
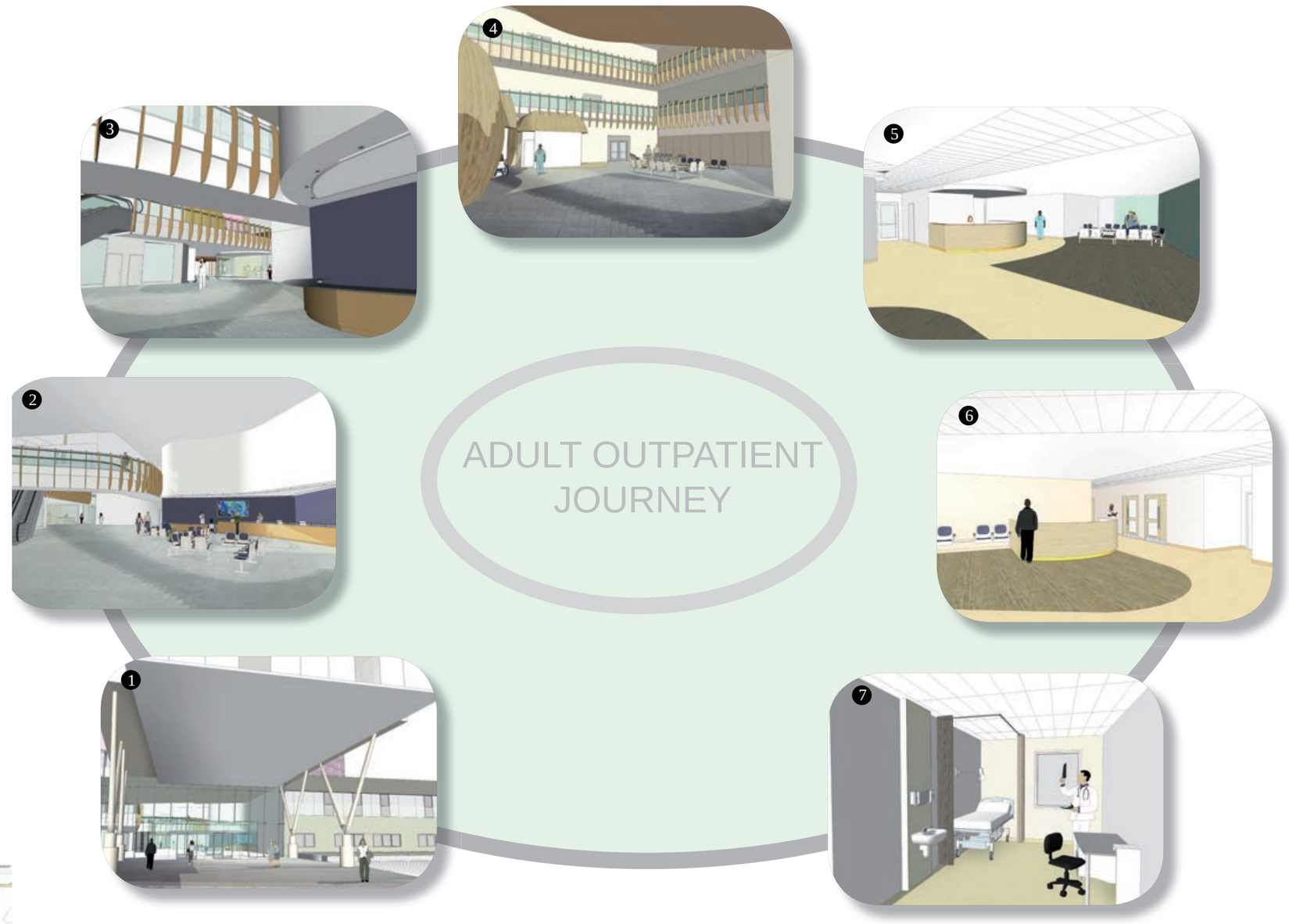
Patient Journey 3 - Adult Outpatients





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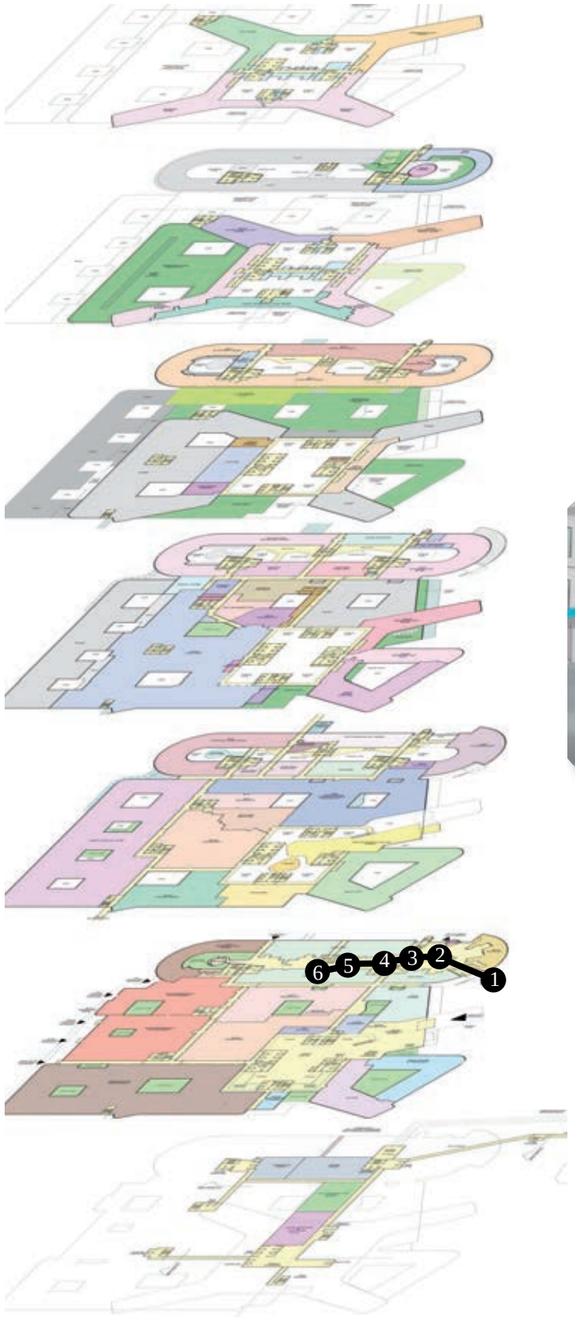
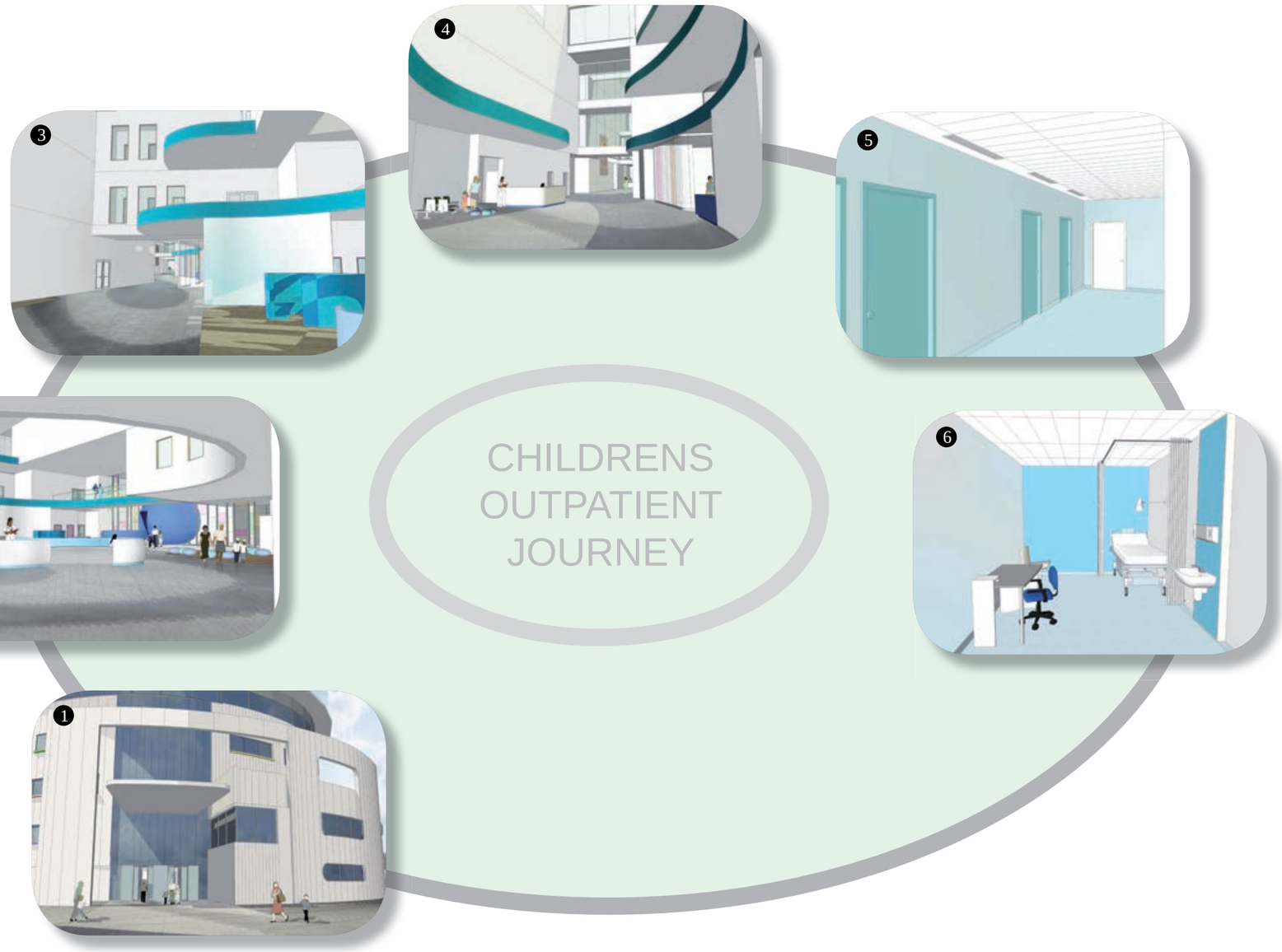
Patient Journey 4 - Childrens Outpatients





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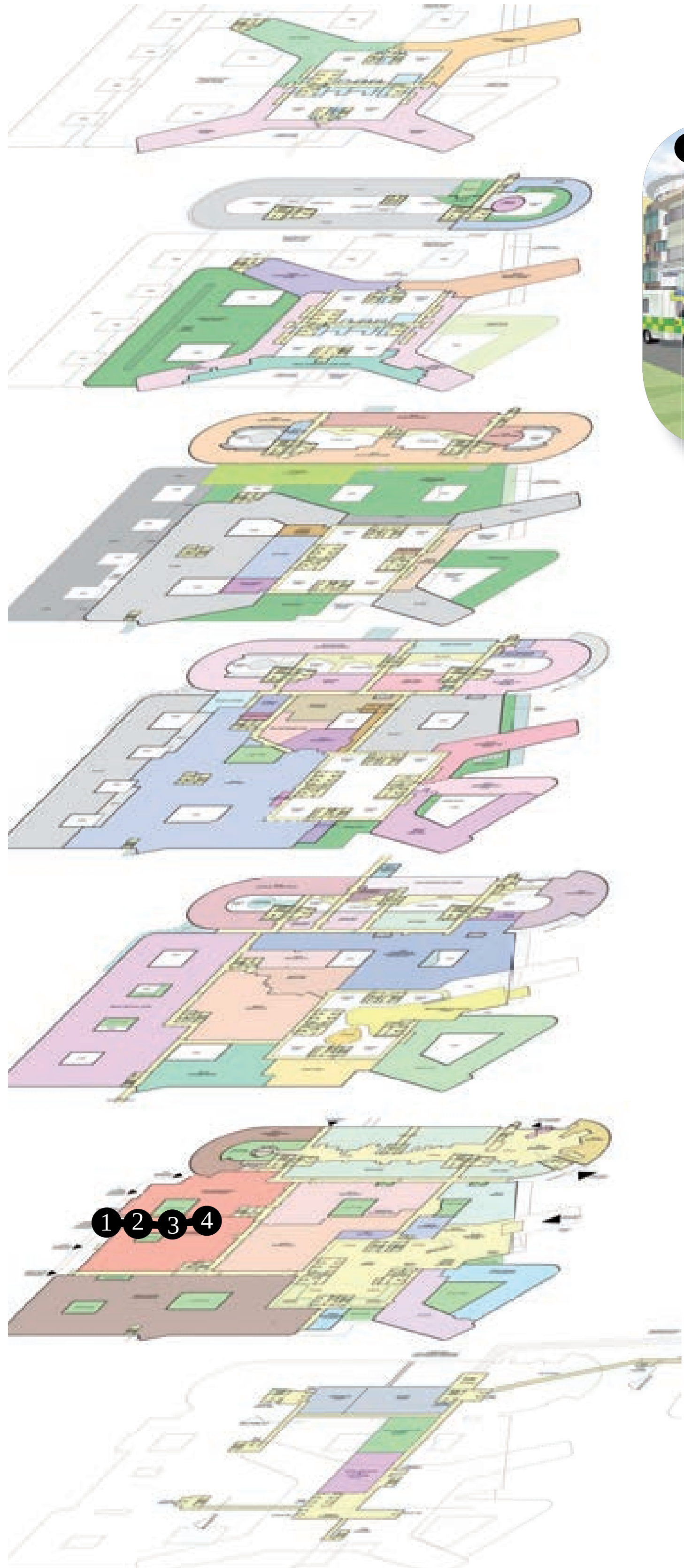
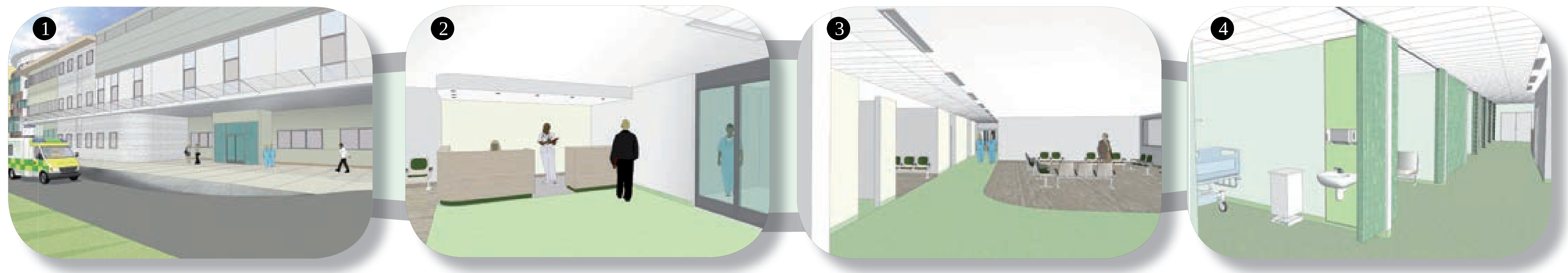
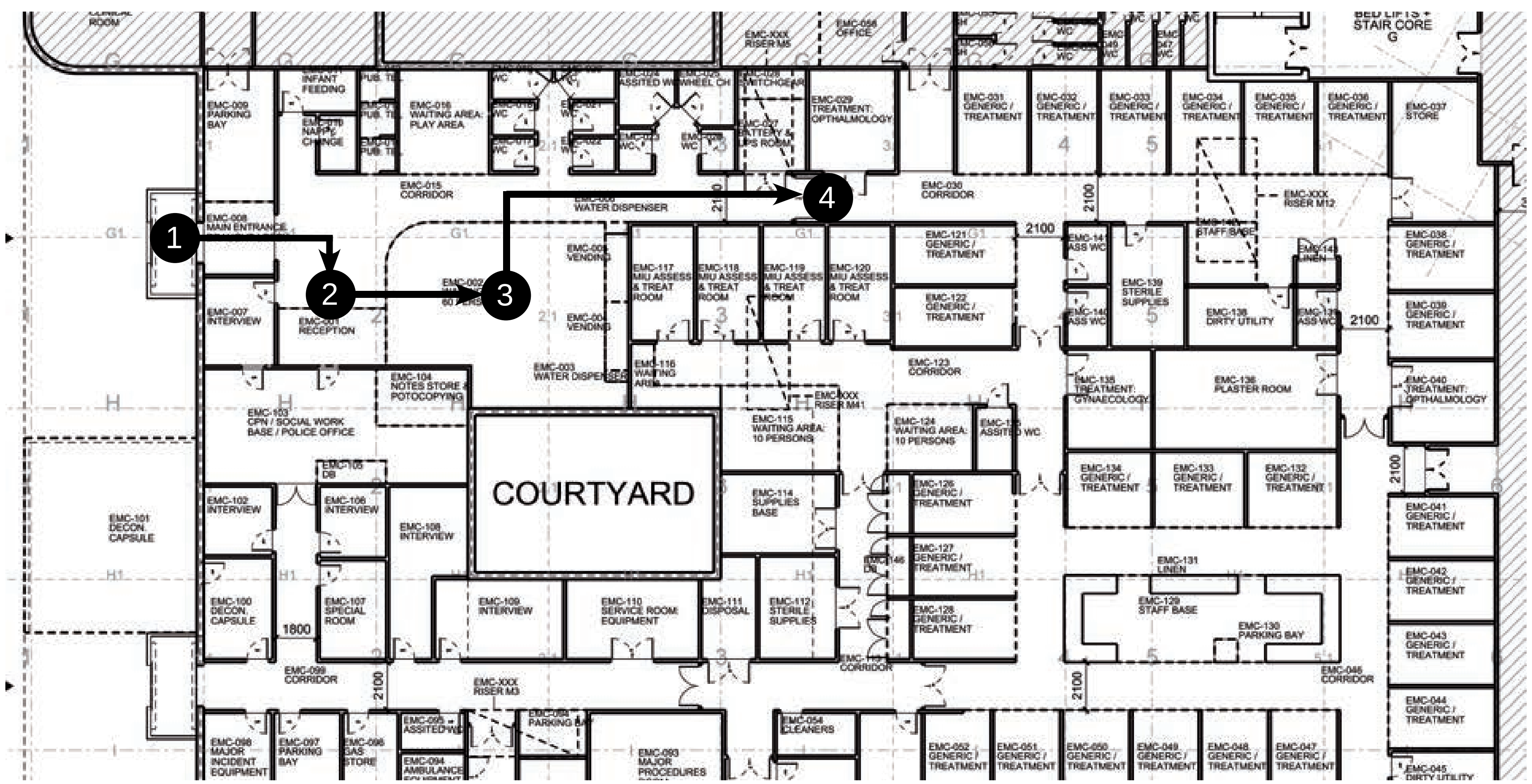
Patient Journey 5 - Adult Accident and Emergency







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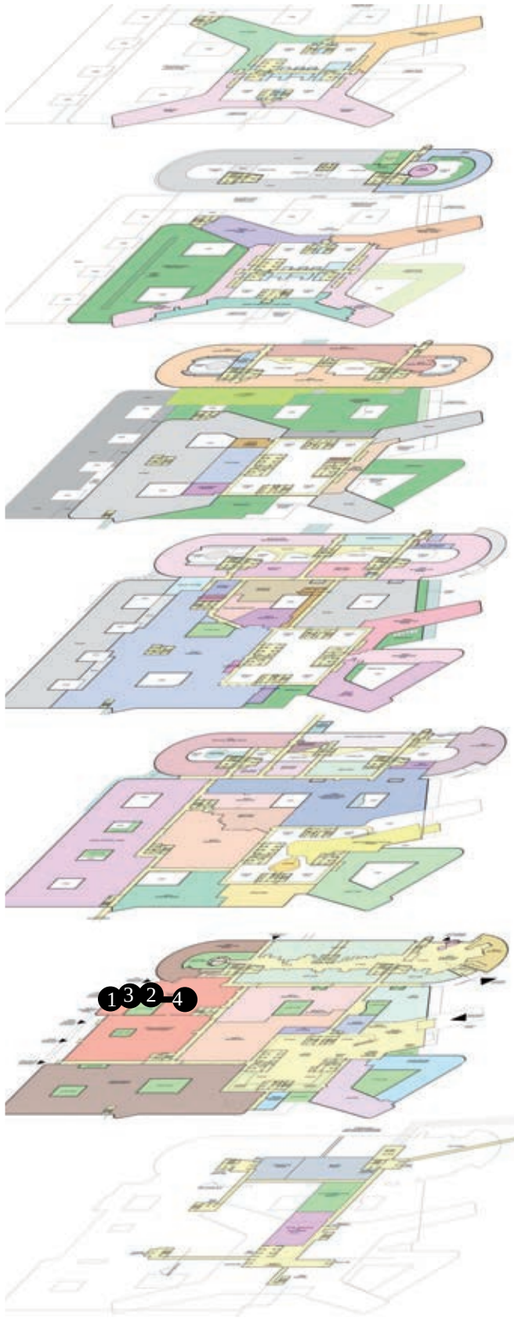
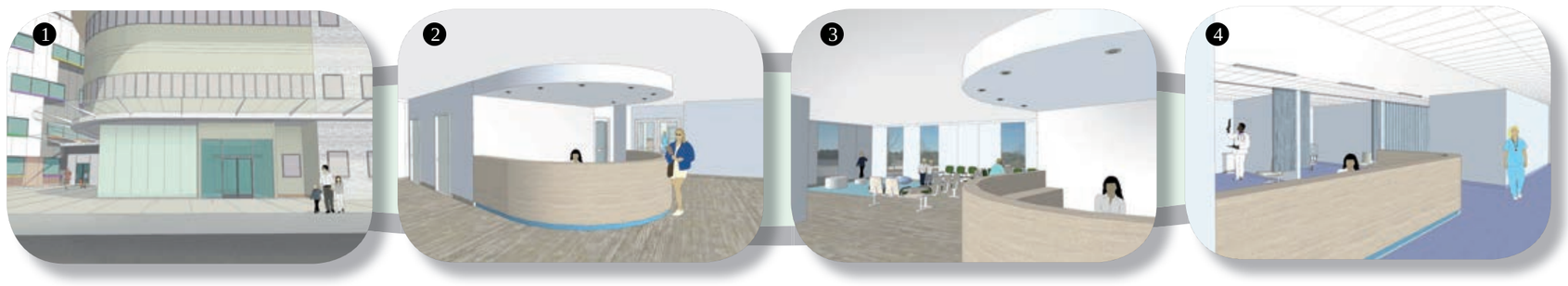
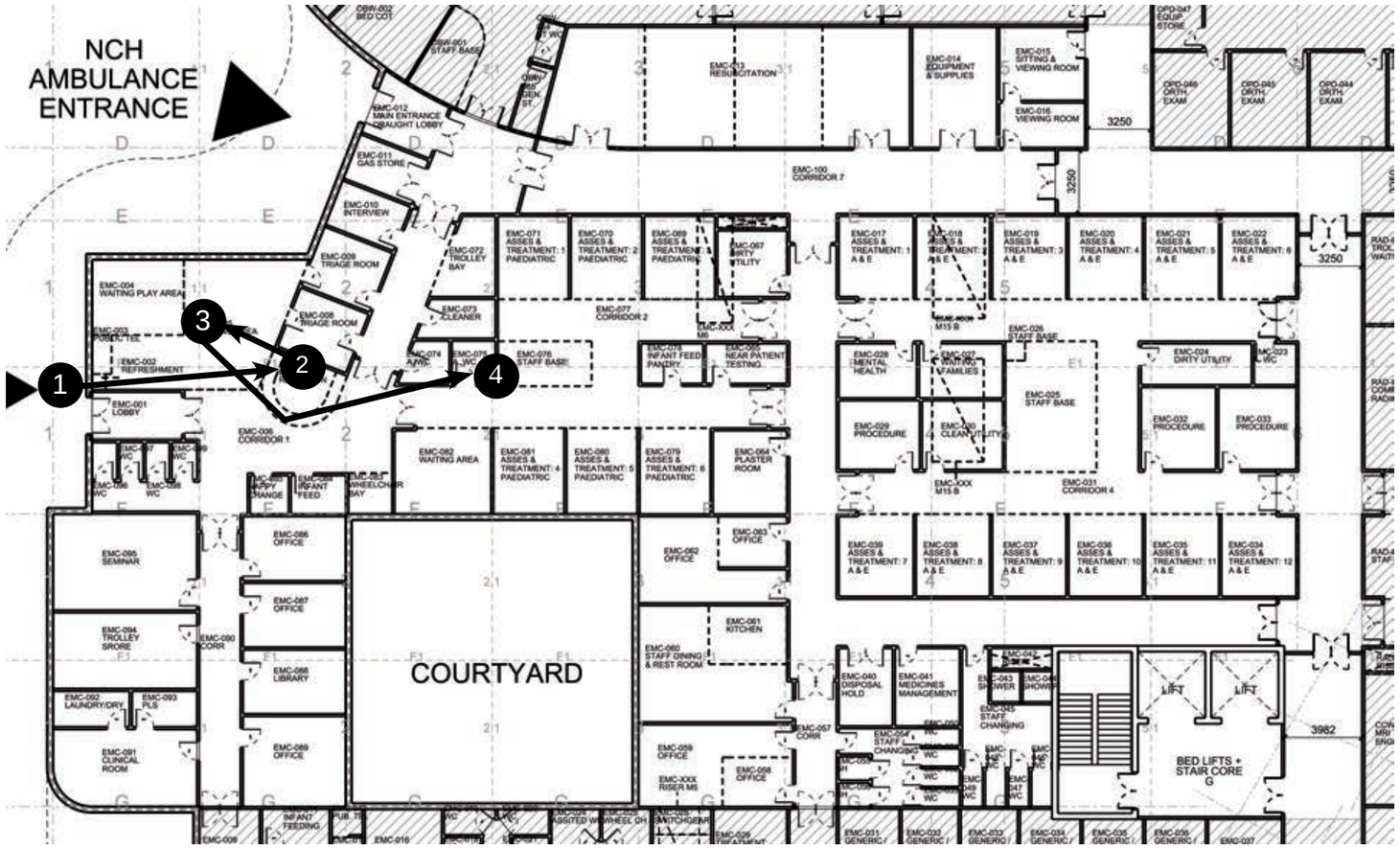
Patient Journey 6 - Childrens Accident and Emergency







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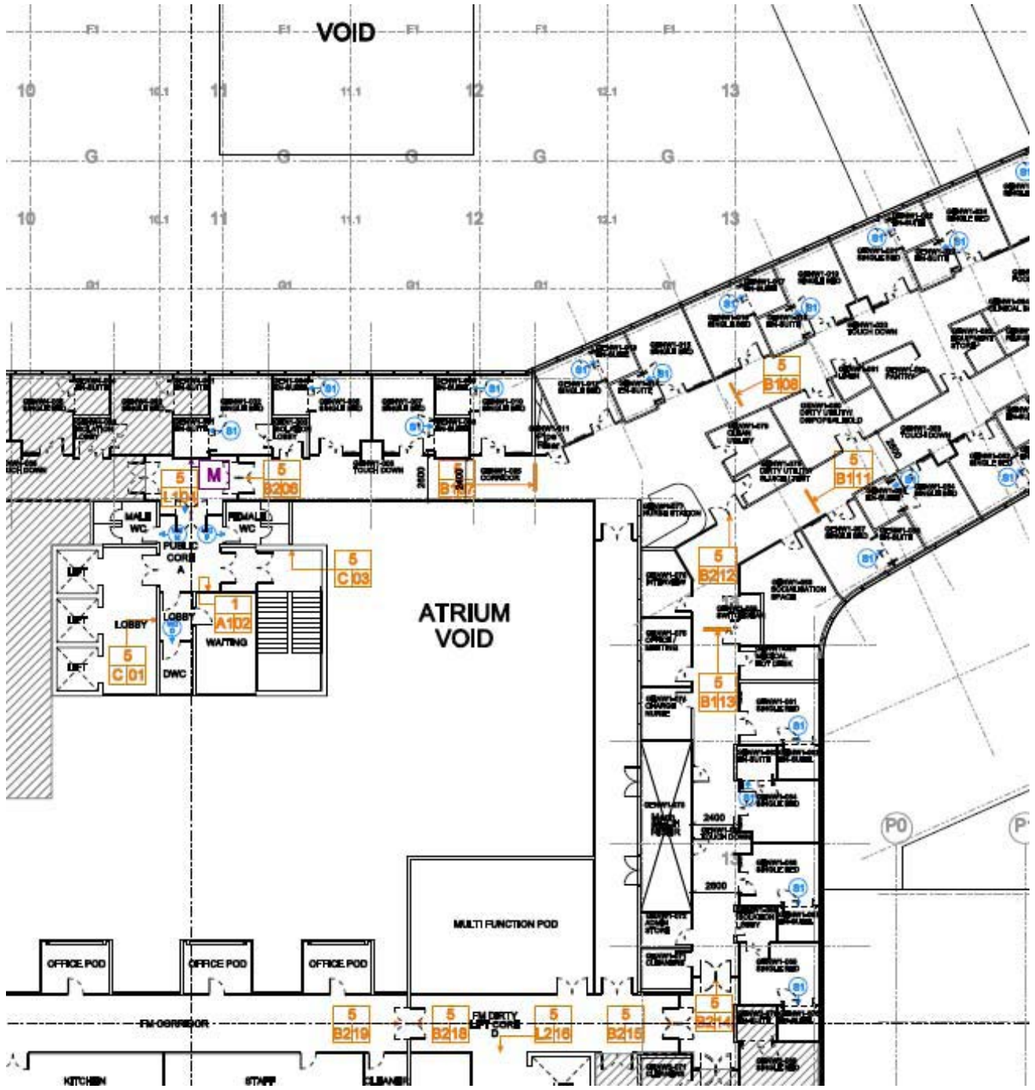
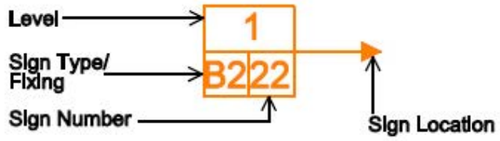
Wayfinding Signage Key and Drawings



The way finding drawings indicate signage types and locations for orientation maps

WAY FINDING SIGNAGE AND PUBLIC INFORMATION SYMBOL KEY



TYPE A - DIRECTORY SIGNAGE

- **A** - Main A to Z building directory, wall mounted
- **A1** - Floor level directory, wall mounted
- **A2** - Floor Level directory, free standing

TYPE B - DIRECTIONAL SIGNAGE

- **B** - wall mounted
- **B1** - suspended from ceiling
- **B2** - wall mounted above door
- **B3** - free standing
- **B4** - projecting away from wall

TYPE C - LOCATION SIGNAGE

- **C** - wall mounted
- **C1** - suspended from ceiling
- **C2** - sign projecting away from wall
- **R** - Reception Sign, wall mounted

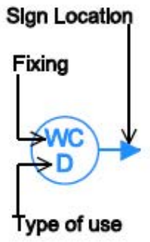
TYPE E - SUPERGRAPHICS

- **E** - wall adhered
- **E1** - suspended

TYPE L - LIFT AND/ OR STAIR CORE SIGNAGE

- **L** - wall mounted
- **L1** - suspended from ceiling
- **L2** - projecting from wall

SANITARY FACILITY SIGNAGE



TYPE OF FIXING (top letter)

- **WC** - fixed to door
- **WCS** - Staff only, fixed to door
- **WC1** - suspended from ceiling
- **WC2** - projecting from wall

TYPE OF USE Pictograms (lower letter)

- **M** - Male
- **F** - Female
- **MF** - Male & Female
- **D** - Disabled

ROOM

- **S** - Shower
- **F** - Baby Feed
- **N** - Nappy Change

FIXING

- **1** - Fixed to door
- **2** - Projecting away from wall above door

YOU ARE HERE MAPS

- **M** - level plan, showing current position
- freestanding or wall mounted
- Interactive In entrance foyers

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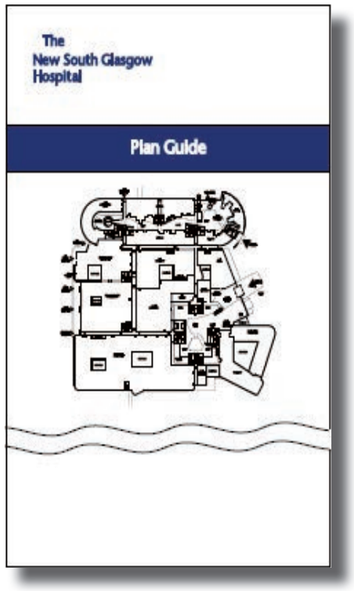
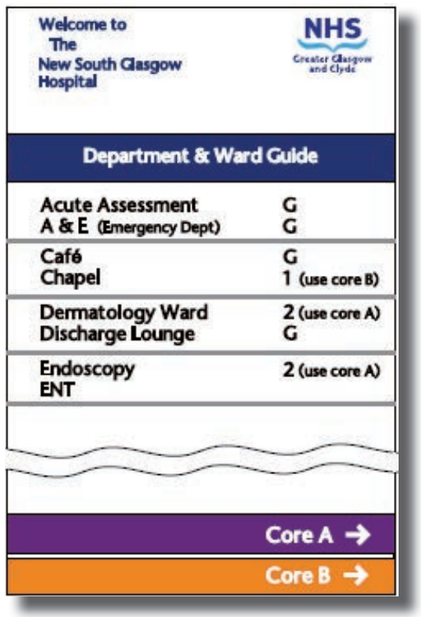
Proposed Internal Signage Examples - Adult

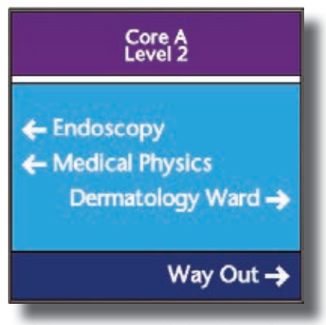
Sign Type A - Directory Signage & Maps





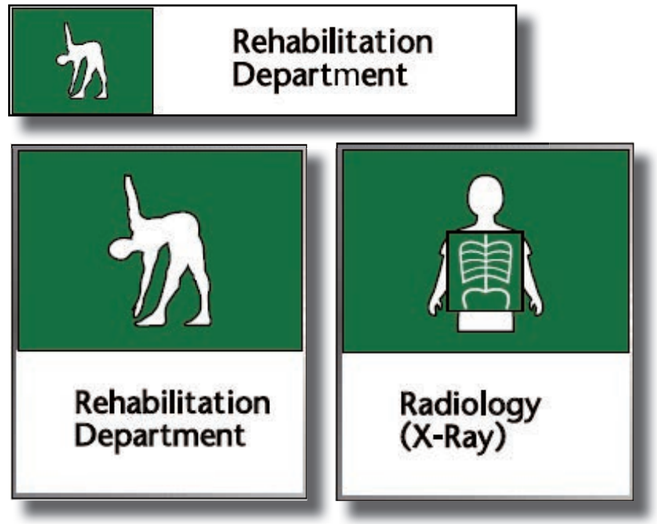
Sign Type B - Directional Signage

Black text white background
(Employer's requirements option)



White text on light blue background
(Compliant with NHS Scotland Signage Guidance)

Sign Type C - Location Signage



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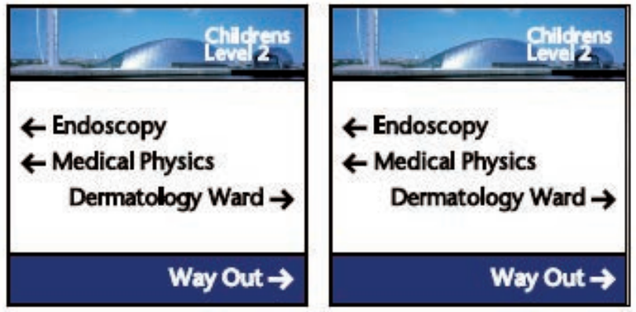
Proposed Internal Signage Examples - Childrens

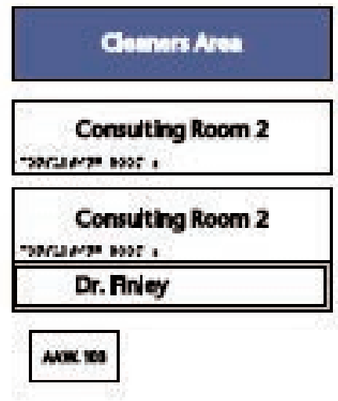
Sign Type B - Directional Signage



Sign Type C - Location Signage

Sign Type E - Supergraphics

Door Signage



We propose a mix of block colours and simple Pictograms to be used in the wayfinding strategy of the New Children's Hospital.

This approach allows for a child friendly though none patronising environment and scheme, and provides a strong base for the pictograms colour range and feel

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Proposed External Pedestrian & Vehicle Signage Examples

Signage Design in line with NHS Scotland Guidance

Signage Design in line with NHS Scotland Guidance

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Masterplan External Wayfinding Strategy & Interactive Information Points

Interactive Information Points
wall mounted and/or freestanding

2D Intelligent wayfinding technology which offers a choice of agreed languages. Department/Ward list in A-Z format appears in preferred language on request and the department route highlighted on a ground floor plan from the location of specific pod being used when touch screen is activated. (The plan on screen will be identical to the plan on the main A-Z wayfinding guide for continuity). The highlighting will indicate either the route to a department if on ground level or to lift/stair core if on upper floor. If upper floor is requested then the appropriate floor will superimpose on the screen indicating use of lift/stair, and then the final destination is highlighted on the upper level plan.

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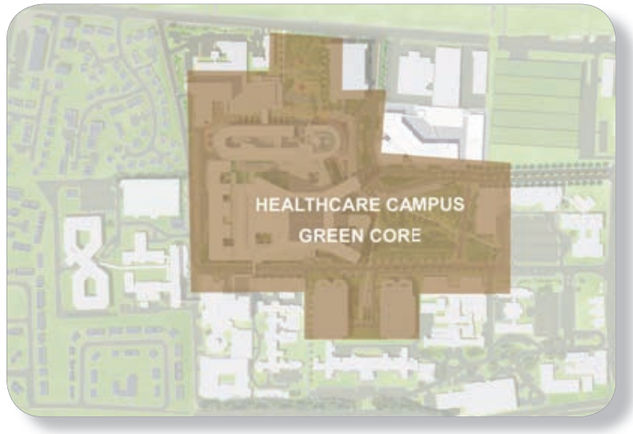
Wayfinding & Identity

Wayfinding is greatly assisted by the creation of identifiable features within the hospital campus as an aid to orientation. For this reason the integrated design process - from the initial masterplanning stage to the more considered design of the architecture, public spaces and external areas - has defined a strong and durable identity for the campus and the various built elements, spaces and places. These identities are considered further in the architectural design strategy.

This approach immediately gives specific identities to physical places within the campus. The large campus environment of the New South Glasgow Hospitals can then be understood as an identifiable whole, consisting of a series of smaller places. This clear hierarchy delivers significant benefits for wayfinding as well as giving a strong sense of place to the hospital.

The same identity principles apply within the hospital buildings and further architectural design features and public art will be used to articulate the character and identity of interior spaces.

A hierarchy of placemaking and identity has been defined to enable the form of the campus to be clearly understood as an aid to wayfinding. The hierarchy is summarised as follows and illustrated on the accompanying plans:



The New South Glasgow Hospitals – whole campus

The creation of a strong campus identity with a green heart has been defined to unify the retained areas of the site with the new buildings. This single healthcare campus will evolve and develop over time and the establishment of strong green infrastructure in the form of approachable public parks and incidental spaces is intended to establish ‘design for the future’. Design for the future has been a significant consideration in the design process to date and during stage 2.

To make the significant scale and potential complexity of the site legible further areas have been defined to simplify understanding of the place through the creation of internal areas with an equally strong identity

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Acute Hospital

The tower presents a strong regional landmark for the new acute hospital facilities and this building is strongly associated with the central park as its setting. The tower has been designed to establish a clear contrast with the Children's hospital. The main hospital entrance addresses the arrival square and the tower is primary landmark within the sequence of three key buildings.

Children's Hospital

The new children's hospital has a unique identity derived from the architectural design. The masterplan and the design of the external spaces have also defined a specific environment as the setting for the new children's hospital, thereby creating a strong identity which will be augmented by a naming strategy for key streets and spaces. The setting for the Children's hospital encompasses maternity and neo-natal services to create a meaningful heart for the provision of exemplary services for children and young people focussed around the children's park and the connecting street. There is a strong connection between internal and external public spaces.

The creation of identifiable places will serve to create a user-friendly and personal feel to the campus. Descriptions applied to journeys can include defined places, such as 'Lollipop Lane' and 'Central Square'. Places within the campus provide identifiable landmarks at a human scale and this process will be augmented by additional wayfinding components and public art.

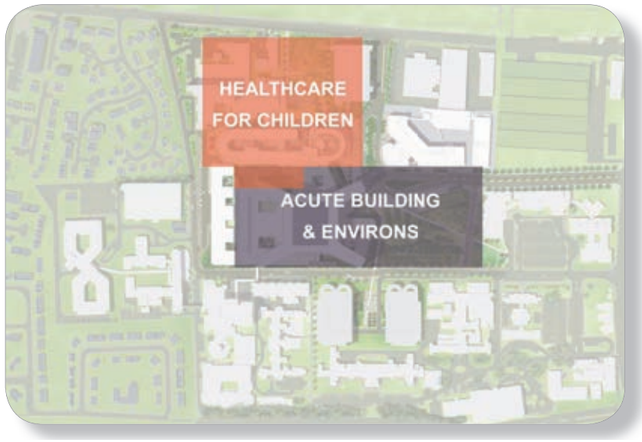
The creation of an identifiable personality for the scheme is an important step in communicating an approachable character for the project.

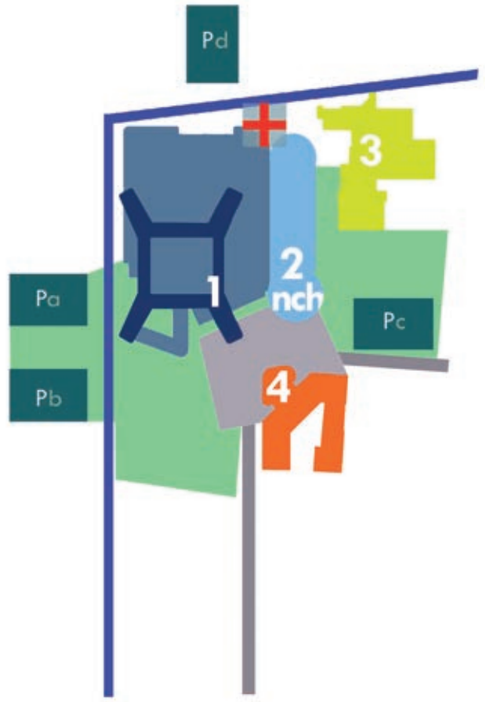
First tier identity – New South Glasgow Hospitals Healthcare Campus
Second Tier Identity – Differentiation between Acute & Children's Areas
Streets and smaller places – Parks, streets and public spaces

Some of the key identifiable public places within the campus are as follows:

Arrival Square
Central Park
Children's Park
Entrance Boulevard
Lollipop Lane

Names for each of these key areas are to be considered as part of the stakeholder engagement during stage 2.





Art and Therapeutic Design Strategy

Vision

The aim of this strategy is to outline the vision and identify the guiding principles for the role of art within the new South Glasgow Hospitals that Brookfield would like to develop in conjunction with the Board.

The Board wishes to introduce an art and therapeutic design strategy for the benefit of patients, staff, visitors and the local community. The programme will use art and design to de-institutionalise and energise the hospital environment, creating a sense of place, culture and identity.

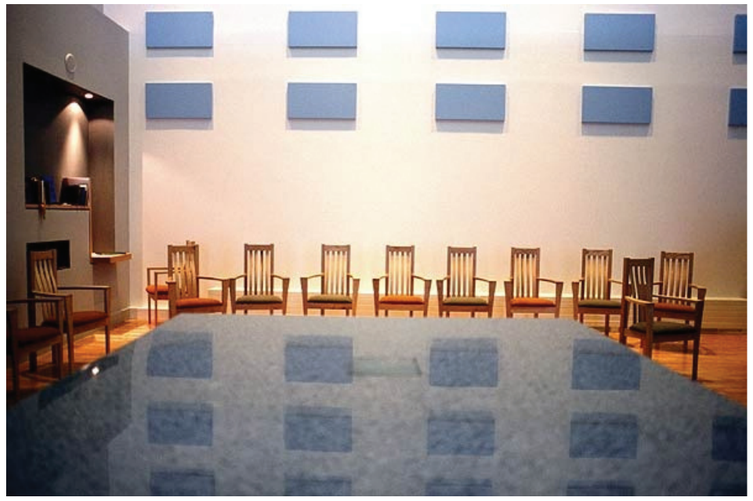
This section provides a strategic context for the relevance, expectations and outcomes of artists' work within the new hospital environment. Developed without a working process with surrounding communities it should be seen a starting point for an arts development process and it would be expected that a further developed strategy and commissioning framework will be produced during Stage 2 that will be able to specifically respond to the working environment and ambitions of the Board.

The main ambitions for the art programme are to:

- help create a positive healing environment in the hospitals' clinical and non-clinical areas
- aid the physical and emotional recovery process
- provide aesthetic enhancement to the hospital environment
- meet the spiritual and emotional needs of patients, staff and visitors
- personalise and de-institutionalise the experience of visiting and staying in hospital
- strengthen the relationship between internal and external spaces
- celebrate and support the hospital's strong cultural relationship with the surrounding community
- increase access for the public to experience high quality contemporary art, craft and design
- enhance the prestige and reputation of the NHS trust during the redevelopment process
- form visual/textural connections around the site to aid wayfinding and orientation
- build on the work to date of by the hospital community.
- The art programme will largely promote the role of visual artists, craft practitioners

and designers within the hospital environment exploring different aspects of the hospital experience; visual, tactile and aural. The role of art forms including performance, dance, music and literature should be encouraged as part of an ongoing programme of commissioning and temporary art provision.

An overall ambition for the strategy is to 'normalise' the role of art within the hospital treating the contribution of artists in the same way as that of other designers and contributors to the hospital environment. Art should not be set on a pedestal. Development and resourcing mechanisms should be developed to allow for this, especially on such a large scale important project for the city. This is a chance for the Board to demonstrate that it is in the forefront of hospital reprovisioning through creating an environment based on supporting wellbeing and health.



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Background

The planning and building of the new hospitals will create an opportunity for a fresh and innovative approach to working with artists within the healthcare environment. This approach will develop a commitment to an art programme focussed around key stakeholders: patients, staff, visitors and the local community.

Underpinning the strategy, it is assumed that:

- The Board aims to create a high quality new hospital that improves the environment for patients, respecting their privacy and dignity
- There is ground level support for arts in hospital from departmental staff and associated art partners
- The overall internal environment of the hospital is important in the healing process and the art programme shall address fundamental ways of influencing this environment rather than just adding another layer of decoration
- Art can significantly contribute to the journey of the patient recovery process and be a spiritual support for visitors
- There is a particular willingness to work with artists on the themes of orientation, wayfinding, placemaking and the connection with the external environment
- The cultural context of the hospital in relation to its community is very important
- The concept of the provision of a hospital gallery or programmable space(s) is important
- That existing cultural activities should be reviewed and if appropriate, incorporated into the new hospitals so as to build on current activities and working relationships
- There is potential for artists to create links with surrounding local, city and sub regional communities especially in the development of creative skills to be applied to the hospital environment
- There are opportunities via the art plan to make links to existing local art programmes and identify areas or establish initiatives where these can be brought into hospital life. These may be participatory arts projects or performance groups, offering an opportunity to work on an ongoing basis with patients and staff.

How Arts Add Value

"People say the effect is on the mind. It is no such thing. The effect is on the body, too. Little as we know about the way in which we are affected by form, colour, by light, we do know this, that they have a physical effect. Variety of form and brilliancy of colour in the objects presented to patients is the actual means of recovery."

Florence Nightingale. 'Notes on Hospitals', 1863

Over a century later than Florence Nightingale's publication, the positive role which art plays in the healthcare environment is now widely acknowledged and documented.

It has been recognized by the Scottish Executive in their document "A policy on design quality for NHS Scotland 2006." This document states that:

"Scotland can benefit in many ways from the adoption of arts in healthcare programmes including better patient environments and an improvement in staff morale."

"There is growing evidence that patient recovery rates and stress levels are improved by the adoption of appropriately selected art in healthcare programmes. An extensive piece of research with the Kings Fund, published by NHS Estates demonstrates:

"The impact of the hospital environment on the patient experience and staff recruitment and retention."

The report illustrates that:

"Where time and attention has been tailored to meet patient needs, the resulting environments have had "therapeutic impact". ….

These environments, which encourage patients to feel looked after and cared for, and for staff to feel valued, demonstrate that public art projects have an impact beyond the physical environment."

Assessment of the Kings Fund public art programme (Evaluation of the King's Fund's Enhancing the Healing Environment Programme. NHS Estates, 2003.) reported that public art engendered the following:

- feelings of calmness and wellbeing
- patients feeling more respected and valued
- a reduction of vandalism and aggressive behaviour
- a perception by patients of receiving better treatment.

The Achieving Excellence Design Evaluation Toolkit (AEDET) developed by The Centre for Healthcare Design, NHS Estates, recommends that design be evaluated under three basic headings: Functionality, Excellence and Impact.

The arts have a significant contribution to make in creating impact. In particular, the arts can be used to:

- Create local distinctiveness
- Ensure that the built environment reflects individual human scale
- Meet the spiritual and emotional needs of patients and staff
- Support and improve wayfinding, for example by creating landmarks at entrances and in key public spaces
- Enhance landscaping and interior design through creative use of materials and finishes
- Enhance the prestige and reputation of the NHS trust during the redevelopment process

Brookfield will develop, in collaboration with the Board, a programme that is the forefront of good practice and will be an exemplar for Glasgow and Scotland.

APPROACH TO DEVELOPING THE ART PROGRAMME

Guiding principles

This art strategy is based on the fundamental belief in the ability of art and artists to help create a healing environment. In order to achieve the most effective integration of art in this environment, artists need to be involved at the earliest stage in the planning and build of the hospital. Therefore the art programme needs to be initially aligned in synergy with the building and public realm programme. Provision has been made to allow for artists to be commissioned for key commissions during Stage 2.

A holistic approach is required, integrating the art programme with the landscape and with the building, thus linking the interior with the exterior coherently.

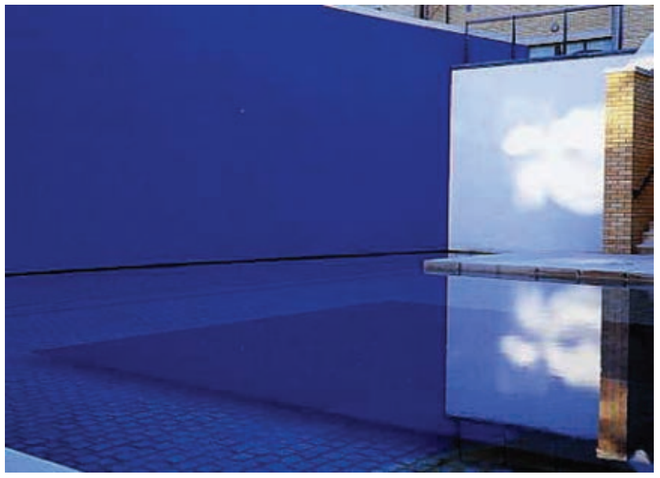
By adopting the practice of an integrated art programme it is possible to create value added, high quality elements through creatively accessing existing building budgets.

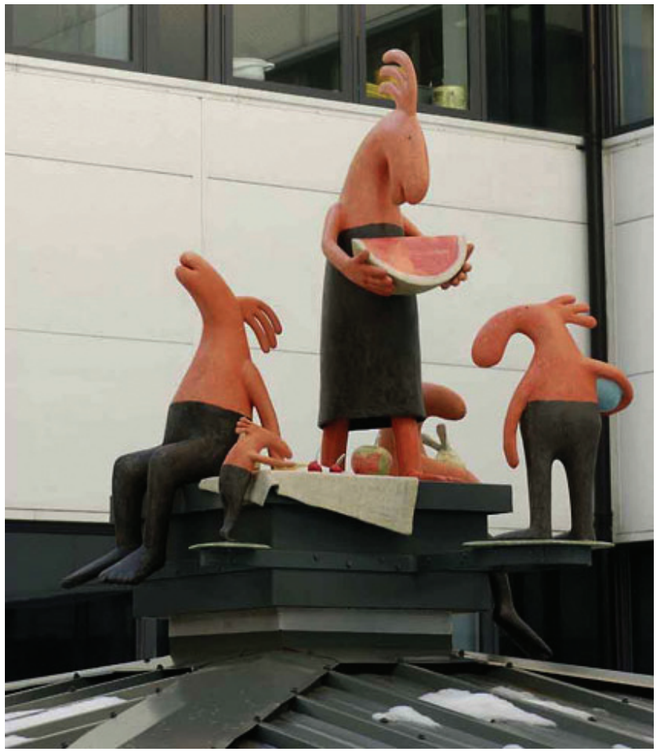
The art programme will be guided by recent research into therapeutic practice, the field of behavioural science that explores the idea of healing patients through contact with their surrounding environment and particularly nature. It will also be guided by information gathered from the field of environmental psychology and from research into the efficacy of Health Care Arts.

If supported by the Board, it is proposed that a partnership with a design based research institution (such as the OPENspace programme at the Heriot- Watt University of Edinburgh, although a Glasgow based relationship would be further encouraged) is established to help guide and frame how the art programme can respond to, and support good practice in the relationship between people, environment, movement and space.

The art programme will seek to add to Scotland's body of research through participation in good practice, innovation and evaluation.

Proposed principles that the detailed art strategy shall develop over Stage 2:





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Principle 1:

Create a positive healing environment focusing on user experience

- Ensure that the built environment reflects individual human scale, providing a positive, healing and therapeutic environment that meets the spiritual and emotional needs of patients, visitors and staff. It shall help to de-institutionalise the hospital environment, creating domestic and comforting public and ward areas.
- Provide high quality visual links between the interior and exterior of the hospital, encouraging and supporting access to nature and the outdoors.
- Support and improve wayfinding and orientation, for example by creating landmarks at entrances and in key public spaces.
- Enhance landscaping and interior design through creative use of materials and finishes, innovating uses of colour, surface and light for the improvement of patient, staff and visitor experience.

Principle 2:

Recognise cultural context and cultivate community links

- Recognise the cultural strengths and opportunities of the region whilst creating local distinctiveness.
- Implement education and outreach programmes that fully extend the programme to a broad audience and make genuine and sustainable links with the community.
- Be informed by a practical and open dialogue between the artists, patients, staff and community.
- Where possible and relevant use local crafts people and skills.
- The strategy will identify physical and cultural characteristics and activities which are unique to the area so as to provide rich source material for artists to investigate and use within their commissions.

Principle 3:

Integrate the role of the artist into the working life and design of the hospital in a fundamental and supported manner.

- Undertake professional and accountable project management procedures developing and implementing projects that evolve with the total confidence of both the artist and the Arts Development Group. Ensure that commissioned work and management procedures are fitting, appropriate and safe for a healthcare environment.
- Work with artists, designers and craft practitioners from the very early stages in all project development, creating the maximum opportunity for work to integrate into its context.
- Foster research and collaboration within different fields such as science to enhance and support the development of the arts in healthcare.

Principle 4:

Uphold artistic quality and contemporary practice.

- Commission artwork that is innovative and of high quality.
- Commission artwork that is sensitive and apt for its environment.
- Create the maximum opportunity for work to integrate into its context and provide a variety of ways for users to access the work of artists.

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PROGRAMME DEVELOPMENT

The role of artists

The role of an artist shall be as examiner and questioner, creator and facilitator.

Artists have a crucial role to play in the humanisation of the newly created internal and external environment, particularly in ensuring that the hospital environment relates to its social, cultural and physical context. This will relate especially to the areas of wayfinding, social spaces, gallery spaces and sanctuary spaces. By allowing artists to engage with the hospital environment and communities, strongly grounded and researched works of art will be created.

Brookfield will work with the Board and artists through a commissioning process that will allow for proper research and development of project ideas and proposals. The role of the programme will be to develop an environment for commissioning where artists are able to interact with the new spaces, patients, staff and visitors to develop projects that can be rooted in the new site. The main emphasis of the programme will be to create new permanent and temporary commissions that reflect and enhance the caring values of the NHS. The programme will be orientated towards the production of works of art that respond to their context.

Where possible, although not exclusively, the skills of local and city artists and craftspeople shall be drawn upon.

The role of staff and patients

The input of patients, staff and visitors will be key to the success of the project. Working processes should be developed to allow for staff participation so as to develop the role that arts can play within the hospital. This involvement is a key aspect to the project's success and this should feed into the art programme.

Patients and visitors will benefit from the programme, however acute patients are unlikely to play a significant role in the creation of work. Within the art programme we will seek to find alternative strategies through which patient experiences and preferences can be fed into the creative process.

An education and outreach programme should be developed for staff and patients where possible, in order that they might learn new skills and build their engagement in the arts programme as it progresses.

The role of the local and city communities

The detailed art strategy will specifically identify methods to involve the local and city communities. This may be through active contribution to artists' consultation, residencies and participatory projects.

Andy Scott, well known for his work throughout Glasgow will be invited to assist in developing an aesthetic and grounded approach to developing an accessible programme.

Design collaborations between landscape architects and artists and the local community will ensure that the building and grounds fit within the local landscape and provide an accessible destination that relates to the cultural context of the area. This will be through careful consideration of the landscape around the hospital and to the form, colour and texture of external spaces and as well as internal spaces. Areas for collaboration might include sensory gardens, children's play within the Children's Park, and development of communal/social spaces such as the chapel/sanctuary.

It is proposed that a dedicated gallery space is considered for the benefit of hospital patients, staff and visitors. Such programmable spaces lead to a sense of vibrancy connecting the hospital to its communities. By introducing the wider community to the hospital via an exhibition programme, such a space will help to reduce the sense of isolation or loss of self often associated with spending time within a healthcare setting.

Potential linkages to city based cultural initiatives and organisations will be researched with the aim of connecting the new hospital to its sub regional and city communities through culture. Many cultural organisations now have to engage audiences out of their normal working areas and this project will offer significant opportunities for new partnerships to be established.

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The role of Brookfield

Brookfield will continue to work with the specialist arts agency Ginkgo Projects during Stage 2 to develop a detailed arts strategy in collaboration with the Board. Further details are set out under 'Programme development and resourcing'. Brookfield's aims will be to develop, manage and facilitate the development and delivery of the art programme, reporting to the Boards Art Development Group.

Programme development rationale

Concept

The concept of providing a seamless Patient Care Pathway is now promoted at the core of patient care. It is proposed that as a starting point, the art strategy is positioned around providing a core rationale to which the guiding principles above can be applied through the notion of journeys.

The notion of 'journey' can be explored in a number of ways, including:

1. Physically:

The provision of well designed and provisioned articulated routes and places is integral to this bid. Artists have a critical role in further helping to provide relief, distraction, humour, orientation and integral design as part of the patient experience of visiting hospital. Priority will be placed on the main points of patient and visitor interaction with these routes and spaces.

2. Emotionally:

Artists have a valuable role to play in helping to reduce the anxiety around visiting hospital and helping to deinstitutionalise the environment. Process and participatory based projects have a significant role to play in developing a working environment that connects people to place through activity based work. Such projects can provide research and resource material for permanent commissions, but often have a critical role in providing change and vibrancy to the hospital environment. Areas for consideration for example include oral history projects, work based on creative play and cross art form work including poetry and literature based projects.

This type of work is often developed through artist residencies developing long term relationships between staff and artists to work with patient groups, both on and off site. The outcomes in themselves can be made visible, but they also provide solid research and inspirational material for permanent art commissions.

In the development of the art strategy it will be important to develop ways of working that support both human relationships and the physical environment.

Brookfield proposes that a long-term commitment is given to incorporating the work of artists within the hospital, and those projects are developed through a phased approach. The intention is to develop art projects along both the routes and the activity places, but it is suggested that initial priority is given to areas that are shared by the majority of user groups, namely staff, patients and visitors/community, working with spaces that have most influence on all users.

Two initial research and development projects are proposed during Stage 2, both of which will result in later physical projects for implementation within the initial stage of the art programme, this work will also provide a platform for further artists commissions.

Firstly, it is proposed that an overall concept for a first project, Way Marking and Orientation is established, and this will be achieved through considering the whole site and the various routes and interactions between activity areas contained within it and the role that artists have supporting wider signage and orientation initiatives.

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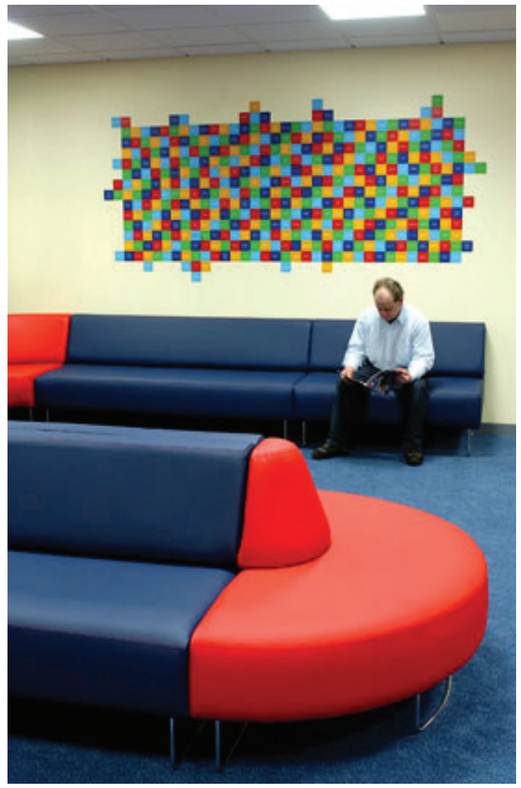
Secondly, it is proposed that a research project, The Healing Environment, is undertaken which will set out to question a number of factors within the hospital environment that might contribute to the healing process and to de-institutionalise the experience of living, visiting or working within the hospitals, it is proposed this project will initially concentrate on areas of relaxation, although this should be agreed with the Arts Development Group. The subject is diverse but will enable a focussed approach to improving the hospital environment. Relaxation is critical to the Care Pathway and recovery process and the spaces associated offer great scope for artist contributions.

Two artists partnered with a research led element (e.g OPENspace or similar) will be commissioned to work with the project teams to develop a framework for further development. Key areas of early artist involvement will be identified, and if appropriate further artists commissioned to develop concept designs for these areas.

The graphic below sets out an overall framework for development, setting out an approach which is research led, leading to projects that clearly relate to the patient experience of the care pathway.

It is proposed that the environmental research project, education and outreach and evaluation programmes feedback into the programme development process providing a means to ensure that the art programme will continue to reflect Board and patient aspirations as it develops.



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ARTIST RESEARCH AND DEVELOPMENT PROGRAMME: projects delivered through artists' residencies working with staff and communities feeding into projects below. Two initial projects are proposed during Stage 2: 1. the Healing Environment and 2. Waymarking and Orientation

ARRIVAL	ENTRANCE	WAITING	TREATMENT	RECOVERY	RELAXATION
Main entrance Car parks Bus stops	Main entrance and atriums to Main building and Children's Hospital Department entrances	Departmental waiting areas Assessment rooms Wards Treatment rooms	Assessment rooms Wards Treatment rooms	Wards External areas Courtyards	Staff/Public restaurants Courtyards Children's park Roof gardens Chapel/Sanctuary Incidental spaces
Gateway works, perhaps incremental on approach. Orientation works Car park lighting	Integrated /standalone commissions Reception areas Thresholds and decision points Hospitals Colour projects Corridor works	Ward furniture/ fittings Furniture Lighting Floorscapes Gallery/ showcasing spaces	Lighting Ceiling photography Sound projects Art trolley Cinema project	Colour projects Furniture and fittings gardens / grounds Sanctuary Personal space furniture	Staff sanctuary Childrens play Planting design e.g sensory planting Gallery/ Showcases Cultural studio/workspace?

ENVIRONMENTAL RESEARCH PROJECT: providing a solid basis for commissioning and prioritisation of projects

EDUCATION / OUTREACH PROJECTS: supporting activities connecting people to projects

EVALUATION AND FEEDBACK MECHANISM:

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Programme Devlopment And Resourcing

It is important that a flexible and appropriate approach is taken to developing the art strategy and programme in line with the Boards expectations.

During stage 2 Brookfield will work with the Board to:

- produce a detailed arts strategy
- consult with key hospital, community and cultural stakeholders
- Initiate two research/development projects: 1. The Healing environment and 2. Waymarking and Orientation. Undertake if required further artist concept design commissions as agreed with the Board.
- develop a community engagement programme
- develop a costed, phased action plan for programme delivery.
- ensure that art enabling works are accommodated within the construction programme
- set out management structures for programme delivery and post build activity
- develop (as an additional activity) a register/audit of exist artworks and cultural assets, if none exists at present.
- develop a donations policy
- work with the Arts Development Group to help promote its own activity and profile as required.

It is anticipated that Brookfield will have the responsibility for delivering the art strategy during the construction phase as directed by the Boards Art Development Group.

As an integral member of the Boards Arts Development Group, during design and construction, Brookfield will provide the specialist advice to (scope to be refined during stage 2):

- ensure that the art strategy is updated and maintained as a live document.
- consult with key hospital, community and cultural stakeholders
- maintain the costed, phased action plan for programme delivery
- develop artist briefs
- develop artist selection and project procurement procedures
- select artists for identified projects
- ensure that art enabling works are accommodated within the construction programme
- manage the development of artist concept and detailed designs, including artist residencies
- maintain a detailed programme for programme development and delivery
- manage the delivery of the art programme up to completion of the construction phase.
- provide advice on specialist arts contracts and procurement
- develop a programme for community engagement and participation
- development of maintenance, management and decommissioning plans
- in collaboration with the Board identify potential external funding sources, (if required)
- develop, with others, a register of existing cultural assets for relocation (if not existing)

Andy Scott has participated in the Competitive Dialogue process and has accepted the role of Local Champion for the art strategy. During Stage 2 Andy will be invited to contribute to the development process to participate in the process of ensuring that a broad range of grounded art opportunities are developed.

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Commissioning practice

The value and professional status of artists shall be respected and the selection, commissioning and contracting of artists shall follow recommended models of good practice as promoted by the Scottish Arts Council. Artists may be selected though direct selection, limited competition and open competition.

It is recognised that research and project development forms a significant part of the contribution that arts programmes make to the hospital environment.

It is suggested that the engagement of a part time or seconded Hospital art coordinator would facilitate the successful delivery of the art programme post construction. This post could be funded through the art programme.

Development Priorities

The level and extent of resourcing of the programme needs to be determined during stage 2 and decisions for investment will be led by the Board. It is recognised that a tiered or staged approach is requested for development to enable budgets to fit with the Boards aspirations.

Resource allocation for Activity undertaken during stage 2:

Stage	Activity	Resourced by
Stage 2	Art strategy production	Brookfield/ Board
	Research projects: 1. The Healing Environment 2. Waymarking and Orientation	Brookfield
	Selected art design concept design work development as agreed	Board / Brookfield

A set of criteria for project priority will be developed during Stage 2 to enable the Board to decide on project benefit and desirability.

First level priority projects

Priority should be placed on projects that:

- can only be delivered as part of the construction phase and are integral to the fabric of the buildings
- are located in areas which have the maximum public benefit e.g. entrances, atria, parks/green space
- Research and development programme to support grounded commissioning

Second level priority projects

- Stand alone artworks
- Integrated works in areas of lower pubic interface e.g treatment areas, waiting areas, corridors
- Education and outreach programmes
- Gallery / programmable spaces

Third level priority projects

- Gallery programming
- Temporary projects

Evaluation

Criteria for evaluation in relation to the art programme shall specifically relate to:

- An overview of how well the art plan incorporates the requirements of the Board and a clear response to the relevant ER's
- Clear evidence of how the art strategy will support the well being of patients, staff and visitors through the four guiding principles as referred to earlier in this documents and as set out below:

Principle 1: Create a positive healing environment focusing on user experience

Principle 2: Recognise cultural context and cultivate community links

Principle 3: Integrate the role of the artist into the working life and design of the hospital in a fundamental and supported manner.

Principle 4: Uphold artistic quality and contemporary practice.

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Public Art Elements

Stakeholder & Community Engagement

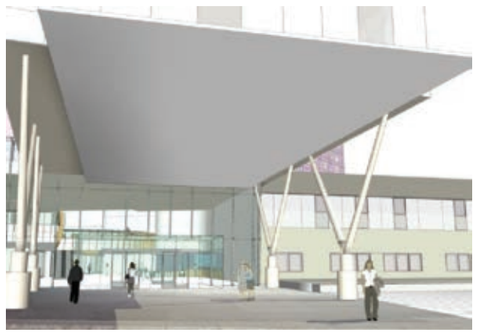
Stage 2 of the design process will enable full engagement with stakeholders to be commenced in support of the significant ambitions for the development of an influential public art programme for the New South Glasgow Hospitals. It has been noted that this will build upon the existing activity of the Board. It has been noted that the NSGH project offers the potential to create a benchmark for creative input into the provision of healthcare and the establishment of excellence in the new healing environment.

Public Art at New South Glasgow Hospitals

A number of elements within the design of the hospital environment will make a significant contribution to the delivery of creative features and community activities. It is intended that public art will be embedded within the fabrication of the buildings and external spaces and will be delivered within the same programme. Artists will therefore continue to be represented within the integrated design team to ensure that opportunities for creative expression are captured during the design process. In this way the delivery of the hospital buildings will include art features which have been firmly embedded within the form and fabric of the building to safeguard delivery and capture the opportunities.

During the design process up to the point of the ITPD submission a range of opportunities have been identified for further development and as a platform for stage 2 design. These are grouped under the following headings, which are briefly explored below:

- Signage & Wayfinding
- Public Space Design
- Building Features & Interior Spaces
- Furniture
- Exhibition Programme



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Signage and Wayfinding
There is a clear requirement for functional signage to respond to the appropriate standards and guidance for NHS sites. In addition to this signage there are additional opportunities to create unique creatively conceived features which forge identity, assist with wayfinding and serve as landmarks. Examples of these include entrance gateway features, sculptural forms in key locations, site maps, design motifs along primary routes, play elements and the use of colour within signage elements, both internally and externally.

Public Space Design
The design of public spaces has created a range of complementary places which provide variety and varying seasonal character. The stage 2 design for these places will include the definition of paving and other features through engagement with artists and the community, under the guidance of the art development group. Paving motifs can also aid wayfinding and public spaces will also offer flexibility for a range of uses, including occasional events. The heritage of the city and the Clyde-side location offer potential for creative interpretation applied to features such as the entrance canopy. Play areas within the Children's Park will also be designed as an expression of local creativity and innovation.

Building Features & Interior Spaces
A number of building features within the ITPD design proposal have been influenced by the desire for creative expression and innovation to shape the character and vitality of the built environment for patients, visitors and staff. The input of artists will continue and be expanded in stage 2 through stakeholder and community engagement. Elements of note for creative expression include reception desks, the atrium pods and aspects of the structure of the building in key locations.

Special building features include the chapel spaces, children's radio station, roof gardens, wall treatments and furnishings. The creation of unique and special places will be a feature of the stage 2 design process. Many of these opportunities are considered further in the wayfinding strategy.

Furniture
Internal end external furniture offers potential for creative design input, balanced with the need for function, cost-effectiveness and minimal maintenance. The integrated design team will work during stage 2 to enhance the scheme through a range of opportunities for identity to be enhanced through the use of appropriate suites of internal and external furniture and special unique features.

Exhibition Programme
The scale of the hospital buildings presents a range of opportunities for the creation and display of works of art. Strategic partnerships will be explored with existing bodies to maximise the potential for the display of artworks. The potential café within the park and the extensive catering areas internally offer additional potential for creative use of building spaces.

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Acoustic Report

Submission Reference:

Section 3.4 Acoustic Report indicating the following information:-

- Specialist Acoustic Engineer's report providing a clear demonstration of compliance with HTM 08-01
- Outline principles adopted underlying bidder approach to acoustics with particular regard to issues around items such as rooftop helipad, atrium etc

Submission Response:

Acoustic Logic has been engaged by Brookfield to provide specialist Acoustic Engineering service. The report as prepared by Acoustic Logic is contained herein.

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INTRODUCTION

This document presents the acoustic design report for the Brookfield - New South Glasgow Hospital bid submission. All acoustic aspects of the hospital have been design to fully comply with the requirements of Health Technical Memorandum (HTM) 08-01: Acoustics. The issues discussed include all aspects of the design covered by HTM 08-01 including:

- Acoustic treatments to the atriums and public spaces
- External noise control including traffic and the rooftop helipad
- Treatment proposed for plant rooms and the energy centre

In addition, the report provides indicative treatment to typical areas within the building to ensure an acceptable environment is provided. It is noted that although the final selection of the plant and equipment will take place in due course, their treatments in principal are outlined.

2. NSGH AND THE APPLICATION OF HTM 08-01

The design of all acoustics aspects of the New South Glasgow Hospital (NSGH) will be guided and determined by the criteria and guidelines set out in HTM 08-01. In order to maintain the intent and standards set out in HTM 08-01, it is proposed to generally maintain these criteria except in cases where the NSGH briefing documents have varied these or it is warranted on the basis of rationalising acoustic performances verses other functional requirements. In all cases, aspects such as hygiene, functionality, space relationships and practicable building outcomes are considered.

Acoustically, hospitals are unique buildings and due to their function do not closely model other buildings which may operate in similar modes. Acoustics becomes an important issue as control of intrusive noise from a range of sources (waste pipes, impact noise, wall transmission, and mechanical services) is essential for peace of mind and amenity.

Hospital buildings combine a number of functions more so than any other building type, and combines aspects such as residential commercial, educational, hostel and retail buildings. Hospitals operate differently to and generally their acoustic requirements are function based. Hospitals combine a number of functions from accommodation of patients in wards, ICU's CCU's, day patients, medical imaging, medical treatment, therapy areas and specialist functions. As such, hospital buildings overlap acoustically with a number of building types, residential, commercial, retail, education and specialist medical.

When selecting acoustic standards for hospitals a number of factors require consideration, including the space relationships, the requirement for general and quick access to the majority of areas, patient monitoring, the large area over which most spaces are planned, in particular ward layout in comparison to residential apartments. There may be 30 to 40 beds on a ward, which all generally require open doors for access by staff and others, whereas in apartments, the space is closed off to all but those within the immediate ownership. Hence, assigning a hospital the acoustic standards that would be used in residential, commercial, education buildings (et al) is not strictly correct, as it does not recognise the unique functions of a hospital.

For NSGH, all acoustic measures will be considered in this light and where adjustment are required to strike a balance between the varying requirements, these will be enacted.

2.1 GENERAL PHILOSOPHY

The acoustic advice for this project has been developed to encompass the broader requirements of the facility. The consulting rooms, counselling offices, executive offices, birthing suites and specialised areas of the hospital such as psychiatric observation are seen as the most critical, requiring adequate acoustic isolation to maintain speech and acoustic privacy. Other associated spaces such as waiting areas, patient wards, general treatment and medical areas will require acoustic standards which provide speech privacy under normal conditions. That is when people are talking at normal volume, these conversations will not be clearly audible in adjoining spaces. Loud events such as screaming or shouting are not seen a normal and hence do not require consideration in these space.

The location of the space is also important in determining the required Rw rating. For example a tutorial or consulting room located in the middle of a corridor and adjoined by storage areas should require a lower Rw rating than the same room type adjoining a patient ward or another consulting room. Note corridors are transitory spaces, where people either pass along or spend short periods of time, and differ greatly from spaces where people are stationed and are in a position to hear or be disturbed by sound in an adjoining area.

2.2 ACOUSTIC DESIGN APPROACH

A suitable acoustic standard for the different space types was determined by evaluating space function against specific acoustic requirements. Accordingly, the required acoustic environment for a space can be seen as a composite of four elements, namely;

1. The perceived sound privacy requirements.
2. The ambient acoustic environment (background noise levels); this is a direct function of the activities which occur and mechanical services noise.
3. The acoustic character of the space.
4. The levels of noise which are likely to be generated within a space, and how they will affect adjoining spaces.

This evaluation process was carried out to determine the acoustic requirements of the various spaces within this development.

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2.3 IMPORTANCE OF SPACE CHARACTER TO PERCEPTION OF SOUND

The acoustic character of a room will determine the quality of the sound and may lead to a space being perceived to be noisy. Acoustic character specifically refers to the sound absorption properties of the room finishes and the resulting nature of sound. A space with little acoustic absorption will sound reverberant and hollow. Noise heard in such a space tends to sound loud and sharp. Where adequate acoustic absorption is provided, sounds tend to be more natural and intelligible. This also makes the space sound quieter and therefore aurally more comfortable. For this development, it is proposed to provide a room character which is suitable for a heath facility environment, i.e. quiet and comfortable.

3. NOISE INTRUSION FROM EXTERNAL SOURCES

The NSGH project brief requires that the façade be designed to comply with the standards given in HTM 08-01 under normal conditions. The design criteria adopted in the Brookfield bid submission are those nominated in HTM 08-01 and are outlined in Table 1 below.

TABLE 1 - HTM 08-01 CRITERIA FOR NOSIE INTRUSION FROM EXTERNAL SOURCES

room type	examples	Criteria for noise intrusion to be met inside the spaces from external sources (dB)
Ward – single person	Single – bed ward, single-bed recovery areas and on-call rooms, relatives' overnight stay	40 LAeq, 1hr daytime
		35 LAeq, 1hr night
		45 Lmax, fast night
Ward – multi-bed	Multi-bed wards, recovery	45 LAeq, 1hr daytime
		35 LAeq, 1hr night
		45 Lmax, fast night
Small office type spaces	Single – bed ward, single-bed recovery areas	40 LAeq, 1hr
Open clinical areas	A& E	45 LAeq, 1hr
Circulation spaces	Corridors, hospital streets, atria	55 LAeq, 1hr
Public areas	Dining areas, waiting areas, playrooms	50 LAeq, 1hr

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room type	examples	Criteria for noise intrusion to be met inside the spaces from external sources (dB)
Personal hygiene (en-suite)	Toilets, Showers	45 LAeq, 1hr
Personal hygiene (public and staff)	Toilets, Showers	55 LAeq, 1hr
Small food-preparation areas	Ward kitchens	50 LAeq, 1hr
Large food-preparation areas	Ward kitchens	55 LAeq, 1hr
Large meeting rooms (> 35m2 floor area)	Lecture theatres, meeting rooms, board rooms, seminar rooms, classrooms	35 LAeq, 1hr
Small meeting rooms (≤ 35m2 floor area)	Lecture theatres, meeting rooms, board rooms, seminar rooms, classrooms	35 LAeq, 1hr
Operating Theatres	Operating theatres	40 LAeq, 1hr
		50Lmax, fast
Laboratories	Laboratories	45 LAeq, 1hr

4. INVESTIGATION OF HELICOPTER NOISE INTRUSION

This section details our review of potential helicopter noise and regenerated structure borne noise impact to the future occupants of the proposed New South Glasgow Hospital.

4.1 HELICOPTER NOISE

HBN 15-03 “Hospital Helipads”, references Planning Policy Guideline 24 which urges caution in measuring and applying noise exposure categories when absolute levels of noise are balanced by an infrequent occurrence and a short duration of such noise. The occasions when ambulance helicopters cause disturbance are likely to be irregular, few in number and short in duration.

Notwithstanding the new proposed helipad is an improvement over the existing helipad, thus reducing the potential for noise impact inline with the mitigating measures proposed in HBN 15-03 as follows;

- New proposed helipad is located on top of the Ward tower, which represents the highest point on the estate (HBN 15-03),
- Elevated helipad reduces air time on approach and takeoff, and enables planning of the flight path to avoid unnecessarily low transits over sensitive areas. High flight path for as long as possible to maintain maximum distance attenuation to receivers.
- Minimising ground idling time.
- Improvement to existing ground pedestrian paths of current hospital by locating helipad on roof.

4.2 HELICOPTER FLIGHT PATH

The helicopter serving NSGH will be landing or taking off on the rooftop of the new building. It is assumed that suitable flight paths will be determined to avoid sensitive receiver locations.

To determine suitable noise levels for the various space types with regards to the helicopter landing pad the following information was examined and evaluated:-

1. The proposed location of the helicopter landing pad.
2. Typical frequency of use of the landing facility.
3. Recommended design sound levels for different areas of occupancy for standard aircraft movements.

4. Extensive experience with hospitals and helipads.

It has been assumed that helicopter movements will be limited to emergency situations. Based on this assumption an acceptable noise level for rare and short term occurrences such as helicopter arrival and departures would be the recommended design levels plus 20 dB(A).

The nominated noise levels for the various spaces types selected following the methodology described above are shown in the table which follows.

Nominated Helicopter Noise Levels

SPACE TYPE	NOISE LEVEL OBJECTIVE Lmax dB(A)
Wards	70
Theatres	65
Treatment rooms	70
Consulting rooms	70
Laboratories	75
Service Areas	85
Private offices, conference areas	70
Offices - general	75

4.3 EVALUATION OF NOISE INTRUSION

Noise intrusion into the habitable spaces within the proposed development was predicted. The calculations were based on the worst case that helicopters pass directly over the development. A façade receiver distance of 20m was taken relative to the helicopter based on the distance to the helipads and expected passing height of the helicopter over the subject development.

Noise levels used for assessment were obtained from measurements taken of a Sea King Helicopter during the following activities;

- Starting up
- Running hard during starting up
- Taking off
- Various approaches

It is noted that Jet Ranger represents the type of helicopter which would arrive at the hospital more frequently. It is acknowledged that Sea King Helicopters may use the hospital helipad. However the difference in design requirements within practicable means for both helicopter types will be equivalent especially based on frequency of the Sea Kings. Hence the design is considered conservative.

Of the above activities, taking off was the loudest and thus this level was used for assessment purposes. Calculations were performed taking into account the orientation of windows, the total area of glazing, facade and roof transmission loss and room sound absorption characteristics. In this way the likely interior noise levels can be predicted. The roof construction is concrete over the Adult hospital.

4.4 TOP THREE FLOORS OF THE HOSPITAL WING WHERE THE HELIPAD IS LOCATED

Glazing:	6mm glass /12mm air gap /10mm glass
Windows:	Not open-able
Facade	To perform a minimum of 10dB above glazing

4.5 STAFF RESOURCE (REMAINING FLOORS)

Glazing	6mm glass /12mm air gap /6mm glass
Windows:	Not open-able
Facade	To perform a minimum of 10dB above glazing

4.6 OTHER CONSIDERATIONS TO SURROUNDING RESIDENTS

As a reference, the Royal London Hospital offered secondary glazing for noise control to residents living nearby. The factors to be considered for NSGH prior to taking this approach would include the fact that the existing helipad and that the proposed helipad location will effectively represent same flight path and that currently the helipad operates without upgraded glazing to surrounding residents. This is an emergency service, thus the proposition to offer secondary glazing like Royal London Hospital may be a premature measure.

Prior to moving forward with this proposition, it is proposed that a review be conducted of the existing operations and then any variations from existing to new hospital operations is evaluated. If it is determined that the new helipad will seriously increase the impact upon existing residences, then suitable amelioration can be considered.

In the case of the temporary operating helipad, a similar study is proposed, if it is found that significant impact is generated, then suitable treatments need to be formulated.

5. TRAFFIC NOISE

Based on the location of the new hospital building being away from the major roadways which surround the site and the results of a cursory noise survey, conducted around the site, and the criteria presented in HTM 08-01 reproduced in this report the following general glazing system is recommended for the NSGH.

Typical Façade based on traffic noise intrusion:

Glazing	6mm glass/ minimum 12mm airgap (greater for integrated venetian)/ 6mm glass

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6. PLANT AND BUILDNG SERVICES NOISE

The specified levels are generally in accordance with HTM 08-01. This is consistent with the normal practice in UK. In the absence of criteria in HTM 08-01, the NSGH bid documents have nominated suitable criteria. In general, these criteria are adopted for the Brookfield bid submission.

The adopted criteria relate to the total noise resulting from simultaneous operation of all plant and building services including structurally transferred noise. Noise from toilet flushes is excluded as per the NSGH bid document notification.

The proposed criteria are set out in tables 2 and 3 below.

TABLE 2 – SERVICES NOISE CRITERIA FOR INTERNAL SPACES COVERED BY HTM 08-01 (For note 1 see section 6.1 below)

Area	HTM 08-01	Proposed in NSGH PROJECT BRIEF	BROOKFIELD CRITERIA	COMMENTS
Single bed wards	NR 30	Nr 30	NR 30	Complies with HTM 08-01
Consulting rooms	NR 35	Nr 35	NR 35 – NR401	Complies with HTM 08-01
Operating Theatres	NR 40	Nr 40	NR 40	Complies with HTM 08-01
Privates Offices, small (≤ 35m2) meeting rooms	NR 35	Nr35	NR 35- NR401	Complies with HTM 08-01
Privates Offices, large (> 35m2) meeting rooms	NR 30	Nr30	NR 30-nR351	Complies with HTM 08-01
Multi bed wards	NR 30	Nr 35	NR 35	Complies with NSGH project brief
Waiting rooms	NR 35	Nr 35	NR 40	Proposed NR40 to increase privacy as NR35 creates a low background environment
Staff rooms	NR 40	Nr 40	NR 40	Complies with HTM 08-01
Relatives' overnight stay	NR 30	Nr30	NR 35	Background sound level increased to improve privacy.
General Office	NR 35	Nr 35	NR 40	Background sound level increased to improve privacy. It is noted normal background from human activity in general offices is NR43
Corridor, Laboratory	NR 35	Nr35	NR 35	Complies with HTM 08-01
Toilet, shower (en-suite)	NR 30	Nr30	NR 351	Background sound level increased to improve privacy.
Washroom, toilet	NR 30	Nr 35	NR 351	Complies with NSGH project brief
Ward kitchens	NR 35	Nr 35	NR 35- NR401	Complies with HTM 08-01

TABLE 3 – SERVICES NOISE CRITERIA FOR INTERNAL SPACES NOT COVERED BY HTM 08-01 (For note 1 see section 6.1 below)

Area		Proposed in NSGH PROJECT BRIEF	PROPOSED BROOKFIELD CRITERIA	COMMENTS
Sports Hall, Gymnasium		Nr30	NR 351	Increased background see note 1
Music room		Nr 35	NR 35	Complies with NSGH project brief
Activity / Group work room / Multi-purpose room		Nr30	NR 35	Complies with NSGH project brief
TV room		Nr35	NR 35	Complies with NSGH project brief
Observation & Recording		Nr 35	NR 35	Complies with NSGH project brief
Recreation rooms, cafeteria		Nr40	nr40	Complies with NSGH project brief
Recreation rooms, cafeteria	Bedroom	nr25	NR301	Complies with standard night-time residential criteria
	Lounge	NR30	nr351	
Residential Living Area / Living Unit	Bathroom	Nr 40	NR40	Complies with NSGH project brief
	Kitchen / Corridor	NR40	Nr40	

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1.1 BACKGROUND NOISE LEVELS AND PRIVACY

Although the selection of background noise levels which are too low may seem a conservative and correct practice, it can lead to excessively quiet spaces which highlight other issues. A quiet waiting room, means that every sound made can be heard and may lead to annoyance and irritation. Also selection criteria for specialised areas such as wards, which are too low means that there is a greater audibility of noise

The Employer's Requirements (Hospitals) Volume 2/1, stated: "The contractor shall endeavour to minimise and mask ambient noise sufficient to preserve patient privacy, confidentially and maintain a calming atmosphere in public and private areas "

Based on the requirements outlined above, the first principle which needs be considered is that if the background is too low, then minimal speech masking will occur and the above objectives will not be met. Furthermore, it is noted that if the background is too low then the patient will be more aware of general sounds which would otherwise be masked by an appropriate level of background or ambient noise.

Hence all services noise criteria need to consider the balance between noise levels that are required for patient well being and those required to provide speech privacy and masking for patient dignity and aural comfort.. In some case the noise levels criteria were marginally increased.

Furthermore HTM 08-10, states: "Sound insulation between rooms – allows rooms to exist side by side. Noisy activities should not interfere with the requirements of adjacent rooms, and private conversations should not be overheard outside the room."

This statement calls for a balance between adjoining spaces, activity generated noise, ambient noise levels and internal partitions. The degree of audibility or inaudibility for each space type will vary depending on the planning or spatial relationships with other parts of the hospital/rooms. This will be further discussed below, but more importantly at this stage is what factors contribute to audibility and inaudibility.

1.2 PROPERTY BOUNDARIES

Noise levels emitted by the mechanical plant at all property boundaries and nearby buildings on adjacent properties shall meet the requirements of:

1. Local Council

2. Environment Protection Authority.

3. Any other relevant statutory authority.

1.3 HOSPITAL ACCOMMODATION

Noise levels emitted by the mechanical plant incident on hospital accommodation are to meet noise intrusion targets with open/closed windows.

1.4 NOISE DURING A FIRE EMERGENCY

Noise from all plant during a fire emergency shall comply with the requirements of HTM 08-01. Noise levels inside the fire control room shall not exceed 65dB (A) during a fire emergency. Anywhere else in the hospital they shall not exceed the background + 10dB (A).

1.5 OUTDOOR AREAS ON THE DEVELOPMENT SITE

Noise levels emitted by the mechanical plant to outdoor public and private areas on the development site shall not exceed the A-weighted background noise level or any level agreed with the local authorities

1.6 VIBRATION PRODUCED BY PLANT

Tactile structure vibration levels produced by the plant should not exceed the criteria given in BS 6481. Where the standard recommends a range of criteria for a particular occupancy, the low end of the range shall be used.

The following measures shall be adopted for mounting of mechanical plant:

- Isolation mounts and connections shall be adopted for all reciprocating and rotating equipment, pipe work and ductwork.
- Selection of suitable vibration system shall be made based on the design minimum isolation efficiency, floor static deflection, and plant/ equipment mass, rotational/ reciprocating speeds and power requirements etc.

The method of vibration mitigation shall be selected for each particular application. The following minimum isolation spring defections are applicable:

- Pump/ motor sets 25mm deflection
- Air handling plant 10mm deflection
- CPEF and CPSF 25mm deflection

Other means included providing a minimum clearance of 50mm between vibrating equipment and nearby building structure and 25mm between the underside of a concrete inertia block or machine base and the top of a concrete slab.

1.7 SERVICES RISERS

Internal services risers shall be selected to meet both acoustic and fire rating requirements. Typically, risers constructed of masonry or Shaft wall or similar are acceptable.

1.8 PLANT ROOMS GENERALLY

Treatment cannot be confirmed to these rooms until equipment and noise levels for that equipment are selected. Typically it is assumed that the slabs in the plant rooms are at least 180mm thick.

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1.9 DIESEL GENERATOR

The proposed diesel generator room will require specific acoustic treatment which is to be finalised once the unit selection is available. Indicatively a suspended 16mm thick plasterboard ceiling below the roof structure spaced 300mm on resilient hangers equal to Embelton RHD series shall be installed. A layer of 75mm thick 11 kg/m^3 glasswool will also be required in the ceiling void. Plant room walls shall be lined with 50mm thick perforated metal faced insulation. Silencers will be required to the air intake/discharge. 45mm thick solid core doors with full perimeter seals will be required. It is recommended that the plant room walls be nominal 190mm masonry block.

1.10 DOORS

It is recommended that plant room doors be min 40 mm thick solid cores with full perimeter acoustic seals. It is noted that the diesel generator room should be min 45mm thick.
All other doors shall be solid core with all gaps minimised. It is noted that door seals to meeting rooms/interview rooms etc will not be required. However there are a few minor instances where consulting offices are located opposite waiting areas and as such in these locations acoustic seals are recommended. Doors shall meet a minimal rating of Rw35, as set out in the NSGH project specification

7. HYDRAULIC SERVICES

The principal requirements for noise from the hydraulic services is that all waste soil pipe passing through the various spaces of the hospital development comply with satisfactory noise levels. The actual treatment of the waste pipe work will be dependant of the receiver space configuration, the ceiling construction system, the material from which the pipework is constructed and the hydraulic practices adopted on the project.

For the purpose of this schematic design report a series of design criteria is presented, these criteria are based on the maximum design levels presented in Table 2 and 3 above.

8. INTERNAL ROOM ACOUSTICS

A hospital is an amalgamation of different spaces with varying hygiene, security and aesthetic requirements. In the determination of suitable acoustic absorption/reverberation control mechanism and materials, the above factors were taken into consideration.
Room acoustics character specifically refers to the sound absorption properties of the room finishes and the resulting nature of sound. A space with little acoustic absorption will sound reverberant and hollow. Noise heard in such a space tends to sound loud and sharp. Where adequate acoustic absorption is provided, sounds tend to be more natural and intelligible. This also makes the space sound quieter and therefore aurally more comfortable. For this development, it is proposed to provide a room character which is suitable for a heath facility environment, i.e. quiet and comfortable.

HTM 08-01 in Section 21.06 nominates that sound absorption should be provided in all areas including corridors except in areas where cleaning and infection control, patient safety, clinical and maintenance requirements do not allow.

The general acoustic philosophy of the Brookfield bid is to fully comply with the intent of Section 21.06. To this end, a general acoustic system has been developed for the hospital to meet the requirements of room to room noise transmission, whilst providing the required level of acoustic absorption. The propose system make use of a high density ceiling tile to achieve the ceiling attenuation from room to room and provides an NRC rating in all allowable areas of ≥ 0.55 on the ceilings. This means that all areas in the hospital that are allowable will have good room acoustic character, and comply with HTM 08-01.

These areas include:-

- Department corridors
- Wards
- Treatment rooms
- Consulting rooms
- Utility rooms
- Open Clinical areas
- Meeting rooms
- Offices
- Entrance areas
- WC’s
- Hospital streets

This design approach will provide a quiet and peaceful environment thought the hospital. This will also assist in reducing externally transmitted noise for spaces located on the building façade and reduce services noise throughout the hospital. The room correction or reverberate noise level difference in a standard room with an absorptive ceiling is between 3 to 5 dB quieter than a room with a hard or non-absorptive ceiling. Hence it can be stated that in general all room is the NSGH will be 3 to 5 dB quieter because of this Brookfield initiative.

In the case of more specialised areas the treatments will vary according to the function. A brief outline is provided below for a few of the more important areas:

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8.1 ATRIUM ACUTE HOSPITAL

This is the principal space in the hospital most people arriving will transit through and hence it can be stated that this is one of the critical area to be addressed. The Architects have formed a grand, light filled voluminous space, which extend to some 11 storeys and is full of various architectural features, the chapel, sky bridges, glass walls etc.

Acoustically, this space is divided into a number of zones; there is the main space and special/peripheral space. The peripheral spaces (reception desk, retail, cafeteria etc) will be treated with localised systems such a ceiling tiles or panel absorbers. In the main spaces, consideration is given to the vast volume where a room correction of – 20dB has been calculated due to sound dissipating into the space. This will provide significant acoustic benefit in controlling room character. Further sound absorption will be provided to available surfaces where it can be applied (glass and windows are excluded) in the form of dense fibreglass (40kg/m3) faced with acoustically transparent material. In addition, any surfaces which may cause echo or strong reflections will be acoustically treated when the final form of the atrium is derived.

Based on the current design of the atrium, normal speech levels will be reduced by approximately 20 to 25dB(A). This will provide an aurally comfortable environment in which people can meet, stand and speak or quietly wait.

8.2 LECTURE THEATRES, SEMINAR ROOMS

These rooms have an important roll and their acoustic design is important for speech intelligibility and general function. A general approach for these rooms will be to have carpeted floors, acoustic treatment on the side wall and rear walls, with approximately 100% of the rear wall covered and 40 – 60 % of the side walls. The ceiling will be evaluated to control strong reflection and diffuse sound.

8.3 PUBLIC SPACES

Other than the atriums, the principal public spaces will be waiting areas, retail (cafeteria) and hospital corridors. The acoustic strategy for these areas has been covered above.

9. INTERNAL AIRBORNE SOUND INSULATION (PARTITIONS)

The sound insulation ratings of the partitions strictly follow the requirements of HTM 08-01. In accordance with HTM 08-01, the walls are designed to comply with the DnTw ratings shown in Table 5 of HTM 08-01. This is the same table title as Figure 1 in the Volume 2/1 Appendix S of the NSGH bid documentation. This table provides a matrix showing the sound insulation performance required (dB DnTw).

In addition and as indicated in the NSGH bid documentation, BB93 has been reviewed for teaching spaces and the Scottish Building Standard Authority (SBSA) Techinal Handbook in living areas. It is noted that the DnTw ratings presented in Table 5 which is reproduced above are on-site performance to be achieved in the completed building. The Rw ratings were and if indicated are laboratory ratings and not equivalent to DnTw, but are approximately 10 to 20% higher.

The proposed wall details are attached in Appendix A. The details are labelled with the appropriate acoustic rating and colour coded to be referenced from the marked-up architects drawings in Appendix B.

The design of the partitions considers all penetrations and joints and flanking paths, required backing boxes, above ceiling treatments, light boxes and plenum boxes to mechanical systems.

In the case of toilet walls to corridors, where there is no door, the walls are rated at a minimum of Rw43.

It is noted that the DnTw ratings used in this report strictly comply with HTM08-01. It is also noted that in the NSGH project brief, one change is made to Table 5 in the Arups' report, namely; the single ward to single ward criterion appears as DnTw 50, as opposed to the DnTw 47 rating shown in Table 5. In the Arup document which is Appendix S of Volume 2/1 (on the second page of Appendix A), they provide a definition of 'Perceived Change in Decibel Level" for 3dB - they noted: "A just noticeable difference "or in other words a barely noticeable difference. The guidance of HTM 08-01 is strictly followed for the selection of all partition ratings.

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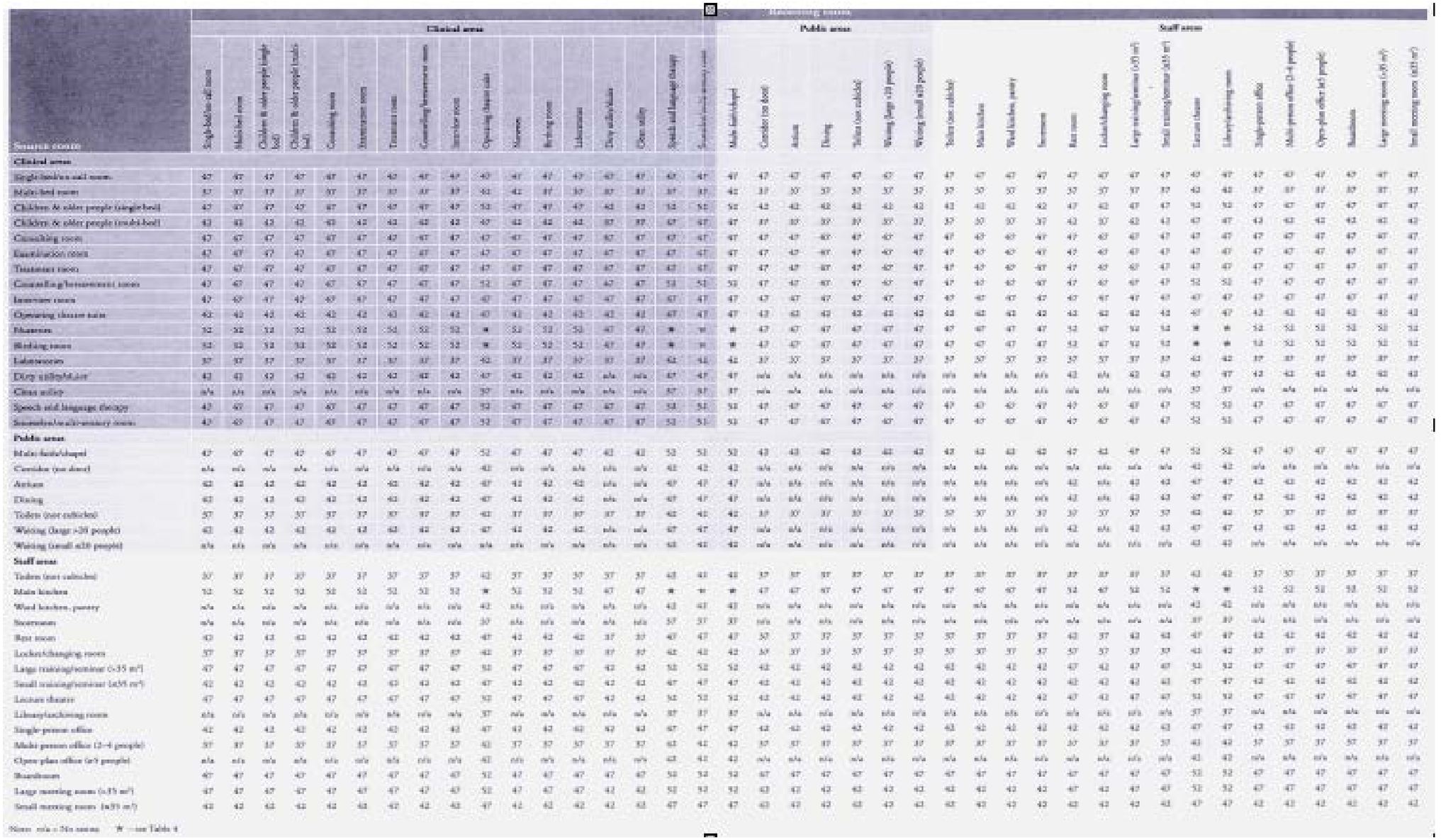

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10. DOORS

The sound insulation ratings of the doors strictly follow the requirements of HTM 08-01. The door rating requirements are set out in table below.

room type	DOOR SOUND INSULATION RATING	COMMENTS
Wards and Duty rooms	Rw30	Proprietary acoustic door with seals to head and jambs
Treatment rooms	Rw30	Proprietary acoustic door with seals to head and jambs
Consulting rooms/Control rooms	Rw30	Proprietary acoustic door with seals to head and jambs
Offices/Seminar rooms	Rw30	Proprietary acoustic door with seals to head and jambs
Plant rooms	Rw35	Proprietary acoustic door with seals to head, jambs and thresholds
Rooms where seals can not be fitted for hygiene, functional or and cleanliness reasons	Rw20-25	Proprietary acoustic door minimal gaps

In section 2.72 of HTM 08-01, it is recognised that doors are an inevitable weakness in partitions and will reduce the overall acoustic performance of most partitions. Reasonable acoustic performance can not be achieved without seals being fitted around the whole door perimeter. In hospitals there can be restrictions on fitting doors seals and they are to be fitted where it is possible. The principal reasons doors seals can not be fitted are:

- Opening force under emergency conditions
- Infection control
- Patient safety
- Ventilation regimes

In the case of the NSGH where door seals cannot be fitted and the room is required to have high noise sensitivity, the door sets will be designed to optimise performance and designed to rating of Rw 20- 25.

In case of non-noise sensitive rooms such as store rooms, no seals are to be fitted.

The acoustic selection of doors for all spaces in the NSGH is shown in the Architects Door Schedule (refer to Volume 2 Section of the bid deliverables).

11. INTERNAL IMPACT SOUND ISOLATION

The weighted standardised sound pressure level will meet L'nTw 65 dB(A) which is the criterion nominated in HTM 08-01 for floors over noise or acoustically sensitive spaces.

12.

13. VIBRATION

Tactile structure vibration levels produced by the plant should not exceed the criteria given in BS 6481. Where the standard recommends a range of criteria for a particular occupancy, the low end of the range shall be used.

13.1 CONTINUOUS VIBRATION

Continuous vibration will be assessed in terms of RMS value (1sec) of the frequency weighted acceleration on the floors of occupied areas. The frequency weighting shall be Wg as specified in BS6481, with the base value frequency weighted acceleration of the being 0,005m/s. Multiplying factors are as per the standard.

13.2 INTERMITTENT VIBRATION

This is to be assessed as continuous to comply with BS6841 and BS6477.

13.3 VIBRATION SENSITIVE EQUIPMENT

All environments around vibration sensitive equipment will be evaluated to ensure that they comply with manufacture specifications for specific equipment. All potential sources of nearby vibration will be considered, including;

- Footfall
- Plant
- Speed humps
- Helicopter
- Vehicle traffic
- Loading docks etc.

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14.

15. AUDIOLOGY / AUDIOMETRIC TESTING

Audiology tests booths will be provided to allow for the following audiometric testing;

- Sound field tests
- Bone Conditions
- Any other requirements of the Board

16. CONSTRUCTION NOISE AND VIBRATION

Construction noise and vibration will be a critical issue on the NSGH due to the surrounding hospital campus being operational during the construction works and the nearby residential premises. This section sets out an outline of proposed construction noise and vibration management strategy.

A demolition, excavation and construction noise and vibration plan will be developed to manage noise and vibration from the construction works. The objectives of this management plan are the minimisation of noise and vibration emissions and to assist in maintaining a satisfactory environment around the site.

To develop this plan, an advanced evaluation of all work to be performed during the demolition, excavation and construction phase of the project will be undertaken to forecast the potential impact of noise. This noise forecasts will be used to formulate and streamline effective controls and mitigation measures. As a part of this process, an on going testing will be used to evaluate the noise regulation strategies and ensure that they are effective.

The principal issues which will be addressed in this plan are:

- Identification of the noise and vibration standards which will be applicable to this project.
- Formulation of a strategy for construction to comply with the standards identified in the above point.
- Development of a monitoring programme to measure and regulate noise and vibration at all potentially affected locations.
- Establishment of direct communication networks between affected groups, the local Authorities, the Hospital Board, Brookfield and Acoustic Logic Consultancy (UK) Ltd.

16.1 POTENTIALLY AFFECTED RECEIVERS

The Potentially affected noise sensitive receivers include the following:

- All operating buildings within the hospital grounds
- Neighbouring residential buildings surrounding the hospital site

16.2 ASSESSMENT CRITERIA

16.2.1 Noise Goals

The guidance contained in British Standard BS 5228 “Noise Control on Construction and Open Sites” does not extend to providing criteria against which to assess construction and demolition noise. This Standard presents an overview of the legislative background to the control of environmental noise and vibration. The Standard is limited in only providing guidance on the importance of community relations, training site personnel, protecting people in the work environment, neighbourhood nuisance, project supervision and the control of noise and vibration. In addition, the Control of Pollution Act 1974, will also be considered.

16.2.2 Vibration Criteria

The British Standard BS 7385 “Evaluation and Measurement for Vibration in Buildings” considers the potential effects of vibration upon buildings. This Standard defines criteria for two different types of building structure - brick-built residential and more heavily-built industrial buildings. The Standard advises that there is a minimal risk of cosmetic damage (i.e. the formation of hairline cracks on drywalls, plaster or in mortar joints) at the specific guidance levels.

For residential buildings, the limit for cosmetic damage varies with frequency: 15mms-1 at 4Hz rising to 20mms-1 at 15Hz and to 50mms-1 above 40Hz. These limits apply to all three orthogonal directions individually.

Limits for transient vibration, above which cosmetic damage to buildings could occur are presented in the table below.

	Peak component particle velocity in frequency range of predominant pulse	
	4Hz to 15Hz	15Hz and Above
Reinforced or framed structures industrial and new commercial buildings	50mms-1 at 4Hz and above	
Un-reinforced or light framed structures residential or light commercial type buildings	15mms-1 at 4Hz increasing to 20mms-1 at 15Hz	20mms-1 at to increasing to 50mms-1 at 15Hz at 40Hz and above

NOTE: The values apply to vibration levels measured at the base of the building.
The above criteria should be halved for continuous vibration.

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16.3 NOISE ASSESSMENT

Noise generated by plant and equipment throughout the duration of the project will be managed to generally comply with the noise level objectives set out in this report.

Predictions of internal noise levels at the sensitive receivers identified above will be undertaken. All such predictions will be made internally within the buildings (given that for all the buildings openable windows are normally closed or facades have fixed windows) and taking into account the expected façade reductions, barrier effects (where applicable), distance losses and using the equipment noise levels tabled above. The process of assessment are summarised below.

16.4 NOISE AND VIBRATION CONTROL METHODS

The determination of appropriate noise control measures will be influenced by the particular activities and construction appliances. This section provides an outline of available methods.

16.4.1 Selection of Alternate Appliance or Process

Where a particular activity or construction appliance is found to generate excessive noise levels, it may be possible to select an alternative approach or appliance. For example; the use of a hydraulic hammer on certain areas of the site may potentially generate high levels of noise. By carrying this activity by use of pneumatic hammers, bulldozers, ripping and/or milling machines lower levels of noise will result.

16.4.2 Acoustic Barriers

Barriers or screens can be an effective means of reducing noise. Barriers can be located either at the source or receiver. The placement of barriers at the source is generally only effective for static plant. Equipment which is on the move or working in rough or undulating terrain cannot be effectively attenuated by placing barriers at the source. Barriers can also be placed between the source and the receiver.

The degree of noise reduction provided by barriers is dependant on the amount by which line of sight can be blocked by the barrier. If the receiver is totally shielded from the noise source, a reductions of up to 15dB(A) can be effected. Where only partial obstruction of line of sight occurs, noise reductions of 5 to 8dB(A) may be achieved. Where no line of sight is obstructed by the barrier, generally no noise reduction will occur.

As barriers are used to provide shielding and do not act as an enclosure, the material they are constructed from should have a noise reduction performance which is approximately 10dB(A) greater than the maximum reduction provided by the barrier. In this case the use of a material such as 10 or 15mm thick plywood would be acceptable for the barriers.

16.4.3 Silencing Devices

Where construction process or appliances are noisy, the use of silencing devices may be possible. These may take the form of engine shrouding, or special industrial silencers fitted to exhausts. In certain cases, it may be possible to specially treat a piece of equipment to dramatically reduce the sound levels emitted.

16.4.4 Silencing Devices

Where construction process or appliances are noisy, the use of silencing devices may be possible. These may take the form of engine shrouding, or special industrial silencers fitted to exhausts.

16.4.5 Treatment of Specific Equipment

In certain cases it may be possible to specially treat a piece of equipment to dramatically reduce the sound levels emitted.

16.4.6 Establishment of Site Practices

This involves the formulation of work practices to reduce noise generation. A noise plan will be developed for this project outlining work procedures and methods for minimising noise.

16.4.7 Noise Monitoring

Noise monitoring can be undertaken to determine the effectiveness of measures which are been implemented. The results of monitoring can be used to devise further control measures.

16.4.8 Combination of Methods

In some cases it may be necessary that two or more control measures be implemented to minimise noise.

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16.5 ESTABLISHMENT OF DIRECT COMMUNICATION WITH AFFECTED PARTIES

In order for any construction noise management programme to work effectively, continual communication is required between all parties concerned including the regulatory authority. This establishes a dynamic response process which allows for the adjustment of control methods and criteria for the benefit of all parties. The objective in undertaking a consultation processes is to:

- Inform and educate the groups about the project and the noise controls being implemented.
- Increase understanding of all acoustic issues related to the project and options available.
- Identify group concerns generated by the project, so that they can be addressed.
- Ensure that concerned individuals or groups are aware of and have access to the Brookfield Complaints Register which will be used to address any construction noise related problems should they arise.

To ensure that this process is effective, regular scheduled meetings will be required for a finite period, until all major issues have been addressed and the evidence of successful implementation is embraced by all parties.

16.6 DEALING WITH COMPLAINTS

Should ongoing complaints of excessive noise or vibration criteria occur; immediate measures shall be undertaken to investigate the complaint, the cause of the exceedance and identify the required changes to work practices. In the case of an exceedance of the vibration limits, all work potentially producing vibration shall cease until the exceedance is investigated. The effectiveness of any changes shall be verified before continuing. Documentation and training of site staff shall occur to ensure the practices that produced the exceedances are not repeated.

If a noise complaint is received the complaint should be recorded on a Noise Complaint Form. The complaint form should list:

- The name and address of the complainant (if provided).
- The time and date the complaint was received.
- The nature of the complaint and the time and date the noise was heard.
- The name of the employee who received the complaint.
- Actions taken to investigate the complaint, and a summary of the results of the investigation.
- Required remedial action, if required.
- Validation of the remedial action.
- Summary of feedback to the complainant.

A permanent register of complaints will be kept by Brookfield. All complaints received should be fully investigated and reported to management. The complainant should also be notified of the results and actions arising from the investigation.

The investigation of a complaint shall involve where applicable, noise measurements at the affected receiver, an investigation of the activities occurring at the time of the incident, inspection of the activity to determine whether any undue noise is being emitted by equipment and whether work practices being carried out either within established guidelines or outside these guidelines. Where an item of plant is found to be emitting excessive noise, the cause is to be rectified as soon as practicable. Where work practices within established guidelines are found to result in excessive noise, then the guidelines should be modified so as to reduce noise emissions to acceptable levels. Where guidelines are not being followed the additional training and counselling of employees should be carried out. The results of any corrective actions arising from a complaint shall be validated by measurement or other method where applicable.

16.7 STAFF TRAINING

Responsibilities and reporting requirements of all members of management and staff responsible for the implementation of each element of the plan shall be defined. Training to introduce the Noise Management Plan and explain details of noise sources, noise level targets, personnel roles and responsibilities, communication and complaint handling procedures shall be undertaken for all relevant employees upon commencement.

16.8 NOISE AND VIBRATION MONITORING

Noise and vibration monitoring would be undertaken for the duration of the construction process to provide historical verification data and to determine the effectiveness of measures that may be implemented or to respond to complaints. Attended vibration monitoring would be undertaken at the commencement of any new process to establish “safe” working distances.

17. COMPLIANCE TESTINGS

Compliance testing will be conducted in accordance with the standards nominated in this document and in full acknowledgement and compliance with the requirements of the Board. It is assumed for the purpose of this document that the minimal testing regime will be that set out in NSGH bid documents Volume 2/1 , Appendix S - Acoustics.

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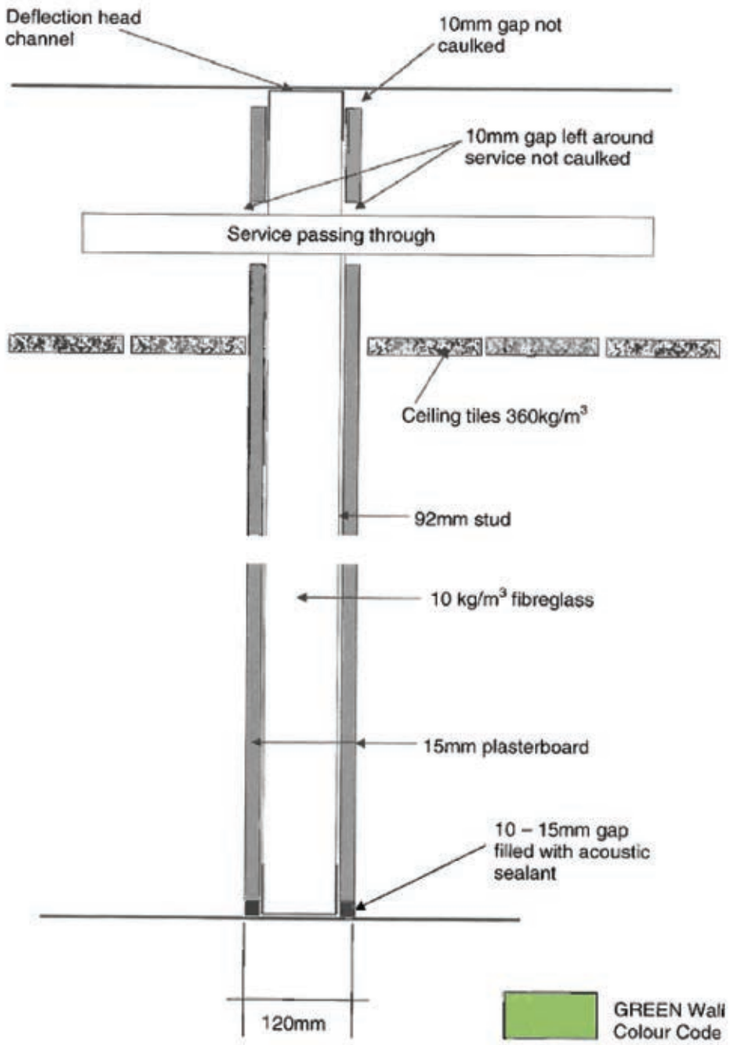
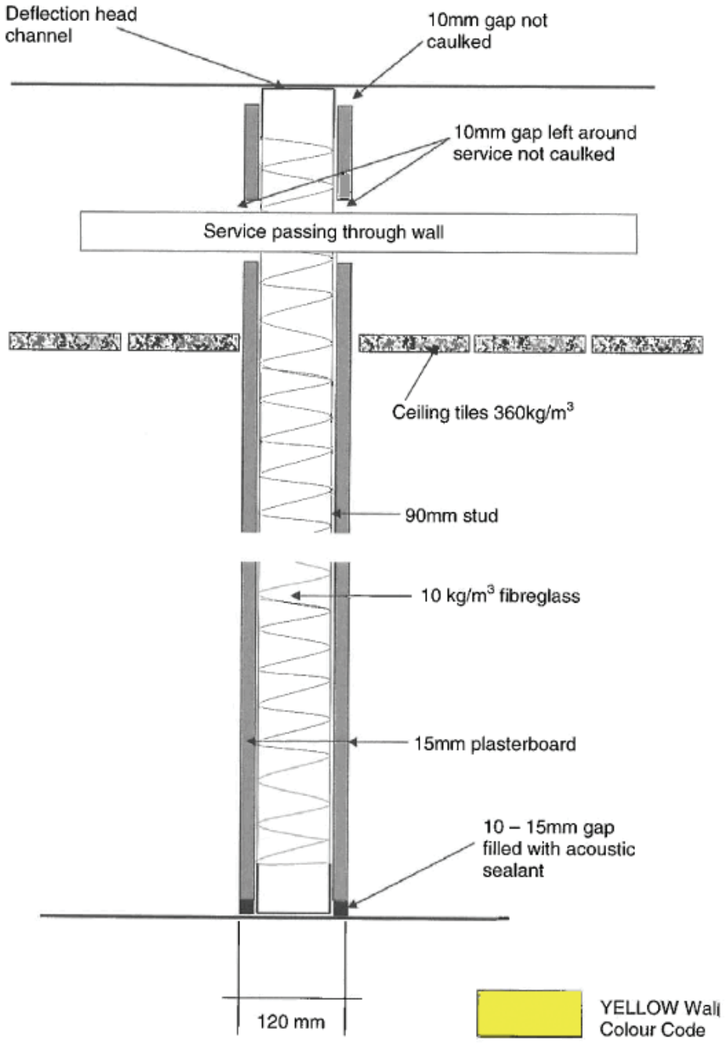
APPENDIX A - ACOUSTIC WALL DETAILS

Proposed NSGH Wall/Ceiling System Rw 35 – Conforming
Note: Service Penetrations and Wall Head do not require sealing.
This detail is also for Rw 40 walls



Proposed NSGH Wall/Ceiling System DnTw 37 – Conforming
Note: Service Penetrations and Wall Head do not require sealing



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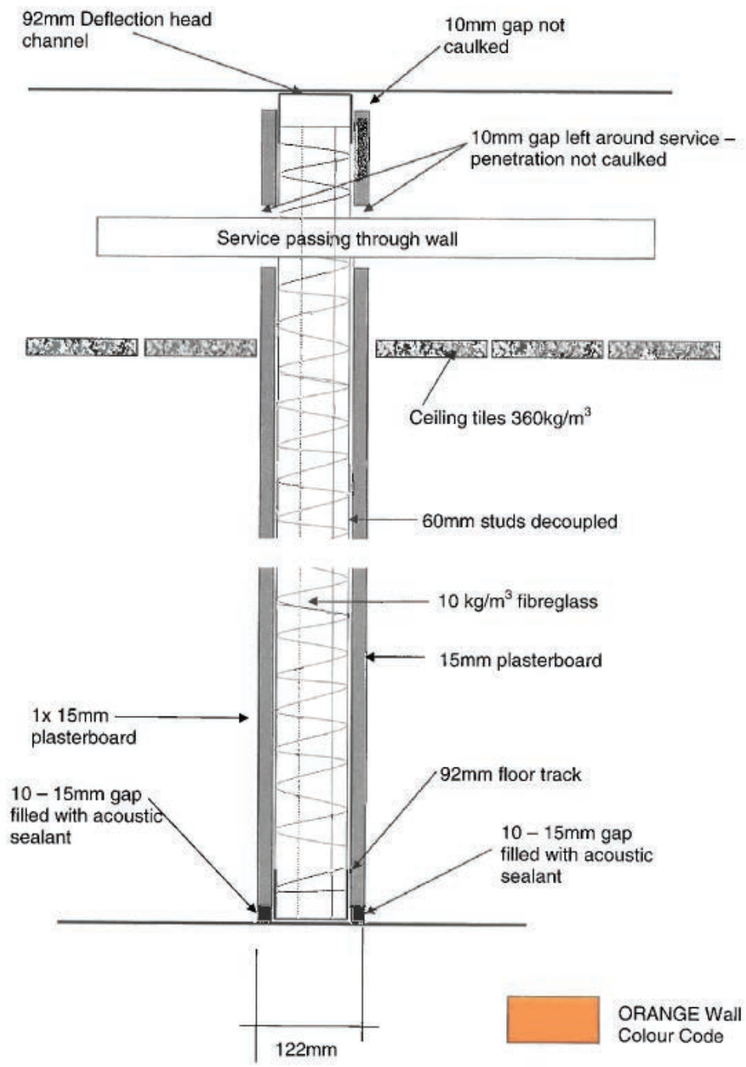
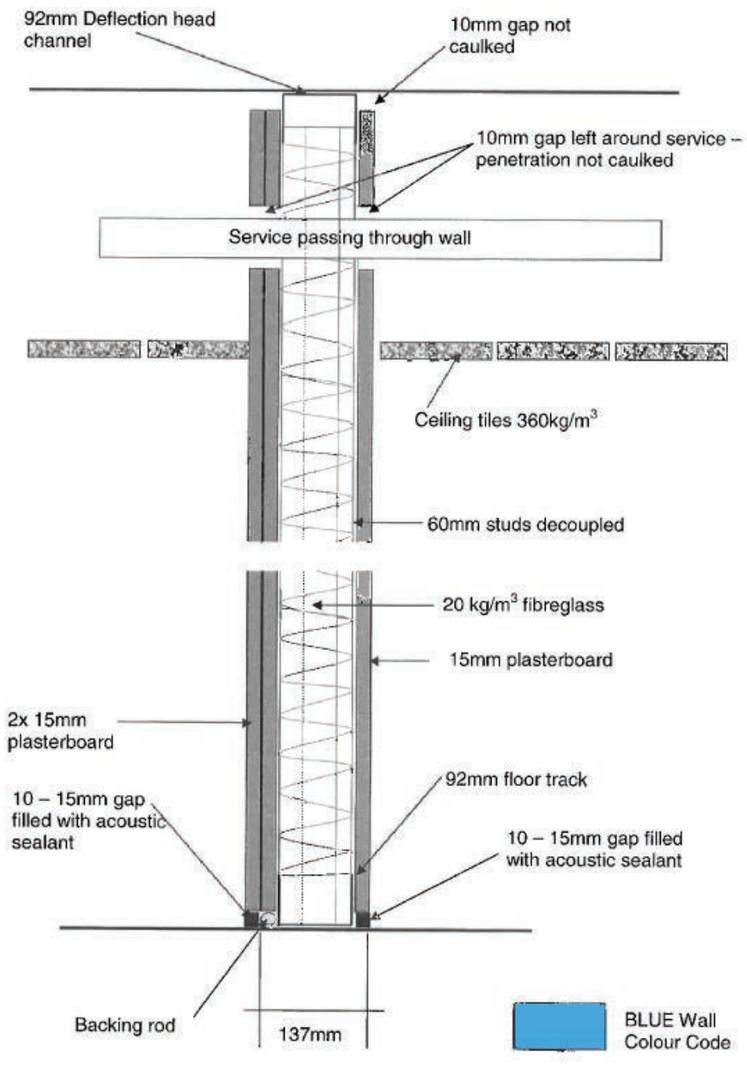
Proposed NSGH Wall/Ceiling System DnTw 42 – Conforming
Note: Service Penetrations and Wall Head do not require sealing



Proposed NSGH Wall/Ceiling System DnTw 47 – Conforming
Note: Service Penetrations and Wall Head do not require sealing



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Appendix B – Partitioning Acoustic Rating Marked-Up Drawings

Note: Refer to Appendix A for the section details of the different coloured partitions on the marked-up drawings herein

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Facilities Management Strategy

Submission Reference:

Section 3.5 Facilities Management Strategy

Submission Response:

3.5.1 Introduction

Brookfield through our own experience as building owners and operators recognise the importance of ensuring a good design is complemented with efficient operational design issues being duly considered. Our design for the New South Glasgow Hospitals Project appreciates that additional to providing first class clinical patient services, there are other very important activities necessary to permit the hospitals facilities management team to deliver their operations in an efficient and effective manner that matches the delivery of health services.

In this section we cover the following:

- Goods In and Out proposals for deliveries and removal off site
- Distribution proposals (hospitals and to lab building) from delivery to site to end user stations and back to location of removal off site.
- Separation of flows
- Systems and technologies
- Interface of systems
- Resilience of systems and proposals
- External façade access (cleaning and maintenance/replacement) solution

We understand that after Completion, the facilities management services will be delivered by a combination of NHS GG&C Health Board staff and specialist service providers working under contract to the Hospital's FM Department. Whilst they may be considered to be 'back of house' they are very necessary to support the delivery of clinical services. These services should be kept separate from patient or public activities and we have sought to meet this wherever possible. Our strategy for the delivery of Facilities Management Services reflects the 'back of house' principles and supports the separation from patient and public flows wherever practical

Key elements of our Strategy include:

- The inclusion of the service tunnel between the hospital and FM areas (particularly the goods in and out locations)
- The separation of vertical transportation routes, not only front and back of house but also clean and dirty FM functions
- The use of an automated movement system for the delivery of many bulk services
- The recognition that plant and equipment will over time need to be overhauled or replaced (refer to Volume 3 Section 3.23)
- The provision of specialised access systems to ensure that the external façade in particular can be cleaned and maintained.

The automated movement system incorporates the use of Automated Guided Vehicles (AGV) manufactured by Swisslog Healthcare (UK) one of our Supply Chain Partners and is a key aspect of our offer. Further detail is contained in subsequent paragraphs.

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3.5.2 Goods In and Out - proposals for deliveries and removal off site

All goods in and out will be managed via the designated areas within the Facilities Management Department. Separate and dedicated areas are provided for goods received, the back loading of empty containers and waste. Refer to Volume 2 Section 2.8a for 1:200 FM departmental drawings for the proposed locations within the Facilities Management Department and details of the service tunnel and basement.

There was much debate during the dialogue stage on the pros and cons and cost of incorporating a service tunnel into the design. We listened! Brookfield see this tunnel as fundamental. Our design incorporates a service tunnel linking the basement and the FM area where all goods are received and waste is collected by specialist contractors. All FM traffic, both pedestrian and AGV will use this tunnel and this is the primary 'structural' means of separating FM traffic from other users of the hospital. Movements to and from the mortuary and the hospitals will also use the service tunnel.

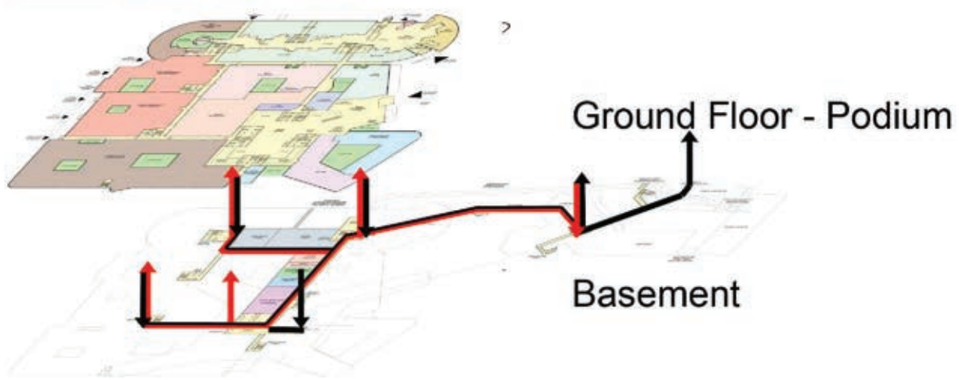
For vertical FM movement through the hospital, our design incorporates dedicated clean and dirty FM lifts. In addition, for the peak FM travel routes through the podium levels, the adult wards and in the FM area (both the main goods in/out and waste disposal areas), we have provided pairs of lifts for both the clean and dirty functions with one dedicated AGV lift within each pair. These lifts are integrated into the AGV Control System and will be 'called' automatically as an AGV approaches. In the event of a temporary failure of an individual lift, operation of the remaining clean or dirty lift in the pair will be converted to shared operation until the repairs are completed.

The FM lifts servicing the children's hospital will be shared between AGV and pedestrian traffic while still maintaining the split between clean and dirty operations.

3.5.3 Facilities Management Distribution Routes and Separation of Flows

The following table summarises the movement of materials, waste and staff into and around the hospital. As it is common to all FM traffic, the graphics contained in the table do not show the tunnel or FM area but focus on the traffic flows through the hospital. The following graphics are indicative only. More detailed sketches are contained in Volume 2 Section 2.2. As requested (updated ITPD volume 3 issued 19/8/09) the FM routes through the wards and other areas are included in Volume 2 Section 2.2.

First Floor - Podium



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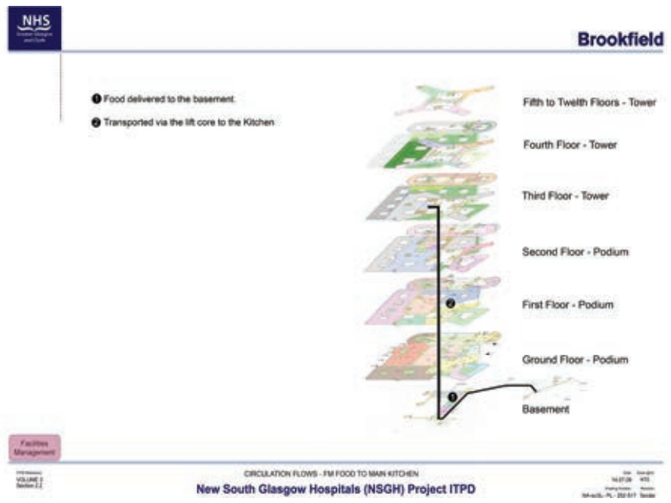
Activity	Description	Normal delivery method from / to receipt / pickup area
Catering – Deliveries to Central Kitchen	Deliveries to central kitchen including chilled food, milk, bread, general provisions, chilled dairy, other items AGV will deliver these items directly to holding areas in the main kitchen on Level 3. Vertical movement via the dedicated Clean FM Lift (AGV).	

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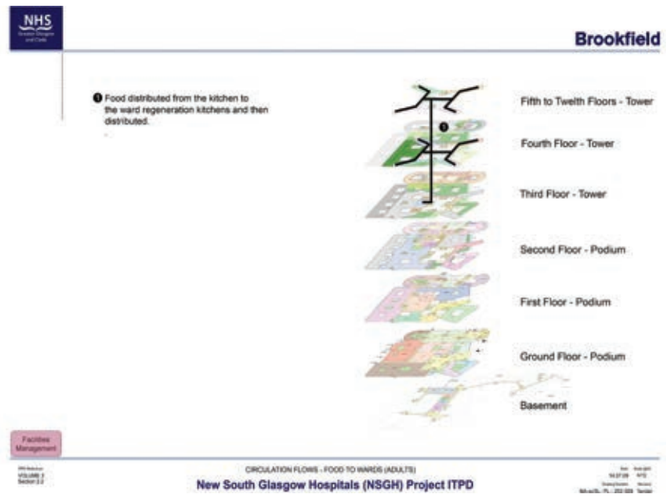
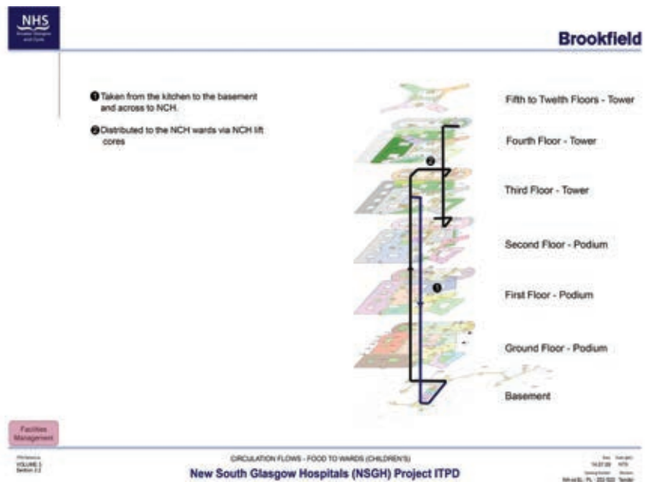
Activity	Description	Normal delivery method from / to receipt / pickup area
Catering – Deliveries from Central Kitchen	Deliveries of prepared food to regeneration kitchens Adult Wards Children's Wards Meals will be despatched from the central kitchen via AGV to the intended destination. The AGV will deliver the meals to holding areas adjacent to each regeneration kitchen. For the delivery to the adult wards, the AGV will use the dedicated Clean FM Lift (AGV).	

Activity	Description	Normal delivery method from / to receipt / pickup area
	For delivery to the children's' wards the AGV will move to the basement via the dedicated Clean FM Lift (AGV) and then use the Clean Shared FM Lift servicing the Children's Hospital. Note that the diagram only shows one lift core being used for this function. This has been done for clarity of the diagram. The clean lift within both cores will be used for this purpose.	
Catering – Deliveries from regeneration kitchens	Deliveries of prepared meals from regeneration kitchen to bedside.	The meals will then be delivered manually from the Regeneration Kitchens to patients under the normal hospital arrangements.

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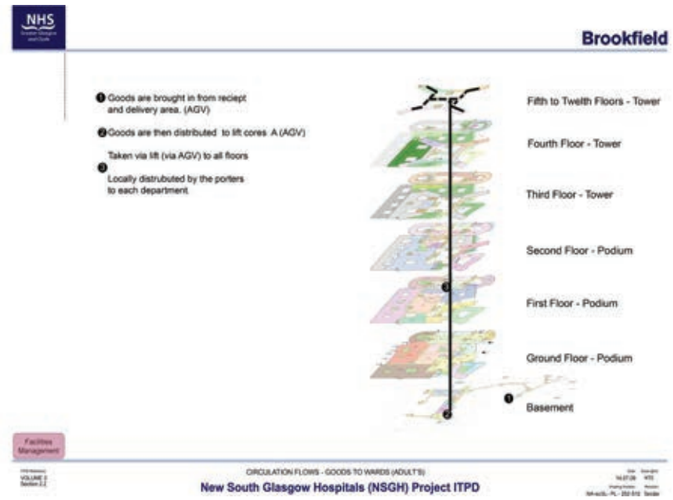
Activity	Description	Normal delivery method from / to receipt / pickup area
Stores and Materials	Medical goods, general stores including NDC deliveries Stores and supplies are transported via AGV compatible carts from the receipt area to the holding area adjacent to the FM lifts on the floor where it is required. Porters will complete the delivery from the holding area to the final destination. For stores delivered via the main lift core, the AGV will use the dedicated Clean FM Lift (AGV) Empty stores carts will be handled in a reverse manner with the cart placed in an outgoing buffer storage area in the FM area to await collection for transport off site For stores for the children's hospital, the AGV will use the shared Clean FM lifts.	

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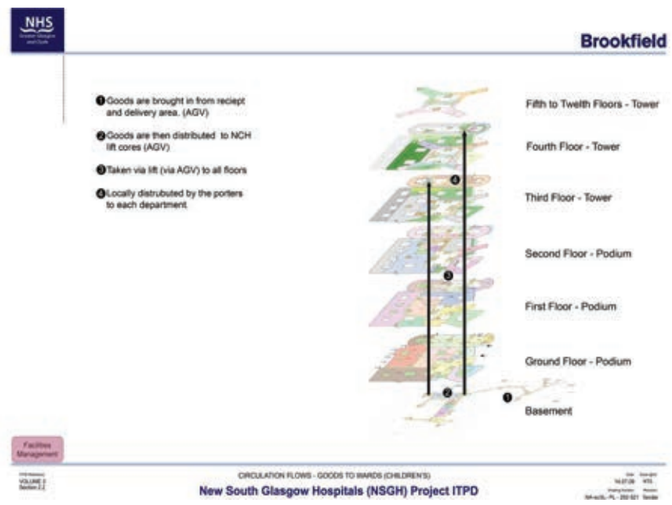
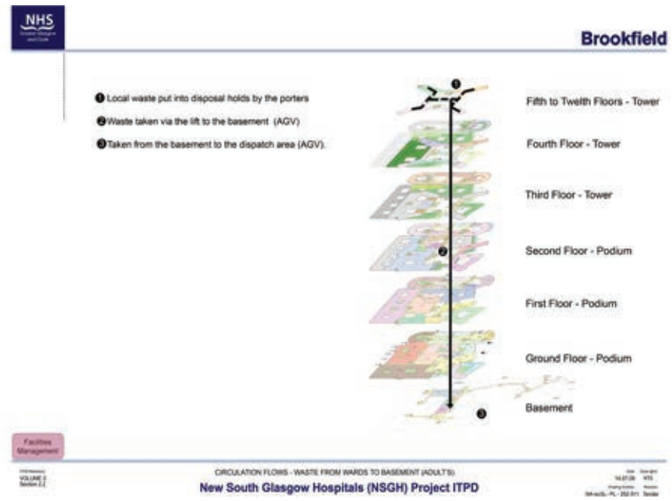
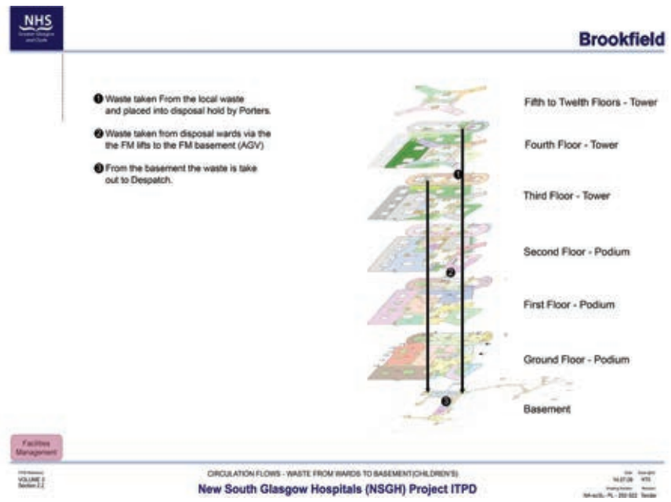
Activity	Description	Normal delivery method from / to receipt / pickup area
		

Brookfield

Activity	Description	Normal delivery method from / to receipt / pickup area
Waste	Including clinical, domestic, recycling, WEE, furniture and equipment site special waste Porters will collect full containers from locations around the hospital and deposit them in the holding area adjacent to the Dirty FM lifts. These are then collected by AGVs and transported to the waste handling centre. For waste moved via the main lift core, the AGV will use the dedicated Dirty FM Lift (AGV). Empty waste containers will be handled in a reverse manner and exchanged by the porters in the holding areas on each level. For waste from the children's hospital, the AGV will use the shared Dirty FM lift.	

Activity	Description	Normal delivery method from / to receipt / pickup area
		

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Activity	Description	Normal delivery method from / to receipt / pickup area
Linen	Clean linen, soiled linen	Linen is transported by AGVs in a manner similar to goods in and waste out described previously except that porters will collect clean linen from the holding area adjacent to the Clean FM lift and deliver it to the appropriate clean linen stores in the wards. Similarly, soiled linen is collected by the porters from the disposal hold and moved to the holding area adjacent to the Dirty FM Lift where they are collected by AGVs and transported to the collection points in the FM area.
Other Products.	Includes retail, mail, drug, laboratory products, retail waste	All items will be moved by porter, other FM staff or retail tenants. These items will be collected from source and delivered directly to the final destination. For movements to and from the main podium and adult, they will used the appropriate dedicated Clean or Dirty FM lift (pedestrian).
Specialist Services	Bed management, medical gases	All items will be moved by porters or FM maintenance staff. For vertical movement within the hospital, dedicated bed lifts have been provided. Medical gases will use the optimum FM route which may include a Dirty FM lift.
FM Staff	Maintenance staff, domestic staff	All vertical FM pedestrian movement will use the appropriate Dirty FM lift. All FM staff will use the service tunnel to move between the FM Department and the hospital.
Mortuary	Movements between Hospitals and Mortuary	All movements between the Hospitals and Mortuary will be via the service tunnel.

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3.5.4 Systems, Technologies and Integration

3.5.4.1 Automated Guided Vehicles (AGV) Strategy

Introduction

By reference to the ITPD Volume 2/1 Employer's Requirements (Hospitals) Appendix M&E 7 identifies the requirements for an Automated Material Transfer System. We understand that the provision of the medical treatment and patient-care core processes at the New South Glasgow Hospitals will generate substantial logistical workloads. Without an automated system, this requirement can only be met by a large number of porters thereby making it operationally inefficient and with it significantly higher costs.

To meet the requirements of an Automated Material Transfer System, Brookfield proposes the use of an Automated Guided Vehicle (AGV) system manufactured by Swisslog Healthcare (UK). We know this solution will streamline the movement of goods, linen and laundry and catering services around the hospital as well as improving the overall efficiency and effectiveness of the these 'back of house' FM functions. AGVs are currently in use in hospitals in Germany, where as you would expect efficiency is at the core of these operations. If appropriate and requested by NHS GG&C Health Board, Brookfield can arrange through Swisslog to facilitate a visit to some existing facilities to witness first hand how these AGV's operate and discuss end users experiences.

Swisslog Healthcare (UK) Ltd has been closely associated with key aspects of the design development and as a consequence our design incorporates the requirements of this system including the appropriate sizing of corridors, the service tunnel, doors and lifts. The AGV system has been fully integrated into the lift operation which will ensure a smooth and seamless operation.

One of the key advantages of this system is the minimisation of the requirement to install fixed infrastructure and the ability to allow both pedestrian and AGV traffic in the same spaces thereby reducing capital expenditure. We are confident that the Automated Guided Vehicles will significantly improve the movement of goods within your hospitals. Furthermore, our analysis indicates that the system provides a lower whole of life cost when compared to a fully manual distribution solution because of the annual savings in manpower costs that can be achieved through a reduced number of porters.

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Design Philosophy

We have sought to optimise the utility of the AGV system by using it for all elements of the service until loads become too small to be carried on an AGV cart. As far as possible the AGV's will be used to carry full loads between major nodes within the hospital.

- Distribution of goods requires decision making on the part of the deliverer.

We anticipate that porters will continue to distribute goods beyond the major nodes particularly when some decision making is required by the person moving the load. For example, we anticipate that porters will continue to distribute linen from the holding areas on each floor to storage locations in each ward.

- Potential for interaction between patients and robots

While the AGV's are safe to use around humans, we have sought to minimise the potential for contact between AGV's and patients/members of the general public. By restricting the use of AGV's to 'back of house' locations and movements between major nodes using the dedicated FM routes, we have ensured the potential for contact with patients and the general public is unlikely. We understand that this principle was generally agreed during the final dialogue session.

Key assumptions

This proposal is based on the following assumptions:

1. All carts for NHS stores, linen, meals and sterile goods will be AGV compatible and details of which will be provided by NHS GG&C Health Board during the Hospital build and procurement programme.
2. Special drop side carts to meet the Swisslog specification will be provided by NHS GG&C Health Board to allow non-AGV compatible stores trolleys and cages to be loaded and transported via the special active buffer system provided by Swisslog as part of the works.
3. Waste carts will be either AGV compatible or will be configured such that they can be transported on drop-side AGV carts. Further discussion and consultation will be required to confirm the particular solution appropriate to the New South Glasgow Hospitals and its waste contractors.

Whilst it is assumed that AGV compatible carts will be provided through the usual NHS procurement channels for use by NHS-controlled distribution centres, Swisslog are able to provide carts to all specifications on request. Swisslog will provide the necessary data and specification for AGV compatible carts. Modifications required to standard manual handling cart designs are minor and do not significantly increase the unit cost over a standard cart at the time of manufacture.

By way of information AGV compatible carts have the following specification requirements:

- 360mm ground clearance to allow the LTC2 AGV to manoeuvre underneath.
- Swivel wheels with magnetic or similar mechanical locking device to ensure wheels are aligned fore-aft when the cart is being carried.
- Specific cart width with a small side overhang to allow the carts to be handled by the active buffer conveyor systems and automatic cart washing machine.
- Fixed magnets on the chassis to allow accurate cart positioning on the AGV.
- Pocket/holder for the RFID tag that identifies the cart's intended destination.
- Optionally, specific door mechanisms if the cart washer is to be fitted with automatic door opening and closing devices.

3.5.4.2 AGV Operations

The general FM traffic flows through the hospital is described in section 3.5.3. This section expands on that concept with particular reference to how AGVs are integrated into those traffic flows.

The identification of individual loads and destinations will be through Radio Frequency Identification (RFID) technology.

Linen

Linen will be ordered electronically and packed at a remote facility (depending on the requirements of specific departmental locations) and loaded onto an AGV compatible cart for transport to site. Following delivery it will be placed in a buffer holding area in the FM area prior to collection by AGV and delivery to the holding area adjacent to the FM lifts on the relevant floor. Porters will complete the delivery process to the final destinations within the wards.

Soiled linen will be handled in a reverse manner with the cart of soiled linen placed in an outgoing buffer storage area in the FM area to await collection for transport off site.

NHS stores & supplies

NHS stores and supplies will be ordered electronically, packed at a remote facility (depending on the requirements of specific departmental locations) and loaded on to an AGV compatible cart for transport to the Hospital. Following unloading in the FM area, it will be placed in a buffer holding area for collection by AGV and delivery to a holding area adjacent to the FM lifts on the relevant floor. If necessary, porters will complete the delivery.

Empty stores carts will be handled in a reverse manner with the cart placed in an outgoing buffer storage area in the FM area to await collection for transport off site.

Stores and supplies from other suppliers

Stores and supplies from other suppliers will be delivered to site in standard (non AGV compatible) cages and trolleys to the FM area. Here they will be loaded directly onto a special AGV compatible cart via an active buffer system that will present the special cart at ground level to allow trolleys and cages to be wheeled straight on. These will be collected by AGV for delivery to the intended destinations as described previously

Waste

Waste may be handled directly by AGV compatible carts, but where this is not possible, empty standard Euro bins will be loaded on to special AGV compatible carts and delivered by AGV to the intended destination as described previously.

Full waste carts will be collected from holding areas on each floor by the AGV and transported to the waste handling centre where the Euro bins will be removed from the AGV cart for transport off site.

Catering

Food deliveries from off site will be managed in a similar way to other stores and materials except that the AGV's will deliver these directly to holding areas in the main kitchen on Level 3.

Meals will be despatched from the kitchen via an active buffer system that ensures that meal carts are handled in a first in, first out manner to ensure timely delivery of the meals by AGV to the intended destination.

The AGV will deliver the meals to holding areas adjacent to each regeneration kitchen where the final preparation activities will be completed. The meals will then be delivered to patients under the normal hospital arrangements.

Cart Cleaning

We recognise that carts must be cleaned regularly as such have included an on-site washing facility with a capacity of around 20 carts per hour.

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3.5.4.3 AGV's The Proposed System

Equipment

Our proposal includes the following elements:

- 22 x LTC2-LC vehicles with NICAD batteries
- 15 x NICAD charging stations
- 2 x control server PC installed with TCMS2 software (Live + backup unit)
- Service laptop installed with TCMS2 software
- 10 bus controllers (PLC interface for doors etc)
- 2 x active buffer units:
- One is located at goods in/out in the FM area to handle special drop side carts for transporting stores on non-AGV compatible trolleys and cages. This buffer fitted with a horizontal diverter to make a loop configuration and also a lifting mechanism to enable carts to be loaded at ground level.
- The second is located in the kitchen to handle outbound meal carts.
- 221 passive cart stations made up of 78 send only stations, 73 receive only stations and 70 combined send/receive stations. These will be located at the FM hub area on ward floors and in passive buffer areas within goods in/out and also the Energy Centre.
- 56 x arrival signal units and 20 AGV approaching warning beacons.
- A two-chamber automatic cart washer.

Interface with other systems

Lifts

The AGV System interfaces directly with the various FM lifts. Our plan shows two lifts (one clean, one dirty) dedicated to AGV use in each FM cluster in the main building core. To service the Children's hospital the lifts will be shared between pedestrian and AGV traffic.

Lifts are automatically called by the AGV traffic management system. After the individual transportation of an AGV is complete the lift is released either for subsequent AGV traffic or manual operation as required.

Doors

All doors on the route of the AGV System will be automated. Fire doors, held open, will be slightly delayed from shutting until any AGV in the immediate area of door operation is clear.

Fire Alarm System

The AGV installation will be connected to the fire alarm system so that in the event of an alarm, AGV movement is controlled in an appropriate and programmable manner to suit the circumstances.

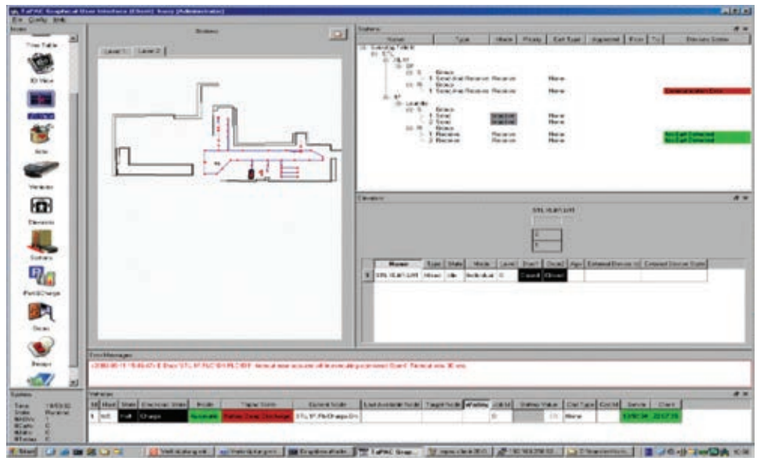
Additional requirements

To be able to provide an operational installation, a compatible network with comprehensive WiFi will be provided. In addition, suitable network connections including provision for Power Over Ethernet will be provided adjacent to all locations required by the peripheral equipment of the AGV installation e.g. sending station transponder readers, charging stations, PLC interfaces for lifts and doors.

We will provide suitable interfaces to connect to lifts, doors, fire alarms and communication systems (BMS etc). The suppliers of this equipment will provide compatible interfaces to ensure appropriate interaction.

Control systems

Swisslog's LTC2 AGV and its Traffic Control & Management System software (TCMS) have been specifically designed for healthcare applications. The compact vehicle design and small turning space is ideally suited for operation in a hospital environment. The bi-directional vehicle minimises manoeuvring space requirements around lifts and send/ receive stations. The AGV's navigation and guidance system does not require any modification or attachments to the building fabric, and hence the scope of the Swisslog AGV's operational routes can be easily altered or extended at any time. TCMS2 is designed for ease of operation with both 2D and 3D visualisations of AGV activity and location. Programming and control functions are easily configured, and the system may be operated with minimal training.



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3.5.4.4 Resilience of Systems

Warranty

We note that at the Commercial Dialogue Meeting No 3 on 15th July 2009, NHS GG&C Health Board confirmed that Bidders should allow for an extended Defects Liability Period of 24 months for all elements post completion of each Stage. The equipment included within the AGV system will be provided with an additional 12 months defects liability warranty period by Swisslog in addition to the 24 months DLP provided as part of the construction contract. During this period the equipment will require servicing procured by the hospitals FM department according to the manufacturer's schedules.

Maintenance

In addition to the system supply and installation, we are pleased to advise Swisslog will also offer a comprehensive service and maintenance for the Swisslog AGV installation including all parts and labour over a five year period for a sum of approximately £300,000 (to avoid doubt this figure is excluded from the Target and Maximum Price). As a comprehensive maintenance offer, this includes all routine maintenance, ad-hoc repairs and consumable items but excludes batteries. Maintenance on the cart washers and active buffer conveyor/lifters is excluded from this estimate.

A comprehensive maintenance agreement with Swisslog will provide NHS GG&C Health Board with confidence that the manufacturer is standing behind its product and that this innovative system will continue to provide operational savings year on year.

3.5.5 External Access Systems

Safety is at the core of Brookfield and we are extremely conscious of the need to provide safe external access to the façade of both the podium and the tower for both cleaning and maintenance activities. We have assessed each facility and set out are proposals to that affect.

Laboratory Building

Our proposal anticipates that the laboratory building will be cleaned externally using an articulated boom lift (commonly known as a "cherry picker").

Podium Levels

We have allowed a 2m wide perimeter to permit access via elevating platform or articulated boom lift (cherry picker) to most of the podium levels and Children's Hospital. The only exception to this is at the Children's Accident and Emergency ambulance entrance as we have allowed a soft border for privacy/screening adjacent to the building (Observation Ward). For work above these locations an articulated boom lift will be necessary to provide sufficient horizontal travel to reach the façade above this area. By way of example, the Nifty Heightrider 17 4x4 lifting platform provides a 17m lift with 9.6m outreach and a working ground width of 2m.

Tower (Adult Hospital)

Our design proposes the use of Manntech Type 1 Building Maintenance Unit supplied and installed by Cento to provide safe access to all sides of the Tower façade.

The Manntech Type 1 Building Maintenance Unit (BMU) is a proven design with over 400 examples installed in the UK between 1972 and 2009 and in excess of 3,500 world wide. This equipment is ideally suited to buildings where a roof level perimeter track system can be installed. The imposed roof loadings are minimal and will allow the use of a non-anchored and non roof penetrating 'freely laid' track system. The freely laid track system is cost effective to produce and fast to install. It reduces associated construction cost and the non-anchored track support detail eliminates the need for weathered fixing details.

This BMU and Track system design is the preferred option for many PFI and other hospital projects for example, Lewisham, UCLH, RVH Belfast, Addenbrookes, and Hull RI. With proper maintenance it will provide a service life of 30 years.

The system is fully powered and is available for use within minutes of maintenance or cleaning staff arriving at the garaging location. Cleaning and maintenance staff will access the roof the building through doors to the roof areas, Safety barriers will be installed to permit access from the door to the BMU 'rest' location.

In the event of emergency service helicopter using the roof landing pad when the BMU is in operation, we propose to install a communication system between the cradle and roof car that can be used to warn BMU occupants of a helicopter approach. Operational procedures will need to be established to resolve interface issues between BMU and helicopter operations. These procedures should be repeated in the 'helipad operations manual'.

Maintenance.

The system must be maintained and tested in accordance with BS 6037: 2003, LOLER 1998 ACoP and PUWER 1998. The manufacturer recommends routine inspections are advised at 3 month intervals and a more thorough inspection at 6 month intervals. Weight test & re-certification is required every 12 months. An estimate from the manufacturer for the annual maintenance and certification of this equipment will be provided.

Training

This system is simple to use and operator instruction is provided by Cento. The manufacturer can provide operator training to permit FM staff to use the equipment. One day's training is sufficient to train six operators. Instruction is always site specific Refresher instruction is not compulsory but is recommended depending on how frequently an operator is using the equipment. This is a client decision. Cento can deliver instruction at the Hospital's request.

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Main Incoming Utilities Design/Connection Strategy

Overview

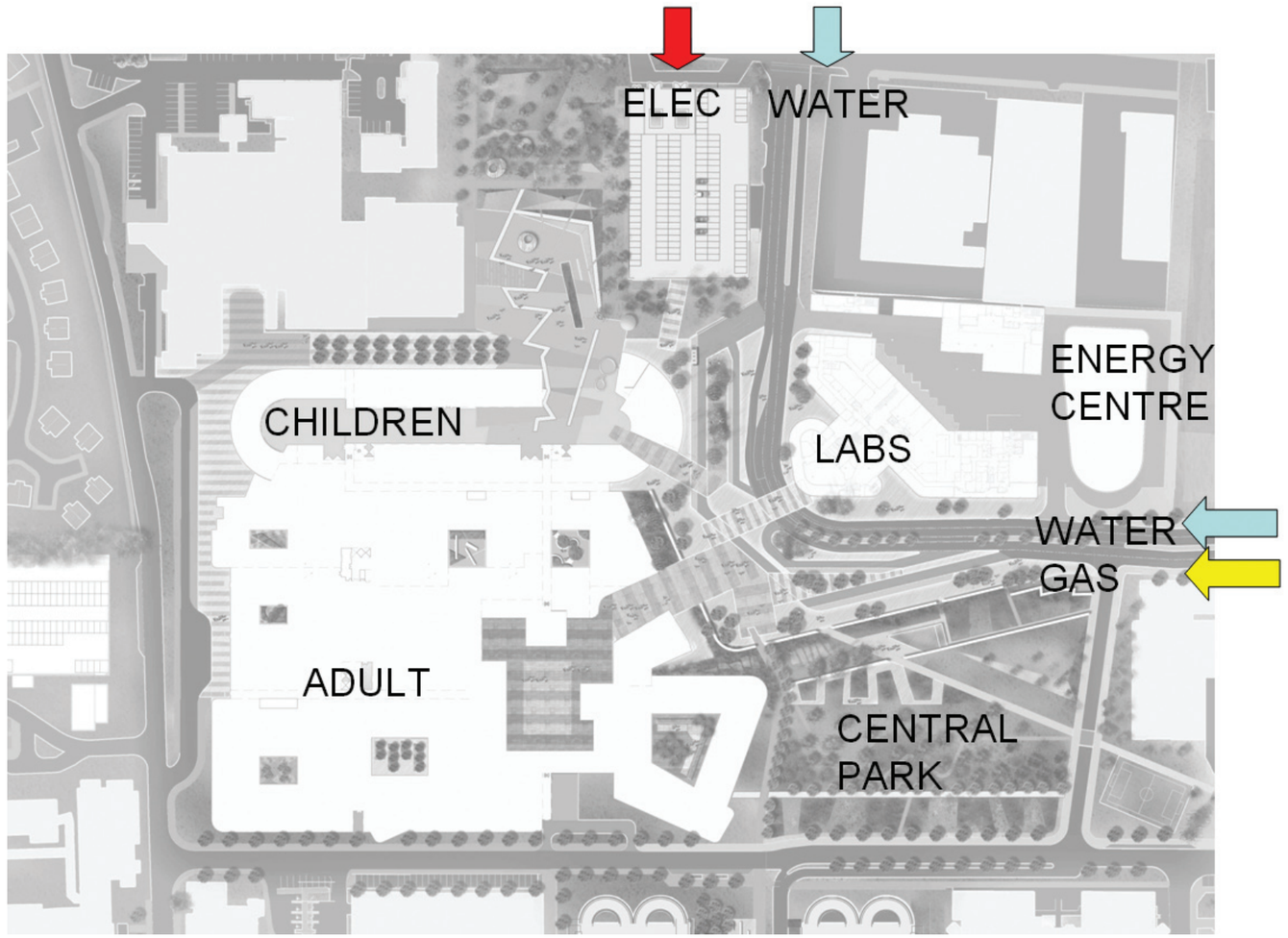
The diagram illustrates the location of the incoming utilities, the water and electricity being taken from the Hardgate road, the gas and a second water supply being taken from the Govan Road.

Electrical Utility

The site will be supplied by Scottish Power at 33,000 Volts, their substation being located off Hardgate Road.

It is estimated that the site load will be in the order of 21.5 MVA, including 25% growth and including the retained estate.

This figure exceeds the estimate in the Employer's Requirements by 1 MVA, however, it is noted that the figure in ITPD of 20.5 MVA is based upon an area for the exemplar scheme of 140,000m_ whereas the measured area of the examplar is approximately 166,000m_. If corrected, the load stated in the ITPD would become approximately 22.5 MVA.



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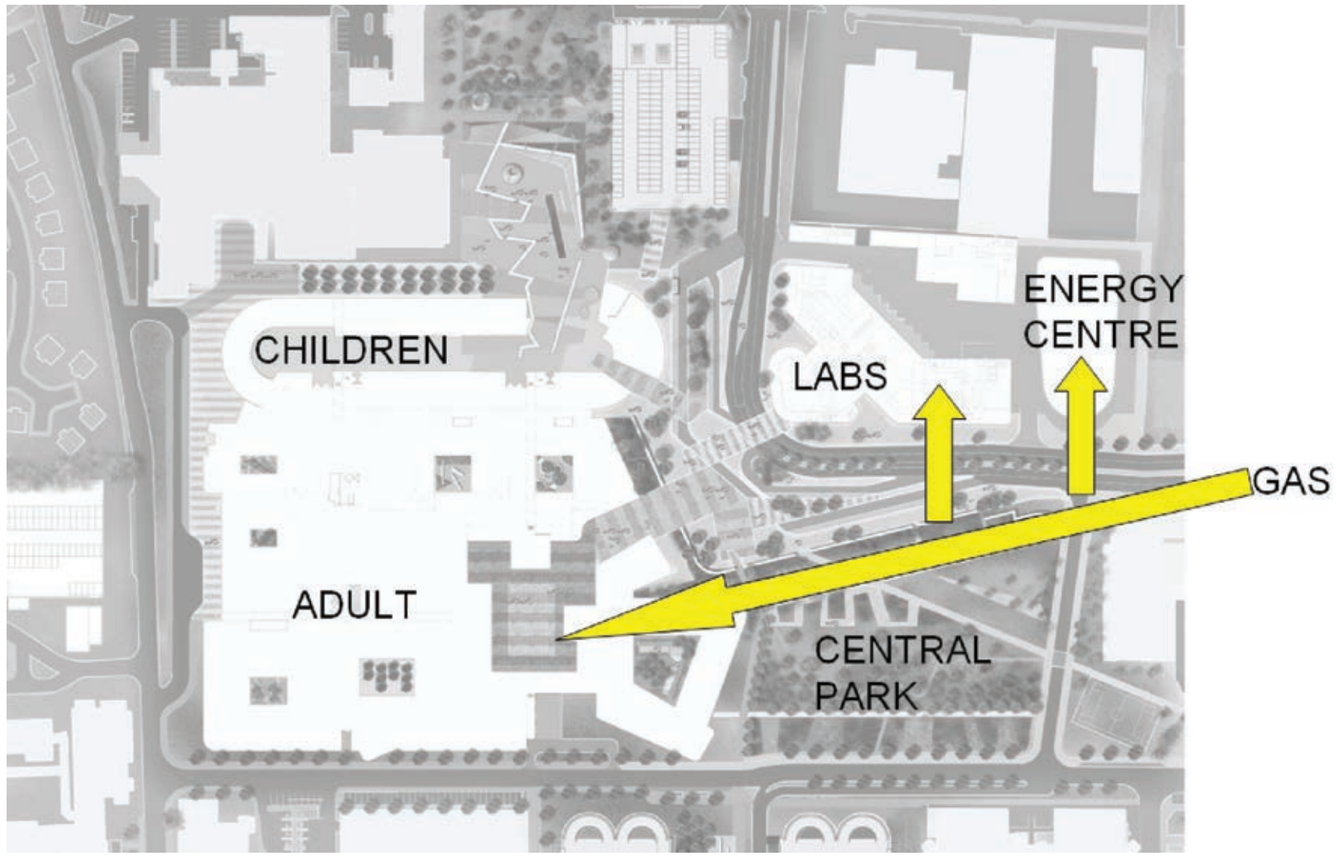
Gas Utility

The gas supply for the Adult Hospital and Children's Hospital will run from a new meter housing and booster station at the boundary of the site on Govan Road and run as a medium pressure supply to the Energy Centre and with a branch to serve the Laboratory Building.

The medium pressure gas main will continue to the Acute building to serve the kitchen/catering.

Whilst the current solution is based on gas supply being brought to the site at Low Pressure, consideration will be given to bringing in a medium pressure supply to avoid the need for onsite boosters.



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Water Utility

Potable mains cold water will be derived from two separate street public water mains with a separate water main entering the site from each main.

The two 150mm respective site water mains will run in a shared trench with the fire and gas main.

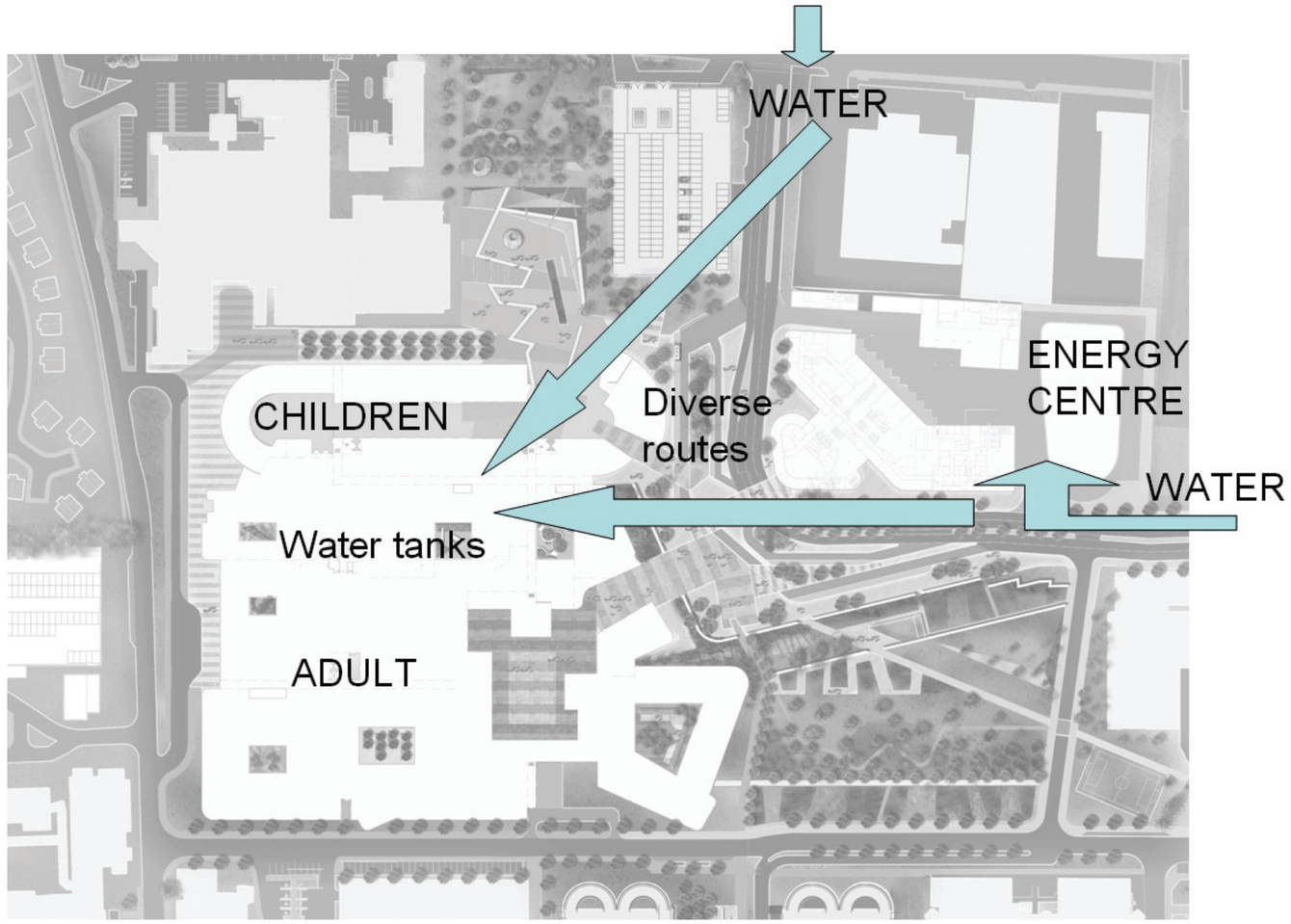
To safeguard against the event of a mains failure from either public street main and ensure resilience to the hospital site water supply the two site mains will be linked by a valve chamber with a normally closed valve for sole use by Scottish Water if and when required.

Fire Mains

The two separate water main connections from Govan Road and Hardgate Road will each have branches to run as fire mains around the site to serve fire hydrants.

The fire mains will form a ring around the building and be interlinked by a normally closed Fire Brigade valve to ensure resilience to the site fire main network.

The fire mains will be unmetered unless specifically requested by the local water authority.



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Energy Centre

The Employer's Requirements Proposal is for two energy centres in separate locations on the site. This has been reviewed and an alternative is proposed.

The proposed energy centre is to be located adjacent to the laboratory block. The single building will be internally separated into two separate compartments each containing half of the required plant and separated by a 4 hour fire wall. This effectively provides for two energy centres within one building envelope.

Each half of the energy centre will be capable of independent operation and together will incorporate the N+I requirements for resilience and maintenance.

The energy centre plant will include generator and boiler capacity for the laboratory block to reduce plant space requirements in the laboratory building and to provide a level of resilience consistent with the rest of the site.

It is proposed that the energy centre will be built at the same time as the laboratory building and fitted out with services to enable the laboratory block to be fully operational in advance of the full fit out of the energy centre.

The energy centre will also house fuel oil for the emergency generators and boiler standby fuel for the retained site.

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Water Services and Drainage Design Strategy

COLD WATER SERVICES

The two incoming potable cold water mains will supply the filtration and storage plant located within the hospital basement.

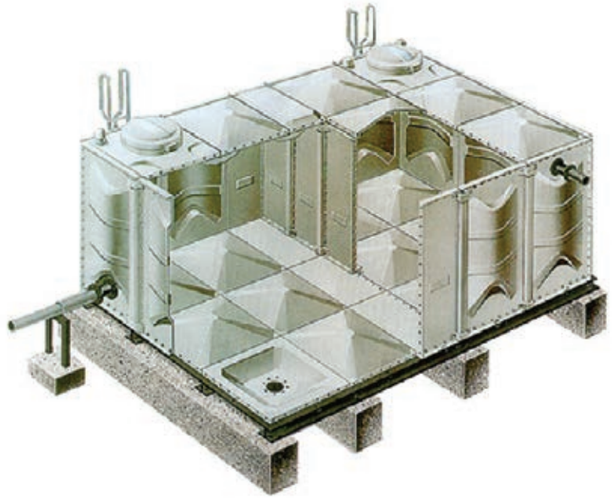
The incoming mains water will supply break tanks before passing through water filters to supply the bulk storage tanks. The water will be stored in a ‘wholesome’ condition and distributed to all sanitary fitting points, thus avoiding the need for a separate drinking water distribution system.

Cold water will pass through electronic water conditioning devices to reduce the build up of scale within equipment and distribution systems.

Water booster sets will pump the filtered water from the basement to the cold water distribution systems throughout the hospital and also supply the domestic hot water systems.

At each floor distribution branch a pressure regulating valve will be provided to maintain similar water pressure at all levels in the building providing convenience of use and minimizing water consumption.

All distribution systems will be capable of being chemically cleaned and disinfected.



Sectional water storage tank

Booster set

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DOMESTIC HOT WATER

The boosted cold water systems will supply the domestic hot water (DHWS) systems therefore they will be pressurised. A number of systems will be provided for the various areas of the hospital. The DHWS will be generated and stored within the building utilising high efficiency semi-storage calorifiers comprising buffer vessels linked to rapid recovery plate heat exchangers. The calorifiers will be located within the plant rooms generally related to the location of the heating stations.

The DHWS distribution system will be configured with a pumped return to maintain temperatures within the system. The pumped return system will minimise “dead legs” and reduce water consumption by providing the correct temperature of water at the outlet with minimum delay.

The storage system will be capable of achieving higher storage temperatures for carrying out a pasteurising process to minimise contamination from Legionella bacterium within the storage vessel. Each storage vessel will be isolated from the distribution system while the process is carried out.

The distribution system will be arranged to minimise conditions of low flow within pipework. The hot and cold water system pressures will be equalised at each service outlet for successful blending of hot and cold water through anti-scalding devices prior to use.

The anti scalding devices will be used throughout the hospital where service outlets provide water for personal hygiene washing.

At each floor distribution branch a pressure regulating valve will be provided to maintain similar water pressure at all levels in the building providing convenience of use and minimizing water consumption.

Packaged HWS plate heat exchanger/buffer vessel

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Heating Design Strategy

Selection of system

The choice of heating medium has been considered and the use of Medium Temperature Hot Water (MTHW) is proposed for the following reasons:-

- There is considerable transmission distances involved on the Southern General Hospital site. MTHW operating at 120oC flow and 90oC return temperatures will reduce the mass flow rate circulated and thus pumping power required.
- Most building on the site will use Low Temperature Hot Water (LTHW) as the final heating distribution medium. Therefore, to maintain adequate temperature at the extremities of the site a high temperature is required at source. MTHW is most suitable for this purpose.
- There is little requirement for process steam on the site, for example laundry and CSSD. Steam systems are generally a more inefficient source of heating due to higher operating temperature, blowdown and other losses, and complications with return condensate back to the plant. Therefore, central steam system has been ruled out. Any steam requirement such as humidification will be met by either local gas fired plant or direct electric units, depending on the size and location of loads.
- In order to reduce the carbon emissions of the development it is proposed to incorporate Combined Heat and Power (CHP) units as part of the heating source. CHP units operate more efficiently at lower temperatures. Whilst LTHW is preferable, incorporation of CHP into MTHW systems is still very beneficial. If operating with a steam system their operation can be severely affected.

Location of Boiler Plant

The Exemplar scheme indentified two separate energy centres on the new development site; a main energy centre to the North of the new acute hospital and a second centre to the East adjacent to car park 1B. This arrangement provided resilience in the event of a catastrophic failure in one of the buildings.

It is proposed to utilise a remote energy centre to concentrate noisy and ‘dirty’ plant away from the main hospital buildings. The energy centre will house not only the central boiler and CHP plant, but also 11kV switchgear, standby generators, oil storage and main hospital cooling plant.

To avoid the need to provide two energy centres the single energy centre building will be divided into two with heating and cooling plant, and standby generators spread across the halves, with four hour fire separation between. The plant will be designated A and B and essentially work as independent systems to provide resilience.

The building will be three storey with accommodation arranged as follows:-

- Ground Floor – oil storage for standby generators, boilers and retained site. Oil fill points for tanker deliveries will be located on the Western face of the energy centre
- First Floor – standby generators and 11kV switchgear
- Second floor – MTHW heating boilers and CHP units, absorption cooling plant
- Roof – main chillers and associated transformers, absorption chiller dry air coolers, wind turbines

A multi-core chimney will collect flue discharges from the standby generators, boilers and CHP units to discharge products of combustion.

Multi core chimney

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Boiler Plant Sizing

The heating load for the site has been assessed for fabric, ventilation and hot water service loads. Loads for the retained estate and proposed developments have based on the information given in Appendix M&E.2 of the Employer's Requirements.

The heating load for the new hospital as discussed above has been established as follows:-

- Fabric heating is based on similar projects and has been taken as 20W/m2
- Ventilation heating has been assessed using the volumetric flow rates calculated from the proposed scheme and are described in section 3.9. An allowance for heat recovery on ventilation plants has been assumed.
- Hot water has been assessed based on the number of sanitary fittings within the hospital and selections made of suitable calorifiers.

MHTW Boiler

The total heating load can be summarised in the following table:

Heating (kW)										
Description	Total AHUs	Heat Recovery	Total AHUs	Duct Heaters	VT Circuit	Misc CT	Total heat load	Pipe Losses 2%	Total HEX Duty	HWS
Plantroom 21	1800	-340	1460	85	300	100	1945	39	1984	300
Plantroom 22	1895	-380	1515	95	100	100	1810	36	1846	300
Plantroom 31	4395	-880	3515	220	440	100	4275	85	4360	1000
Plantroom 32	3320	-660	2660	165	1200	100	4075	80	4155	450
Plantroom 33	-	-	-	-	-	-		-	-	450
Plantroom 41	1700	-320	1380	80	350	100	1910	38	1948	450

Total	14293	2950
Diversity	10%	10%
Load Diversity	-1430	-295
Mains losses 1%	143	-
Corrected loads	13006	2655
New build total		15661
Retained Estate(1)		5670
Future Developments(1)		5700
Total Boiler Load (kW)		**27031**

Heating loads taken from ITPD Volume 2/1 App. M&E.2 Base Building Loads

Therefore, the total heating load for the new hospital will be in the order of 28,000kW, which equates to 120W/m^2. The compares favourably with similar projects as noted below;

Princess Royal University Hospital	157 W/m^2
Barnet Hospital	120 W/m^2
Peterborough Hospital	110 W/m^2 (Designed to 2006 Building Regulations)
Kings College Hospital	189 W/m^2

The total site load to be met by the boiler plant in the energy centre is 28,000kW.

Boiler Plant Arrangement

As described earlier, for resilience, the boiler plant will be divided into two. The total load to be supported by each part will therefore be some 14,000kW, which will be met by three boilers at 5,000kW. Allowing for standby capacity on each half (N+1) gives four boilers, and a total installed load for each side of 20,000kW. Therefore, each boiler plant can meet 66% of the total site load, which should be sufficient to allow the hospital to continue to function in the event of a catastrophic failure on one system. This allowance will also include for a service reserve capacity.

For further resilience connections will be made available on each system header to allow a temporary trailer mounted boiler to be connected to boost the capacity of the heat source.

The boiler plant will be dual fuelled using natural gas as the primary fuel and 35 second gas oil as the emergency fuel. Automatic changeover between primary and emergency fuels will be automatic to prevent disruption in operation. The arrangement of the natural gas and fuel oil systems are described later.

Combined Heat and Power System

In order to reduce carbon emissions from the Southern General Hospital, a number of Low and Zero Carbon strategies are proposed. One of these strategies is to use combined heat and power (CHP) plant to generate electricity on site and use the waste heat from the generator cooling jacket and exhaust gases to provide heating and cooling, via absorption chiller plant, to the building.

An analysis of the use of CHP is further described in Section 3.20.

Heating Distribution

From the energy centre MTHW will be distributed to the main hospital to serve the various major plant zones. It is proposed to employ buried underground heating mains to avoid the need for a major tunnel system, with the associated complications of access, ventilation and fire protection, etc.

The two heating systems (A & B) will be replicated in the heating distribution between the energy centre and the main hospital building, thus providing resilience in the event of a pipework problem necessitating the shutdown of one circuit. At the main hospital the two circuits will be brought together for final distribution to the main load centres.

The final heating medium for fabric heating and ventilation systems will be LTHW to provide safe operation of plant. MTHW will be used for hot water service calorifiers to give rapid heating and recovery.

To separate MTHW and LTHW heat exchange stations will be formed at load centres.

Whilst the Exemplar Design utilized a constant volume pumping distribution arrangement with 3-port bypass valves at the load centres this does mean that the pumps have to run at constant speed and offer no facility to reduce pump power across the site. It has been estimated that this could consume up to 1.4GWh across all pumping systems more than is necessary equating to 4kg/m^2 of CO_2, which with such a stringent carbon and energy target needs careful consideration.

It is therefore proposed to employ variable volume pumping arrangements and 2-port valve control to maximise pumping efficiency, with the pump speed being varied automatically as the heating load changes.

Retained Estate

Allowance has been made in the boiler capacity to serve the retained estate together with future developments, such as the laboratory/FM building. Separate pumped circuits from the A and B sides are allowed for the laboratory/FM building and connections have been allowed on the B side plant for future provision for the retained estate and other buildings.

This will allow the CHP heating capacity to be further utilized and therefore increase system efficiency and reduce site carbon emissions further.

It is envisaged that when it is planned for the retained estate to be linked to the central system a new pumped circuit will be established and heating mains run out from the energy centre using a buried pipework system, similar to that used for the new hospital buildings. Connections would be left at each load centre on the heating mains and then the decentralised boiler plant sequentially decommissioned and fed via plate heat exchangers from the central system. As with the new buildings it is proposed that variable volume pumping is employed to reduce pumping power.

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Ventilation and Air Treatment Design Strategy

Purpose of ventilation

Ventilation in the healthcare environment can be naturally or mechanically driven and serves a number of purposes which can be summarised as follows:

Providing fresh air for normal respiratory purposes
Diluting the level of CO^2 in the space
Removal of odours and pollutants
Control of temperature and humidity
Control of infection
Specialist process requirements
Occupants experience a feeling of wellbeing

The use of natural ventilation will minimise the need for energy to drive fans. However many clinical requirements, in for example Operating Theatres, necessitate the use of mechanically driven ventilation for close environmentally controlled spaces and departments having high equipment heat gains. Furthermore, despite carefully considered planning, building constraints invariably lead to spaces that do not have access to natural ventilation.

The other major consideration with regard to the ventilation strategy for the building is the construction. The thermal mass and 'u' values or thermal characteristics of the structure have been carefully selected as they determine the optimum thermal lag of the building which controls the rate of heat transfer into the space and therefore how quickly the space may overheat.

Studies have been carried out into particular areas of the hospitals – wards, for instance, which make up a significant proportion of the hospital – to determine whether natural ventilation can be employed to achieve the purposes as set out above, within the targets set down by the Board in the ITPD documents.

Use of natural ventilation

As indicated above the main benefit of employing a natural ventilation strategy in a hospital building is the reduction in energy consumption. Windows aid a feeling of connection for the occupant with the outside world and manual opening can increase the perception of control over their internal environment.

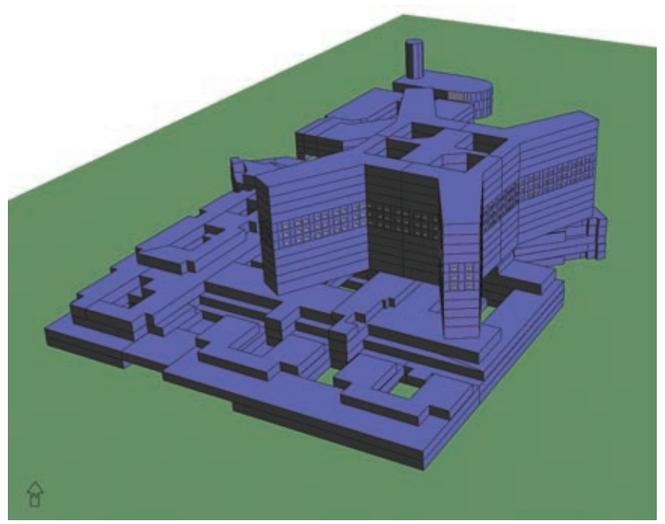
However there are a number of situations in which natural ventilation may not be suitable or desirable. The ventilation solution needs to take into account a number of local factors, which include, but are not restricted to, the following:-

- Air permeability - Building Regulations now legislate for the airtightness of buildings in order to help reduce heating requirements by minimising the uncontrolled infiltration/exfiltration of external/conditioned air.
- Outdoor air quality – The quality of outdoor air needs to be considered when determining the use natural ventilation where treatment of the incoming air is not available.
- Indoor air quality – Natural ventilation from windows on the external face of the building will only be effective internally for a zone of 5-6m from the openings.
- Pollution – In addition to common airborne pollutants, the site is susceptible to other sources of pollution including the noise and downdraft from the emergency helicopters landing on the helipad and the odour from the nearby sewage works.
- Thermal comfort – The disadvantages of natural ventilation include the increased risk of overheating in summer and low external temperatures in winter may discourage the opening of windows. Both situations will lead to poor air quality if insufficient ventilation is provided.

As stated above the new hospital building will contain departments or some rooms within departments that have to be mechanically ventilated however consideration has been given to naturally ventilating the maximum possible number of areas. The analysis below has concentrated on the option of naturally ventilating the wards as they form a large proportion of the building.

Analysis of the ventilation strategy for the building

The Building Regulations recommend acceptable limits for overheating based on the number of hours experienced per year over a limiting temperature. However, the analysis has been based on an amendment to the ITFD documents which stated that the overheating threshold was to be set at '50 hours per year above 26°C'. A virtual 3-dimensional thermal model has been produced, as shown below, based on the floor layouts and the thermal mass and properties of the selected constructions. Using the model extensive thermal dynamic modelling has been undertaken to determine the rooms in which overheating is likely occur.



The thermal modelling has concentrated on the typical ward layouts on the 3 mid-tower floors and three top-floor wards and specifically considered two adjacent ward bedrooms located on each face of the tower. In association with the thermal modelling, daylight simulation calculations have been undertaken as part of a strategy to achieve a BREEAM 'Excellent' rating for the new hospital. These calculations determined the optimum window sizes required for the daylighting percentage. Due to the low envelope air permeability mechanical make-up ventilation

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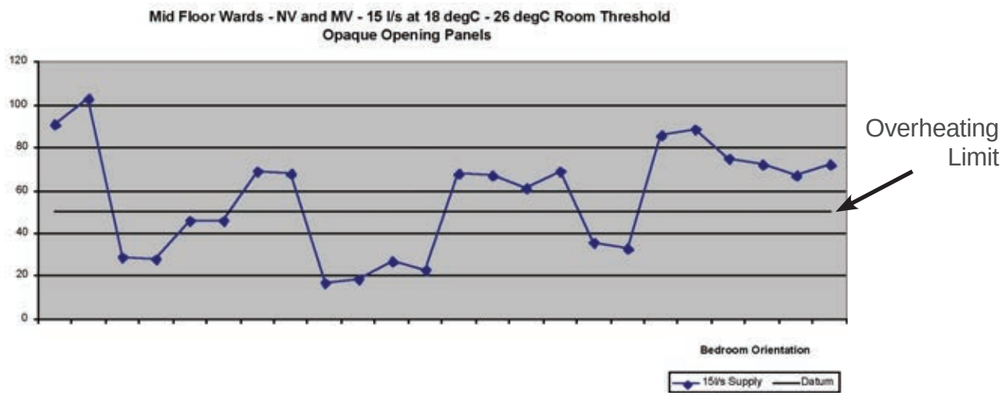
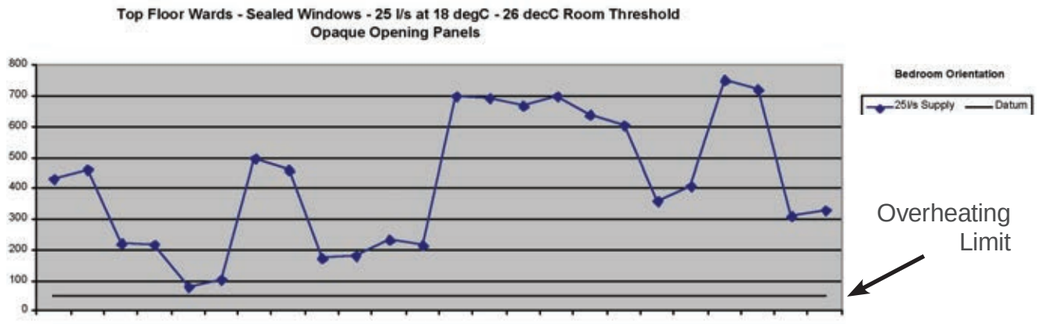
is provided to the bedrooms to match the extract from the adjacent bedroom en-suite toilet/ shower rooms. This adds the benefit of being able to condition this air, particularly in warm weather, to assist in reducing overheating.

Below are two examples of simulations that were carried out to reach a final solution, however, these are the culmination of many other simulations carried out using differing design criteria and options.

A simulation for the three mid-tower floors was undertaken with the bedroom mechanical ventilation set to 15 litres per second at 18ºC supply air temperature to provide only sufficient make-up air for the en-suite extract together with natural ventilation provided via an opaque 200mm high opening louvred panel. A full height section of high performance glazing was used on all the elevations. The results in the graph below show that overheating would be experienced on approximately 60% of the elevations:



A similar simulation of the three top-floor wards was undertaken with mechanical ventilation set to 25l/s at 18ºC supply air temperature. There is no natural ventilation provided via the full height section of high performance glazing or the opaque section as all the windows were sealed to avoid nuisance from helicopter noise and downdraft. The results in the graph below show that overheating would be above the threshold on a 100% of the elevations:



Odour Control

The issue with the problem of odours from the adjacent sewage works in association with the design of the mechanical ventilation has been addressed with the provision of carbon filters on the fresh air side of the air handling units.

Conclusion

Both sets of results show that in the wards a mixed mode, natural and mechanical ventilation combination, together with optimising the glazing area and type does not provide the solution to meeting the overheating criteria in the majority of the rooms. It is proposed that all ward rooms be provided with a means of mechanical cooling in the form of an active chilled beam as pictured below. The active chilled beams operate most effectively with the windows sealed as this reduces the likely hood of condensation.

It is envisaged that generally only small perimeter non clinical rooms with low occupancy and low heat gains will be able to be solely naturally ventilated. Other similar but larger more densely populated rooms will employ a mixed mode system. Then as stated above the majority of the clinical spaces will be mechanically ventilated or mechanically or air conditioned.

With the overheating design target set at ‘50 hours per year above 26ºC’ and the summer external design temperature also 26°C the target is an onerous one to achieve with natural ventilation. In progressing the ventilation design strategy a number of calculations have been carried using ‘50 hours per year above 28ºC’ (in accordance with the guidance in SHTM 03-01) as the target and it has been found that the mixed mode method is a feasible solution in the majority of the ward rooms.

Mains Power Distribution Design Strategy

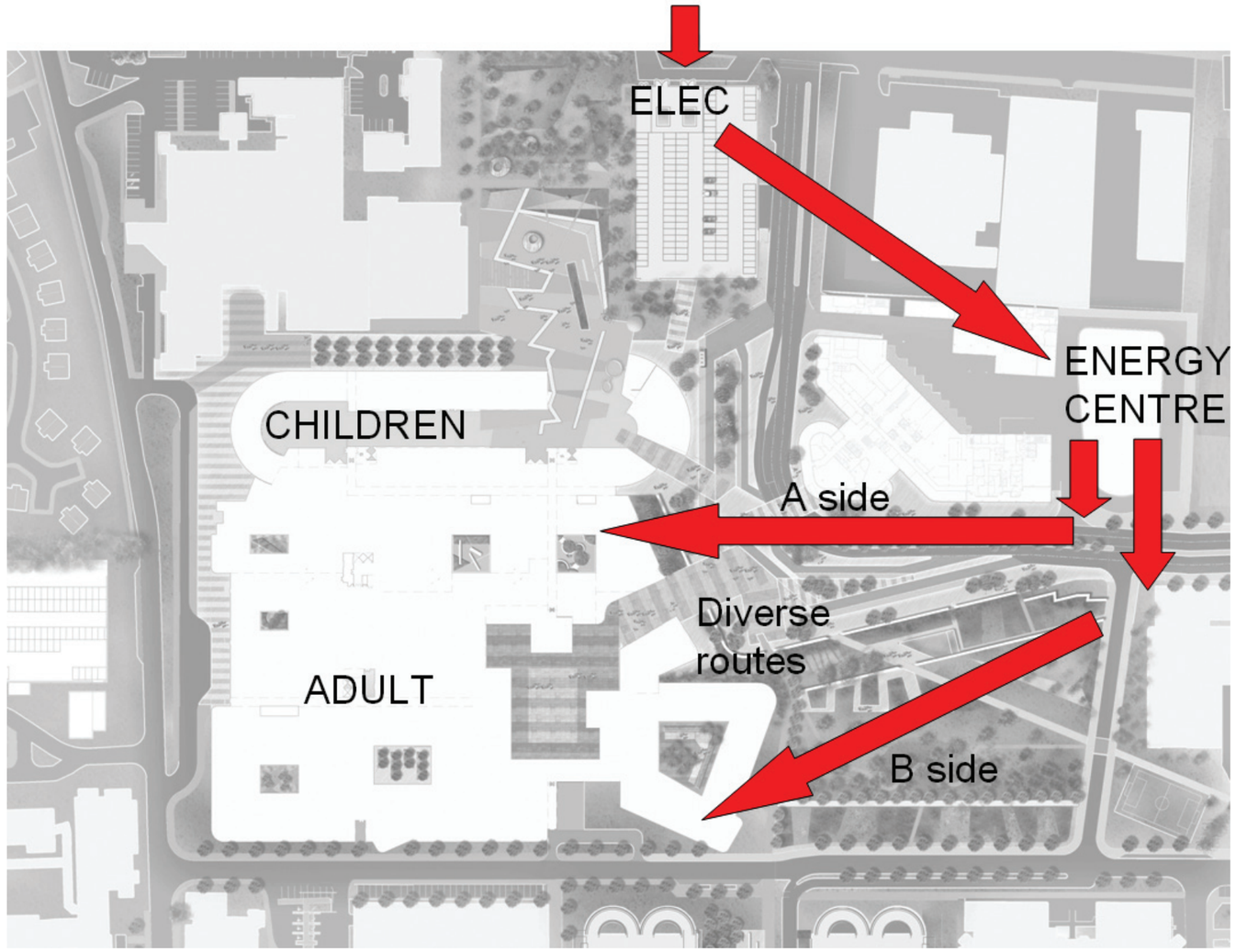
The Incoming Utility supply will be derived at 33kV from the Govan Grid Connection Point. The11kV supply up to and including the Utility Primary 11kV switchboard will, under normal supply conditions, provide two independent incoming 11kV supplies to the Hospital's 11kV system. The configuration of Utility 33kV and 11kV feeders and switchgear will allow the Utility Company to maintain or rapidly restore the 11kV supply to the hospital under most scenarios of a planned outage, or during any unplanned failure, of part of a leg of the Utility 33kV/11kV supply system. This will be achieved by the Utility switching the 33kV and 11kV feeder and bus section switchgear.

Two main incoming 11kV Utility supplies from the Utility Primary 11kV Switchboard are proposed, entering the site routed via diverse routes. Each of these will be terminated into one of the two NSGH 11kV main intake switchboards, each located within one of the two Energy Centre generator halls. Under normal supply conditions the supply arrangement will provide two independent incoming 11,000V supplies to the Hospital's 11,000V system. The two separate sections of the Energy Centre, and the equipment contained in them, will be designated A and B respectively.

The segregation of the two parts of the Energy Centre will provide a high degree of fire separation between the two sections.

In the event of a loss of supply from either section of the Utility Primary 11,000V switchboard, or one of the metered services from it, the lost Utility service will be replaced by automatic switching of the incoming and interconnector 11,000V switches on both NSGH Main Intake Switchboards to isolate the failed service and replace it with a feed from the remaining service. This will be done via the automatic controls for the NSGH 11,000V distribution system.

The overall arrangement will provide an incoming 11kV supply having an inherently high degree of resilience. This incoming supply will also be backed up by the Standby generator provisions; refer to the later section of this specification, "Standby Generators", for a description of this system.



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The switchboards will be equipped to supply 4 new 11kV rings, two for the new hospital building and two for the retained site.

From the energy centre, the mains power distribution will follow the principles of a dual-unified distribution network as described in SHTM 06-01 whereby primary and secondary circuits are provided, each fully rated to provide a resilient distribution network and routed by diverse routes as illustrated in the diagram.

To achieve this, the HV network will be formed of open rings, each limb of which is effectively a radial circuit.

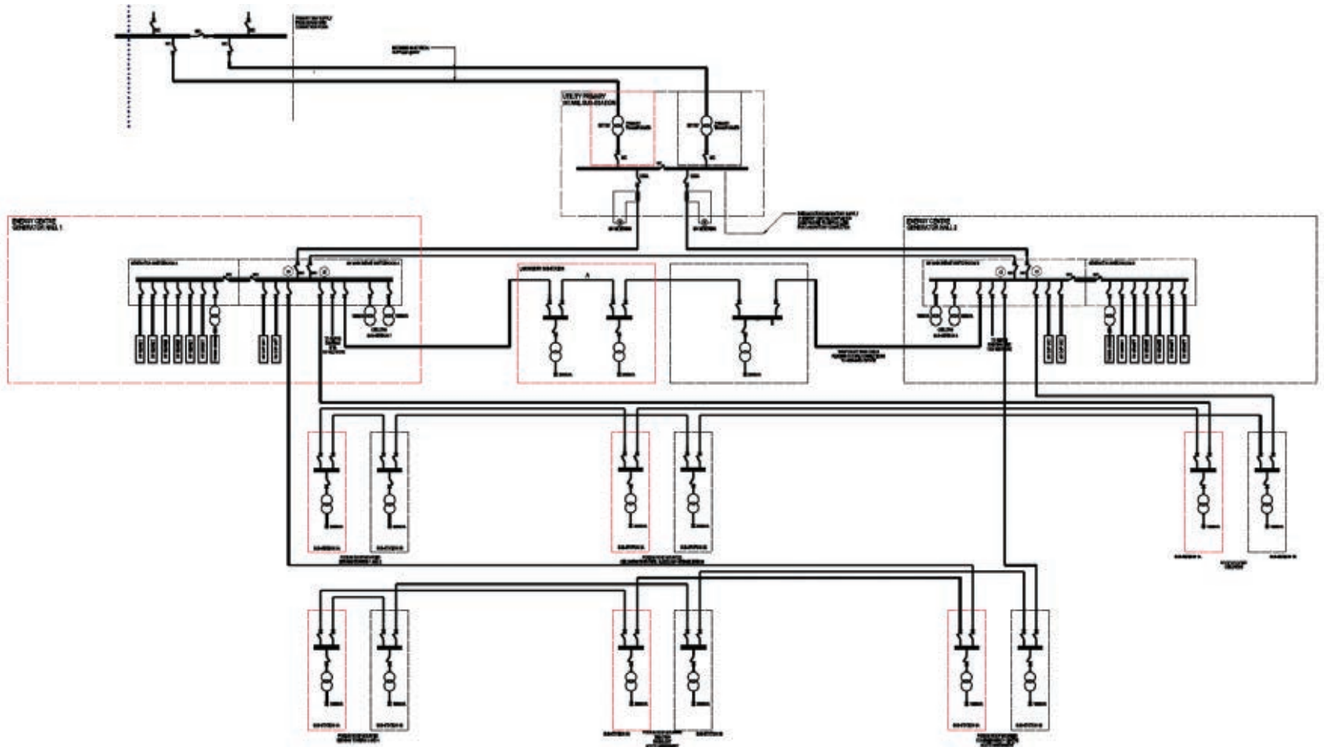
The cables will be selected to carry the whole load, this will enable the open point position to be changed in the event of a fault thereby isolating the fault. Refer to specification section 4.55 for further technical details.

The laboratory building will be fed from one of the rings which will later be extended to serve the retained estate. Provision will be made for connection to the retained estate as follows:-

- Adequate cable ducts and access pits from the energy centre to the opposite side of the main access road
- Cable ducts from the laboratory building for extension of that ring to the edge of the retained estate
- HV switchgear arranged in laboratory for safe extension of ring to serve retained estate

The schematic diagram illustrates the principles described so far.

- Two rings are illustrated serving the childrens and adult hospitals and two rings for the retained estate, one of which serves the laboratory building.
- The building is divided into 6 electrical zones with one substation per zone and a pair of transformers per substation.
- The transformers are connected in sequence so that they are allocated to the A side and B side of the HV ring.

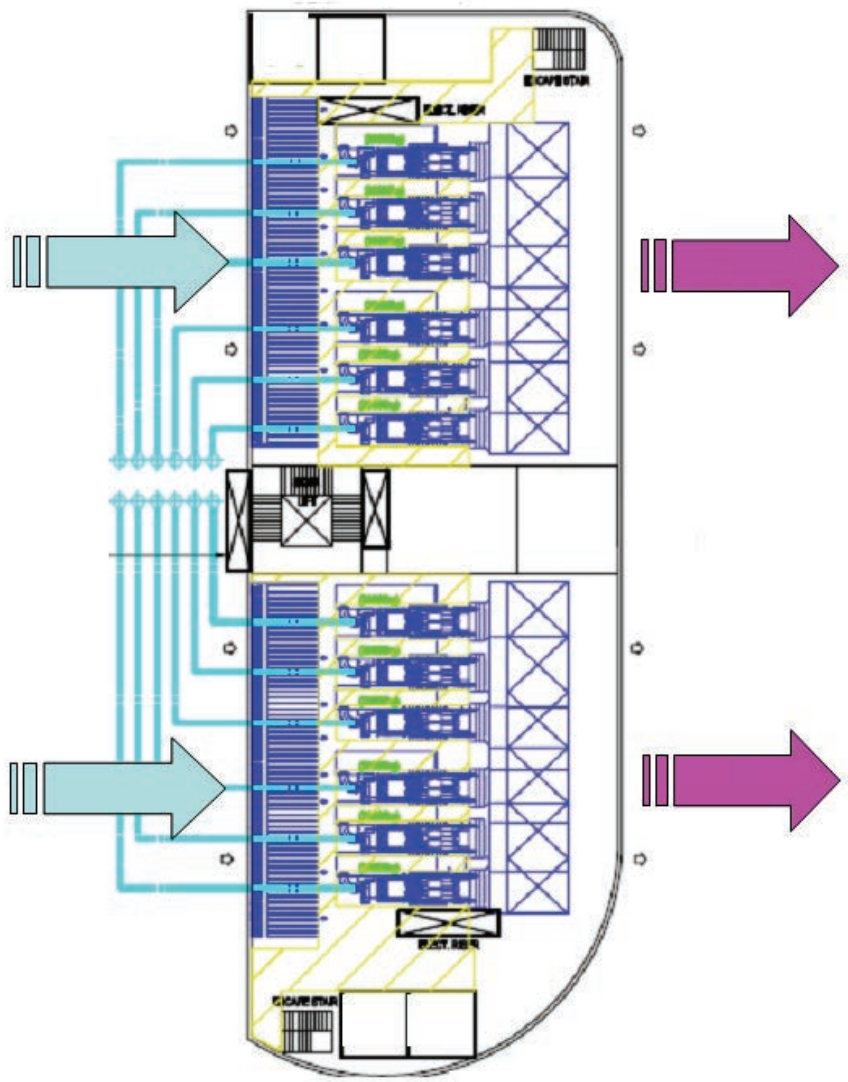


The Energy Centre will accommodate the standby generators. The estimated site load will be 21.5 MVA / 20MW (at a high power factor). The generators must be rated for Watts, thus 2 MW/2.5MVA Generators will be provided in an N + 1 configuration, hence 12 generators will be provided in total.

The generators will operate at 11,000 volts. Step up transformers will be included for future connection of mobile low voltage generators.

The generators will be housed in two fire separated generator halls as illustrated in the diagram.

The energy centre will be located to allow free flow of combustion and cooling air to the generators.



Mains failure

A load management control system will be provided to schedule the reconnection of power on mains failure in accordance with the principles laid down in Appendix 1 “Maximum interruption times to the primary supply” of SHTM06-01. Automated motorised switchgear will be provided controlled by an automated load management control system. Each main LV switchboard will incorporate Power management System controls.

Refer to section 4.55 for a more detailed description of the mains failure and reconnection scenario and details of the Power Management System.

Refer also to section 3.11 for a description of the strategy adopted in the event of failure of LV components.

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Sub-mains Power Distribution Design Strategy

The high voltage network is described under 3.6 and 3.10. This document covers the LV distribution network within the building.

The sub-mains power distribution will follow the principles of a dual-unified distribution network as described in SHTM 06-01 whereby primary and secondary circuits are provided, each fully rated to provide a resilient distribution network.

The principle adopted is that the first single point of failure will be as close as possible to the point of use. Thus the possibility that the failure of a single component will cause a major power outage has been removed as far as is practicable.

In simple terms, there will be two of everything: two transformers per substation, two main LV switchboards linked by an automatic bus coupler, two submain feeds to sub switchboards and two distribution boards per department (minimum).

The Adult Acute and Children's Hospitals will be served by six substations, each comprising two transformers, one fed from what is termed the A side of the 11,000V ring the other fed from the B side.

Each transformer will serve a 400/230V LV switchboard which in turn will serve sub switchboards within the electrical zone served by that substation.

The main LV switchboards and the sub switchboards will be provided with automatically operated bus switches so that on loss of the A side supply the switch will close and the switchboard will be entirely supplied from the B side, and vice versa. The transformers will each be rated to support the entire load in an electrical zone, thus during normal circumstances each transformer will support half of the load.

Submains cables from the main LV switchboards will be contained in electrical riser cupboards, A side cables will be segregated from B side cables within the risers.

Departments requiring specialist or heavy loads (Imaging Departments, Catering etc.) will be provided with their own LV panel fed directly from the respective main LV panel.

The sub switchboards will feed local distribution boards, a minimum of two per department, one from the A side sub switchboard and one from the B side. Distribution boards will serve lighting and power.

Fixed items of equipment will not be provided with dual supplies, in risk category 3, 4 and 5 areas such supplies will be derived from sub switch panels which themselves have a dual supply.

Each Ward Tower will be provided with two risers each accommodating local distribution boards fed from a rising bus bar. Two bus bars will be provided per tower, one fed from the A side and one from the B side.

The Ward Towers will each be provided with two rising bus bars feeding two distribution boards per ward.

Final circuits in departments will be interleaved so that each room, so far as is practicable, will be provided with circuits from diverse sources.

A and B side submains cables will be housed in separate electrical risers.

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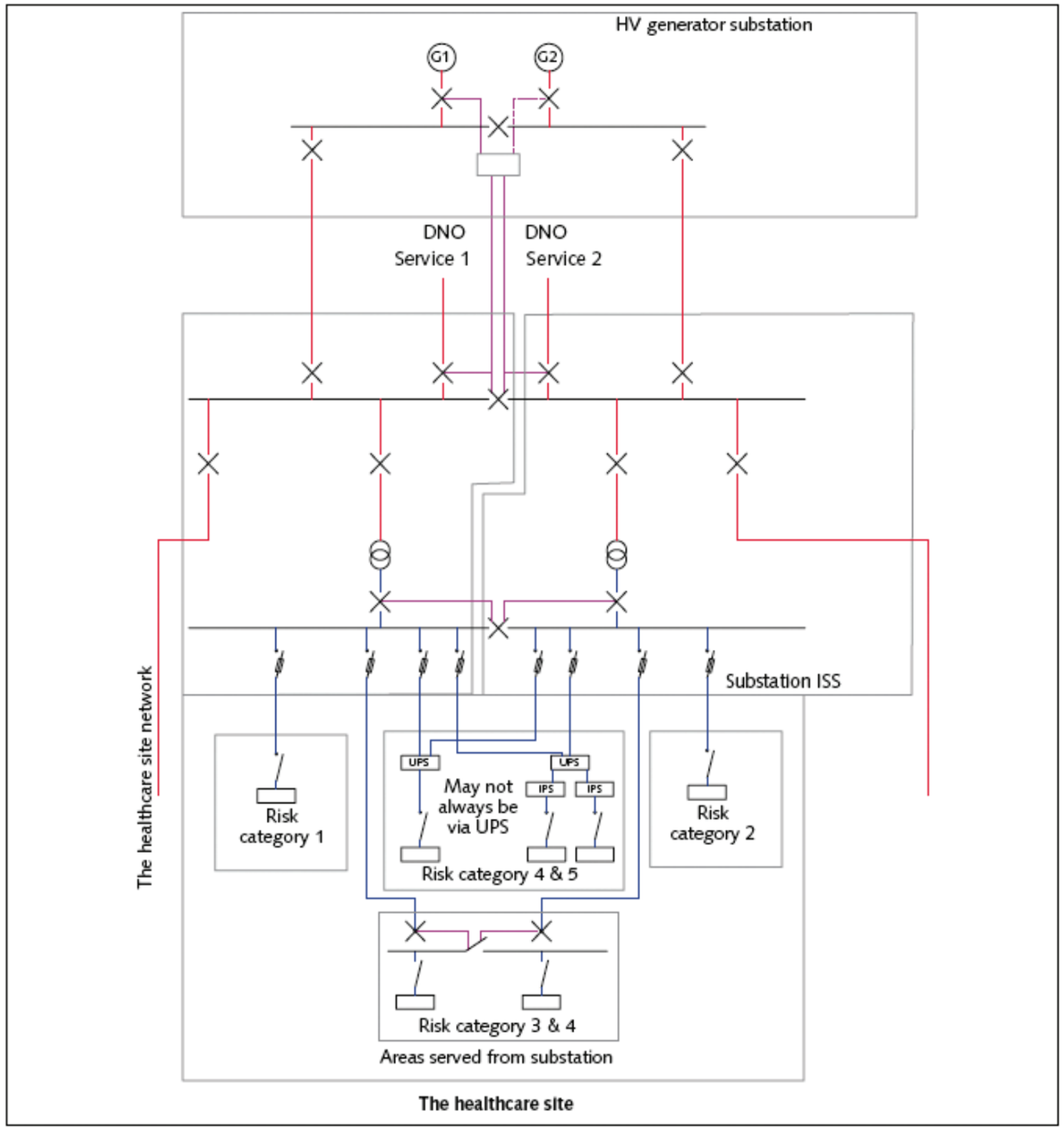
The diagram below is reproduced from SHTM 06-01, and illustrates the general principles adopted, with the exception that the Employer's Requirements state that dual distribution boards are required to all departments, regardless of risk category.



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The following sequence of diagrams illustrates the resilience of the distribution network and its operation during failure of its component parts.

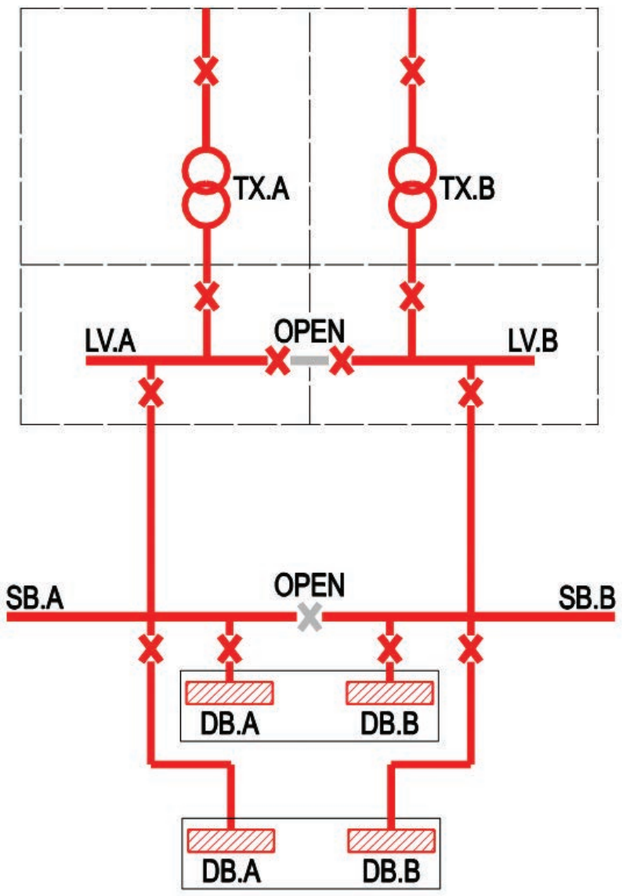
Consider a substation comprising two transformers, fed from different legs of an open HV ring, termed ‘A side’ and ‘B side’.

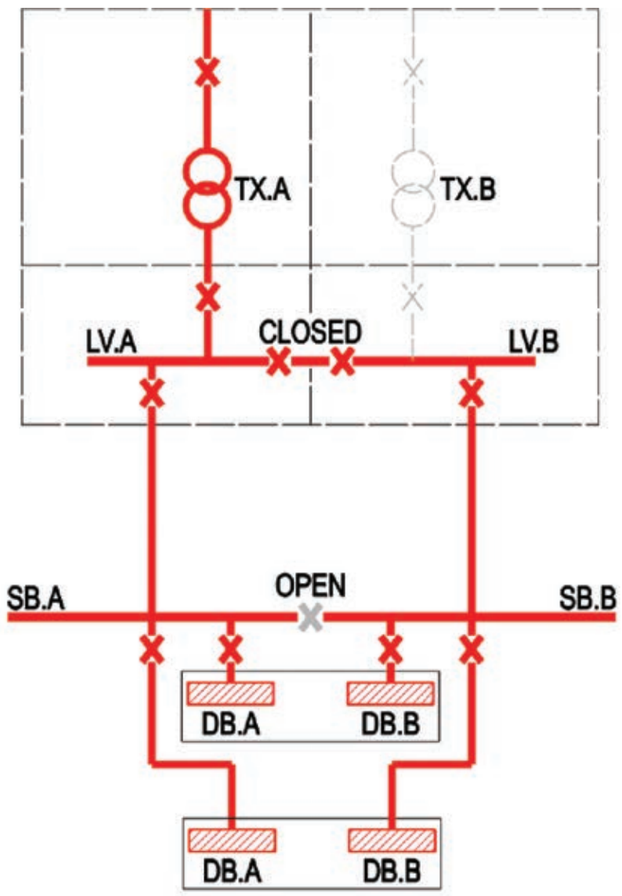
On mains healthy the low voltage distribution will be divided into two sides, A and B, one side being fed from one transformer and the other side being fed from the other transformer.

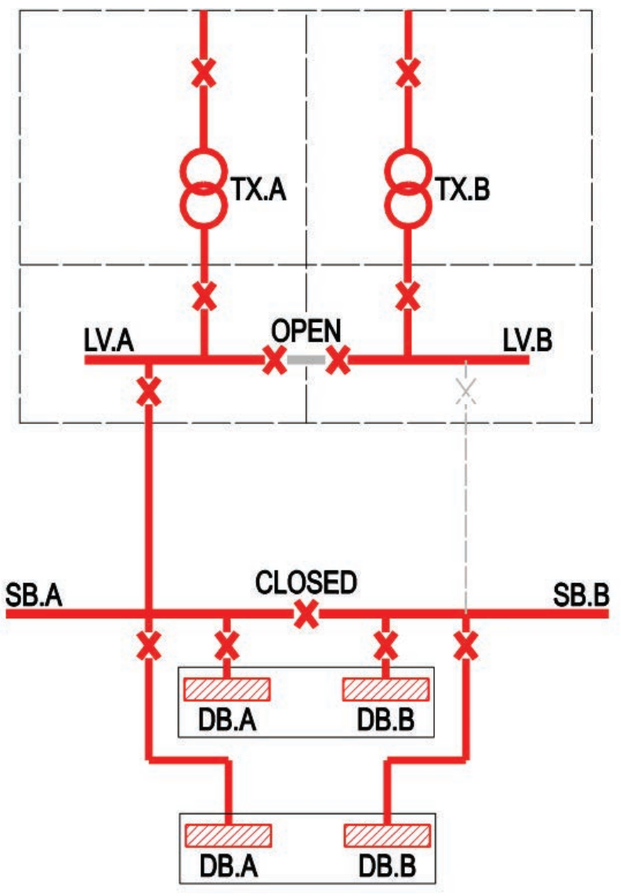
The transformers and main low voltage switchboards will be located in fire rated compartments so that an incident in one room will not affect the others.

On the failure of one transformer the automatically operated bus coupler in the LV switchboard will close. The remaining transformer will support the whole load.

On the failure of a submains cable to a sub switchboard, or a fire in one of the main LV switchrooms, or during maintenance of one of the main LV switchboards, the bus coupler on the affected sub switchboards will close and the A and B side submains cables to the switchboard will be capable of supporting the total load on that switchboard.







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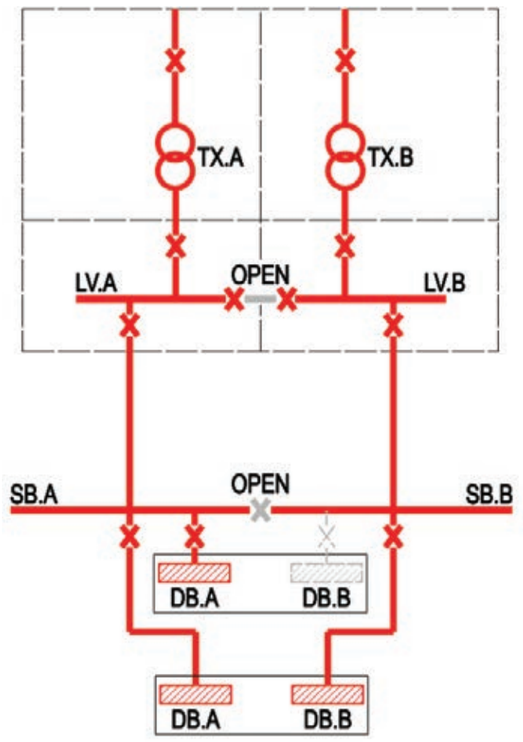
Each department will be fed by at least two distribution boards. Distribution boards will be three phase, fitted with miniature circuit breakers and RCBOs as appropriate. Failure of one distribution board will lead to the loss of 50% of the lighting and power to that department. To mitigate against this, final circuits will be interleaved so that 50% of the light and power to a room will be maintained.

These distribution boards will be contained within electrical cupboards within each department. Adjacent to each of these electrical cupboards will be located an equipment cupboard for ancillary components such as power supplies to nurse call panels, fire alarm interface units, security control equipment and door hold equipment.

To limit the quantity of distribution boards to a manageable and economic number, each board will feed lighting and small power final circuits (otherwise there would be at

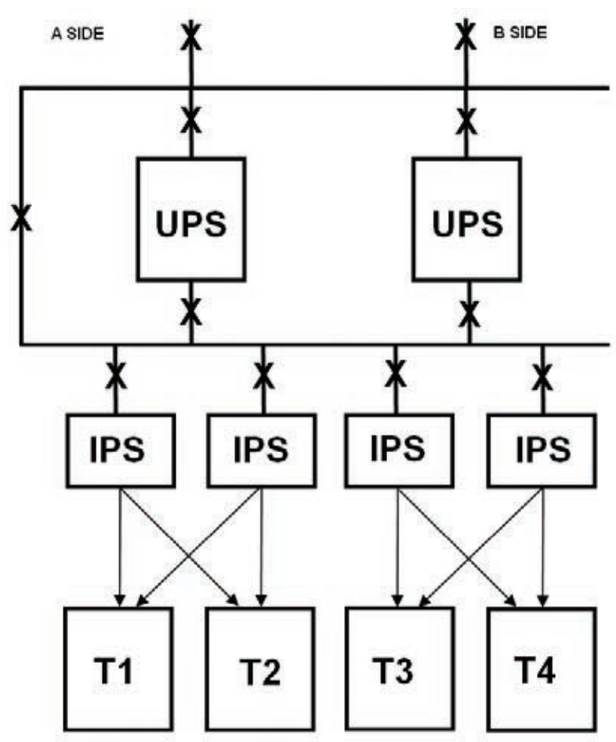


Power Supplies to Plant

It is proposed that horizontal bus bars will be run around plant rooms to provide power to plant. Duplicate bus bars will be provided (A and B side) to minimise disruption due to power failure. Plant will be provided with integral motor starters/inverter controls and will be plugged in to the nearest plantroom bus bar.

Uninterruptible Power Supplies and Isolated Power Supplies

Isolated Power Supplies will be provided as required by IEE Guidance Note 7, Chapter 10 and MEIGaN Annex “Health Care Interpretation of IEE Guidance Note 7 (Chapter 10) and IEC 60364-7-70 for Electrical Installations in Medical Locations”. The quantities of IPS units included in the bid are detailed on the accompanying LV schematic diagrams.



Socket outlets in Group 2 locations, as defined by IEE GN7 and MEIGaN will be IPS protected where serving medical electrical equipment and medical systems which are intended for life support and equipment located in the patient environment. Non critical / non life support electrical equipment in Group 2 locations will be RCD protected.

Socket outlets in Group 1 locations will be RCD protected but not IPS protected, including at patient bedheads.

The Employer’s Requirements state that Isolated Power Supplies should be supported by Uninterruptible Power Supplies.

The diagram illustrates the principles to be adopted in the theatres. Each pair of theatres will derive supplies from a pair of IPS units, the final circuits being interleaved.

UPS serving IPS units and two main server rooms will be configured in an N+1 arrangement, generally in pairs, each capable of supporting the full load for 50% of the required autonomy. Dedicated UPS rooms will be provided in the plantrooms so as to reduce plant space in the occupied areas.

Batteries or UPS will be provided to support:-

- Engineering hub cabinets, 2KVA, 10 minute autonomy
- FM office engineering hub, to suit load, 1 hour autonomy
- BMS front end, to suit load, 1 hour autonomy
- BMS outstations, to suit load, 1 hour autonomy
- Generator/HV network control and monitoring system
- Central UPS for Server Rooms, 15 minutes autonomy
- Central UPS for IPS units, to suit load, 15 minutes autonomy, except for theatres 60 minutes
- ICT nodes, 15 minutes, rack mounted
- Emergency lighting luminaires will incorporate self contained battery packs
- Battery back up will be integral to security, access control, fire alarms and nurse call (central data logger)

Final Circuits

Final circuits will generally be LSF insulated copper conductors run in concealed steel conduit and trunking. Modular wiring systems will be used in non clinical areas.

Power Quality

Provision will be made for future harmonic filters (space for free standing filters to be provided in each switchroom)

Miscellaneous Systems

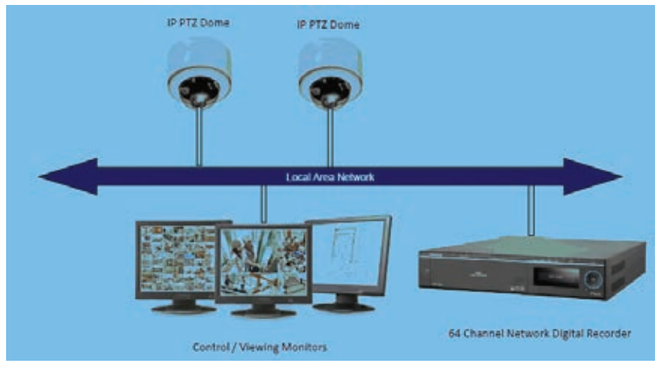
CCTV System

The system will comprise of a number of external PTZ colour/mono change over dome cameras, internal PTZ colour dome cameras and internal fixed colour dome cameras to provide coverage of external car parks, building entry/exit points, internal entry/exit points and general public areas and corridors.

The proposal will utilise PoE CAT6 cabling to central IT equipment rooms and a dedicated TCP/IP network infrastructure which will be provided by others.

All cameras will be streamed direct to Network Video Recorders located within central IT equipment rooms throughout each floor level and full control and viewing capability will be provided at the central security control room and other main reception areas within the building.

The choice of an IP based CCTV system with a graphical front end will provide the platform for full flexibility and future growth throughout the hospital buildings.



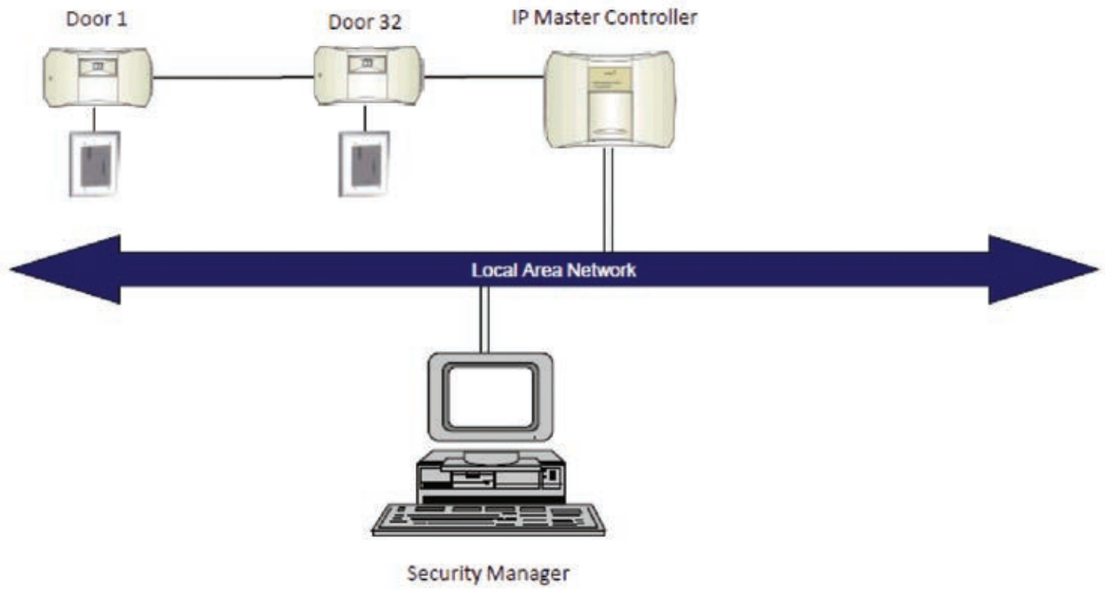
Access Control System

The system will comprise of a number of proximity access control readers along with push to exit egress buttons to allow for controlled access and egress for authorised staff throughout the hospital building. Typically this will cover building entry/exit points, internal entry/exit points and general ward areas and corridors not authorised to the general public.

The proposal will utilise dedicated CAT6 cabling from each off the door controllers to the master controller located within the central IT equipment rooms and a dedicated TCP/IP network infrastructure which will be provided by others.

The access system will be based on Mifare reading technology which will also allow interfacing with other systems such as cashless vending etc.

A management PC complete with software and Mifare enrolment reader will be located at the central security control room.



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Lighting Design Strategy

Introduction

The design of internal lighting installations is paramount and will greatly influence the aesthetics along with patients, visitors and the staff's perception of the building and therefore its importance should not be undervalued.

The first aim of lighting design in a hospital is to meet the required service illuminance for each area in the building.

Secondly, the design will create a lit environment which is visually appealing and compatible with the healthcare environment.

Design Considerations

The lighting design will take into account a number of considerations including:

- provide illumination levels and select luminaires which are appropriate for the task being carried out,
- select and arrange luminaires which are sympathetic, co-ordinate with and compliment the overall interior design concept,
- minimize ongoing maintenance costs by selecting luminaires and lamps from a limited number of sources and types,
- available daylight,
- glare,
- the lit appearance,
- illuminance at task areas,
- lamp colour,
- colour rendering,
- energy efficiency.

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Service Illuminance

The target service illuminances will be as given in the ADB Sheets and where not defined they will be as scheduled in CIBSE Lighting Guide 2, 2008.

Given available lamp lengths and lamp configurations within luminaires it is not possible to exactly match the required service illuminances. It is proposed that design illuminances will be no lower than 10% below the target and no more than 25% above the target. (Refer to the section on energy below for further comment on the upper level.)

The Lit Appearance

The lighting design will aim to promote a sense of well being in the patients and an air of competence and quality throughout the building.

In public areas the emphasis will be on creating a pleasing environment with gentle but deliberate contrasts. Consideration will be given to the use of LED luminaires in public spaces.

Computer modelling will be employed to illustrate the lit appearance of sensitive areas. The image above is a 3D model of the entrance mall of an Acute hospital. The lighting creates interest and contrast and highlights architectural features such as the glass roof and suspended artwork.

Glare will be controlled and luminaires positioned so as not to cause discomfort to patients who may be in a prone position.

The selection of luminaires will be carefully considered so as to be aesthetically appropriate to the area.

The lighting design in public areas will be developed in tandem with the art component.

Lighting will be used as part of the way-finding strategy to highlight landmarks, reception desks and enquiry desks.

The image on this page is a 3D model of a waiting area.

AREAS OF KEY INTEREST

Typical Single Bed Ward Room

Lighting to the single bed ward room should be treated with care and thought since the patient will identify it as their own space; where they will spend the most amount of time and which will contribute the most to the overall healing process – both physically and mentally.

Our general approach to Ward Room lighting is to develop a strategy that will provide a comfortable and domestic level of lighting that will differentiate it from other more institutional areas that the patient may experience during their stay in the hospital. This can be achieved through careful selection of luminaire types and lamp selection.

Luminaires:

- Selected based on performance and function to suit medical uses that include features such smooth and simple finishes which are wipe-clean and snag-free to minimise the build-up of dust and other particles, are relatively sealed, are of sufficient build and material quality so as to provide a long-term lighting installation.
- Selected based on appearance and finishes to achieve the desired aesthetic design, we look at the type of trim type and finishes, colours, quality of detailing, user comfort and appearance (ie. louver or opal diffusers) Lamp selection tends to favour fluorescent or compact-fluorescent lamps for their long service-life, efficiency, colour-rendering properties and instant-switch/dimming capabilities. Being a large area lamp source they are ideal lamps for general lighting applications where uniform lighting levels are desired to all room surfaces.

Corridor lighting should be clear, concise and economic. Our lighting approach is a surface mounted or semi-recessed linear fluorescent fitting running parallel to the line of the corridor and off centre to one side. A surface-mounted or semi-recessed fitting can spill light further horizontally minimising high-level shadow marks on the walls, as well as putting some light onto the ceiling which would otherwise be directly unlit. This will help give the corridor an overall feeling of brightness. Orientating the luminaires to run parallel with the line of the corridor helps to fill the corridor out with light as well as give a strong perspective to the line of travel down the corridor. The luminaires are placed off centre to minimise strobing for bed-ridden patients being transported to other areas of the hospital. In specific single patient ward corridors the lighting may respond to the architectural layout of the rooms and doorways similar to a hotel corridor. This can still achieve the required light and uniformity levels demanded while contributing to create a less institutional environment. Major intersections or nodes along corridors can be marked through a change in lighting or the use of a different luminaire (size, shape, proportion). This assists way-finding through internal corridors and creates an identifying, repeating pattern throughout the building.

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Communal Spaces

Communal and social areas should benefit from interesting lighting, not just in the form of interesting luminaire selection, but also of differing lighting intensities within the space that add interest and life into it. An effective tool is the use of spotlighting wall hung artwork as well as wall washing. Staff/nurse bases can be made more visible though increased lighting onto counter surfaces and through wall-washing vertical surfaces behind them to increase their lit presence. Illumination of vertical surfaces plays just a vital role as horizontal illumination and helps create interest and visible markers within a space.

Colour Rendering and Colour Temperature

Generally all lamps will have a colour rendering index of Ra≥80 except where identified in table 1 of LG2 as requiring Ra≥90.

The colour temperature of fluorescent lamps will generally be 4000K; except in certain circumstances identified in LG2, e.g. ophthalmology test rooms where the CCT will be 6500K.

Energy

The lighting design will be compliant with Section 6 of the Building (Scotland) Regulations 2007. The philosophy to be employed will be to utilise high efficacy lamp/gear combinations, luminaires with high light output ratios and to minimise use by means of automatic controls and use of available daylight.

A “DEER” value of level A will be achieved, i.e. minimum of 66 luminaire lumens per circuit watt.

Lighting control methods will be employed to maximize the potential for energy saving. In all cases the Building Regulations Part ‘L’ requires that switches should be no more than 8m away from the luminaire it controls. Whilst this will be achieved and users will have good access to switches as required, energy saving measures, which rely solely on users remembering to switch lighting off will not maximize their potential. Most often smaller spaces such as Store Rooms, Consultation Rooms, Laboratories and the like, which are out of use overnight and weekends may have lighting left on only because no one person is designated to switch lighting off. Therefore it is proposed to investigate automatic switching systems to maximize energy savings.

We propose the following simplified lighting control strategy:

A mixture of automatic ‘absence’ and ‘presence’ detection will be provided.

Presence detection: detector switches lighting on and off.

Extent of provision: intermittently occupied areas such as WCs, en suites, corridors, ward kitchens, stores, plant rooms, services risers, hospital streets, bathrooms etc.

Absence detection: lights manually switched on, detector extinguishes lighting in unoccupied room.

Extent of provision: offices, consulting rooms etc.

In addition, in rooms benefiting from daylight, luminaires near windows will be dimmable, regulated by the amount of daylight available.

Daylighting is an incredibly important factor for all buildings, but more importantly for hospitals. It has been proven to improve patient healing and greatly adding to their sense of well-being, mood and general health.

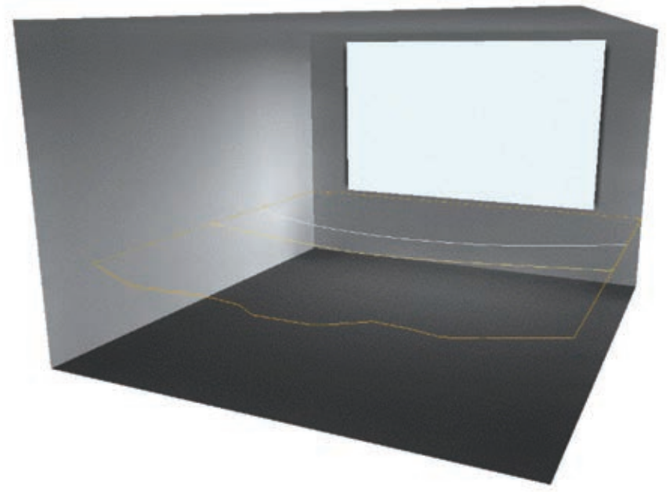
It connects people with the larger cycles of day and night and that of the seasons, which can help alleviate the stress of having to spend most of the day bed ridden inside. Daylight is also free, therefore having the added advantage of energy-savings in rooms that receive adequate amounts of daylighting through the reduced need for electric lighting during daylight hours. A dimmable control system can take advantage of this through smart monitoring of daylight presence within individual rooms.

A function of daylighting in hospital ward rooms is also the view that may be provided through the window and helps to further create a connection between the patient and outside world. Being a tower block, the rooms for New South Glasgow Hospital have a greater potential for increased natural daylighting and can benefit from longer views over the city below.

The ERs require lighting in corridors to be dimmed when unoccupied and scheduled by BMS. We do not believe that this will be necessary as the detectors will extinguish lights in unoccupied areas regardless of the time of day.

Dimmable lighting throughout has not been included, except where specifically required by the ADB sheets.

Automatic control of lighting in rooms which have plenty of natural light will be regulated by means of a photocell within the space to ensure the required LUX is achieved by the combination of ambient and artificial light. The image illustrates the graphical output of a daylighting calculation for a single bedroom.



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General Lighting Installation

General lighting will be provided throughout the new development in accordance with the design criteria as issued through the NHS but summarised briefly as follows:-

- DHSS Engineering Reference Data “Standard Reference Luminaires for Hospital and Health Building Use”.
- SHTM 2007, SHTM2011
- CIBSE Guide 2.
- ADB sheets.
- “Designing for the Disabled”

Generally lighting will be by fluorescent tubes with recessed fittings.

Luminaires will be manufactured and tested in accordance with the requirements specified in the relevant sections of BS 4533. Their location will afford ready access for lamp changing and maintenance, but with the overriding requirement that the recommended standard of illuminance is provided to the task area. Many areas, however also require a domestic ambience, i.e. non-clinical and the design will reflect this requirement.

In areas where computer terminals are to be used, the lighting will be designed to avoid bright light reflections on the screen and to ensure that the contents of the screen are legible. Specific guidance is available in CIBSE Lighting Guide LG03 entitled “Areas for Visual Display Terminals”.

Patient’s bedroom lighting, other than high dependency and recovery, will be switched from the door and the bedhead unit: a watch light with dimmer controlled from the door, and an overbed light.

Dimmable night lighting is provided at Nurses Stations and in patient bedrooms and corridors. Care will be taken in design to ensure that night lighting does not spill into patient bedrooms, thereby causing discomfort to patients.

The lighting design will incorporate a flexible switching arrangement to allow for varying activities within each room and for cleaning. Where more than one luminaire is to be provided in a room a minimum of two switches will be provided. Switches for public areas will be positioned so that lighting cannot be switched by unauthorised persons.

Alternative circuits and two way/intermediate switching at all doors and corridor direction changes will be provided for lighting in corridors and circulation areas.

Kitchens and areas in which food is prepared or handled are to have food factory type luminaires. Clinically clean areas, eg all rooms requiring theatre level environment, will have recessed, sealed luminaires as required for the area.

Emergency and Standby Lighting

Maximum interruption times to the primary supply will be as scheduled in Appendix 1 of SHTM06-01.

Only fixed medical lighting and escape lighting will be supported by standby batteries. This will include operating theatre lamps and fixed examination lamps in clinical risk category 3, 4 and 5 areas. General lighting will not be battery supported. Power to general lighting will be restored within the times required by Appendix 1 of SHTM06-01.

A complete Emergency Lighting System covering all internal and external areas as required by BS 5266: Part: 1988 and the Building Control and Fire Officers requirements will be provided.

The emergency lighting will comprise self-testing addressable lighting units which will be connected to an addressable emergency lighting, testing and monitoring panel.

A software control package will be provided to monitor and manage the system.

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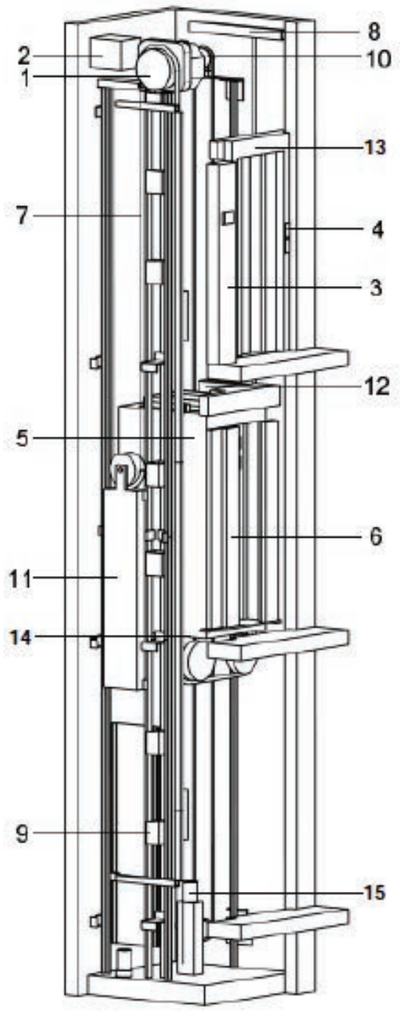
Lift Engineering Design Strategy

General Preambles

Consideration has been given to efficient reliable and secure vertical transportation throughout the site.

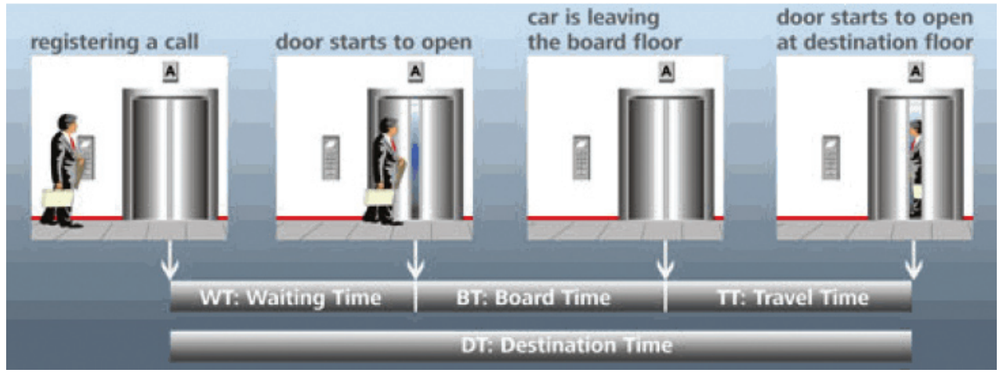
The elevator systems proposed are all Machine Room Less technology and will feature energy efficient equipment .



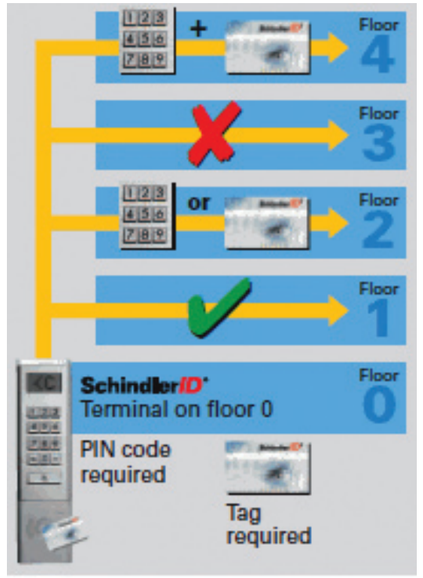
Pos.	Main component
1	Gearless permanent magnet synchronous machine with traction sheave brake
2	Frequency converter
3	Control
4	Fixtures
5	Car
6	Door
7	Ropes
8	Load measuring device
9	Guide rails
10	Overspeed governor*
11	Counterweight
12	Car interface box
13	Door interlock*
14	Safety gear*
15	Buffer*

* safety component

Traffic Simulations have been carried out on the main lifts in the Main Hospital Tower and the Children's Hospital which are appended to this section. The results of these simulations generally reflect the requirements of the exemplar report.



In some areas of the hospital we are proposing the use of ID technology and Destination Control Systems to provide efficient service and levels of personalised security and individualised access



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Main Hospital

The Main Hospital features six Visitor and six Bed Passenger lifts serving all floors. These lifts feature additional security and lift control specifications

The traffic simulations show that these lifts will provide good lift service to visitors, patients and staff.

To provide adequate access for FM four dedicated lifts have been provided, these lifts are integrated in to the Automated Vehicle System.

There are also various other lifts within the podium area which provide access to all levels for passengers and patients.

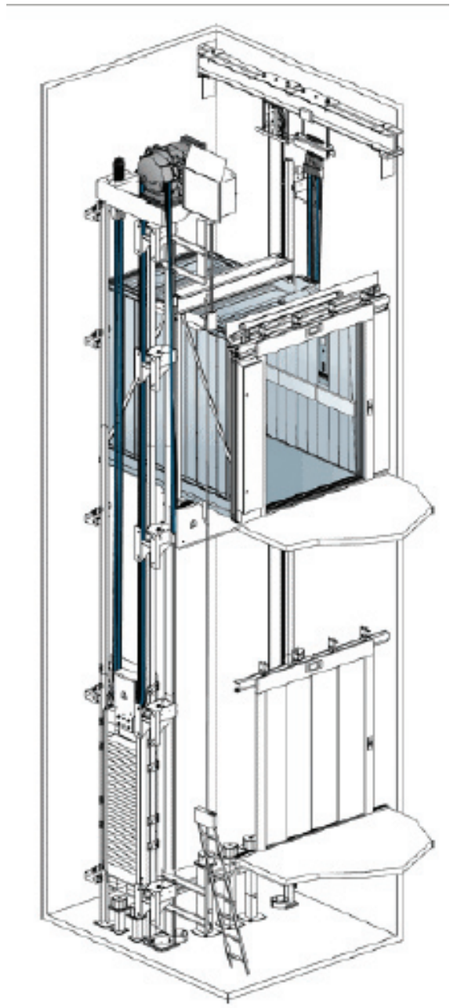
A dedicated lift is allowed for serving the Helipad.

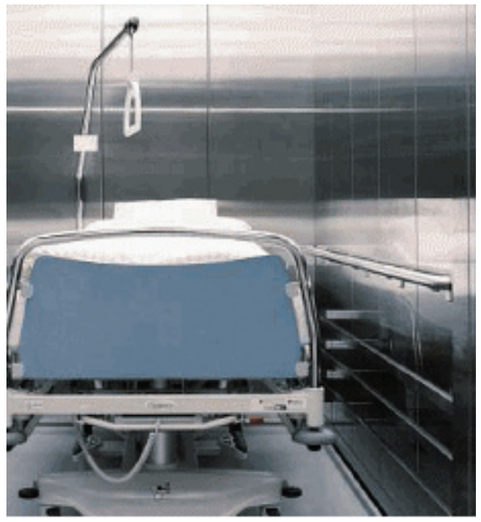
Three escalators will take visitors from the main entrance to reception level.

Children's Hospital

Traffic simulations have indicated that four visitor and 4 bed passenger lifts will provide excellent service to The Children's Hospital, again special security and control features are envisaged.

Facilities Management will be provided with three dedicated lifts.





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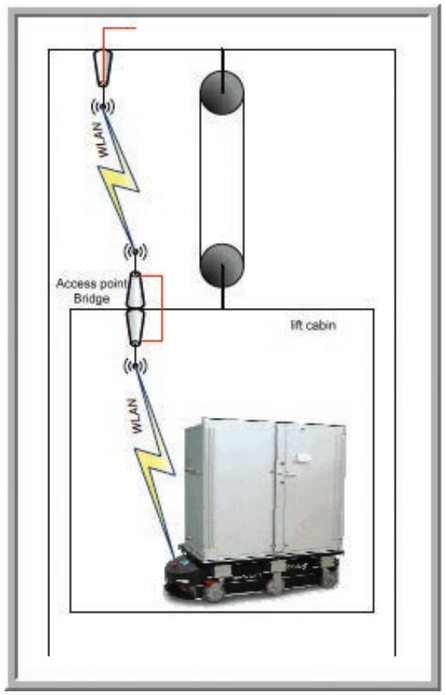
Laboratory Block

The proposal allows for sixteen lifts of various specifications, these include four FM lifts which will be linked to the Automated Vehicle System.



The freight lifts proposed are purpose designed for goods lift application and feature a traditional sling and platform car design together with heavy duty lift car and landing doors and tracks to ensure robust and reliable FM lift service.

Energy Centre

One purpose designed Goods Passenger Lift is proposed.

Technical

All lifts proposed will comply with the relevant EN Code Requirements.

The lifts will comply with EN81-70 which relates to lifts suitable for use by disabled passengers.

Certain lifts will comply with EN81-72 Fire Fighting application.

The HTM2024 NHS Design Considerations for Lifts is met in principle in so far as it reflects current industry standards ,engineering and manufacturing innovations.

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Whole Life Costs and Maintenance Proposals

The submission includes 7 years maintenance which commences on Practical Completion of each phase.

The maintenance is fully comprehensive and includes 24 hour cover.

Communication Links to the manufacturers call centre are included.

The maintenance covers all replacement parts other than those damaged thorough misuse.

Whole Life Cost proposals are indicated, these reflect the efficient technology and energy saving features that the lift and escalator systems provide.

BREAAM Credits are also available with the equipment proposed.

Consideration has been given to the environmental impact of manufacturing, installing and operating the lifts and escalators and considerable data can be provided to provide more information if required.

System electricity consumption in 20 years	
Operation [kWh]	68107
Stand-by [kWh]	37104
Total [kWh]	105211

System electricity consumption per annum	
Operation [kWh]	3405
Stand-by [kWh]	1855
Total [kWh]	5261

Impact category	Unit	Material supply[1]	Usage phase[2]	Ratio usage/material
Global warming potential	[kg CO_2-eq.]	16001.0	62005.6	3.9
Acidification potential	[kg SO_2-eq.]	238.6	455.2	1.9
Ozone formation potential	[kg Ethene-eq.]	24.9	87.6	3.5
Eutrophication potential	[kg PO_4-eq]	4.7	15.4	3.3
Ozone depletion potential	[kg CFC11-eq.]	0.015	0.04	2.7

Innovation

The lifts proposed utilise the latest lift drive and control technology all lifts feature Permanent Magnet Gearless drive with VF Drive and Control Strategy

Various groups of lifts will utilise Hall Call Destination and ID control.

These features allow for the most efficient method of handling passenger traffic and provide the best lift service to visitors, staff and patients.

Of particular benefit is the facility to consider disabled use via the wheelchair button, this allocates a lightly loaded lift to a wheelchair bound passenger, it also activates a audible signal leading partially sighted passengers to the appropriate lift, in all cases it allows the lift doors to remain open longer to provide time to access the lift.

The ID Control feature will provide personalised lift service to staff and allow for the following features:

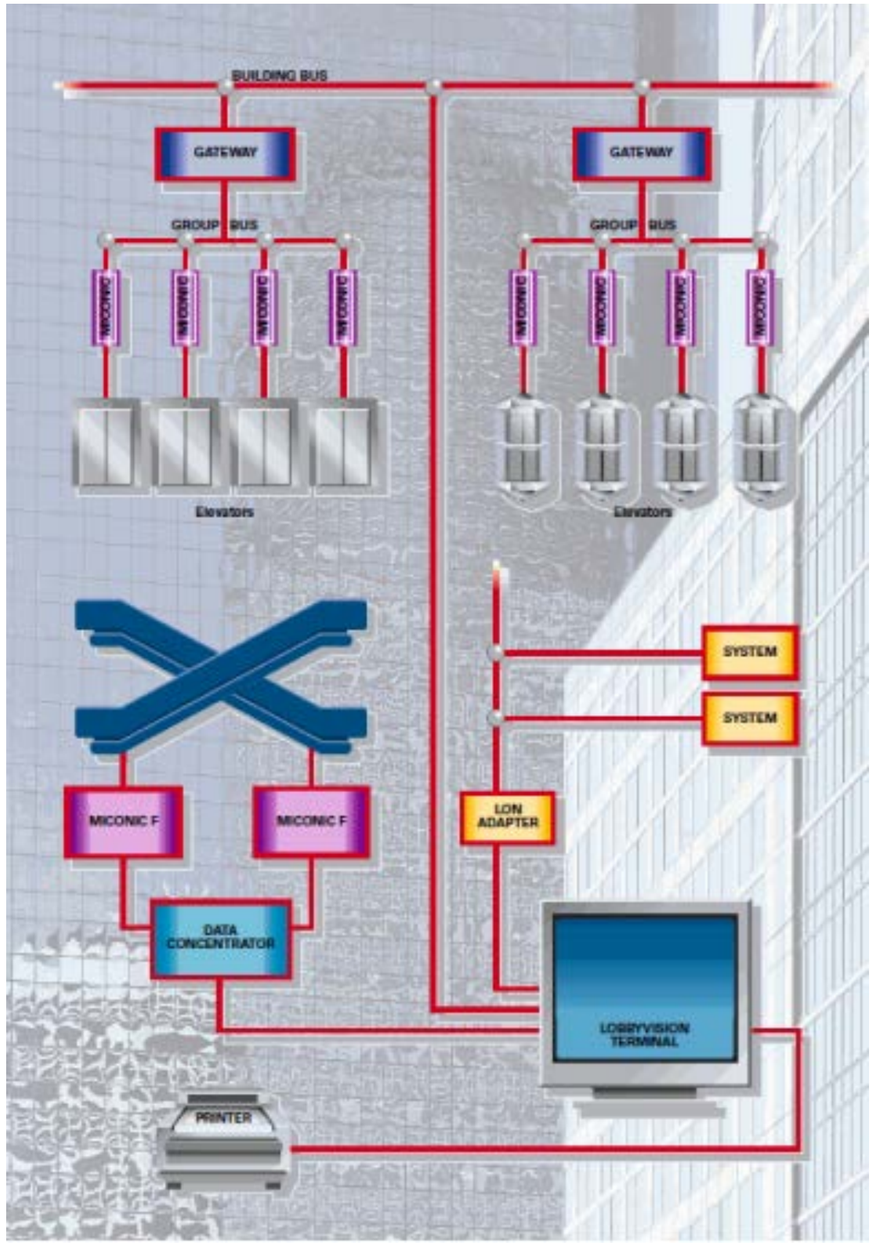
- Restricted Security Access to certain floors via data held on ID cards
- Dignity Trips – allowing bed bound passengers to travel in dedicated lifts
- Code Blue emergency response.
- Personalised Elevator Service

The integration of building management and emergency systems has been considered and together with the incorporation of the automatic vehicle systems off site proving and commissioning of the lift control systems has been allowed for.

The flexibility of the ID control system will allow for on site programming of staff data to allow for personalised service

Building +Lift Monitoring Systems

A dedicated Elevator and Escalator Monitoring System is proposed to allow for instant access to performance and operational date.



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Traffic Analysis Report

Preliminary Vertical Transportation Proposals for The Glasgow Southern General Hospital

Schindler

Brookfield

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Summary

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Standards and Recommendations

3

Results

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How Schindler Undertakes Traffic Analyses

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2009 July 27th

This traffic analysis has been prepared by John Bradshaw.

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Summary

The Preliminary Traffic Simulation Analyss have been carried out for both the Visitors and Bed Passenger Lifts.
The Data is based on the Population for Lift Assessment included in the exemplar report.
Traffic Paterns have been generated to reflect a two way flow of passengers.
Schindler ID control has been proposed for the Bed Passenger lifts .

NSGH VISITOR 6 LIFTS. LF 1 6 elevators		Miconic 10 control			1.6 m/s		1600 kg	
Traffic Situation	Floors	Population	Rating		HC5	WT	DT	IS
Two-Way Hotel	0..1,4..11	1984	3.4	★★★☆☆	11.8 %	35.9 s	92.5 s	1.7

NSGH BED LIFTS (6 Lifts). LF 1 only 1 pers per	6 elevators	Schindler ID control			1.6 m/s		2500 kg	
Traffic Situation	Floors	Population	Rating		HC5	WT	DT	IS
Lunch (Single Tenant)	0..11	565	3.0	★★★☆☆	11.0 %	39.9 s	60.3 s	0.0

In both situations the recommended 6 lifts will provide excellent lift service to the Hospital visitors and patients

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Standards and Recommendations

Depending on the type of building, one or two of the following traffic situations are analysed:

Traffic Situation	Incoming	Outgoing	Inter-floor	Type of Building
Up-Peak	100 %	0 %	0 %	Office (all)
Lunch Single Tenant	40 %	40 %	20 %	Office (single-tenant)
Lunch Multi-Tenant	45 %	45 %	10 %	Office (multi-tenant)
Two-Way Hotel	50 %	50 %	0 %	Hotel
Two-Way Residential	50 %	50 %	0 %	Residential

For other types of buildings, an Up-Peak situation and optionally one of Lunch Single Tenant, Lunch Multi-Tenant, or Two-Way Hotel are analysed.

Every analysis covers a full range of arrival rates, reporting handling capacity HC5 and average waiting time WT as main criteria. As a general guideline, Schindler defines a rating in the range of 0.0 (worst) to 6.0 (best) based on these criteria. Recommended ratings are 3.0 or higher:

Schindler Traffic Analysis Ratings 2008

	Rating >= 3.0		Rating >= 4.0		Rating >= 5.0	
Traffic Situation	HC5	WT	HC5	WT	HC5	WT
Up-Peak	>= 12 %	<= 30 s	>= 14 %	<= 20 s	>= 16 %	<= 15 s
Lunch Single Tenant	>= 11 %	<= 40 s	>= 13 %	<= 30 s	>= 15 %	<= 20 s
Lunch Multi-Tenant	>= 11 %	<= 40 s	>= 13 %	<= 30 s	>= 15 %	<= 20 s
Two-Way Hotel	>= 11 %	<= 40 s	>= 13 %	<= 30 s	>= 15 %	<= 20 s
Two-Way Residential	>= 6 %	<= 80 s	>= 7 %	<= 60 s	>= 8 %	<= 40 s

Ratings are also displayed by a corresponding number of stars and may be interpreted on a global basis as follows:

Rating	Stars	Office	Hotel	Residential
>= 3.0	★★★☆☆	Standard office buildings	Up to approx. 3-star hotels	Basic segment
>= 4.0	★★★★☆	Mid-to-higher requirements	Up to approx. 4-star hotels	Medium segment
>= 5.0	★★★★★	Premium sites	Up to approx. 5-star hotels	Premium segment

Results

3.1 NSGH VISITOR 6 LIFTS. LF 1

3.1.1 Building and Population

Number of Floors: 12 floors
Building Population: 1984

Floor Name	Floor Height [m]	Floor Level [m]	Description	Quantity	Unit	Density	Density Unit	Gross Population	Vacancy Factor	Visitor Factor	Net Population	Σ
11	4.00	44.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
10	4.00	40.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
9	4.00	36.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
8	4.00	32.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
7	4.00	28.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
6	4.00	24.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
5	4.00	20.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
4	4.00	16.80	Wards	124.0	persons	1.0	*	124		100 %	248	+
3	4.20	12.60	Plant / Kitchen		persons	1.0	*					
2	4.20	8.40	Theaters / Staff Accomodation		persons	1.0	*					
1	4.20	4.20	Visitor Dining / Radiology	113.0	seats	3.0	meals / seat	339			339	
0	4.20	0.00	Lobby		persons	1.0	*					

3.1.2 Elevators

Control: Miconic 10

		A	B	C	D	E	F
Rated Load	[kg]	1600	1600	1600	1600	1600	1600
Weight per Person	[kg]	75	75	75	75	75	75
Pass./Deck gross		21	21	21	21	21	21
Car Filling Rate		70 %	70 %	70 %	70 %	70 %	70 %
Pass./Deck net		15	15	15	15	15	15
Drive Type							
Max. Speed	[m/s]	1.60	1.60	1.60	1.60	1.60	1.60
Max. Acceleration	[m/s2]	0.70	0.70	0.70	0.70	0.70	0.70
Drive Jerk	[m/s3]	1.00	1.00	1.00	1.00	1.00	1.00
Door Type		S	S	S	S	S	S
Door Width	[mm]	1100	1100	1100	1100	1100	1100
Opening Time	[s]	1.9	1.9	1.9	1.9	1.9	1.9
Closing Time	[s]	2.6	2.6	2.6	2.6	2.6	2.6
Number of Decks		1	1	1	1	1	1
Travel Height	[m]	44.80	44.80	44.80	44.80	44.80	44.80
Transfer Time per Person	[s]	1.0	1.0	1.0	1.0	1.0	1.0
11 Wards							
10 Wards							
9 Wards							
8 Wards							
7 Wards							
6 Wards							
5 Wards							
4 Wards							
3 Plant / Kitchen							
2 Theaters / Staff Accomodation							
1 Visitor Dining / Radiology							
0 Lobby							

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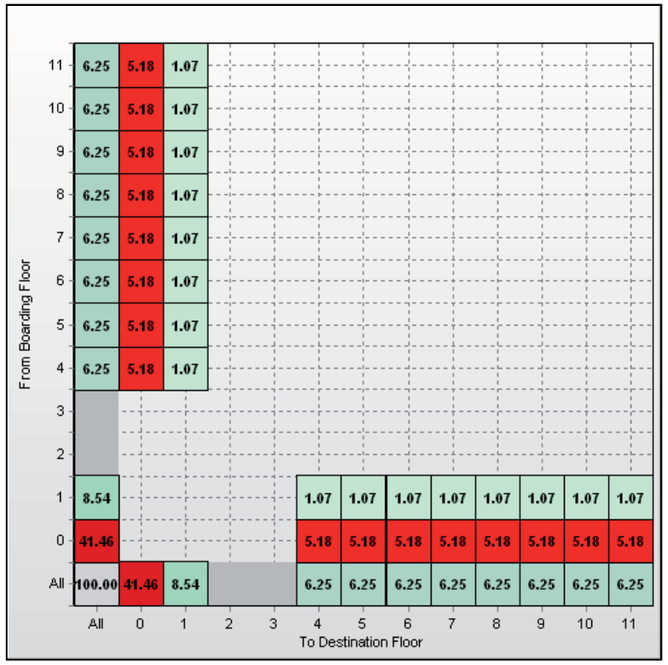
3.1.3 Two-Way Hotel

Traffic Definition: Probability Distribution of Calls

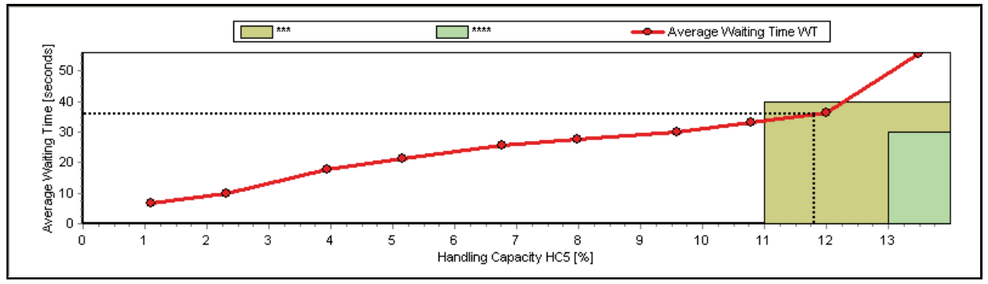


Brookfield

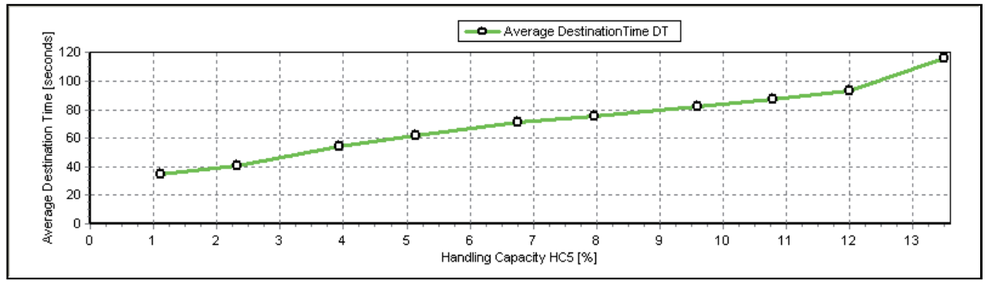
1 2 3
4 5 6
7 8 9
0

Results
NSGH VISITOR 6 LIFTS. LF 1
Two-Way Hotel

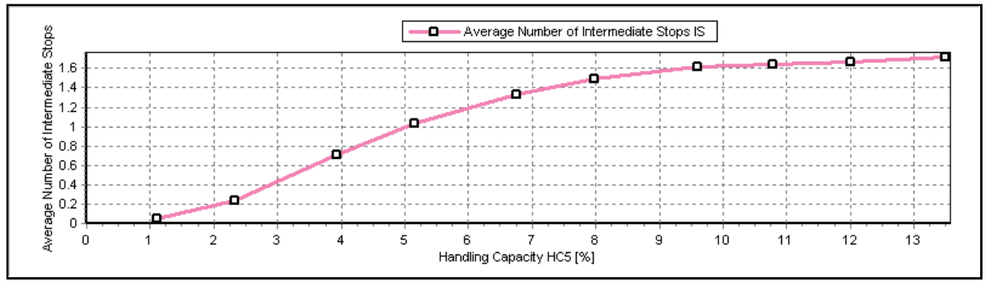
Waiting Time (WT)



Destination Time (DT)



Number of Intermediate Stops (IS)



HC5	1.1 %	2.3 %	3.9 %	5.1 %	6.8 %	8.0 %	9.6 %	10.8 %	12.0 %	13.5 %
P5	22	46	78	102	134	158	190	214	238	268
WT	6.6	10.1	17.6	21.3	25.8	27.5	30.1	33.2	36.4	55.5
DT	35.2	40.7	53.8	61.8	71.1	75.9	81.9	87.6	93.3	116.1
IS	0.0	0.2	0.7	1.0	1.3	1.5	1.6	1.6	1.7	1.7

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3.2 NSGH BED LIFTS (6 Lifts). LF 1 only 1 pers per lift (1)

3.2.1 Building and Population

Number of Floors: 12 floors
Building Population: 565

Floor Name	Floor Height [m]	Floor Level [m]	Description	Quantity	Unit	Density	Density Unit	Gross Population	Vacancy Factor	Visitor Factor	Net Population	Σ
11	4.00	44.80	Wards	124.0	persons	1.0	*	124			124	
10	4.00	40.80	Wards	124.0	persons	1.0	*	124			124	
9	4.00	36.80	Wards	124.0	persons	1.0	*	124			124	
8	4.00	32.80	Wards	124.0	persons	1.0	*	124			124	
7	4.00	28.80	Wards	124.0	persons	1.0	*	124			124	
6	4.00	24.80	Wards	124.0	persons	1.0	*	124			124	
5	4.00	20.80	Wards	124.0	persons	1.0	*	124			124	
4	4.00	16.80	Wards	124.0	persons	1.0	*	124			124	
3	4.20	12.60	Plant / Kitchen	25.0	persons	1.0	*	25			25	+
2	4.20	8.40	Theaters / Staff Accomodation	270.0	persons	1.0	*	270			270	+
1	4.20	4.20	Visitor Dining / Radiology	270.0	persons	1.0	*	270			270	+
0	4.20	0.00	Lobby		persons	1.0	*					

3.2.2 Elevators

Control: Schindler ID

		A	B	C	D	E	F
Rated Load	[kg]	2500	2500	2500	2500	2500	2500
Weight per Person	[kg]	75	75	75	75	75	75
Pass./Deck gross		33	33	33	33	33	33
Car Filling Rate		3 %	3 %	3 %	3 %	3 %	3 %
Pass./Deck net		1	1	1	1	1	1
Drive Type							
Max. Speed	[m/s]	1.60	1.60	1.60	1.60	1.60	1.60
Max. Acceleration	[m/s2]	0.70	0.70	0.70	0.70	0.70	0.70
Drive Jerk	[m/s3]	1.00	1.00	1.00	1.00	1.00	1.00
Door Type		S	S	S	S	S	S
Door Width	[mm]	1300	1300	1300	1300	1300	1300
Opening Time	[s]	2.1	2.1	2.1	2.1	2.1	2.1
Closing Time	[s]	3.0	3.0	3.0	3.0	3.0	3.0
Number of Decks		1	1	1	1	1	1
Travel Height	[m]	44.80	44.80	44.80	44.80	44.80	44.80
Transfer Time per Person	[s]	1.0	1.0	1.0	1.0	1.0	1.0
11 Wards							
10 Wards							
9 Wards							
8 Wards							
7 Wards							
6 Wards							
5 Wards							
4 Wards							
3 Plant / Kitchen							
2 Theaters / Staff Accomodation							
1 Visitor Dining / Radiology							
0 Lobby							

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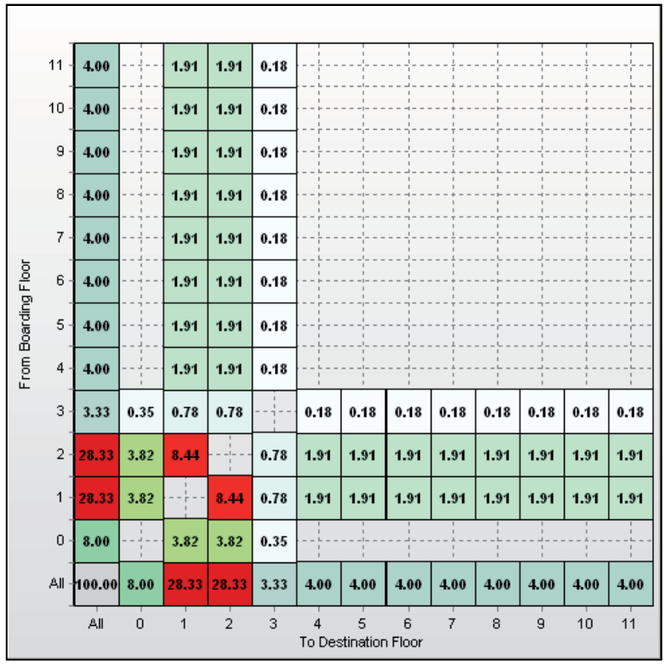
1 2 3
4 5 6
7 8 9
0

Results
NSGH BED LIFTS (6 Lifts). LF 1 only 1 pers per lift (1)
Lunch (Single Tenant)

3.2.3 Lunch (Single Tenant)

Traffic Definition: Probability Distribution of Calls



Brookfield

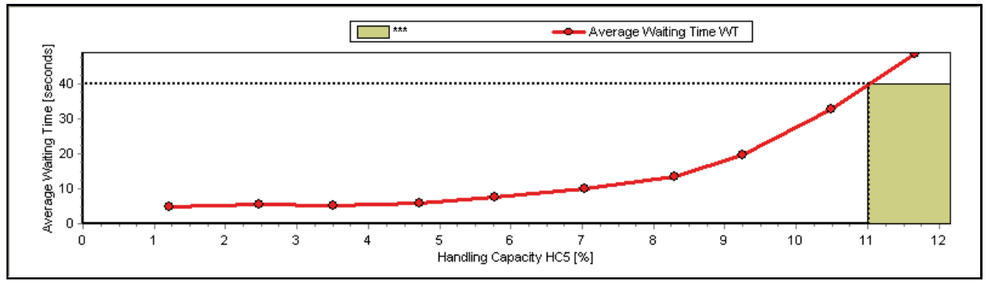
1 2 3
4 5 6
7 8 9
0

Results

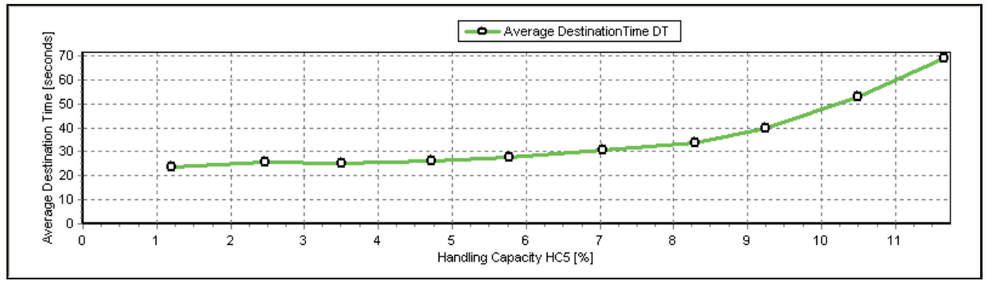
NSGH BED LIFTS (6 Lifts). LF 1 only 1 pers per lift (1)

Lunch (Single Tenant)

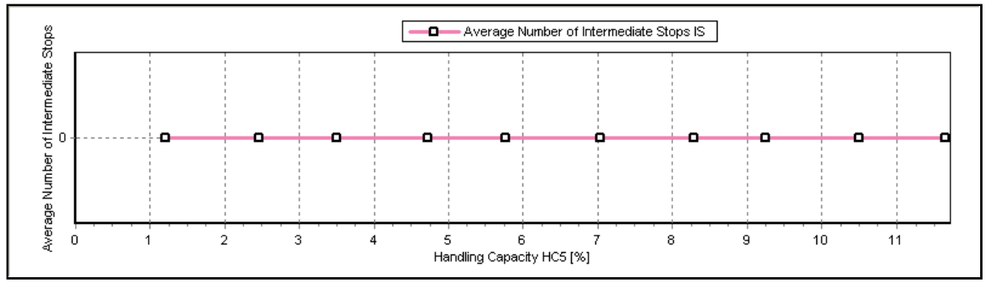
Waiting Time (WT)



Destination Time (DT)



Number of Intermediate Stops (IS)



HC5	1.2 %	2.5 %	3.5 %	4.7 %	5.8 %	7.0 %	8.3 %	9.2 %	10.5 %	11.7 %
P5	7	14	20	27	33	40	47	52	59	66
WT	4.7	5.4	5.1	6.0	7.5	10.0	13.6	19.7	32.6	48.5
DT	23.9	25.5	25.4	26.0	27.9	30.5	33.7	39.7	53.0	69.0
IS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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How Schindler Undertakes Traffic Analyses

4.1 Introduction

A traffic analysis studies the performance of a group of elevators, based on assumptions about the expected traffic situation. The main performance measurements are handling capacity and waiting time. Reliable and comparable performance results are found by means of benchmark simulations which reflect the expected real behavior of a group of elevators under a wide range of traffic situations.

4.2 Measures and Definitions

The elevators' main task is to manage the traffic, i.e., the transportation needs of passengers and goods, in such a way that the highest possible density of arriving passengers and goods can be transported in the building at the highest possible perceived service quality.

4.2.1 Arrival Rate and Handling Capacity (P5, HC5)

For a specific elevator group, the arrival rate describes the density of arriving passengers in an observed time period. In contrast, the handling capacity is the number of passengers transported in an observed time period. As long as the elevator group is able to transport all the arriving passengers without building up waiting queues, the arrival rate and the handling capacity are equal.

Handling capacity is measured by P5 and HC5:

- P5 is the number of persons that is transported on average within 5 minutes.
- HC5 is the percentage of the population on the floors served by the elevator group that is transported on average within 5 minutes:
  HC5 = P5 / (population on floors served by elevator group).

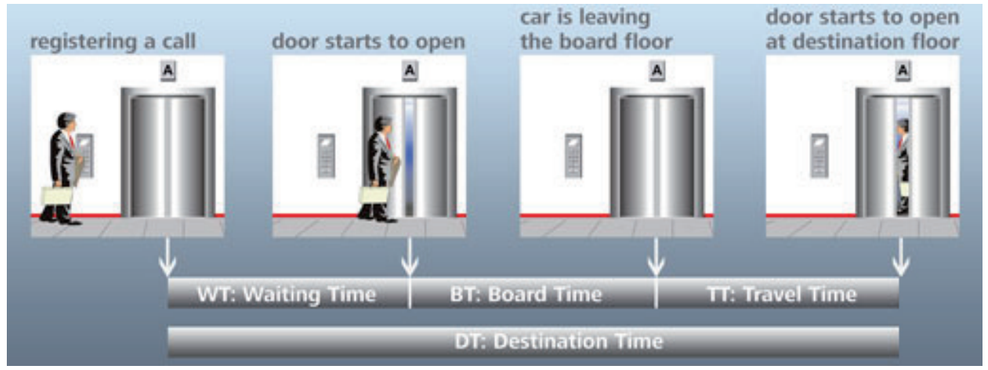
Example: Consider an elevator group which serves floors with a population of 1000 people. By observation, there are 600 passengers transported within 30 minutes, therefore:

- P5 = 600 persons * (5 minutes / 30 minutes) = 100 persons,
- HC5 = 100 persons / 1000 persons = 10.0 %.

4.2.2 Waiting Time (WT) and Destination Time (DT)

Waiting time and destination time for an individual passenger are defined as follows:

- waiting time: time from when the passenger registers a landing call (or joins a queue) until the door of the serving elevator begins to open on the boarding floor (zero if the door is not closed when the passenger arrives)
- destination time: time from when the passenger registers a landing call (or joins a queue) until the door of the serving elevator begins to open on the destination floor



For a number of served passengers in an observed period of time, the average waiting time WT and the average destination time DT are defined in the usual way as mean values of the passengers' individual waiting time and destination time, respectively.

4.2.3 Number of Intermediate Stops (IS)

The number of intermediate stops for an individual passenger is the number of times an elevator stops with the passenger between boarding floor and destination floor. For example, for a passenger with a direct (non-stop) trip from boarding floor to destination floor the number of intermediate stops is zero.

For a number of served passengers in an observed period of time, the average number of intermediate stops IS is defined in the usual way as mean value of the passengers' individual number of intermediate stops.

4.3 Methods of Traffic Analysis

A traffic analysis should cover a variety of important traffic situations, especially when planning new buildings. Reported values should be as reliable and comparable as possible. However, performance values depend on the methods of the traffic analysis and the basic traffic assumptions.

4.3.1 Simulation vs. calculation methods

In *simulation methods,* a real passenger flow is being replaced by a virtual one, which was created with the help of a random generator and loaded into the same control algorithm as used in a real elevator controller. Thus the results can be measured under different traffic conditions and reflect the expected reality to a very large extent.

In contrast, *calculation methods* are based on formulas which only cover a very limited range of traffic situations (usually, only up-peak traffic). The formulas reflect theoretical assumptions rather than a realistic behavior of elevator groups, and results are usually too optimistic. Therefore, calculation results should not

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be compared with simulation results.

Schindler Traffic Analysis Reports are based on simulations in order that the reported results are the most reliable and realistic achievable.

4.3.2 Wide Range of Traffic Assumptions

The traffic flow in a building keeps changing all the time; no two days are the same. As a rule, traffic depends on many factors (such as location of building, tenant structure, etc.) and may vary considerably during operation of the building. A traffic analysis should take such factors into consideration and try as far as possible to cover future traffic situations.

In a complex building, a single traffic assumption is not sufficient. E.g., it is not sufficient to apply a traffic pattern measured in some other existing building for the design of a new building. In particular, the limits of the handling capacity of the elevators cannot be found by such "spot light" examinations.

Predictions about the range of handling capacity of an elevator group can only be made by actually simulating a wide range of traffic situations. A benchmark method applies a reference traffic situation from low to very high traffic intensity; by this, the limits of the elevators' handling capacity can be detected. Schindler uses a benchmark method which gives a neutral system assessment.

Schindler Traffic Analysis Reports are based on different traffic situations (see Section 2) tested by benchmark methods. This ensures that the traffic analysis covers a full range of applications and reports reliable and comparable performance predictions.

Traffic Analysis Report

Preliminary Vertical Transportation Proposals for The Glasgow Southern General Childrens Hospital

Schindler

Brookfield

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How Schindler Undertakes Traffic Analyses

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2009 July 27 12:13

This traffic analysis has been prepared by John Bradshaw.

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This document has 19 pages.

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Summary

The Preliminary Traffic Simulation Analysis have been carried out for both the Visitors and Bed Passenger Lifts .
The data is based on the Population for Lift Assessment included within the exemplar report.
The simulations have been based on the folowing:
Visitor Lifts:
Simulation 1 Visitors only - conventional control
Simulation 2 Visitor and Staff populations - conventional control
A two way traffic flow has been considered.
Bed Passenger Lifts
Simulation 3 - Based on Staff Numbers and single occupancy levels within the car - Schindler ID Control

Visotor Passenger Lifts - Childrens Hospital (includir	4 elevators	Conventional control	1.6 m/s	1275 kg

Traffic Situation	Floors	Population	Rating	HC5	WT	DT	IS
Two-Way Hotel	0..3	723	5.5 ★★★★★	18.3 %	9.0 s	37.9 s	0.7

Visitor Lifts - Childrens Hospital (1)	4 elevators	Conventional control	1.6 m/s	1275 kg

Traffic Situation	Floors	Population	Rating	HC5	WT	DT	IS
Two-Way Hotel	0..3	465	5.6 ★★★★★	18.8 %	7.5 s	31.2 s	0.5

Bed Passenger Lifts - Childrens Hospital (3	4 elevators	Schindler ID control	1.6 m/s	2500 kg

Traffic Situation	Floors	Population	Rating	HC5	WT	DT	IS
Two-Way Hotel	0..3	264	5.4 ★★★★★	17.5 %	11.5 s	26.1 s	0.0

The traffic simulations for both the Bed Passenger and Visitor/Staff Lifts show the proposed arrangements will provide excellent lift service.

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Standards and Recommendations

Depending on the type of building, one or two of the following traffic situations are analysed:

Traffic Situation	Incoming	Outgoing	Inter-floor	Type of Building
Up-Peak	100 %	0 %	0 %	Office (all)
Lunch Single Tenant	40 %	40 %	20 %	Office (single-tenant)
Lunch Multi-Tenant	45 %	45 %	10 %	Office (multi-tenant)
Two-Way Hotel	50 %	50 %	0 %	Hotel
Two-Way Residential	50 %	50 %	0 %	Residential

For other types of buildings, an Up-Peak situation and optionally one of Lunch Single Tenant, Lunch Multi-Tenant, or Two-Way Hotel are analysed.

Every analysis covers a full range of arrival rates, reporting handling capacity HC5 and average waiting time WT as main criteria. As a general guideline, Schindler defines a rating in the range of 0.0 (worst) to 6.0 (best) based on these criteria. Recommended ratings are 3.0 or higher:

Schindler Traffic Analysis Ratings 2008

	Rating >= 3.0		Rating >= 4.0		Rating >= 5.0	
Traffic Situation	HC5	WT	HC5	WT	HC5	WT
Up-Peak	>= 12 %	<= 30 s	>= 14 %	<= 20 s	>= 16 %	<= 15 s
Lunch Single Tenant	>= 11 %	<= 40 s	>= 13 %	<= 30 s	>= 15 %	<= 20 s
Lunch Multi-Tenant	>= 11 %	<= 40 s	>= 13 %	<= 30 s	>= 15 %	<= 20 s
Two-Way Hotel	>= 11 %	<= 40 s	>= 13 %	<= 30 s	>= 15 %	<= 20 s
Two-Way Residential	>= 6 %	<= 80 s	>= 7 %	<= 60 s	>= 8 %	<= 40 s

Ratings are also displayed by a corresponding number of stars and may be interpreted on a global basis as follows:

Rating	Stars	Office	Hotel	Residential
>= 3.0	★★★☆☆	Standard office buildings	Up to approx. 3-star hotels	Basic segment
>= 4.0	★★★★☆	Mid-to-higher requirements	Up to approx. 4-star hotels	Medium segment
>= 5.0	★★★★★	Premium sites	Up to approx. 5-star hotels	Premium segment

Results

3.1 Visotor Passenger Lifts - Childrens Hospital (including staff)

3.1.1 Building and Population

Number of Floors: 4 floors
Building Population: 723

Floor Name	Floor Height [m]	Floor Level [m]	Description	Quantity	Unit	Density	Density Unit	Gross Population	Vacancy Factor	Visitor Factor	Net Population	Σ
3	4.20	12.60	Wards	241.0	persons	1.0	*	241			241	+
2	4.20	8.40	Wards	241.0	persons	1.0	*	241			241	+
1	4.20	4.20	Wards	241.0	persons	1.0	*	241			241	+
0	4.20	0.00	Lobby		persons	1.0	*					

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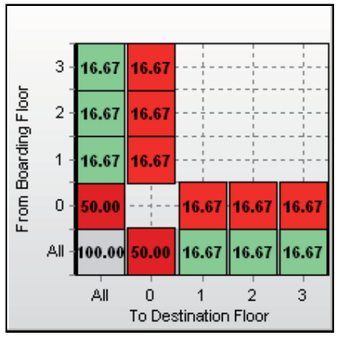
3.1.2 Elevators

Control: Conventional

		A	B	C	D
Rated Load	[kg]	1275	1275	1275	1275
Weight per Person	[kg]	75	75	75	75
Pass./Deck gross		17	17	17	17
Car Filling Rate		80 %	80 %	80 %	80 %
Pass./Deck net		14	14	14	14
Drive Type					
Max. Speed	[m/s]	1.60	1.60	1.60	1.60
Max. Acceleration	[m/s2]	0.70	0.70	0.70	0.70
Drive Jerk	[m/s3]	1.00	1.00	1.00	1.00
Door Type		V 50	V 50	V 50	V 50
Door Width	[mm]	1100	1100	1100	1100
Opening Time	[s]	2.1	2.1	2.1	2.1
Closing Time	[s]	3.5	3.5	3.5	3.5
Number of Decks		1	1	1	1
Travel Height	[m]	12.60	12.60	12.60	12.60
Transfer Time per Person	[s]	1.0	1.0	1.0	1.0
3 Wards					
2 Wards					
1 Wards					
0 Lobby					

3.1.3 Two-Way Hotel

Traffic Definition: Probability Distribution of Calls



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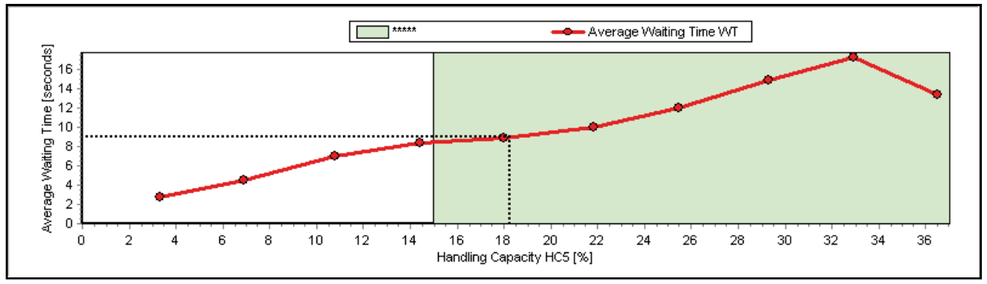
1 2 3
4 5 6
7 8 9
0

Results

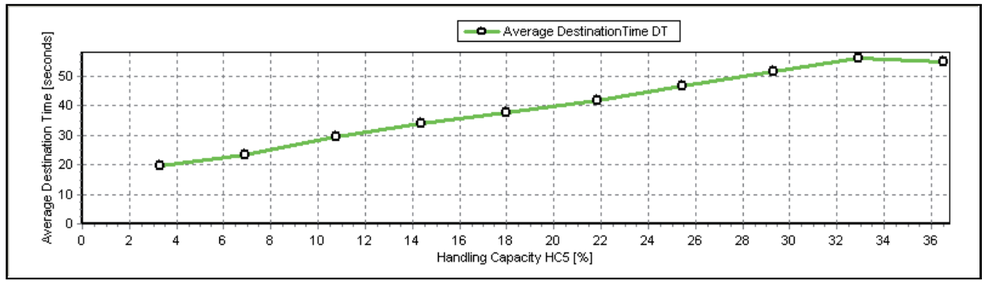
Visotor Passenger Lifts - Childrens Hospital (including staff)

Two-Way Hotel

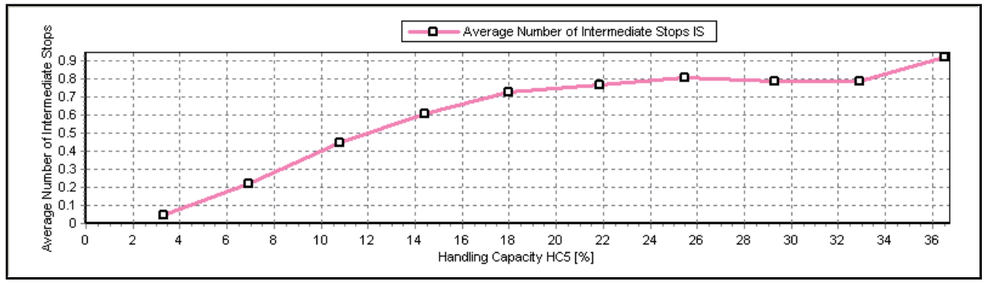
Waiting Time (WT)



Destination Time (DT)



Number of Intermediate Stops (IS)



HC5	3.3 %	6.9 %	10.8 %	14.4 %	18.0 %	21.9 %	25.5 %	29.3 %	32.9 %	36.5 %
P5	24	50	78	104	130	158	184	212	238	264
WT	2.8	4.6	7.0	8.4	8.9	10.1	12.0	14.9	17.3	13.5
DT	19.6	23.4	29.4	34.0	37.6	41.7	46.7	51.6	56.0	54.9
IS	0.0	0.2	0.4	0.6	0.7	0.8	0.8	0.8	0.8	0.9

3.2 Visitor Lifts - Childrens Hospital (1)

3.2.1 Building and Population

Number of Floors: 4 floors
Building Population: 465

Floor Name	Floor Height [m]	Floor Level [m]	Description	Quantity	Unit	Density	Density Unit	Gross Population	Vacancy Factor	Visitor Factor	Net Population	Σ
3	4.20	12.60	Wards	155.0	persons	1.0	*	155			155	+
2	4.20	8.40	Wards	155.0	persons	1.0	*	155			155	+
1	4.20	4.20	Wards	155.0	persons	1.0	*	155			155	+
0	4.20	0.00	Lobby		persons	1.0	*					

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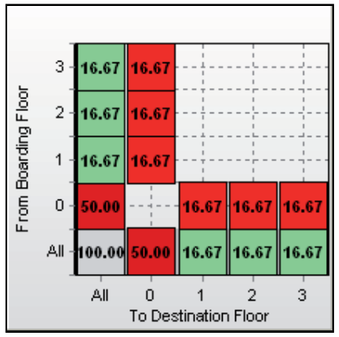
3.2.2 Elevators

Control: Conventional

		A	B	C	D
Rated Load	[kg]	1275	1275	1275	1275
Weight per Person	[kg]	75	75	75	75
Pass./Deck gross		17	17	17	17
Car Filling Rate		80 %	80 %	80 %	80 %
Pass./Deck net		14	14	14	14
Drive Type					
Max. Speed	[m/s]	1.60	1.60	1.60	1.60
Max. Acceleration	[m/s2]	0.70	0.70	0.70	0.70
Drive Jerk	[m/s3]	1.00	1.00	1.00	1.00
Door Type					
Door Width	[mm]	1100	1100	1100	1100
Opening Time	[s]	2.1	2.1	2.1	2.1
Closing Time	[s]	3.5	3.5	3.5	3.5
Number of Decks		1	1	1	1
Travel Height	[m]	12.60	12.60	12.60	12.60
Transfer Time per Person	[s]	1.0	1.0	1.0	1.0
3 Wards					
2 Wards					
1 Wards					
0 Lobby					

3.2.3 Two-Way Hotel

Traffic Definition: Probability Distribution of Calls

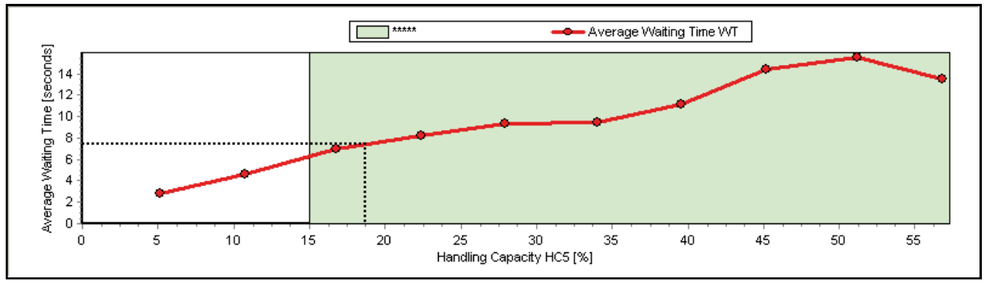


Brookfield

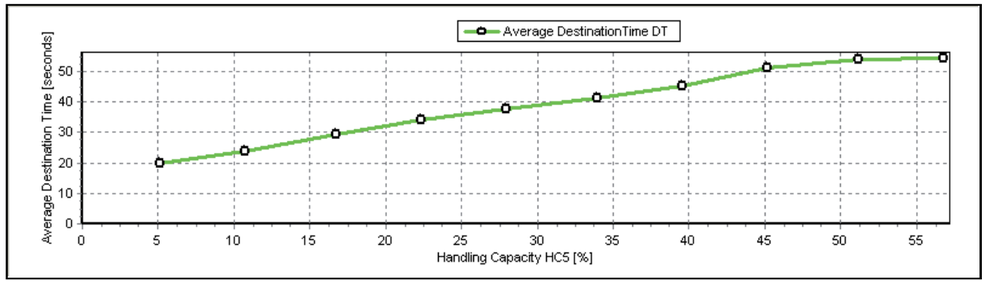
1 2 3
4 5 6
7 8 9
0

Results
Visitor Lifts - Childrens Hospital (1)
Two-Way Hotel

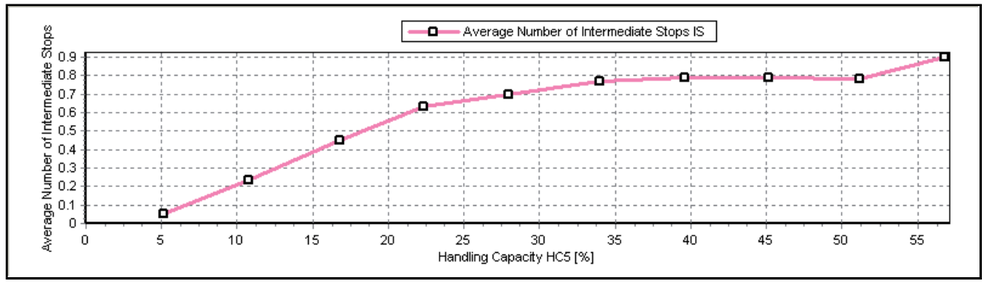
Waiting Time (WT)



Destination Time (DT)



Number of Intermediate Stops (IS)



HC5	5.2 %	10.7 %	16.8 %	22.4 %	27.9 %	34.0 %	39.6 %	45.2 %	51.2 %	56.8 %
P5	24	50	78	104	130	158	184	210	238	264
WT	2.9	4.6	7.0	8.2	9.3	9.5	11.1	14.4	15.5	13.5
DT	19.7	23.7	29.5	34.1	37.8	41.1	45.4	51.2	54.0	54.3
IS	0.0	0.2	0.4	0.6	0.7	0.8	0.8	0.8	0.8	0.9

3.3 Bed Passenger Lifts - Childrens Hospital (3)

3.3.1 Building and Population

Number of Floors: 4 floors
Building Population: 264

Floor Name	Floor Height [m]	Floor Level [m]	Description	Quantity	Unit	Density	Density Unit	Gross Population	Vacancy Factor	Visitor Factor	Net Population	Σ
3	4.20	12.60	Wards	88.0	persons	1.0	*	88			88	+
2	4.20	8.40	Wards	88.0	persons	1.0	*	88			88	+
1	4.20	4.20	Wards	88.0	persons	1.0	*	88			88	+
0	4.20	0.00	Lobby		persons	1.0	*					

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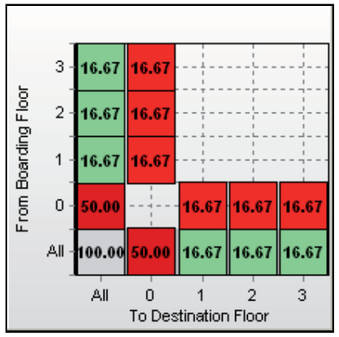
3.3.2 Elevators

Control: Schindler ID

		A	B	C	D
Rated Load	[kg]	2500	2500	2500	2500
Weight per Person	[kg]	75	75	75	75
Pass./Deck gross		33	33	33	33
Car Filling Rate		2 %	2 %	2 %	2 %
Pass./Deck net		1	1	1	1
Drive Type					
Max. Speed	[m/s]	1.60	1.60	1.60	1.60
Max. Acceleration	[m/s2]	0.70	0.70	0.70	0.70
Drive Jerk	[m/s3]	1.00	1.00	1.00	1.00
Door Type					
Door Width	[mm]	1300	1300	1300	1300
Opening Time	[s]	2.1	2.1	2.1	2.1
Closing Time	[s]	3.0	3.0	3.0	3.0
Number of Decks		1	1	1	1
Travel Height	[m]	12.60	12.60	12.60	12.60
Transfer Time per Person	[s]	1.0	1.0	1.0	1.0
3 Wards					
2 Wards					
1 Wards					
0 Lobby					

3.3.3 Two-Way Hotel

Traffic Definition: Probability Distribution of Calls



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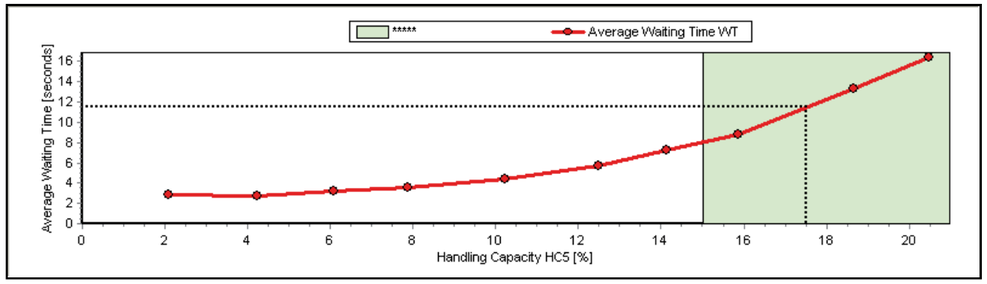
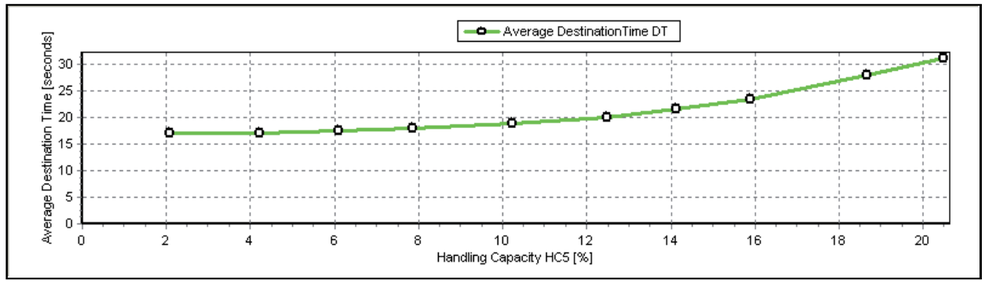
1 2 3
4 5 6
7 8 9
0

Results
Bed Passenger Lifts - Childrens Hospital (3)
Two-Way Hotel

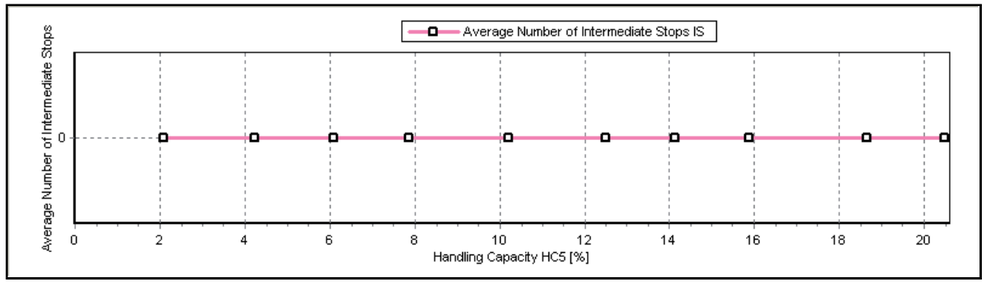
Waiting Time (WT)



Destination Time (DT)



Number of Intermediate Stops (IS)



HC5	2.1 %	4.2 %	6.1 %	7.9 %	10.2 %	12.5 %	14.1 %	15.9 %	18.7 %	20.5 %
P5	5	11	16	21	27	33	37	42	49	54
WT	2.9	2.7	3.2	3.6	4.4	5.7	7.2	8.8	13.3	16.4
DT	17.2	17.1	17.5	18.0	19.0	20.1	21.7	23.3	28.0	31.1
IS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

How Schindler Undertakes Traffic Analyses

4.1 Introduction

A traffic analysis studies the performance of a group of elevators, based on assumptions about the expected traffic situation. The main performance measurements are handling capacity and waiting time. Reliable and comparable performance results are found by means of benchmark simulations which reflect the expected real behavior of a group of elevators under a wide range of traffic situations.

4.2 Measures and Definitions

The elevators' main task is to manage the traffic, i.e., the transportation needs of passengers and goods, in such a way that the highest possible density of arriving passengers and goods can be transported in the building at the highest possible perceived service quality.

4.2.1 Arrival Rate and Handling Capacity (P5, HC5)

For a specific elevator group, the arrival rate describes the density of arriving passengers in an observed time period. In contrast, the handling capacity is the number of passengers transported in an observed time period. As long as the elevator group is able to transport all the arriving passengers without building up waiting queues, the arrival rate and the handling capacity are equal.

Handling capacity is measured by P5 and HC5:

- P5 is the number of persons that is transported on average within 5 minutes.
- HC5 is the percentage of the population on the floors served by the elevator group that is transported on average within 5 minutes:
  HC5 = P5 / (population on floors served by elevator group).

Example: Consider an elevator group which serves floors with a population of 1000 people. By observation, there are 600 passengers transported within 30 minutes, therefore:

- P5 = 600 persons * (5 minutes / 30 minutes) = 100 persons,
- HC5 = 100 persons / 1000 persons = 10.0 %.

4.2.2 Waiting Time (WT) and Destination Time (DT)

Waiting time and destination time for an individual passenger are defined as follows:

- waiting time: time from when the passenger registers a landing call (or joins a queue) until the door of the serving elevator begins to open on the boarding floor (zero if the door is not closed when the passenger arrives)
- destination time: time from when the passenger registers a landing call (or joins a queue) until the door of the serving elevator begins to open on the destination floor

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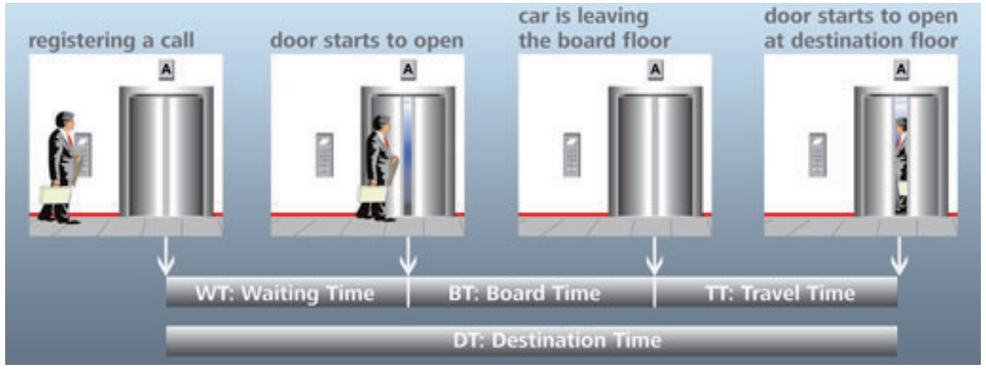

For a number of served passengers in an observed period of time, the average waiting time WT and the average destination time DT are defined in the usual way as mean values of the passengers' individual waiting time and destination time, respectively.

4.2.3 Number of Intermediate Stops (IS)

The number of intermediate stops for an individual passenger is the number of times an elevator stops with the passenger between boarding floor and destination floor. For example, for a passenger with a direct (non-stop) trip from boarding floor to destination floor the number of intermediate stops is zero.

For a number of served passengers in an observed period of time, the average number of intermediate stops IS is defined in the usual way as mean value of the passengers' individual number of intermediate stops.

4.3 Methods of Traffic Analysis

A traffic analysis should cover a variety of important traffic situations, especially when planning new buildings. Reported values should be as reliable and comparable as possible. However, performance values depend on the methods of the traffic analysis and the basic traffic assumptions.

4.3.1 Simulation vs. calculation methods

In *simulation methods,* a real passenger flow is being replaced by a virtual one, which was created with the help of a random generator and loaded into the same control algorithm as used in a real elevator controller. Thus the results can be measured under different traffic conditions and reflect the expected reality to a very large extent.

In contrast, *calculation methods* are based on formulas which only cover a very limited range of traffic situations (usually, only up-peak traffic). The formulas reflect theoretical assumptions rather than a realistic behavior of elevator groups, and results are usually too optimistic. Therefore, calculation results should not

be compared with simulation results.

Schindler Traffic Analysis Reports are based on simulations in order that the reported results are the most reliable and realistic achievable.

4.3.2 Wide Range of Traffic Assumptions

The traffic flow in a building keeps changing all the time; no two days are the same. As a rule, traffic depends on many factors (such as location of building, tenant structure, etc.) and may vary considerably during operation of the building. A traffic analysis should take such factors into consideration and try as far as possible to cover future traffic situations.

In a complex building, a single traffic assumption is not sufficient. E.g., it is not sufficient to apply a traffic pattern measured in some other existing building for the design of a new building. In particular, the limits of the handling capacity of the elevators cannot be found by such "spot light" examinations.

Predictions about the range of handling capacity of an elevator group can only be made by actually simulating a wide range of traffic situations. A benchmark method applies a reference traffic situation from low to very high traffic intensity; by this, the limits of the elevators' handling capacity can be detected. Schindler uses a benchmark method which gives a neutral system assessment.

Schindler Traffic Analysis Reports are based on different traffic situations (see Section 2) tested by benchmark methods. This ensures that the traffic analysis covers a full range of applications and reports reliable and comparable performance predictions.

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Communication Design Strategy

Introduction

For the New South Glasgow Hospitals Project, Brookfield knows the Telephone Distribution Systems and Information Technology (IT) Equipment and Distribution Systems are critical to the success of the hospital and operation. This section sets out an overview description on the telephone distribution systems and information technology description and distribution systems (TDS and ITEDS) infrastructure for consideration by the NHS GG&C Health Board.

The strategy document highlights the key components of TDS & ITEDS systems proposed for the project including distribution networks.

Brookfield have included for all requirements as stated in the ITPD Volume 2/1 Employer's Requirements section 8.3.5 to 8.3.20 The Telephone Distribution And Information Technology Equipment and Distribution Systems design strategy has been developed by the Brookfield team to comply with these requirements and key points discussed during the design dialogue process with the NHS GG & C Health Board.

Brookfield strategy includes for the development using of the latest technologies for each system to ensure optimum future proof systems that will be determined at the time of final design during stage two of the project.

Detailed information about network technology (active equipment, including PABX, switches routers fire walls etc.) is not included in this section as the design and provision of these active items were confirmed to be procured by NHS GG&C Health Board.

TDS and ITEDS spaces such as the main communications room (MCR) located with in the Adult and Children's hospital area will contain all main servers and core switches, a secondary communications room (SCR) containing only duplicate critical servers will be located in another fire compartment within the hospital to provide a level of resilience. The main communications systems will be connected to a system of communications rooms located throughout each floor via a backbone network system.

Each communication room will contain various communications and control systems equipment such as; patch cabinets, interface modules etc that support the hospital services serving a specific area to ensure optimal performance of each system are described in this section.

Connections between these rooms are also outlined with details on the containment dedicated to the TDS and ITEDS infrastructure and electrical risers within the various buildings.

The route for the incoming TDS ducting is to be provided from the Govan and Hardgate Roads up to each hospital entrance on the hospital campus. The two alternate routes ensure resilience via providing physically diverse routes. The two entrance facilities for the purposes of these ducts are designated Entrance Facility 1 (EF1) and Entrance Facility 2 (EF2). These shall be used as termination points by the various Service Providers (SP).

EF1 and EF2 termination points will be located in close proximity to the main communications room.

Data and Voice will be run in a combined services trench with connections to the new Adult Hospitals, Laboratories, Energy Centre and existing hospital buildings.

NHS GG&C Health Board shall be responsible for engaging the Service Provider(s) to provide telecommunication services into the new facilities.

A network of underground PVC ducts will be routed in a resilient fashion from the main control room in the Adult and Children hospital to the Laboratory, Energy Centre and existing hospital buildings. This network of ducts will facilitate the TDS and ITEDS infrastructure cabling (optic fibre and copper) that will service the buildings around the hospital campus.

Brookfield has included to consider new technologies and systems that maybe able to use modern wireless network

It is envisaged that in the future new hospitals will use wireless technology for public, staff data, patient monitoring, equipment tracking and automated transfer system connections, this will require the design and implementation of strategically located wireless access points to meet reliable robust performance and maintain the efficient operation of the hospital.

Facilities Management systems require a cabling infrastructure to enable effective communication between the various buildings. There is a requirement to provide an Independent Protocol network to support communication, interaction, data transfer and data retrieval from and between the various engineering systems that provide service to the buildings. The Building Management System will be fully integrated with this network and will provide control over the engineering plant and facilities to enable management of maintenance and to monitor energy usage. Systems such as metering, pressure monitoring status, general lighting controls and presence detection will use the Facilities management backbone network. The network will be totally independent of the clinical network except for an interface, which will be engineered into the final solution via the server.

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Telephone Distribution Systems and Information Technology (IT) Equipment and Distribution Systems Room Allocations

Spaces distributed across the hospital to enable an efficient resilient network include:

- EF1 - Termination point for Service Providers
- EF2 - Termination point for Service Providers
- MCR and SCR.
- Communications rooms on each floors.

Networks

The voice and data clinical network will use a combination of optic fibre, category 6A (10G) copper cabling and copper multi-core telecommunications cable. NHS GG&C Healthy Board advised they will source and install all active network equipment, including the PABX and all associated telephone equipment.

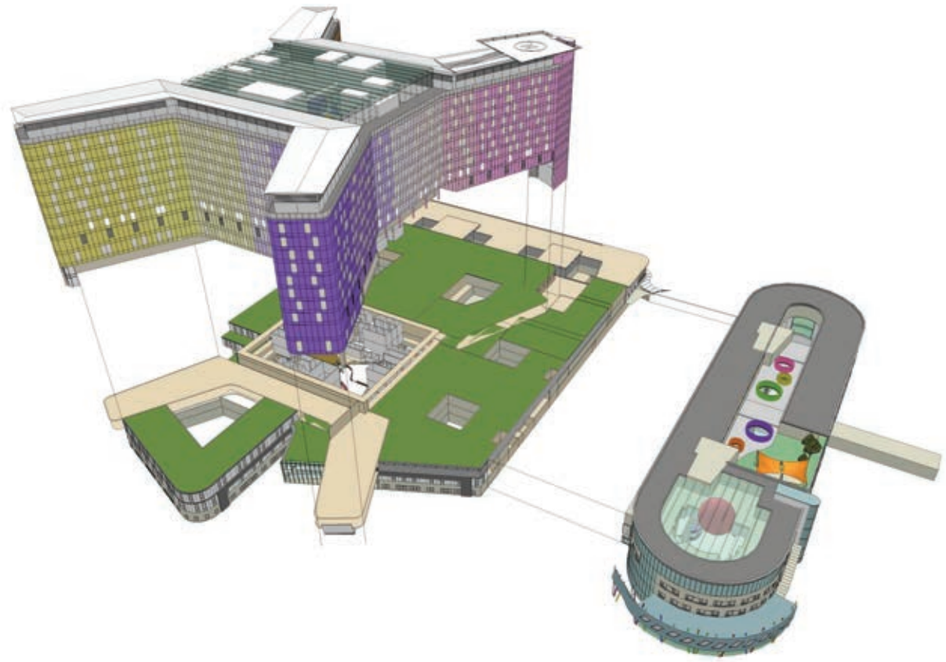
The core of the voice/data network will be located in the two main communication rooms located with in the Adult and Children's Hospitals. These rooms will contain all core routers and switches, as well as all server equipment to drive services delivered across the Structured Cabling System (SCS).

Local communication rooms will be distributed on each floor, the quantity of these rooms will be dependant on maintaining optimum performance of each system such as 90 metre cabling loops for fire alarms etc. These rooms will have connections back to the main communications rooms in a meshed configuration.

The first image shows a structural overview of the Adult and Children's Hospitals with the 3 distinct elements:-

- Podium
- Tower
- Children's Hospital

The next image outlines the different levels in the hospitals where we will now identify where the potential communications rooms will be located.



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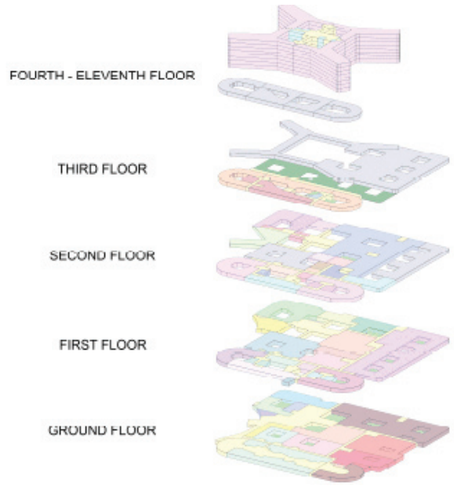

For the Adult Hospital, we would envisage having the main communication room at the Podium Level, where a level of security can be provided given the type of equipment that will be located here and a secondary communications room located in an alternate fire compartment. Access to each room will be required frequently.

Local communication rooms will be provided on the Podium and Tower levels, Children hospital, Laboratory, Energy Centre, Facilities Management areas and will be based on maintaining optimal performance of each system such as limiting to 90 metre maximum loop distance. The maximum distance limitation will dictate the number of communication rooms required. The majority of the communications rooms will be located in mechanical and electrical plant rooms where possible or located in dedicated riser rooms etc.

Access to these communication rooms will be less frequent than the main communication rooms (MCR & SCR) All rooms will be design with sufficient to house all equipment and allow future space for new technology or some additional future systems.

Users

We envisage that the number of users that will require access to the voice and data clinical network will include; consultants, nurses, administration staff, doctors, visiting medical personnel, maintenance and operations staff. Each user will be managed by setting up appropriate level of access authorisation controlled by a designated hospital IT manager. The Brookfield training program will provide all necessary training to use the system to set up each system with levels access and authorisation. However it is imperative for security that there is a physical and logical separation between internal users and external users. NHS GG&C Health Board will have sole control and management of the physical and logical patching of the network.

Ducting

Ducting has been designed to deliver internal & external communication network services across the site. The routes for the underground ducting will be provided from the Govan and Hardgate Roads up to each EF1 and EF2. We have calculated that a total of six ducts will need to be provided to each Entrance Facility, two ducts will be provided to the new Laboratory and two ducts to the current Estates Department. It is envisaged that at least four Service Providers will have connectivity to the new Hospitals.

Electrical risers facilitate the routing of the incoming cables and also aid the distribution of network cables within the building. All cables will be supported and fixed to proprietary containment and it should be noted that there will be no active or switching equipment in these locations. Riser access will be secured with lock and key.

Cable routes have been designed to ensure the internal networks are coordinated appropriately within each new building.

Copper network cabling and other various systems lengths will not exceed 90m from patch panel to socket or device. This requirement has been considered throughout the design.

Outlet provision

The voice/data outlet provision is based on the ADB Room Data Sheets. These ADB sheets define the location and quantity of the service types defined earlier in this report. Different colour patch leads will be used to distinguish the various services. In the bedrooms, outlets will be provided on the medical trunking where they will cater for data applications, voice applications, telemedicine applications and patient entertainment applications.

Outlets serving critical elements such as emergency phones will be clearly coloured and labelled. Outlets will be provided in the various rooms ensuring that all applications are served with an adequate quantity of these outlets.

Wireless Network Installation

Brookfield has included to consider new technologies and systems that maybe able to use modern wireless network

It is envisaged that in the future new hospitals will use wireless technology for public, staff data, patient monitoring, equipment tracking and automated transfer system connections, this will require the design and implementation of strategically located wireless access points to meet reliable robust performance and maintain the efficient operation of the hospital.

We are cognisant of the changing technologies in the wireless arena and note the widespread use of the “n” standard.

During stage two Brookfield will liaise with manufacturers such as Cisco and Trapeze to review wireless technologies and provide the NHS GG&C Health Board with a detailed proposal for a first class wireless infrastructure.

Noting the Employer’s requirement to provide an Independent Protocol network, this is to support communication, interaction, data transfer and data retrieval from and between the various engineering systems that provide service to the new buildings. The Building Management System (BMS) will be fully integrated with this network and will provide control over the engineering plant and facilities to enable management of maintenance and energy usage. Systems such as metering, pressure

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monitoring status, general lighting controls and presence detection will use this Facilities management backbone network.

The network will be totally independent of the clinical network except for an interface, which will be engineered via the server.

Public Address Systems (PA)

PA system will be provided that allows zoned emergency messaging throughout the hospitals, lifts, building link tunnel, facilities management and energy centre together with mustering areas, supplemented with voice and background music to entrances, main reception, atria, changing rooms, waiting areas, coffee shop and at each remote reception including nurse base for radiology, outpatients, pharmacy, A&E etc, inline with Clinical Requirements.

A vibrating disc or pager based system will be provided to indicate to patients that their appointment is available. This system will be operated via the wireless access system. Three separate systems will be provided, with power supply, data connection to the wireless system, each with twenty pagers.

Background music for the comfort of patients and visitors and public address facilities to main and sub-waiting area entrances and hospital streets are provided by input devices, amplifiers, distribution cabling and loudspeakers. Local volume control to each area, waiting or sub waiting etc will be provided with full volume on PA announcement.

The emergency messaging shall be controlled from two locations and the system shall incorporate pre-coded messages.

Audio Induction Loop System

Comprehensive Audio Induction Loop Systems (fixed or portable) will be provided:

- Reception areas.
- Bedded bays.
- Single room.
- Treatment rooms.
- Consulting rooms.
- Counselling rooms.
- Interview rooms.

The system shall be provided in compliance with the Disability Discrimination Act, the final locations and provisions will be agreed with the board.

Each induction loop will comply with the requirements of BS 6083: 1981 and in particular Part 4: Magnetic Field Strength in Audio Induction Loops for Hearing Aid Purposes.

A vibrating disc or pager based system will be provided to indicate to patients that their appointment is available. It is considered that this system may be offered via the wireless access system.

Patient Entertainment

Adult Hospital Patient entertainment provisions will be in accordance with the guidelines and include provision for local bedside TV, Radio, and telephone facilities with the capability of integration to satellite TV, local hospital radio, chapel services, internet services Brookfield have included to provide the latest technology that allows the patient entertainment system to interface with the hospital data communication system. The patient entertainment system will comprise Free-to-view Digital TV signals and shall be decoded in the Patient Entertainment Room server and shall be extended to each of the TV's located throughout the hospital building.

Brookfield acknowledge the differing requirements for the Adult and Children's hospital (ITPD 8.3.19.1/2 and 8.3.19.3/4) and has included to the design to meet those requirements accordingly.

Cabling and infrastructure provisions will be in accordance with the chosen suppliers requirements. Consideration will be given to procurement rather than renting of such system to enable greater flexibility to extend the functionality of the services and for patient charges and tariffs.

Cabling Infrastructure

The main TV signal shall be extended in coaxial cable to the Patient Entertainment Room where the signals shall be decoded for transmission over copper 4pair twisted pair cables. Multicore copper cables shall extend from the Patient Entertainment communications room to each of the CWP's. The Patient Entertainment TV distribution shall be via category 6 copper twisted pairs extending from patch panels within the CWP's to RJ45 Outlets at the TV points.

Nurse Call, Alarm Systems

Nurse Call system and emergency alarm services will provide a comprehensive system integrated within the BMS networking system at all bed locations (and en-suites), Nurse stations, Toilets, showers, TV rooms and all other areas frequented by patients in accordance with S/HTM's and S/HBN's. Brookfield will agree with the Board all enabled on-screen alerts and their locations.

The system will be capable of emitting both audible and visual warnings for the following situations:

- To summon a nurse (Patient to Nurse)
- To highlight a medical emergency (Nurse to Nurse)

The nurse call system will be part of the bed head service. A patient hand unit with a call button will linked to an indicator panel in the ward nurse station.

The system shall include:

- Ensuite protection.
- Over-door indicator lights.
- Ability to link calls between adjacent wards.
- Cardiac arrest or ‘crash’ call alarms taken back to a 24 hour manned point to allow the “crash” team to be paged

All equipment and materials to provide fully operational independent monitored Nurse Call Systems will be provided as described below to facilitate the summoning of nurse assistance throughout the areas by a ‘follow lamp’ system and separate nurse paging.

Resetting of each system will be carried out at the initiating point of the call by means of reset pushes either located in or separate from the call panels generally as detailed on the appropriate drawings.

Once the call has been initiated the system will remain operational both audibly and visually until the system is reset. A linked automatic paging system will be provided and interface with the ward call system, send ward, room No, call type etc to a central encoder transmitter via a wired network to provide the information to individual nurses mobile pagers.

Each bed system shall be transferable to adjacent and remote nurse stations via a hierarchical password control system to meet Nursing requirements of the flexible ward configuration.

Cardiac Alarm Systems

Cardiac Arrest facilities will be provided for use by patients and staff that can be operated by the telephone system and a dedicated alarm button located within certain areas to call adjacent staff.

Personal Attack Alarm System

Personal Panic and Attack Alarm System will be provided and installed in each ward and department in accordance with S/HTM’s S/HBN’s that will be based on a system using:-

- Portable transmitters carried by staff to initiate an alarm via the wireless connection points.
- An audible alarm installed within the various indicator panels located in security rooms and agreed locations that until the call is cancelled will continue to sound alarm.
- Local indicator lights that will signal alarm until the emergency call has been cancelled.
- All pagers will respond to the priority alarms.

In circumstances where staff could be at risk of attack whilst travelling across external areas of the hospital, suitable portable transmitters using modern digital technology will be provided linked to the security system. Upon activation, calls will be indicated visually and audibly at the various security panels until the call is cancelled.

External areas are provided with security lighting and CCTV that can be used to view areas where the alarm has been raised.

Staff Location Paging System

Staff pager and patient to staff message system will provided that will enable communication between staff to staff.

All Nurse Call Equipment will be as manufactured by the named firms in the Schedule of Specified Equipment and Materials.

The pagers will be integrated in the BMS and Telephone Systems to suit the Board requirements.

Clinical Equipment Alarms

Each clinical drug cupboard shall be alarmed as follows:

- Light externally over door to room.
- Back to Nurse station.
- Back to office to warn of unauthorised access.

Clinical equipment alarms such as blood fridges located as defined on the ADB sheets will be provided with an alarm and will have audible and visual remote alarms and auxiliary contacts wired back to the local BMS outstation. The remote alarm panels will have a mute button fitted.

The system provided by Brookfield by which clinical equipment alarms can be annunciated at designated locations during working hours, however out of hours alarms can be directed to a designated staff member off site.

Asset Tagging System

An asset tagging system will be provided based on RFID technology and have a system interface that will define the rules for particular assets and will provide a reporting facility.

The main benefits of this system are:

- Lowers acquisition costs
- Reduces lease expenses
- Trims asset shrinkage
- Increases asset utilization
- Boosts staff productivity
- Enhances work flow
- Reduces equipment hoarding
- Advances Accredited maintenance & calibration compliance
- Cuts risk & litigation exposure

Brookfield has included a digital web based asset management system that will be developed from the start of the project phase 1 and used as the main hand over process. The result is a complete comprehensive asset management system.

Further details of the electronic handover asset management system are contained in document 3.24.

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Protective Systems Design Strategy

Submission Reference:

3.15 Protective Systems Design Strategy

Submission Response:

The protective systems described below comprise the design strategy for the hospital and the installation of these provides the following benefits:

- Saving lives of, and preventing injuries to, occupants and fire fighters.
- Preventing fire spread.
- Reducing property damage.
- Reducing environmental impact.
- Reducing water damage compared with water used during fire-fighting activities.
- Reducing social impact e.g loss of community facilities, loss of employment.
- Reducing financial losses.

This protective systems design strategy should be read in conjunction with the fire safety design strategy (Volume 2 Section 2.10).

The provision of the protective fire system described below will be monitored and controlled from a central fire control room which will be sited adjacent to the main service entry point into the building.

Fire Detection and Alarm System

The fire detection and alarm system will comply with BS 5839-1 2002 and SHTM 82 and be a category L1 installation.

The primary purpose of the system is for staff alert and the activation/warning design will consider a voice alarm system to be audible throughout the hospital, a coded message system for staff alert in certain areas and/or the use of indicators at staff bases to ensure the intelligibility of phone conversations during an alarm scenario.

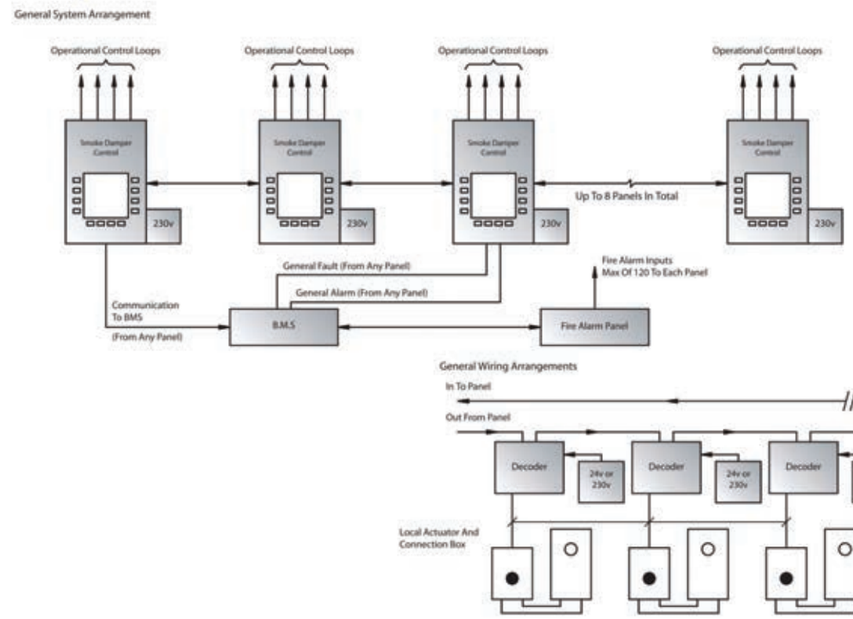
The system will comprise multiple analogue fire panels located throughout the building. The fire panels will be networked. Repeat indicators will be distributed throughout the hospital to provide local indication. Repeat panels will display any fire fault and disablement information. A mimic diagram will be provided adjacent to each fire alarm and repeat indicator panel. The main fire alarm panel will be located at the main reception and the repeater panels at certain staff bases.

An administration PC will be provided to give full administration facilities for the fire system.

Detection devices will be a mix of optical and heat sensors as appropriate to the area protected. Sensors will be provided with a number of different states of operation to enable configuration suitable for the area protected.

Sounders to BS EN54 will be incorporated into the sensors or separate units as appropriate. Manual call points will be provided.

General Wiring Arrangement
Addressable Damper Control



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The system will be interfaced with the other fire protection systems and the ventilation system fire/smoke dampers which will prevent the spread of smoke and fire. These will be wired and controlled by a fully addressable damper control system incorporating local and master control panels with fireman's override facilities.

The damper control system shall be programmed to operate in accordance with the cause and effect strategy that will be developed for the New South Glasgow Hospitals. The damper system control panels will display the operating status and report faults on a continuous monitoring basis. The main fire alarm panels will have the facility to manually operate either collectively or individually the dampers

Gaseous Extinguishing Systems

Aspirating detection will be provided in the two main server rooms, interfaced with the fire alarm system. The server rooms will also be provided with gaseous extinguishing systems operating a 'double knock' confirmation facility. The system will comprise a zone control panel adjacent to the protected space which interfaces with the alarm system, ventilation and air conditioning systems, power supplies and the extinguishing system. The panel will control the shut down of these power, ventilation and air conditioning systems in the event of a signal from the fire alarm system and then activate the extinguishing system.

Sprinkler Installation

The automatic sprinkler installation for the hospitals will comply with BS EN 12845, LPC standards, SHTM 82 and, due to the height of the building, with the high system requirements layout in accordance with BS EN 12845:2004 Annex E. The system will protect the building from serious fire damage. The water supply for the system will comprise two multistage electric pump sets drawing water from tanks located in the basement of the building.

The design of the system will use the Ordinary Hazard Group III classification. Sprinkler protection will be installed at ceiling level throughout the protected areas from Level -1 to Level 12 in the adult hospital and Level -1 to Level 4 in the children's hospital, with the pipe work concealed in the ceiling void. The installation will be subdivided into zones in accordance with Annex D and Annex F of the BS EN12485. Each zone valve arrangement will comply with the Life Safety requirements and each zone will not exceed 2,400 m^2.

Sprinkler protection will be provided throughout the building apart from optional permitted exceptions, so that if a fire starts at any location in the building it is suppressed and controlled and /or extinguished quickly and efficiently, preventing fire spread to other parts of the building.

All the monitored sprinkler equipment such as pumps valves and flow switches will be wired to an addressable panel. A flow alarm switch will be provided on the alarm valve riser to give remote alarm indication.

Wet Risers

A wet risers system will be provided in the Adult and Children's hospital with a landing valve at each floor and each staircase. The water supply for the system will be from an electric booster pump set drawing water from a tank. Four wet risers will be installed in the Adult hospital and two in the Children's hospital. The booster pumps will act as duty and standby with automatic changeover.

A landing valve will be provided at each floor level where personnel can connect and fill hose lines in relative safety before entering the fire compartment. Each landing valve will be sited in the stairway enclosure and will be protected and installed within a box in accordance with BS 5041-2.

Escape Lighting

The hospitals will be provided with emergency lighting to aid the escape and therefore protection of staff and patients. The systems will be in accordance with BS5266: Part 1: 1999 and SHTM 2007. Further details on lighting are provided in Volume 3 Section 3.12 (Lighting Design Strategy) and Volume 4 Section 4.36 (Electric Lighting Specifications).

Kitchen Fire Suppression systems

Localised kitchen extract fire suppression systems will be installed within the kitchen extract canopies.

Fire Extinguishers

Fire extinguishers will be provided and installed throughout the hospital building in accordance with BS5306: PART 8

Appropriate types of extinguishers will be incorporated in order to cover varying types of potential fire risk.

Fire Hydrants

A system of water fire hydrants, with a sufficient incoming water supply, will be located externally to the building and distributed around the building so that every external elevation of the hospital is within 60m of a hydrant. The hydrants will be at least 6m from the building and be constructed in accordance with BS 750: 1984.

Helipad

The helipad located on the roof of the Adult hospital will be supported by a fully equipped foam extinguishing system in compliance with NFPA 418, CAA guidance and Health Building Note 15-03: Hospital helipads design. The foam extinguishing system will be connected to the nearest wet riser.

In addition, the fire protection system for the helipad will be supported by two 50Kg Multipurpose Dry Powder Chemical Wheeled Fire Extinguishers located at the same level. Further details are provided in the Helipad M&E services design strategy in Volume 3 Section 3.22.

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Medical Gases Design Strategy

Central gas storage

A medical gas storage compound will be located on the southern perimeter road adjacent to the multi-storey car park as indicated on the external services layout drawing.

The positioning of the compound provides the required safe separation distances as required by HTM02-1. Access for tanker and bottled gas deliveries will be provided so as not to cause obstruction of the roadways.

Oxygen supply plant

Oxygen will be supplied from two separate VIE compounds. The VIE (Vacuum Insulated Evaporator) units will be arranged as main supply and emergency reserve.

The VIE oxygen supply equipment will be sized and installed by B.O.C under direct leasing arrangements with the Board; a valved connection being left in each compound for continuation by the medical gas specialist.

From each VIE unit an oxygen supply will be taken underground to enter the main Acute Hospital and then connect to the oxygen ring main running at ground floor level. The ring main will connect to the major risers serving the upper floors of the Acute and Children's Hospitals. The risers will be cross-connected at roof plant level to provide additional resilience to the distribution system.

Manifold supplied services

Nitrous Oxide will be provided from manifold rooms in the medical gas compound. Separate manifolds will be provided for the Acute Hospital and Children's Hospital theatre departments.

A single pipeline for each service will run below ground from the manifold room to enter the main Acute Hospital where it will run to rise within ventilated service risers to the various departments to be served.

Central compressor plants

Central Plant will be located at roof plant room level for the following systems:-

(a) *Medical Air*

- Medical Air 4bar plant be installed within plant room 121/122. This supply all wards on level 4 through to level 11. There be two risers each riser supplying two wards on each level.
- Second air compressor be installed within plant room 41 on the fourth floor to supply the children's block.
- The third air compressor be installed within plant room 31 above the main theatres this plant cover ground, first, second & third floors of the main building.

Emergency reserve bottle manifold to supply each of the 4bar plant will be installed in plant rooms 121/122, 31 & 41

(b) *Medical Vacuum*

- The vacuum pumps be located in plant room 121/122 to serve the wards on level four through to level 11, there be two risers each riser supplying two wards on each level.
- The second vacuum plant be installed in plant room 41 to serve the Children's Building.
- The third vacuum plant to be installed in plant room 31 to serve the main block levels ground, first & third floors.

(c) *Surgical Air*

- One 7bar plant to be installed in plant room 41and one 7bar plant to be installed in plant room 31 supply the requirements of all Ultra Clean Theatres, Cardiac department and General Theatres.

Emergency reserve bottle manifolds to supply each of the 7bar plants will be installed in plant rooms 41 & 31

Plant Noise

The sound pressure level within the compressor plantrooms need to be carefully considered. It is, therefore, intended that screw compressors will be used whenever possible to reduce the sound pressure levels.

Anesthetic gas scavenging systems (agss)

Anesthetic Gas Scavenging Systems will be provided for wherever Nitrous Oxide is used for anesthetic purposes and pumped to local exhauster sets within the roof plantrooms.

Within the departmental areas wherever AGSS terminal outlets are provided, local starter panels with plant run/fault indications will be provided.

Terminal units

Terminal units will be single outlets, wall mounted or part of a horizontal medical trunking or part of a ceiling pendant.

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Area valve service units (AVSUs)

These will be generally located for both departmental isolation units located within the hospital street adjacent to departmental doors and local area isolation units located adjacent to nurses stations etc.

Medical gas alarms

Medical gas alarm systems will be stand-alone systems and only give status and alarm facility to the central BMS via volt free contacts on the Main Alarm Panel.

All central panels will have audible and visual alarms for all remote plant conditions and visual pipeline pressure fault conditions. Repeater panels will show all the alarm conditions on the control panel.

Main alarm panels will be located in the main hospital switchboard room with a repeater panel within the Facilities Management office.

At the main alarm monitoring panel and repeater panels, the pipeline status in critical care areas will also be indicated, e.g. Theatres, and Intensive Care Areas

AGSS alarms will local to the area served.

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Design Strategy for Pneumatic Tube System

General

A PC controlled pneumatic tube system (PTS) will be installed in the Acute and Children's Hospitals with links to the Laboratory building via the service link tunnel.

The preliminary plan for the PTS is a ten zone network to serve around 92 stations within the hospital buildings, with four zones covering the Ward Tower itself. A dedicated zone between A&E and Pathology will be provided to maintain a high priority service, three dedicated systems will be provided between the network hub and specimen reception to maximise traffic handling capacity with automatic empty carrier return using transponder fitted carriers.

The system will be capable of supporting 300 (carriers) per hour on the power assisted links and 40 (carriers) per hour on the direct link from A&E. A proposed layout is illustrated on the schematics drawings accompanying this document

A front end PC will be provided complete with dedicated printer and modem for remote operation and analysis.

The system will incorporate an advanced platform software control package with full automatic dual control redundancy to provide optimal flexibility, performance and convenience in the management and maintenance of the pneumatic tube system.

The controller will have battery backup for system memory and status, and be capable of being remotely controlled through the PC.

Tubing will be 160 mm diameter solvent welded rigid UPVC, with intumescent fire sleeves when passing through firewalls or floors.

The equipment will be supplied and installed in accordance with SHTM2009, utilising optical carrier detectors, safety extra low voltage cabling to the stations, electronic positioning sensors, volt free contacts for BMS alarm status and fire alarm interface at the controller.

Stations

The stations will generally be of front-loading design with a wipeable membrane type keypad.

A 'spare carrier' rack holding up to four carriers will be wall mounted adjacent to the station.

The stations are to be designed to comply with the latest Health & Safety Regulations. Access to the station mechanism is to be protected by an electronically controlled opening/closing guard door with full mechanical interlock.

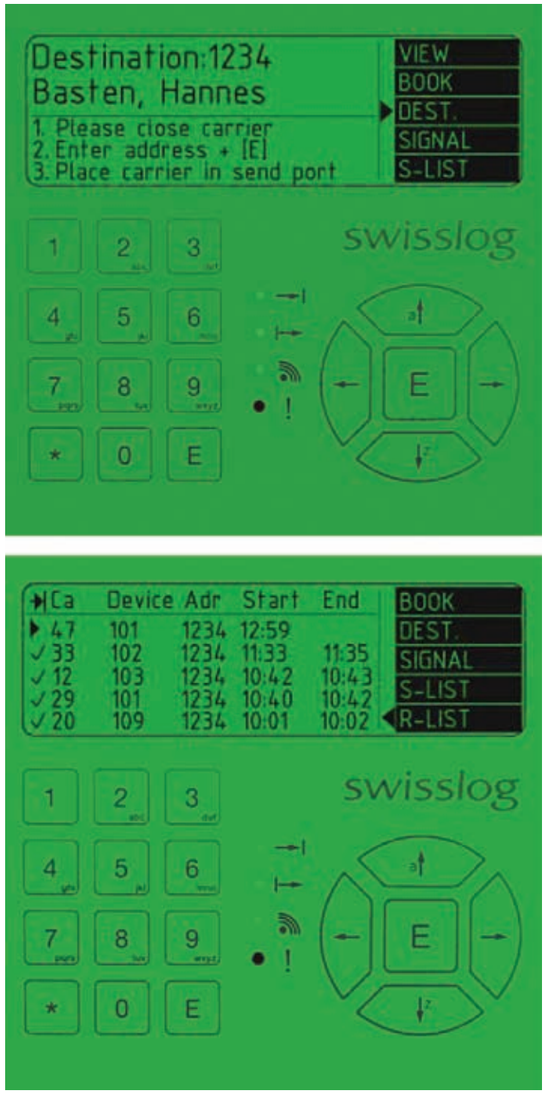
The stations in-built LCD display will show:

- Time and date
- Carrier destination
- The station the last carrier arrived from
- Station status - ready, selection OK, out of use, maintenance, faulty, basket full, invalid address and purge

The display will also have a directory of all system station names and numerical addresses.

The stations indicators display will show:

- Carrier being despatched
- Carrier incoming
- Carrier arrived at destination
- System busy
- System faulty



Station display information

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Stations will be fully automatic and capable of accepting a carrier when another carrier is incoming to that station.

Destinations will be addressed by the use of the 4 digit number or by accessing the station name through the directory.

Destinations may be restricted if required.

The destination setting can be optionally set to return to 1 of 3 settings after a carrier

has been sent:

- Force new address input
- Default to a pre-set address
- Default to “last number re-dial”

Wrongly addressed carriers will not be accepted by the system. A code reader at the station will allow only carriers to be introduced into the system, e.g. objects such as cans will not be accepted.

Incoming carriers will be able to be re-directed to another station.

All stations will be fitted with air control to ensure carrier soft arrival. This system will provide total safety of even delicate glass samples.

The station will automatically clear and eject a blocked carrier exit by agitating the station mechanism.

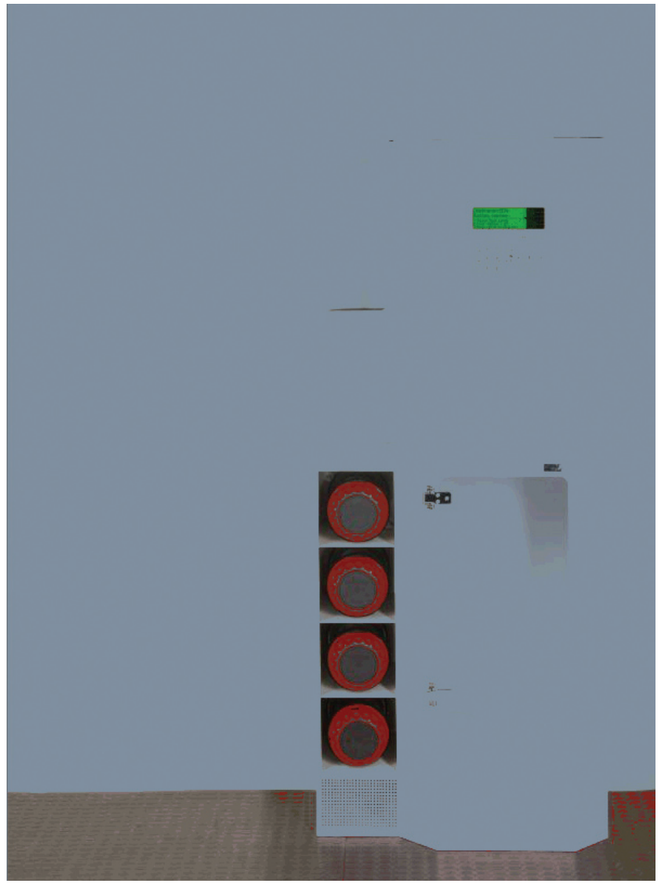
The station will be set to automatically return a carrier to the station from where it has been received by use of a single keystroke.

Carriers will be received into a cabinet below the station. The cabinet will be either an open type, or secure, accessible only by the use of a swipe card. Arrival signal units will be able to be programmed to discriminate to different user addresses, thereby allowing urgent full carriers to be immediately notified to the user, whilst allowing no alarm for empty returns.

The use of the station will be restricted by a user identifiable touch key and security card.

The station will include an in-built carrier arrival indicator consisting of a warning bleep and light. The bleep is to be enabled or disabled as required at the station by the user.

Remote indicators will be provided in some locations to indicate the arrival of a carrier at the station, as indicated in the schedule. These are generally from the Clean Utility Rooms to the appropriate Staff Base, and indicate on the Nurse Call Panel.

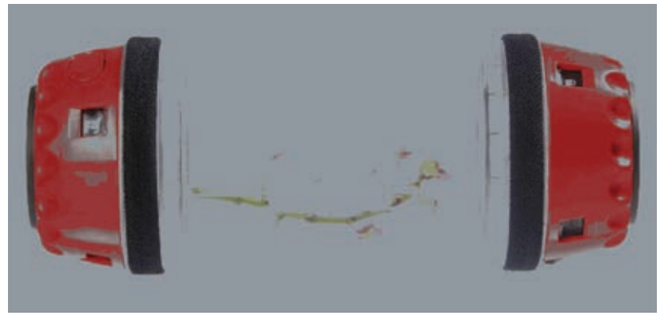


Carriers

Carriers will have transparent bodies with coloured ends and are available in various lengths The coloured ends can be used for different purposes, for example red for pathology or green for Pharmacy.

Each carrier will come complete with transponder technology that allows automatic redistribution and allow only correct carriers to be sent from any station.

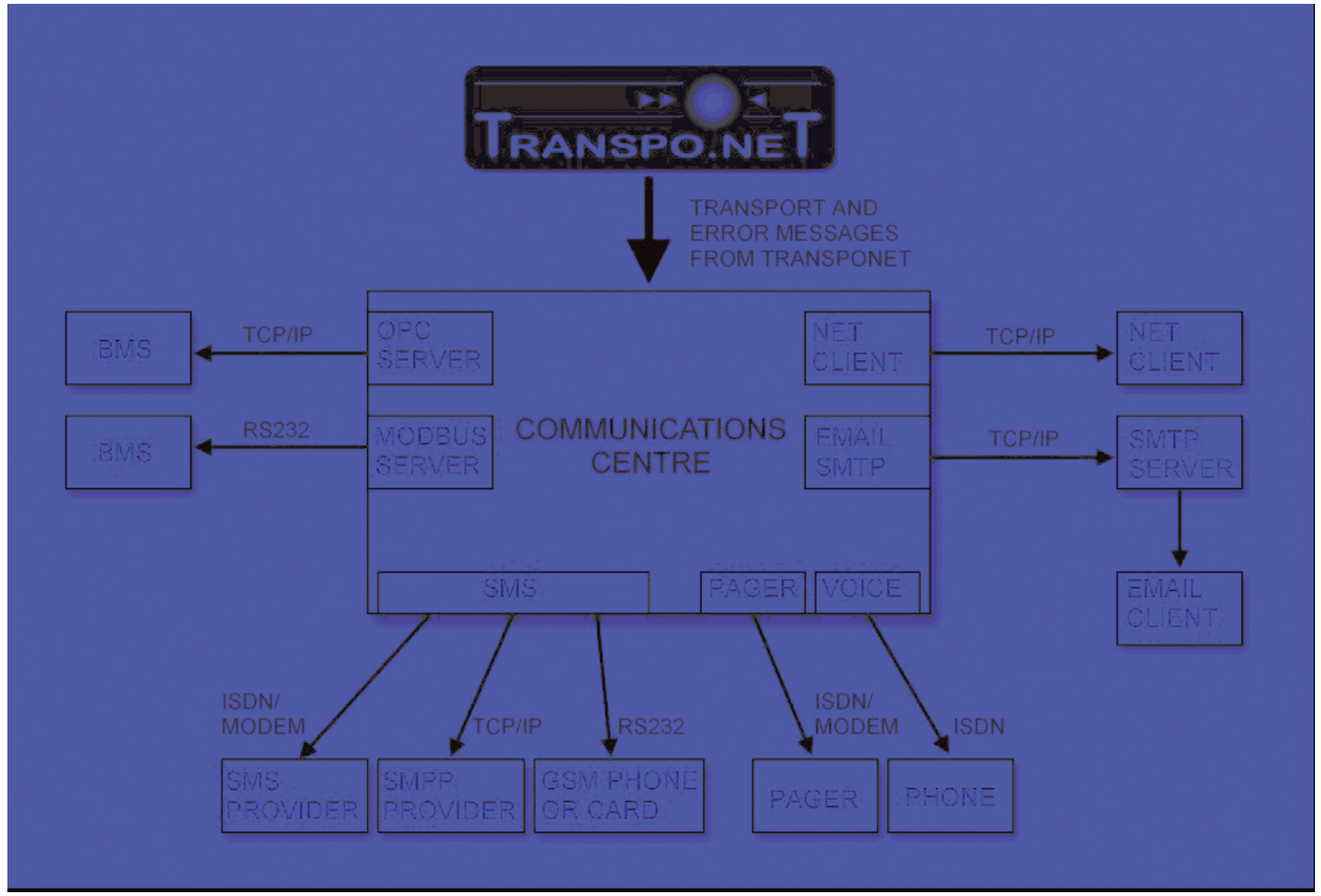
Carriers will be secured during both the send and receive operations.



PC & Printer

A PC based maintenance System Control Center will be provided for use by the hospital engineering and operations departments to configure the system, monitor system operations, schedule system operations and troubleshoot system errors, and to run a remote facility management PC and Communications Centre which will provide all external communications interfaces as illustrated below.

The supervisor terminal will be positioned in allocation to be agreed with the Board, and be used to monitor the activity of the system, all carrier movements plus the status of all of the equipment.



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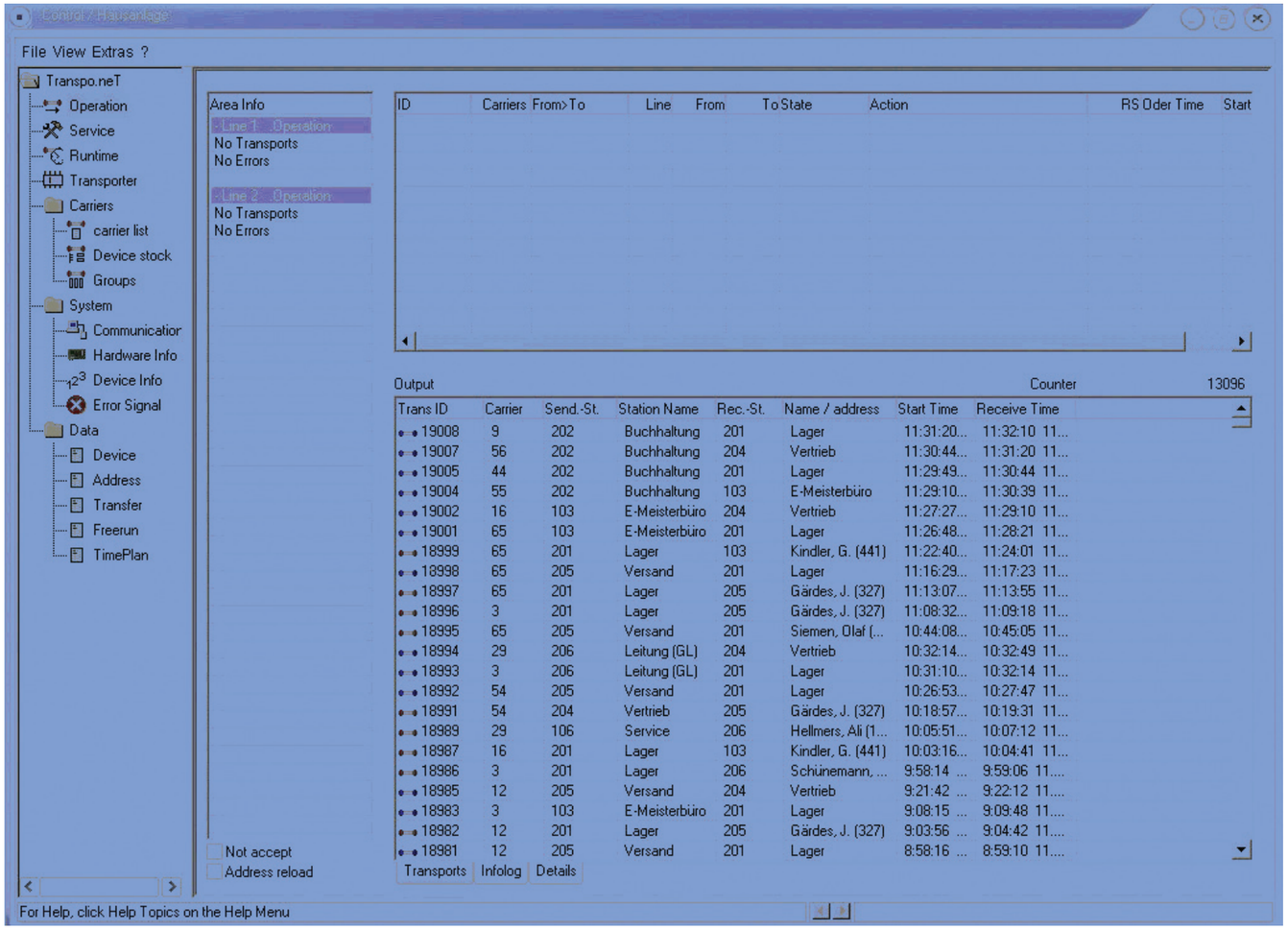
In the event of the requirement to track down individual sending of carriers from particular stations on the network it will be possible to interrogate the PC to display all transactions between a particular requested timeframe between any 2 stations. This function can be repeated right across the network.



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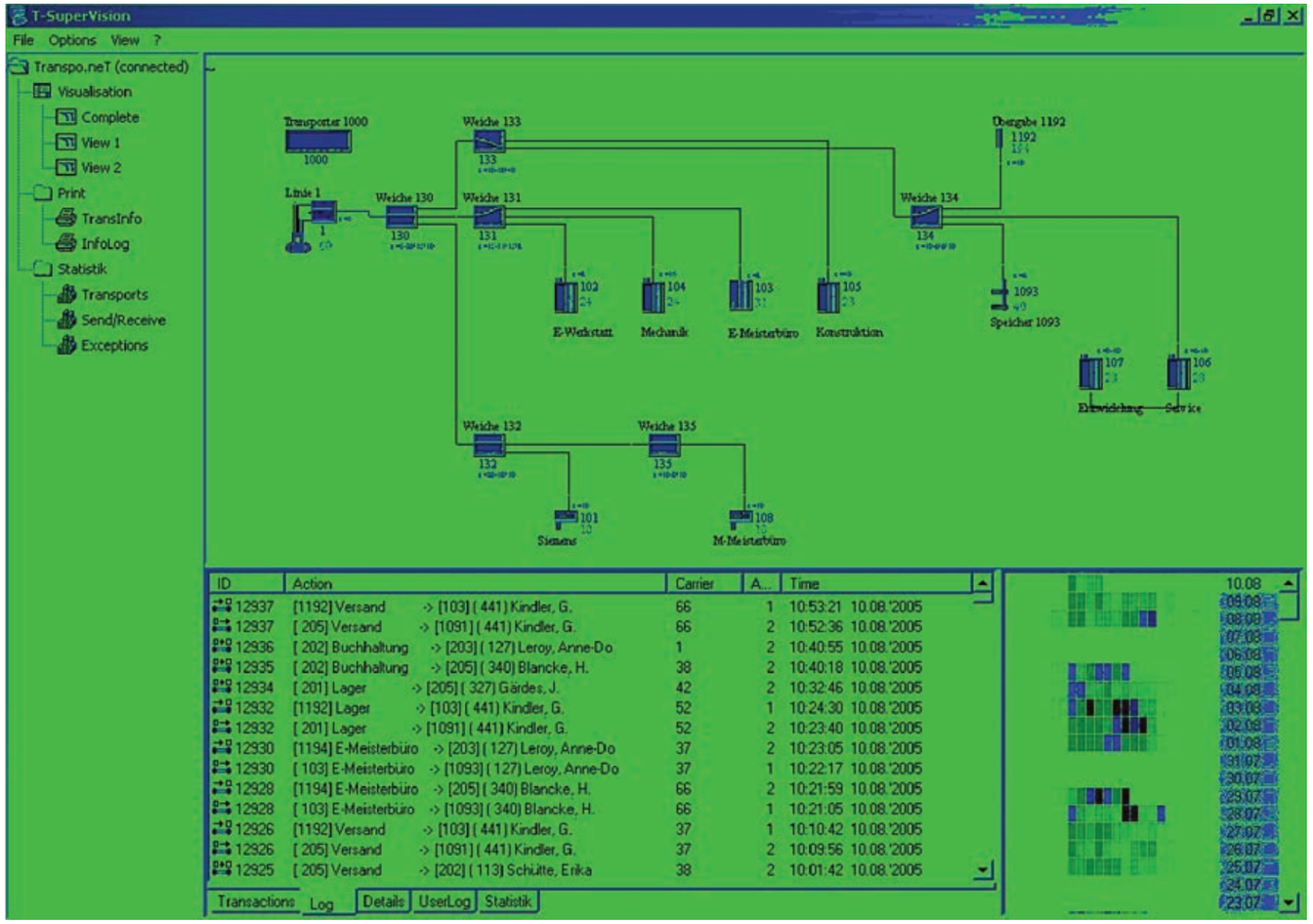
For historical information the PC will be able to produce the last 20,000 transactions.

In addition the monitoring PC will identify the load time of each carrier into the load / despatch tube of each and every single station on the network. The time that the carrier is accepted into the station ready to be transported will also be registered. The PC will also log the time that each carrier is discharged from the network. In the event of a localised power failure to the PC the system will continue to operate.



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Additional Features

Follow Me / Redirection Facility.

Each station on the network will have this ability, and will be controlled by the user. This will allow users to divert their station address to any other one within the network, enabling them to still receive carriers even if they are working within another area of the hospital.

Automatic Isolation of stations

Stations can be isolated electronically on a ‘timed’ basis if required.

This facility will be programmed at the central processor unit PC.

Manual Operation of Station

Any station nominated by the user can be closed locally without affecting any other station or diverter on the network, thus giving the user full control of their station.

Alpha Numeric Address

The system will include Alpha Numeric address facilities. Once an address code is inserted the user has the opportunity to check it before accepting the displayed, programmed target address. If satisfied then the confirmation key can be pressed.

Modem

This will enable external connection to allow remote technical support from the Facilities Management Department or any other external point.

Carrier Monitoring

All carrier transactions through the network will be monitored in real time.

Power Failure

In the event that a power failure occurs, the system will automatically be reinitiated and any carriers that are contained within the system will be removed and taken to their pre-programmed destination or to the assigned ‘dump’ station.

Fire Alarm

In the event that the fire alarm system is activated (either in a real event, by accident or a planned test) then the system will close down following completion of any transaction in progress. As and when the Fire Alarm is reset then the system will be reinstated. This can be carried out either manually or automatically. A manual ‘test’ key will be provided to override and disable this facility for fire alarm testing, so as to avoid disruption to the system operation. This is to be positioned at the main control location (to be agreed).

The system will be linked to the BMS via volt free contacts within the main control unit. In a fault condition the system will activate the alarm.

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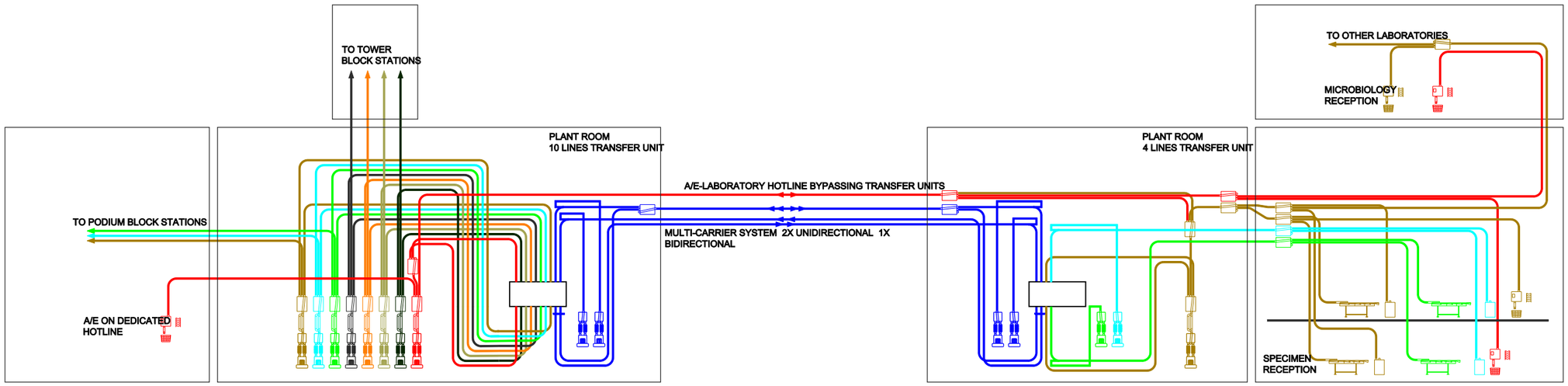

ITPD Reference:
VOLUME 3
Section 3.17

PNEUMATIC TUBE SYSTEM - SCHEMATIC

New South Glasgow Hospitals (NSGH) Project ITPD

Date: AUG 09
Scale @A1: NTS
Drawing Number: MER-XX-XX-SC-569-120
Revision:

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NHS Greater Glasgow and Clyde

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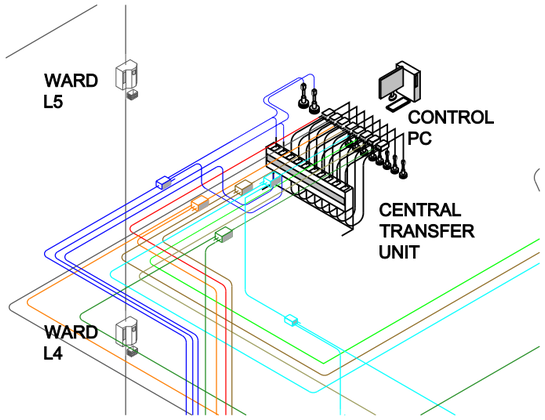

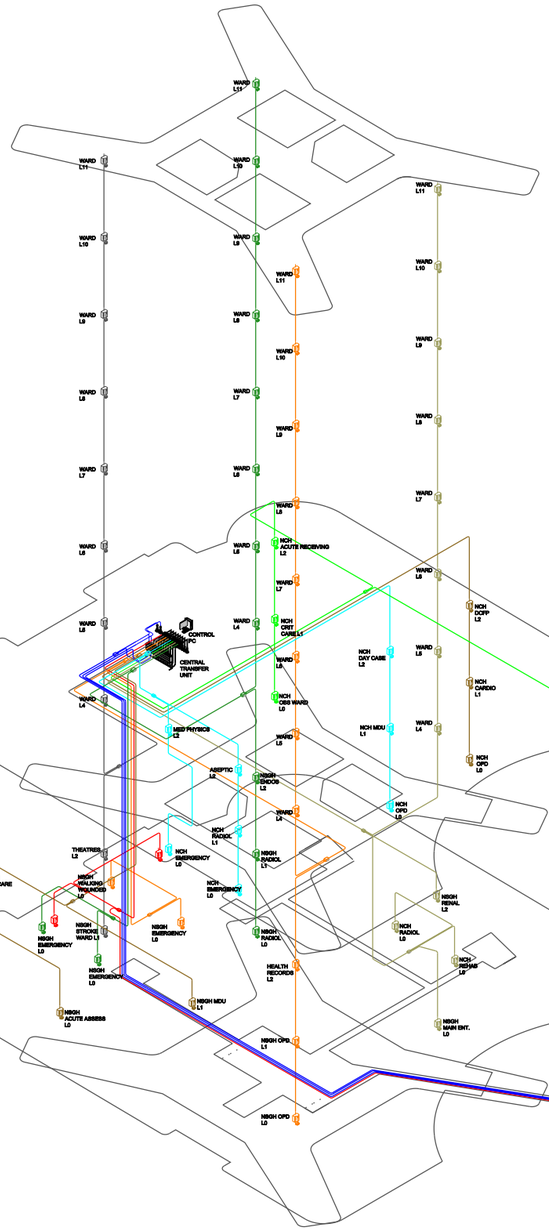

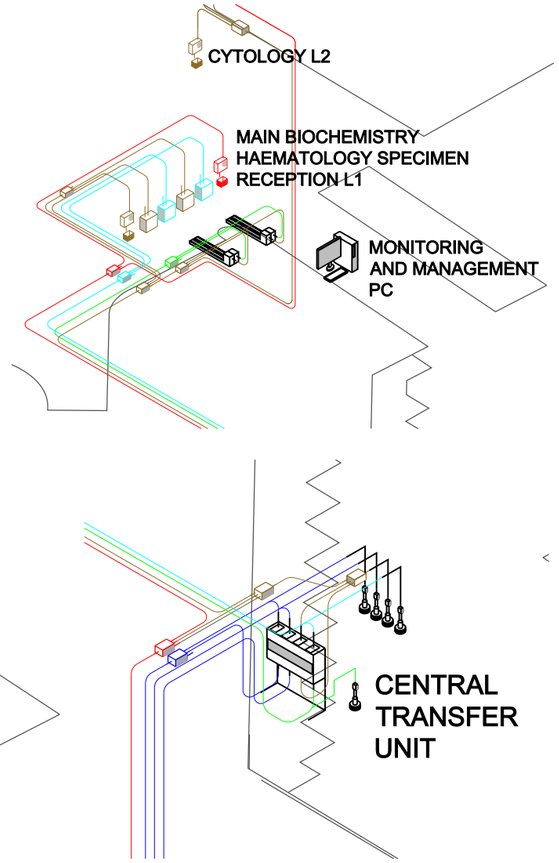

ITPD Reference:
VOLUME 3
Section 3.17

PNEUMATIC TUBE SYSTEM - ISOMETRIC LAYOUT

New South Glasgow Hospitals (NSGH) Project ITPD

Date: AUG 09
Scale @A1: NTS
Drawing Number: MER-XX-XX-SC-569-121
Revision:

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Fire Engineering Design Strategy

Selection of system

The choice of a fire fighting strategy has been considered and the use of automatic sprinkler for the main parts of the buildings is proposed following for the following reasons:

- Saving lives of, and preventing injuries to, occupants and fire fighters.
- Preventing fire spread
- Reducing property damage
- Reducing business interruption
- Reducing environmental impact
- Reducing water damage compared with water used during fire-fighting activities
- Reducing social impact,e.g loss of community facilities, loss of employment
- Disincentive to arsonists
- Reducing financial losses

Standards

Sprinkler systems will be designed, installed and maintained to a recognized standard to ensure the effective performance of the system in the event of a fire and to satisfy insurers and /or approving authorities.

In the UK, the current recognized principal standards relevant to design, installation and maintenance of sprinkler in buildings are:

- BS EN 12845: Fixed firefighting systems – automatic sprinkler systems – design, installation and maintenance.
- The LPC rules for automatic sprinkler installations incorporating BS EN 12845. These rules are for property protection purposes and contain the text of BS EN 12845 and a series of technical bulletins, which amplify the requirements of standard or cover additional requirements for insurers.

In the UK, the recognized principal standards that cover requirements for components of sprinkler systems in buildings are:

- BS EN 12259: Fixed firefighting systems, components for sprinkler and water spray systems. This is a companion standard to BS EN 12845.

Key elements of the system

The key elements that need to be considered for the design, Installation and Maintenance of sprinkler systems are:

- Documentation
- Extent of sprinkler protection ,including permitted exceptions
- Classification of occupancies and fire hazards, including protection of special hazards
- Hydraulic design criteria, including design density and area of operation
- Water supply and type
- Pumps
- Installation type and size
- Spacing and location of sprinklers
- Pipe sizing and layouts
- Sprinkler design characteristics and uses
- Valves
- Alarms and alarm devices
- Pipework
- Signs, notices and information
- Commissioning and acceptance tests, periodic inspection
- Regular maintenance
- Special requirements for property protection systems or life safety systems.

Sprinkler protection and hazard classification

Sprinkler protection will be provided throughout the building apart from optional permitted exceptions, so that if a fire starts at any location in the building it is suppressed and controlled and /or extinguished quickly and efficiently, preventing fire spread to other parts of the building. All exceptions to sprinkler protection will be agreed with the relevant Jurisdictional authorities.

Limitations of automatic sprinkler systems

Automatic sprinkler systems, like other fire protection systems, have limitations. Sprinkler systems are designed to protect a particular hazard and therefore will not be suitable for protecting special hazards that are not allowed for in the design for example:

- Greater hazards than the system is designed for
- Saving people in contact with flames
- Unprotected areas in a building, i.e. Areas with no sprinkler protection
- Fires with a great degree of shielding
- Compartments with very tall ceilings
- Electrical fires
- Explosions
- Exposure fires with rapid spread (fire originating externally to the sprinkler protected building)
- Extreme events resulting in mechanical damage, e.g. earthquakes and impacts
- Small fires, producing insufficient heat generated by the fire to operate a sprinkler head that can be extinguished promptly by other means.

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WET RISER

Location
Wet rising mains will not be located against or near external walls unless they are adequately insulated or otherwise satisfactorily protected against frost.

Landing valves
A landing valve will be provided at each floor level where personnel can connect and fill hose lines in relative safety before entering the fire compartment. When selecting the position of landing valves, consideration will also be given to ease access; exposure to fire from the accommodation if a door is open; obstruction of fire doors by the hose line; and the risk of unintentional discharge of water hitting the lift doors or controls.

Each landing valve will be sited:

1. within a ventilated lobby of a lobby approach stairway, where this is provided; or
2. in a stairway enclosure; or
3. in any other position as agreed with the appropriate authority

In all cases a landing valve will be installed with its lowest point about 750 mm above floor level.

Landing valves for fire mains will preferably be protected by, and installed within, a box accordance with BS 5041-2. Landing valves will also be protected against interference and attack by thieves and vandals as far as possible to do so without adversely affecting operational capability.

Adequacy of basic supply
In all cases where town's mains supply is involved, the capacity of the mains is important and will be checked. Generally a water supply capable of provided a minimum of 1500 L/min at all times will be required.

Supplementing the basic supply for wet mains
We are assuming that the towns main supply will not provide sufficient pressure and capacity to provide the necessary supply, each fire main should be fed from two interconnected tanks of nominal equal capacity and having a total minimum capacity of 45 000 l.

The tanks will be automatically supplied from a towns main's controlled by ball valves and the capacity of these mains together with the contents of the tanks should be such as to maintain a flow of water capable of supplying two fire fighting jets for 45 mins when water is being used at a total rate of 1 500 1/min. Each tank will be fitted with isolating valves to enable one tank to be taken out of service for maintenance or repair.

Pumps for wet fire mains
Two automatic pumps will be installed to feed the wet fire main, one of which should act as standby, and be arranged so that when acting as duty pump it will operate automatically, i.e. on a flow of water or a fall in pressure on the installation. The secondary pump will be so arranged that it will operate automatically on a failure for any reason of the duty pump. Both pumps will be primed automatically at all times. This will be affected if the pumps are sited so that at least two thirds of the effective capacity of the suction tank is above the level of the top of the pump casings. The pumps will be driven by electric motors.

They will be driven from the same supply with an automatic changeover to a completely independent secondary supply in the event of failure of the primary supply.

All pumps will be capable of being started and stopped manually.

An audible and visual alarm should be provided at an agreed position to indicate that the equipment and the pumping plant have operated.

Each pump will be capable of providing a flow of water of at least 1 500 L/min in the fire main, i.e. sufficient to serve lines of hose from two separate landing valves simultaneously. A running pressure of 8 bar will be maintained at each landing valve when fully opened.

Helipad
The helipad located on the roof of the Adult hospital will be equipped with a Foam extinguishing system in compliance with NFPA 418. This foam extinguishing system will be connected to the nearest wet riser.

Also the fire protection will be completed by two 50Kg Multipurpose Dry Powder Chemical Wheeled Fire Extinguishers located at the same level.

Extinguishers
Fire extinguishers will be provided and install throughout the hospital building in accordance with BS5306: PART 8

Various type will be fitted in order to cover all types of fire risk.

Fire suppression system
A localised kitchen extract fire suppression system will be installed within the extract canopies.

Plantroom Design Strategy

The plantrooms have been located so that plant is positioned close to the areas and departments served. Thus, the majority of the plant space will be directly over the most heavily serviced areas, for example theatres, critical care, radiology and A&E.

Plant will also be located above the adult and children's wards.

The plantrooms will accommodate air handling units, extract fans, circulation pumps, pressurisation units, medical gases plant, calorifiers, heating and cooling plate exchangers, and water treatment plant as well as transformers, LV switchgear and UPS systems.

The plant will be laid out to allow safe access for maintenance and commissioning, and components that require regular access, such as valves, will be positioned at low level avoiding the need for step ladders. Adequate draw out space has been allowed for items such as withdrawable switchgear, coils, motors, fans and so on. The plantrooms have been planned with plant replacement and maintenance in mind; refer to the plant replacement strategy (Volume 3 Section 3.23) for further details.

Air handling plant will introduce outside air via louvres around the face of the plantrooms. Deep plan or 'land locked' plantrooms will also be provided with louvred 'turrets' on the plantroom roof.

Plantroom floors will be tanked to prevent spillage passing to the areas below.

Services will be distributed horizontally within plantrooms to vertical riser shafts which will be optimally positioned to deliver the services as close as possible to the final point of use, thus reducing system pressure drops and hence pump and fan power energy consumption. Plant items will be positioned so that horizontal distribution runs are as short as possible.

A valve room will be located at basement level of the hospital to receive incoming chilled water and medium temperature hot water generated in the energy centre. The basement will also accommodate domestic water storage and sprinkler water storage tanks. With the tanks being located as close as practical to the points of use temperature 'pick up' will be minimised.

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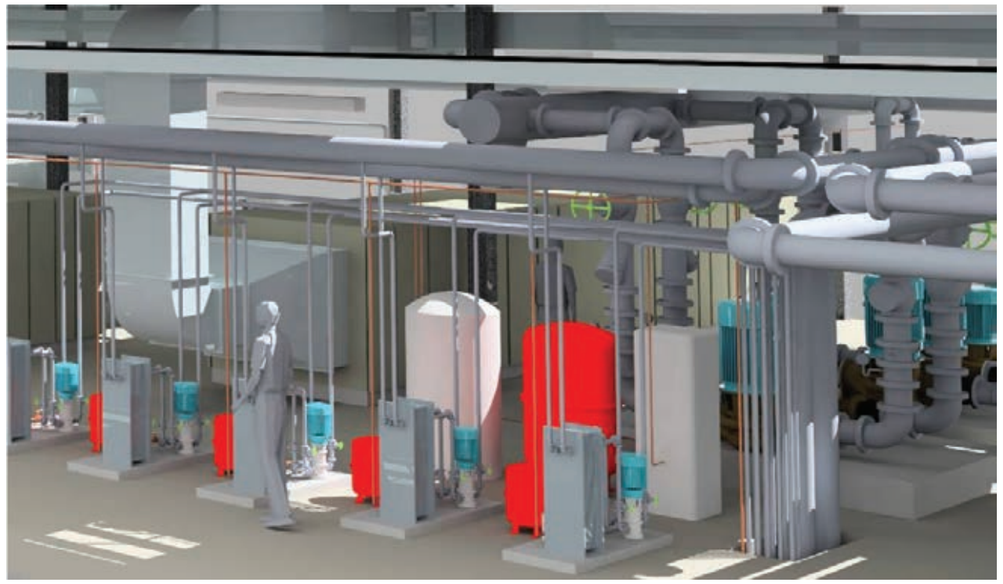
The electrical services for the plantrooms has been designed to facilitate a quick installation and easy maintenance. Motor control centres for mechanical plant will not be used; power to plant will be distributed by means of high level plug-in bus bars, a method very commonly employed in industrial applications. Plant will be delivered with on-board controls and power wiring for simple 'plug and run'.

Transformers and main LV Switchboards will be segregated in 4 hour rated fire compartments. Refer to the Electrical Services design strategies for further details on the approach taken to resilience and redundancy.

The central energy centre for the hospital and laboratory buildings will be located to the north of the new development and will house major plant items which can be considered as noisy and dirty, and requiring fuel deliveries and major cranage, in the event of plant replacement. These operations will therefore take place well away from the main clinical operations reducing disturbance and potential hazards to patients and staff. The energy centre building will be constructed and engineering in a different form to allow noise, etc to be better controlled than if it were part of the hospital building.



The energy centre building will be three storey with accommodation arranged as follows:-

- Ground Floor – oil storage for standby generators, boilers and retained site. Oil fill points for tanker deliveries will be located on the Western face of the energy centre
- First Floor – standby generators and 11kV switchgear
- Second floor – MTHW heating boilers and CHP units, absorption cooling plant
- Roof – main chillers and associated transformers, absorption chiller dry air coolers, wind turbines

Oil tanker deliveries are noisy and potentially hazardous

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Design Strategy for Engineering Systems Reserve Capacity

In respect of Clause 8.1.3.2 of Volume 2/1 of the ITPD documents the following reserve capacity is proposed for each of the major engineering services systems:

System	Proposed Reserve Capacity	Description
Electrical substations/ transformers and switchgear	25% reserve capacity	In addition to the provision made for emergency resilience, electrical distribution systems will incorporate 25% reserve capacity, for example, cable capacity, distribution board spare ways, etc.
Ventilation plant	25% reserve capacity	All air handling plant includes 25% reserve capacity for future expansion with inverter drives fitted to motor for capacity adjustment. All heating and cooling coils will by default incorporate this reserve capacity. *It should be noted that oversizing plant in this way will result in poor control performance and increased energy consumption.*
Boiler plant	Reserve capacity incorporated from terminal loads	Systems being served from the boiler plant incorporate 25% reserve capacity, e.g ventilation plant, which is accounted for in the sizing of boiler plant and distribution systems. Therefore no additional reserve capacity is included. However, with the arrangement of A & B boiler systems additional capacity has been included.
Cooling plant	Reserve capacity incorporated from terminal loads	Systems being served from the cooling plant incorporate 25% reserve capacity, e.g ventilation plant, which is accounted for in the sizing of chiller plant and distribution systems. Therefore no additional reserve capacity is included. The provision of N+1 on the plant, which is unusual in healthcare premises, will give an additional 15% reserve capacity.
Cold water storage	Nil reserve capacity	The provision of spare capacity in cold water systems is discouraged as this can lead to increased risk of Legionella. Water storage volume should not exceed 24 hours usage and ideally be less.
Hot water storage	Nil reserve capacity	The provision of spare capacity in hot water systems is discouraged as this can lead to increased risk of Legionella. However, a standby calorifier is provided in each location which for the vast majority of time will achieve reserve capacity
Pneumatic tube	25% reserve capacity	The pneumatic tube system will be able to accommodate an additional 25% traffic movement over and above that anticipated from the traffic analysis
IT/telephone installation	25% reserve capacity	Distribution containment will incorporate space for 25% additional cabling. The hub room racks will be sized to accommodate a 25% reserve capacity, but active equipment will only be provided as and when the capacity is required.

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Energy Strategy, Including Approach to Renewables and Sustainability

Introduction

The New South Glasgow Hospital, to be located to the west of the city centre, will include both a general acute hospital and the National Children's Hospitals. The hospital will be formed from a four storey podium, housing acute treatment areas and ward areas, and an eight storey tower, accommodating ward areas.

The net occupied floor area for the new hospitals, as defined in EnCO$_2$de, will be approximately 136,000m^2 (gross 165,000m^2).

It is the aim of this report to provide an estimate of the total energy consumption for the New South Glasgow Hospital at the present stage of design, and to determine the measures required so that the design, and ultimately the constructed hospital in operation, complies with the required energy targets.

Objectives

The Board has committed through its Carbon Management Programme and Carbon Management Plan to reduce CO_2 emissions by a minimum of 25% by 2016.

This objective is supportive of Scottish Government Planning Policy 6, which states the following:

"…all future applications proposing development with a total cumulative floor space of 500 square metres or more should incorporate on-site zero and low carbon equipment contributing at least an extra 15% reduction in CO_2 emissions beyond the 2007 building regulations carbon dioxide emissions standard."

"The Scottish Ministers have set a target of generating 40% (since quantified as 6GW) of Scotland's electricity from renewable sources by 2020 and confirmed that this target should not be regarded as a cap."

The new hospital development must therefore encompass these objectives and strive to provide the lowest practical energy and carbon footprint possible.

It is also a requirement for at least 0.5% of the building's CO_2 emissions to be met by a visible renewable energy source, such as solar thermal, photovoltaics or local building mounted wind turbines.

Energy and carbon targets

The new hospital will achieve the following targets:

Energy consumption below	55 GJ/100m^3/year
Carbon emissions below	80 kg CO2/m^2/year
EPC asset rating less than	40

Analysis of energy and carbon targets

While the energy consumption target is equal to the mandatory Department of Health target, the target for CO_2 emissions and the required EPC rating reflects the drive for low carbon design within the building.

SHTM 07-02: 'EnCO$_2$de – Making Energy Work in Healthcare' gives details of average CO2 emissions from existing general acute hospitals as well as good practice benchmarks for new general acute hospitals:

Average emissions from existing sites	145 kg CO_2/m^2/year
Good practice benchmark	<105 kg CO_2/m^2/year

The target for CO_2 emissions is well below the published benchmark figure, and when compared with the calculated CO_2 emissions of other recent projects, the scale of savings required within the new design becomes apparent.

Peterborough Hospital (completion 2010)	151 kg CO_2/m^2/year
Kings College Hospital Jubilee Wing (2002)	121 kg CO_2/m^2/year

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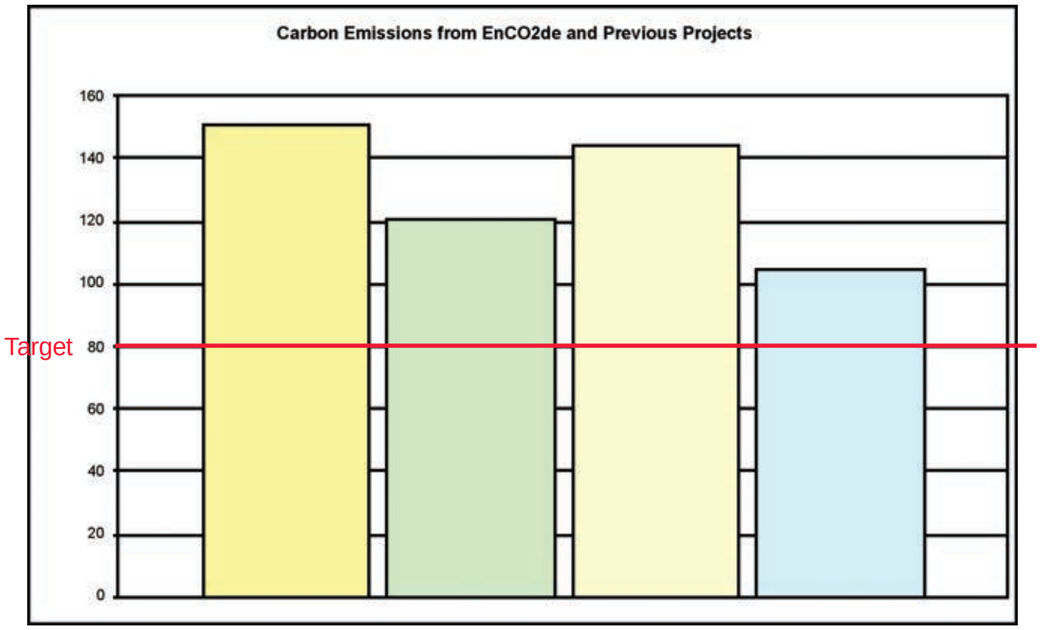

Graph showing CO_2 emissions from EnCO_2de and previous projects

When attention is turned to the other two targets set for the new hospital, both the examples given above meet the energy consumption target of 55 GJ/100m^3/year.

In addition, Peterborough Hospital, the more recent of the two, achieves an EPC asset rating of 28, comfortably below the minimum requirement of 40 for the new hospital.

As a result of this analysis, priority has been given to the reduction of carbon emissions in order to meet the target of 80 kg CO_2/m^2/year. Previous projects had satisfied the remaining targets while displaying relatively high calculated carbon emissions. As such it can be assumed that a reduction in carbon emissions would lead to a consequential improvement in the overall building energy performance.

Methods to both reduce energy consumption and improve energy efficiency within the building have been considered, as have low and zero carbon technologies. An energy performance model of the building has been created in order to assess the impact that these methods and technologies have.

In order to assist is monitoring the overall a low carbon design development and operation the Low Carbon Design Tracker has been developed. The tracker has been completed for this stage of the project and is included in Volume 8, Section 20.

Energy model

To assess the new hospital building' energy consumption and hence carbon emissions footprint the development has been modeled within a Microsoft Excel based model. The energy model also details the assumptions made within the model, and the outputs obtained. The full version of the energy model is contained in Appendix A.

The model has been developed using a number of similar projects, and incorporates real data based on past experience to estimate the building's energy consumption.

The model calculates the energy consumption from the use of both electrical systems and fossil fuels. General power, lighting and all mechanical plant are used to produce a total for the energy consumption for electrical energy. Fabric heating, air heating and hot water services are used to provide a total for the energy consumption for the fossil fuel systems.

In order to inform the overall energy model the hospital has been modeled within IES Virtual Environment, a dynamic thermal simulation program. The simulations have been used to carry out provisional predictions of heat gains within rooms and summer time temperatures within the ward towers and sample podium spaces. The simulations also support the solar shading study, and are used to obtain a provisional EPC rating.

The energy model is intended to be a live document and will be regularly updated as the detailed design progress and final information becomes available. This allows the Team to monitor the targets and make any adjustments necessary to the designs to ensure the targets are maintained. The criteria used in the model will be based on real data available from the supply chain, for example heat recovery efficiencies, and will form the basis of the final construction specifications, thus giving a link between procurement and the energy model, which will be regularly monitored throughout the construction period.

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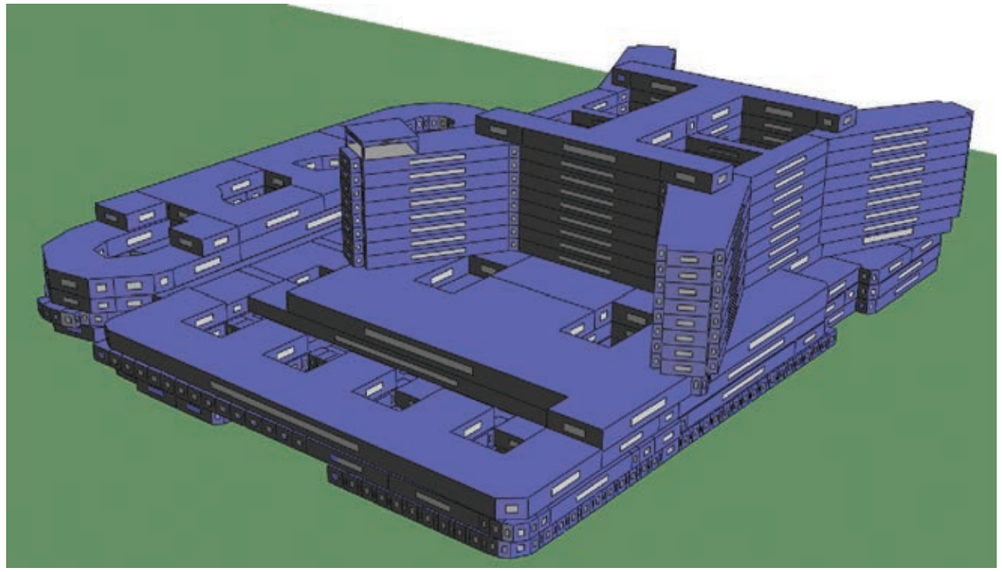

IES Virtual Environment Model of the building

External Cladding

Energy reduction and efficiency measures

Before considering low and zero carbon technologies, measures to reduce energy consumption and improve energy efficiency within the building have been explored. By reducing the overall energy consumption of the building, the task of achieving the emissions target of 80 kg CO_2/m^2/year through the use of low and zero carbon technologies becomes less onerous.

The following technologies have been assessed and implemented within the energy model to reduce consumption and/or improve efficiency:-

External Fabric By improving the U-value of the external fabric and glazing of the building, the amount of heat lost to outside can be reduced. This in turn reduces the amount of energy required to heat the building.

The cladding proposed for the hospital building has a calculated U-value less than the minimum requirements set out in the Building Regulations, which will help to minimise the energy required to heat the building.

Natural Ventilation

Wherever possible, natural ventilation will be used within the building. This will be by means of openable windows and reduces energy consumption associated with mechanical ventilation.

The use of mechanical ventilation has been analysed and is discussed in Section 3.0 ‘Ventilation and Air Treatment Strategy’.

The studies conducted to compile the report concluded that it is likely that non-clinical areas with low occupancy and heat gains could be naturally ventilated.

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Lighting Energy

Lighting Energy efficient lighting is proposed to reduce the overall electrical demand from the hospital. Automatic controls will ensure that the lighting is only used when required in many areas.

The proposals for automatic lighting control are described in Section 3.12 ‘Lighting Design Strategy’.

Hospital Lighting

Mechanical Ventilation

Mechanical Ventilation Heat recovery on the majority of air handling units will allow potentially wasted heat energy to be recovered from the exhaust air by transferring it to the supply air. Thermal wheels, which offer the highest efficiencies, will be used in most non-ward areas. Plate heat exchangers will be used in wards to remove any potential cross-contamination.

Thermal wheel for ventilation heat recovery

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Cooling

Cooling High efficiency chillers, using magnetic bearings within the compressors are proposed, as described in Section 3.27 ‘Cooling Design Strategy’.

A High Efficiency Indigochiller

Pumps

Pumps Variable volume circulation systems for heating and cooling using two port control valves and variable speed pumps are proposed. When demand for heating or cooling is reduced, the fluid flow required within the system is reduced, allowing the pumps to slow down and save electrical meter energy.

Variable Volume Pump

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Overall energy consumption

Following the inclusion of all the energy reduction and efficiency measures within the energy model, the overall energy consumption and carbon emissions from the building were calculated. The model can be found within Appendix A.

As anticipated, the drive to reduce energy consumption and improve energy efficiency within the model helped reduce the overall energy consumption comfortably below the required 55 GJ/100m^3/year.

The calculated carbon emissions rate of 123 kg CO_2/m^2/year is higher than the target of 80 kg CO_2/m^2/year. In order to reduce the emissions rate below the target, a number of low and zero carbon technologies have been considered.

Strategy to meet CO2 target

To meet the target of 80 kg CO_2/m^2/year, low and zero carbon technologies must offset 43 kg d carbon emissions rate of 123 kg CO_2/m^2/year is higher than the target of 80 kg /year.

In order to determine which technology has the best potential for meeting the emissions target, the split between emissions from electricity and fossil fuel sources has been taken from the energy model as:

Fossil fuel	37 kg CO_2/m^2/year
Electricity	86 kg CO_2/m^2/year

It can be seen that the CO_2 emissions caused as a result of electrical use within the building are 70% of the total building CO_2 emissions, with 30% from the use of fossil fuels. This shows that, in order to meet the target, electrical generation through low carbon or renewable means must be a major part of the carbon reduction strategy.

The available technologies for carbon reduction have been considered and their contribution to achieving the target analysed. These assessments are shown in Appendix B and can be summarized as follows:-

Photovoltaic Panels

Photovoltaic panels convert light energy in to electrical energy. Photovoltaic panels are an established technology and can be integrated within the building fabric. Once installed, panels are low maintenance. However, panel efficiencies are low and a large area is required to generate a reasonable quantity of power.

For example, a 200m2 array of photovoltaic panels will reduce the CO_2 emissions by only 0.11 kg CO_2/m^2/year. Whilst this is a very small contribution to the target and cannot provide a practical solution, a small area of photovoltaic panel in a prominent position will demonstrate the Board's commitment to carbon reduction.

Solar collection systems

Solar Thermal Hot Water

Solar collectors use the suns energy to heat water for use within the building. Unlike photovoltaic panels, solar thermal systems require regular maintenance. Solar thermal systems are effective during the summer months; however efficiency significantly reduces during the winter.

For the main hospital 200m^2 of collector panels would reduce the CO_2 emissions by 0.13 kg CO_2/m^2/year. Whilst this is a relatively small contribution to the main hospital's carbon reductions, there may be a more significant impact for the laboratory building, and if positioned on the roof would be visible and appreciated from the upper levels of the acute hospital.

Groundwater Cooling

Cool ground water is extracted from the water table via vertical boreholes drilled into the ground and used to cool the building. Once used, it is returned to the ground. Generally, due to the water temperature available from ground water cooling is limited to use with chilled beams rather than primary air handling plant. In the case of the new hospital there is a requirement for chilled beams, mainly in the ward areas, which could make use of ground water cooling. Although the groundwater provides 'free' cooling, energy is required to extract it from the ground, and site ground conditions need to be appropriate.

Assuming that ground water can be used for the chilled beam circuit serving the ward tower, it has been assessed that a carbon reduction of 0.76 kg CO_2/m^2/year will be achieved.

Borehole rig

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Wind Energy

Wind turbines convert use energy from the wind velocity to produce electricity. The output from turbines depends largely on the rotor size, wind speed and wind quality. Economics of scale currently favor turbines with a capacity of 1MW or greater.

Considering a large scale 2MW wind turbine this could meet 49% of the overall CO_2 emissions reduction target. Therefore, in order to meet the target by means of wind alone, three turbines of this size would be required.

A 2MW wind turbine is relatively large, standing at approximately 80m tall. As a result of this, it is unlikely that the turbine could be practically located on or close to the hospital site, particularly as helicopters regularly land at the hospital, and it is relatively close to Glasgow Airport.

Alternative available methods of securing electricity from a larger wind turbine include locating the turbine off site, or investing in an existing or proposed wind farm.

A wind turbine located off site would be owned by the hospital and the electricity generated would be fed in to the national grid. By feeding electricity generated by a renewable source in to the grid, the hospital can claim this electricity to offset CO_2 emissions from the building.

However, whilst it would not be practical to install a large wind turbine on site, smaller vertical axis wind turbines could be installed on the hospital's energy centre. Despite making a very small contribution to the target reduction in CO_2 emissions (0.03 kg CO_2/ m^2/year each), their presence would act as a visible statement of the Board's low carbon commitment.

The installation of twelve small vertical axis wind turbines would meet the Board's requirement to generate 0.5% of the building's CO_2 emissions by means of a visible renewable energy source.

A Vertical Axis Wind Turbine

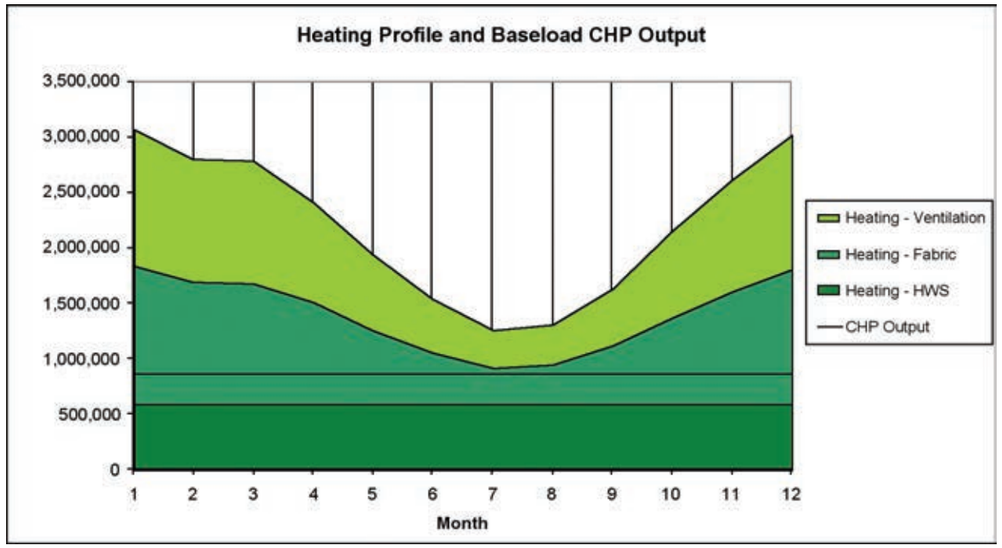
An 80m Turbine

Combined Heat and Power

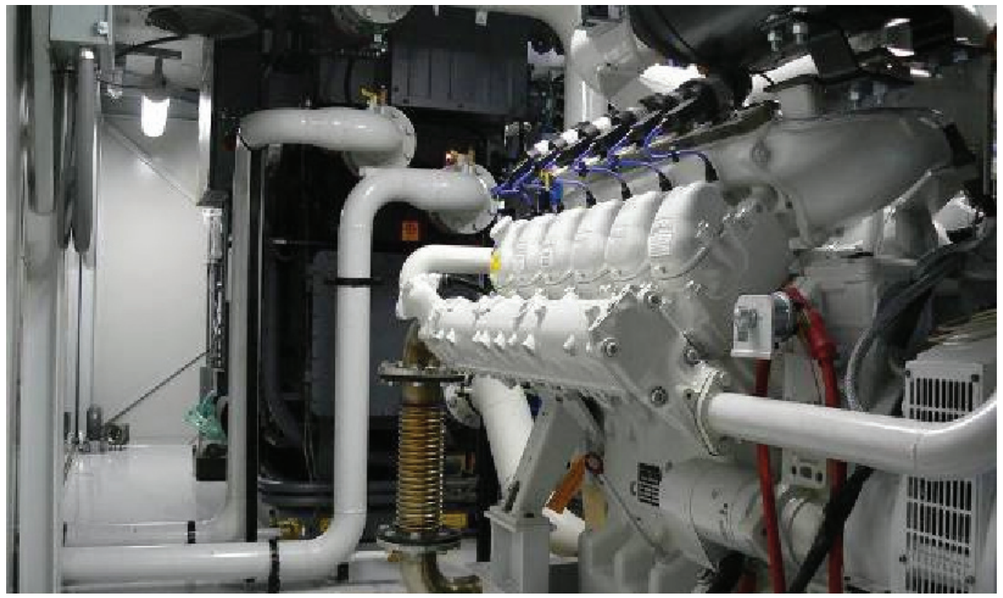
Combined heat and power (CHP) units generate both electricity and heat. An engine drives an electric alternator and the engine's exhaust and jacket heat are used to produce hot water. This technology provides a more efficient method of generating electricity compared to grid electricity and thus reduces overall CO_2 emissions.

CHP units are well suited to hospital buildings due to the relatively large and constant demand for heat, allowing the units to operate at peak efficiency. The engines are generally fired with natural gas, although diesel and biofuel units are available.

CHP units are generally sized to meet the base heat load of the building, as shown in the graph below. The graph shows the building's projected annual heating load and the heat output from the CHP unit. For example, a 1.25MWe unit that is sized on this philosophy, as displayed in the graph below, would achieve 49% of the target reduction.



Graph showing the heating profile and the output from a CHP matched to the base load



CHP Unit

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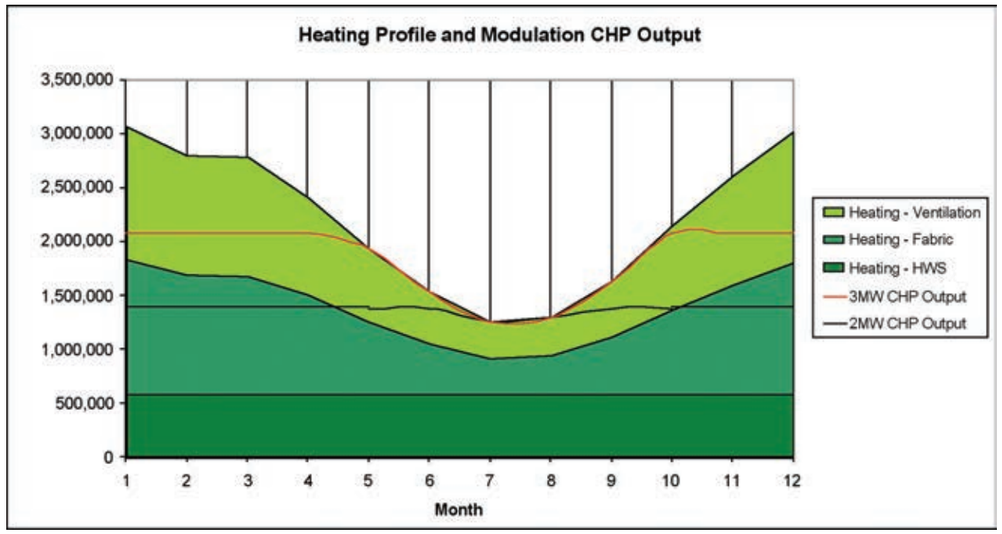
As a result of the limited CO_2 savings, methods of increasing the CHP capacity within the building have been investigated to determine the maximum potential CO_2 savings achievable from this technology

It can be seen from the previous graph that, as expected, the building's heat load throughout the year is not constant, and reduces in the summer months. As the number of CHP units increase, the likelihood of generating an excess quantity of heat during these months increases. Simply dumping the excess heat during these months whilst generating electricity is not an economic solution. Therefore, in order to avoid this scenario, the units could modulate to match the heat load, or chiller units that utilise heat to produce chilled water could be installed. These chillers are known as absorption chillers and operate in this manner.

By modulating multiple CHP units, as shown in this graph, up to 100% of the total target savings could be met. The units turn down when the building's heat load reduces during the warmer months.

By adding absorption chilling, 100% of the target could be met. The heat required by the absorption chiller fills the gap left by the reduction in heating demand from the hospital. The absorption chiller operates during the summer months as the demand for cooling also increases at this time. This allows the CHP units to run constantly at peak efficiency throughout the year, avoiding drops in efficiency associated with modulating.



Graph showing the heating profile and the output from two sets of CHP units modulating to match the load

All results for CHP units thus far have been based on a natural gas fired engine.

In order to increase CO_2 savings generated by a CHP unit an alternative low carbon yielding fuel could be considered, usually referred to as a biofuel.

Alternatively, the output of electricity generated by the CHP units can be increased. By increasing the electrical output of the units, the CO_2 savings are increased considerably, as the CO_2 savings made through the generation of electricity are much greater than the savings made through the generation of hot water.

Alternative Fuels

A feasibility study has been conducted on the potential for the use of biodiesel fired CHP units. A bi-fuel CHP unit, fueled by a combination of biodiesel and natural gas, has been considered for this study, as this combination of fuels gives the lowest input CO_2 emission rating when compared with other fuels, for example a diesel and biodiesel blend.

Biofuels sourced from sustainable or waste materials, have a lower CO_2 emission rating than natural gas. CHP engines can be modified to operate on both biogas and biodiesel. However, the use of biodiesel requires storage and transportation to site from the producer.

Using biodiesel fired units can achieve 100% of the target when used to track the building's heat load. Further savings are achieved when using this type of unit with an absorption chiller.

On a practical side there are problems associated with the security of the fuel, its storage and distribution, as well as its delivery. Biodiesel is also generally more expensive than other available fossil fuels. For this reason a biodiesel option has been discounted.

The use of biogas as a fuel has also been considered. Modifications to the sewage works adjacent to the hospital site, currently being explored between the Board and Scottish Water, would allow the production of biogas, which could be used to fuel CHP units within the hospital. Further investigation of the use of biogas will be carried out during stage 2 design phase.

Increasing electrical output

Increasing the electrical output from the gas fired CHP units can result in greater CO_2 savings being achieved.

CHP units, when supplied, are tuned to meet the application required by the purchaser. By altering the outputs from the units, additional electrical output is achievable; however there are limits to the maximum electrical output from a CHP unit.

The ability to adjust the output ration will very much depend on the manufacturer of the unit and the precise electrical load on the CHP unit. Therefore, this could only be confirmed once a detailed analysis is carried at a later stage in the design.

Additional electrical output can also be generated by an ORC turbine generator in tandem with the CHP unit alternator. An ORC (Organic Rankine Cycle) turbine generator is driven by waste heat and uses a refrigerant driving fluid in the system.

The generator uses heat to vaporise the refrigerant, which drives a turbine to generate electricity. The process is similar to that used in power stations, where steam drives a turbine to generate electricity. An ORC turbine generator would use the surplus heat in the CHP exhaust to generate additional electricity.

However, there are technical complications and major maintenance issues associated with an ORC system and uncertainty of the ability to modify the CHP output ratio.

As such, the use of an ORC generator is not considered viable for the project.

Whilst increasing the electrical output from the CHP units by 6% has the potential to achieve 100% of the CO_2 reduction target, further investigation in to potential modifications to the CHP output ratio is required, and will be carried out during stage 2 design phase.

As a result, modifications to the CHP output ratio to increase electrical output has not been considered as a potential solution to meeting the CO_2 reduction target at this stage.

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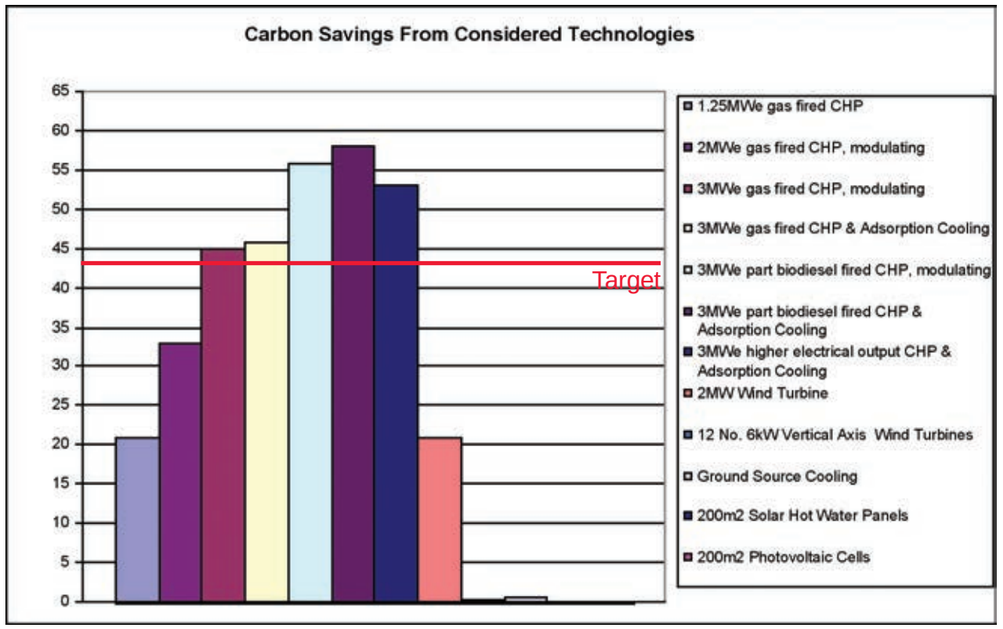
Preferred solution

The technologies considered displayed graphically below, showing their contribution to meeting the 43 kg CO_2/m^2/year target savings.



Graph showing technologies considered and their respective carbon savings

The above graph shows that a number of the options explored achieve the target emissions rate of 80 kg CO_2/m^2/year, a World benchmark for a major hospital project.

The preferred solution to meet the CO_2 emission targets is a combination of on site wind power, CHP units and absorption cooling. As discussed earlier in the report, the use of biofuels and the increase of the CHP electrical output have not been considered at this stage and will be investigated further during design stage 2.

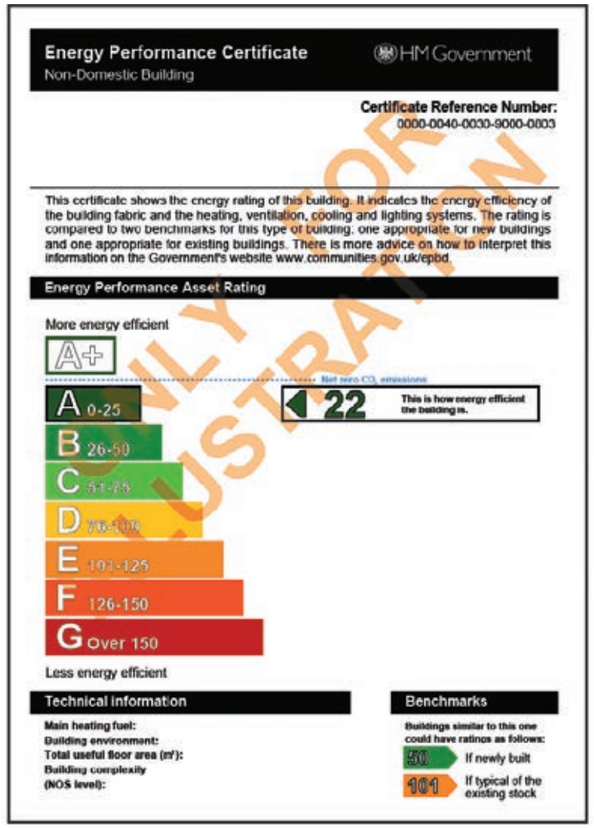
The combination of CHP units and absorption cooling will achieve the target emissions rate of 80 kg CO_2/m^2/year. By combining CHP units with absorption chillers, the CHP units would be able to operate at maximum efficiency throughout the year.

The use of CHP units and absorption cooling also allows all aspects of the building's energy strategy to be located within the energy centre.

The requirement to generate 0.5% of the building's design energy target by means of a visible renewable energy source will be achieved by twelve small vertical axis wind turbines, installed on the roof of both the energy centre and laboratory building.

EPC Rating

Following the energy saving measures and carbon reduction strategy, the IES thermal simulation software produced a provisional EPC asset rating of 22, which is comfortably within the target of 40.



The provisional Energy Performance Certificate for the New South Glasgow Hospital

A48235836

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Public Engagement

It is important that, in a building where the reduction in carbon emissions is integral to its overall design, it is possible that this can be displayed to those who will be using the building.

The CHP units will be located within the energy centre, and therefore out of sight of the building users. If they were to be prominently located elsewhere, it is unlikely that the units would be identifiable by the general public and building users.

Therefore, a method of displaying information on the quantity of carbon savings achieved by the various technologies within the building should be explored.

This could take the form of a ‘carbon counter’ display within the main entrance to the building, detailing the savings being achieved by the installed technologies.

By displaying this information, the Board can show its commitment to a low carbon future and ensure that those who use the building are aware of it.

Carbon Display Example

Carbon Counter at the IMechE Reception Desk

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APPENDIX A
ENERGY CONSUMPTION MODEL

ASSUMPTIONS MADE IN PREPARING THE MODEL

The Energy Consumption Model has been produced assuming the following statements.

Design Conditions
1. External conditions are set to: Winter: -6oC
Summer: 26.2oC db, 18.5oC wb
2. Internal conditions are set to: Heating: 21oC
Cooling: 18oC db, 16oC wb
General
1. Plant will be maintained to optimum operating efficiency.
2. Any change to the building shape or size will affect the energy consumption total.
Electrical Systems Energy Usage - General Power
1. Intermittently occupied departments to have their power consuming equipment switched off out of hours.
Electrical Systems Energy Usage – Lighting
1. Intermittently departments to have their lights switched off out of hours.
2. Automatic presence detectors with adjustable time delay timers for switch OFF are provided within storerooms, linen cupboards, toilets, changing rooms and offices.
4. Energy efficient lighting has been used throughout.
Electrical Systems Energy Usage - Ventilation
1. Diffusers will be maintained in a clean order and will not be blocked, which may increase the pressure thereby increasing the ventilation electrical consumption.
2. The BMS will control the operation of the AHUs as outlined in the usage profiles and set-back rates where applicable.
Electrical Systems Energy Usage - Humidification
1. Any deviation in weather conditions from average yearly conditions have not been accounted for.
Electrical Systems Energy Usage – Pneumatic Tube
1. The Pneumatic Tube System will remain blockage free to prevent the blowers being overused.

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Electrical Systems Energy Usage - Chillers
1. The BMS will control the operation of the chillers and pumps as per the indicated usage profile.
2. Any deviation in weather conditions from the average yearly conditions such as higher than average temperatures have not been accounted for.
Electrical Systems Energy Usage - Lifts
1. The lifts will not be overloaded.
2. 50 No. lifts have been allowed for in the model.
Fossil Fuel Energy Usage - Fabric Heating
1. Doors and windows will remain closed and the fabric of the building will be sufficiently maintained.
2. The operational times of the building and type of plant will not change.
Fossil Fuel Energy Usage - Air Heating
1. Only the AHUs indicated will provide air heating at the levels shown.
2. There will not be any additional diffuser/grilles installed or existing ones adjusted or blocked.
3. Windows will be maintained to prevent excessive air infiltration.
Fossil Fuel Energy Usage - Hot Water Services
1. Improper use of the hot water system will affect the final consumption figure.
2. The domestic hot water consumption used is 135litres/bed/day, plus an additional 30% allowance for non-bedded areas.

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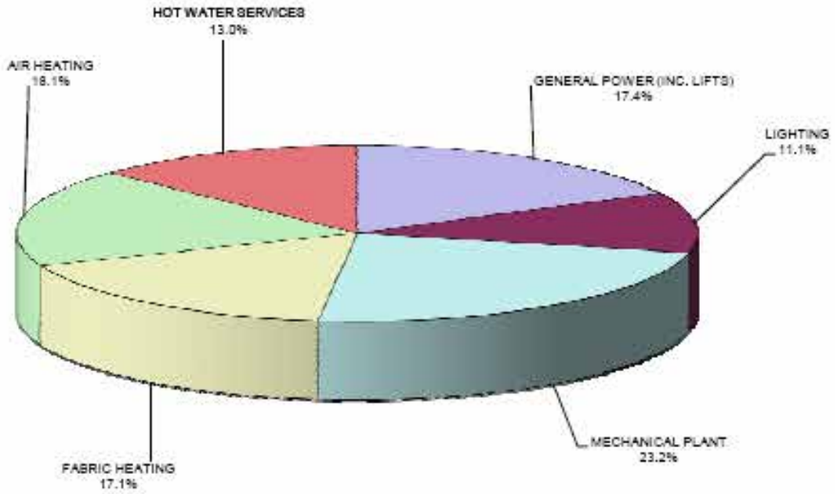
BID STAGE ENERGY CONSUMPTION MODEL SUMMARY

A) ELECTRICAL ENERGY	kWh/YEAR	GJ/YEAR	BUILDING VOLUME m^3	GJ/100m^3 /YEAR
GENERAL POWER (INC. LIFTS)	9404346	33856	530202	6.4
LIGHTING	6008963	21632	530202	4.1
MECHANICAL PLANT	12533766	45122	530202	8.5
SUB TOTALS	27947075	100609	530202	19.0
B) MECHANICAL FOSSIL FUELS				
FABRIC HEATING	9247803	33292	530202	6.3
AIR HEATING	9749825	35099	530202	6.6
HOT WATER SERVICES	6988421	25158	530202	4.7
SUB TOTALS	25986050	93550	530202	17.6

ESTIMATE OF TOTAL ANNUAL ENERGY CONSUMPTION 36.7 GJ/100m^3/YEAR [1]



CO2 per m2 per year

Mechanical

25,986,050 kWh/year
0.194 Kg CO2 per kWh — 190 kWh/year per m2

5,041,294 Kg CO2 / year — 36.9 Kg CO2/year per m2

Electrical

27,947,075 kWh/year
0.422 Kg CO2 per kWh — 205 kWh/year per m2

11,793,666 Kg CO2 / year — 86.4 Kg CO2/year per m2

TOTAL

16,834,959 Kg CO2 / year

Building Area

Net Occupied Floor Area — 136,490 m2

Gives 123 Kg CO2 per m2

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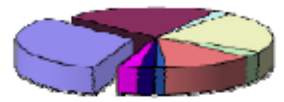
A) ELECTRICAL SYSTEMS ENERGY USAGE

GENERAL POWER ELECTRICAL CONSUMPTION

The total consumption associated with general power usage has been calculated by applying a load assessment figure to each departmental area. Usage factors are then applied for two time periods in a day, the first 10 hours (day) then the remaining 14 hours (night). This produced a daily maximum load value that was then converted to a weekly value. The weekly load values for each department were then summed to obtain an annual total for the general power usage.



Intermittent deptartments are highlighted in yellow and based on a 5 day working week[1]

DEPARTMENT		LOAD ASSESSMENT (W/m^2)	U.F		MAX LOAD (kW)	CONSUMPTION (kWh)			
NAME	AREA (m^2)[5]		DAY	NIGHT		DAY	NIGHT	DAILY	WEEKLY
Basement	4329	2.00	1.00	0.10	8.66	86.58	12.12	98.70	691
NCH Entrance	1483	7.00	1.00	0.10	10.38	103.81	14.53	118.34	592
NCH Entrance Support	385	7.00	1.00	0.10	2.70	26.96	3.77	30.73	215
NCH OPD 1	561	7.00	1.00	0.10	3.93	39.29	5.50	44.79	224
NCH OPD 2	336	7.00	1.00	0.10	2.35	23.49	3.29	26.77	134
NCH OPD 3	222	7.00	1.00	0.10	1.55	15.54	2.18	17.72	89
NCH OPD 4	301	7.00	1.00	0.10	2.10	21.05	2.95	24.00	120
NCH OPD 5	478	7.00	1.00	0.10	3.35	33.46	4.68	38.14	191
NCH OPD 6	311	7.00	1.00	0.10	2.18	21.80	3.05	24.85	124
NCH OPD 7	448	7.00	1.00	0.10	3.14	31.36	4.39	35.75	179
NCH OPD 8	309	7.00	1.00	0.10	2.16	21.60	3.02	24.63	123
NCH Child Protection	122	7.00	1.00	0.10	0.85	8.53	1.19	9.72	49
NCH Observation Ward	849	7.00	1.00	1.00	5.94	59.44	83.22	142.67	713
NCH Emercency Department	1995	7.00	1.00	0.10	13.97	139.66	19.55	159.22	1115
NCH Radiology	1852	9.00	1.00	0.10	16.67	166.67	23.33	190.00	1330
NCH Rehabilitation	956	7.00	1.00	0.10	6.69	66.91	9.37	76.27	381
NCH Atrium	0	7.00	1.00	0.10	0.00	0.00	0.00	0.00	0
NSGH Main Entrance	1225	7.00	1.00	0.10	8.58	85.75	12.01	97.76	684
NSGH Retail / Cores	3666	7.00	1.00	0.10	25.66	256.59	35.92	292.51	2048
Local Pharmacy	284	7.00	1.00	0.10	1.99	19.91	2.79	22.70	159
NSGH Rehab & Therapies	1009	7.00	1.00	0.10	7.06	70.63	9.89	80.52	403
NSGH OPD	1449	7.00	1.00	0.10	10.14	101.43	14.20	115.63	578
NSGH Discharge Lounge	185	7.00	1.00	0.10	1.30	12.95	1.81	14.76	74
NSGH Acute Assessment	5646	7.00	1.00	1.00	39.52	395.20	553.28	948.48	4742
NSGH Emergency Department	2638	7.00	1.00	0.10	18.47	184.69	25.86	210.54	1474
NSGH Radiology	2071	9.00	1.00	1.00	18.64	186.38	260.93	447.31	3131
Circulation / Cores	2287	2.00	1.00	1.00	4.57	45.74	64.04	109.78	768
NCH Critical Care (PICU)	1686	7.00	1.00	1.00	11.80	118.04	165.26	283.30	1983
NCH PICU Support 1	180	7.00	1.00	0.10	1.26	12.57	1.76	14.33	100
NCH PICU Support 2	319	7.00	1.00	0.10	2.23	22.33	3.13	25.46	178
NCH MDU	454	7.00	1.00	0.10	3.18	31.79	4.45	36.24	181
NCH 23 Hr Unit	967	7.00	1.00	0.10	6.77	67.70	9.48	77.18	540
NCH Cardiology Ward	862	7.00	1.00	0.05	6.03	60.33	4.22	64.55	452
NCH Special Needs	33	7.00	1.00	0.10	0.23	2.33	0.33	2.66	13
NCH Theatres	3192	7.00	1.00	1.00	22.34	223.43	312.80	536.22	3754
NCH Radiology	1151	9.00	1.00	0.10	10.36	103.56	14.50	118.06	826
NSGH Critical Care	6283	7.00	1.00	0.10	43.98	439.82	61.57	501.39	3510
NSGH Radiology	2471	7.00	1.00	0.10	17.30	173.00	24.22	197.22	1381
Nuclear Medicine	834	7.00	1.00	0.10	5.84	58.39	8.18	66.57	333
Chapel	152	7.00	1.00	0.10	1.07	10.65	1.49	12.15	61
Restaurant/Visitor Dining/WCs	1067	7.00	1.00	0.10	7.47	74.71	10.46	85.17	596
NSGH OPD	2460	7.00	1.00	0.10	17.22	172.20	24.11	196.31	982

Brookfield

DEPARTMENT		LOAD ASSESSMENT (W/m^2)	U.F		MAX LOAD (kW)	CONSUMPTION (kWh)			
NAME	AREA (m^2)^5		DAY	NIGHT		DAY	NIGHT	DAILY	WEEKLY
NSGH MDU	849	7.00	1.00	0.10	5.94	59.44	8.32	67.76	339
NSGH Stroke Ward	1422	7.00	1.00	0.10	9.96	99.57	13.94	113.51	795
Circulation / Cores	3727	2.00	1.00	0.10	7.45	74.54	10.44	84.98	595
NCH Acute Receiving Ward	1681	7.00	1.00	0.10	11.77	117.67	16.47	134.14	939
Aseptic Suite	499	7.00	1.00	0.10	3.49	34.91	4.89	39.80	279
Ward Support 1	160	7.00	1.00	0.10	1.12	11.20	1.57	12.77	89
Ward Support 2	228	7.00	1.00	0.10	1.60	15.98	2.24	18.22	128
NCH Teenager Cancer Trust	89	7.00	1.00	0.10	0.62	6.24	0.87	7.11	36
NCH Schiehallion Ward	1105	7.00	1.00	0.10	7.74	77.35	10.83	88.18	617
Ward Support 3	59	7.00	1.00	0.10	0.41	4.13	0.58	4.71	33
NCH Day Case Unit	423	7.00	1.00	0.10	2.96	29.62	4.15	33.77	169
Equipment Store	231	7.00	1.00	0.10	1.62	16.16	2.26	18.42	129
Sterile Store	188	7.00	1.00	0.10	1.32	13.19	1.85	15.03	105
Medical Physics	812	7.00	1.00	0.05	5.69	56.87	3.98	60.85	304
NSGH Endoscopy	442	7.00	1.00	0.10	3.09	30.93	4.33	35.26	176
Decontamination	453	7.00	1.00	0.10	3.17	31.70	4.44	36.13	253
NSGH Theatres	6794	7.00	1.00	0.10	47.56	475.55	66.58	542.13	3795
Telephone Services	151	7.00	1.00	0.10	1.06	10.57	1.48	12.05	84
NSGH Renal	1480	7.00	1.00	0.10	10.36	103.60	14.50	118.10	827
NSGH Dermatology	754	7.00	1.00	0.10	5.28	52.78	7.39	60.17	301
Hotel Services	665	7.00	1.00	0.10	4.66	46.55	6.52	53.07	371
Health Records / Library / Meeting Rooms	605	7.00	1.00	0.10	4.24	42.35	5.93	48.28	241
Circulation / Cores	3151	2.00	1.00	0.10	6.30	63.02	8.82	71.84	503
NCH In-Patient Ward 1	1218	7.00	1.00	0.10	8.53	85.29	11.94	97.23	681
NCH Ward Support 1	503	7.00	1.00	0.10	3.52	35.20	4.93	40.13	281
NCH Ward Support 2	545	7.00	1.00	0.10	3.81	38.12	5.34	43.46	304
NCH In-Patient Ward 2	1136	7.00	1.00	0.10	7.95	79.55	11.14	90.68	635
NCH Ward Support 3	212	7.00	1.00	0.10	1.48	14.85	2.08	16.93	118
NCH In-Patient Ward 3	1073	7.00	1.00	0.10	7.51	75.08	10.51	85.59	599
NCH Nephrology / Renal	122	7.00	1.00	0.10	0.85	8.53	1.19	9.73	49
Kitchen	954	7.00	1.00	0.10	6.68	66.76	9.35	76.11	533
Staff Areas (Change, Accom, Stores)	847	7.00	1.00	0.32	5.93	59.27	26.55	85.82	601
Circulation / Cores	1800	2.00	1.00	0.32	3.60	36.00	16.13	52.13	365
NCH DCFP	860	7.00	1.00	0.32	6.02	60.17	26.95	87.12	436
Admin Support	284	7.00	1.00	0.32	1.99	19.87	8.90	28.78	144
Medi-Cinema	196	7.00	1.00	0.32	1.37	13.69	6.13	19.83	99
Wards	6652	4.50	1.00	0.32	29.93	299.34	134.10	433.44	3034
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953
Wards	6475	4.50	1.00	0.32	29.14	291.38	130.54	421.91	2953

TOTAL ELECTRICAL CONSUMPTION FOR GENERAL POWER (kWh/Week) 74879

Brookfield

SPECIFIC DEPARTMENT LOADS

DEPARTMENT	LOAD PER AREA (kW)	No. AREAS/	U.F		CONSUMPTION (kWh)			
			DAY	NIGHT	DAY	NIGHT	DAILY	WEEKLY
Cafés	10	2	0.30	0.30	60	84	144	1008
Kitchens	3	2	0.30	0.10	18	8	26	185
Pantries	3	5	0.30	0.10	45	21	66	462
Staff Rest Rooms	3	8	0.30	0.10	72	34	106	739
Imaging Department X-Ray Machines	2	8	0.30	0.00	48	0	48	336
ICU Beds (kW/bed)	2	20	1.00	1.00	400	560	960	6720
CCU Beds (kW/bed)	2	20	1.00	1.00	400	560	960	6720
NICU Beds (kW/bed)	2	25	1.00	1.00	500	700	1200	8400
Endoscopy (kW/bed)	2	6	1.00	1.00	120	168	288	2016
Angio (kW/bed)	2	1	1.00	1.00	20	28	48	336
Day/Elective Theatres	6	20	0.50	0.20	600	336	936	6552
Trauma Theatres	6	9	1.00	0.75	540	567	1107	7749
Server Rooms	30	2	1.00	1.00	600	840	1440	10080

TOTAL ELECTRICAL CONSUMPTION FOR SPECIFIC DEPARTMENT LOADS (kWh/Week) 51303

REGEN KITCHEN - 1 WARD

EQUIPMENT	LOAD PER UNIT (kW)	No. UNITS	No. KITCHENS	U.F		CONSUMPTION (kWh)			
				DAY	NIGHT	DAY	NIGHT	DAILY	WEEKLY
Regen Machine - Regen Mode	8.0	1	20	0.15	0.00	240	0	240	1680
Regen Machine - Fridge Mode	0.5	1	20	0.50	0.00	50	0	50	350
Refrigerator	0.5	1	20	1.00	1.00	100	140	240	1680

TOTAL ELECTRICAL CONSUMPTION FOR REGEN KITCHEN (kWh/Week) 3710

PATIENTS CATERING AREA

ESTIMATED TOTAL ELECTRICAL CONSUMPTION FOR PATIENTS CATERING AREA (kWh/Week) 10670

STAFF & VISITORS RESTAURANT

ESTIMATED TOTAL ELECTRICAL CONSUMPTION FOR STAFF AND VISITORS RESTAURANT (kWh/Week) 25560

TOTAL

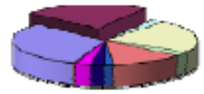
TOTAL WEEKLY ELECTRICAL CONSUMPTION FOR ALL GENERAL POWER (kWh/Week) 166121

ANNUAL TOTAL (kWh/Year) 8638302

Brookfield

LIGHTING ELECTRICAL CONSUMPTION

The total consumption associated with lighting usage has been calculated by applying a load assessment figure to each departmental area. Usage factors are then applied for two time periods in a day, the first 10 hours (day) then the remaining 14 hours (night). This produced a daily maximum load value that was then converted to a weekly value. The weekly load values for each department were then summed to obtain an annual total for the lighting usage.



Intermittent deptartments are highlighted in yellow and based on a 5 day working week[1]

INDIVIDUAL FLOOR/DEPARTMENT LOADS

DEPARTMENT		LOAD ASSESSMENT	U.F (%)		MAX LOAD	CONSUMPTION (kWh)			
NAME	AREA (m^2)		DAY	NIGHT		DAY	NIGHT	DAILY	WEEKLY
Basement	4329.00	10.00	0.75	0.10	43.29	324.68	60.61	385.28	2697
NCH Entrance	1483.00	16.00	0.75	0.10	23.73	177.96	33.22	211.18	1478
NCH Entrance Support	385.10	16.00	0.75	0.10	6.16	46.21	8.63	54.84	384
NCH OPD 1	561.30	16.00	0.75	0.10	8.98	67.36	12.57	79.93	400
NCH OPD 2	335.50	16.00	0.75	0.10	5.37	40.26	7.52	47.78	239
NCH OPD 3	222.00	16.00	0.75	0.10	3.55	26.64	4.97	31.61	158
NCH OPD 4	300.70	16.00	0.75	0.10	4.81	36.08	6.74	42.82	214
NCH OPD 5	478.00	16.00	0.75	0.10	7.65	57.36	10.71	68.07	340
NCH OPD 6	311.40	16.00	0.75	0.10	4.98	37.37	6.98	44.34	222
NCH OPD 7	448.00	16.00	0.75	0.10	7.17	53.76	10.04	63.80	319
NCH OPD 8	308.60	16.00	0.75	0.10	4.94	37.03	6.91	43.94	220
NCH Child Protection	121.80	14.00	0.75	0.10	1.71	12.79	2.39	15.18	76
NCH Observation Ward	849.20	11.60	0.75	0.50	9.85	73.88	68.96	142.84	714
NCH Emercency Department	1995.20	14.00	0.75	0.10	27.93	209.50	39.11	248.60	1740
NCH Radiology	1851.90	16.00	0.75	0.10	29.63	222.23	41.48	263.71	1846
NCH Rehabilitation	955.80	14.00	0.75	0.10	13.38	100.36	18.73	119.09	595
NCH Atrium	0.00	14.00	0.75	0.10	0.00	0.00	0.00	0.00	0
NSGH Main Entrance	1225.00	14.00	0.75	0.10	17.15	128.63	24.01	152.64	1068
NSGH Retail / Cores	3665.60	14.00	0.75	0.10	51.32	384.89	71.85	456.73	3197
Local Pharmacy	284.40	14.00	0.75	0.10	3.98	29.86	5.57	35.44	248
NSGH Rehab & Therapies	1009.00	14.00	0.75	0.10	14.13	105.95	19.78	125.72	629
NSGH OPD	1449.00	14.00	0.75	0.10	20.29	152.15	28.40	180.55	903
NSGH Discharge Lounge	185.00	14.00	0.75	0.10	2.59	19.43	3.63	23.05	115
NSGH Acute Assessment	5645.70	14.00	0.75	0.50	79.04	592.80	553.28	1146.08	5730
NSGH Emergency Department	2638.40	16.00	0.75	0.10	42.21	316.61	59.10	375.71	2630
NSGH Radiology	2070.90	16.00	0.75	0.50	33.13	248.51	231.94	480.45	2402
Circulation / Cores	2287.00	10.00	0.75	0.50	22.87	171.53	160.09	331.62	2321
NCH Critical Care (PICU)	1686.30	12.00	0.75	0.50	20.24	151.77	141.65	293.42	2054
NCH PICU Support 1	179.60	14.00	0.75	0.10	2.51	18.86	3.52	22.38	157
NCH PICU Support 2	319.00	14.00	0.75	0.10	4.47	33.50	6.25	39.75	278
NCH MDU	454.10	14.00	0.75	0.10	6.36	47.68	8.90	56.58	283
NCH 23 Hr Unit	967.20	14.00	0.75	0.10	13.54	101.56	18.96	120.51	844
NCH Cardiology Ward	861.80	11.60	0.60	0.05	10.00	59.98	7.00	66.98	469
NCH Special Needs	33.30	14.00	0.75	0.10	0.47	3.50	0.65	4.15	21
NCH Theatres	3191.80	14.00	0.75	0.50	44.69	335.14	312.80	647.94	4536
NCH Radiology	1150.70	16.00	0.75	0.10	18.41	138.08	25.78	163.86	1147
NSGH Critical Care	6283.10	12.00	0.75	0.10	75.40	565.48	105.56	671.04	4697
NSGH Radiology	2471.40	18.00	0.75	0.10	44.49	333.64	62.28	395.92	2771
Nuclear Medicine	834.20	14.00	0.75	0.10	11.68	87.59	16.35	103.94	520
Chapel	152.20	10.00	0.75	0.10	1.52	11.42	2.13	13.55	68
Restaurant/Visitor Dining/WCs	1067.30	10.00	0.75	0.10	10.67	80.05	14.94	94.99	665
NSGH OPD	2460.00	14.00	0.75	0.10	34.44	258.30	48.22	306.52	1533

DEPARTMENT		LOAD ASSESSMENT	U.F (%)		MAX LOAD	CONSUMPTION (kWh)			
NAME	AREA (m^2)		DAY	NIGHT		DAY	NIGHT	DAILY	WEEKLY
NSGH MDU	849.10	14.00	0.75	0.10	11.89	89.16	16.64	105.80	529
NSGH Stroke Ward	1422.40	11.60	0.75	0.10	16.50	123.75	23.10	146.85	1028
Circulation / Cores	3727.00	10.00	0.75	0.10	37.27	279.53	52.18	331.70	2322
NCH Acute Receiving Ward	1681.00	11.60	0.75	0.10	19.50	146.25	27.30	173.55	1215
Aseptic Suite	498.70	14.00	0.75	0.10	6.98	52.36	9.77	62.14	435
Ward Support 1	160.00	11.60	0.75	0.10	1.86	13.92	2.60	16.52	116
Ward Support 2	228.30	11.60	0.75	0.10	2.65	19.86	3.71	23.57	165
NCH Teenager Cancer Trust	89.10	14.00	0.75	0.10	1.25	9.36	1.75	11.10	56
NCH Schiehallion Ward	1105.00	11.60	0.75	0.10	12.82	96.14	17.95	114.08	799
Ward Support 3	59.00	11.60	0.75	0.10	0.68	5.13	0.96	6.09	43
NCH Day Case Unit	423.20	14.00	0.75	0.10	5.92	44.44	8.29	52.73	264
Equipment Store	230.80	10.00	0.75	0.10	2.31	17.31	3.23	20.54	144
Sterile Store	188.40	10.00	0.75	0.10	1.88	14.13	2.64	16.77	117
Medical Physics	812.40	14.00	0.60	0.05	11.37	68.24	7.96	76.20	381
NSGH Endoscopy	441.80	14.00	0.75	0.10	6.19	46.39	8.66	55.05	275
Decontamination	452.80	10.00	0.75	0.10	4.53	33.96	6.34	40.30	282
NSGH Theatres	6793.60	14.00	0.75	0.10	95.11	713.33	133.15	846.48	5925
Telephone Services	151.00	12.00	0.75	0.10	1.81	13.59	2.54	16.13	113
NSGH Renal	1480.00	12.00	0.75	0.10	17.76	133.20	24.86	158.06	1106
NSGH Dermatology	754.00	12.00	0.75	0.10	9.05	67.86	12.67	80.53	403
Hotel Services	665.00	12.00	0.75	0.10	7.98	59.85	11.17	71.02	497
Health Records / Library / Meeting Rooms	605.00	12.00	0.75	0.10	7.26	54.45	10.16	64.61	323
Circulation / Cores	3151.00	10.00	0.75	0.10	31.51	236.33	44.11	280.44	1963
NCH In-Patient Ward 1	1218.40	11.60	0.75	0.10	14.13	106.00	19.79	125.79	881
NCH Ward Support 1	502.90	11.60	0.75	0.10	5.83	43.75	8.17	51.92	363
NCH Ward Support 2	544.60	11.60	0.75	0.10	6.32	47.38	8.84	56.22	394
NCH In-Patient Ward 2	1136.40	11.60	0.75	0.10	13.18	98.87	18.46	117.32	821
NCH Ward Support 3	212.10	11.60	0.75	0.10	2.46	18.45	3.44	21.90	153
NCH In-Patient Ward 3	1072.50	11.60	0.75	0.10	12.44	93.31	17.42	110.72	775
NCH Nephrology / Renal	121.90	12.00	0.75	0.10	1.46	10.97	2.05	13.02	65
Kitchen	953.70	12.00	0.75	0.10	11.44	85.83	16.02	101.86	713
Staff Areas (Change, Accom, Stores)	846.70	14.00	0.75	0.10	11.85	88.90	16.60	105.50	738
Circulation / Cores	1800.00	10.00	0.75	0.10	18.00	135.00	25.20	160.20	1121
NCH DCFP	859.50	14.00	0.75	0.10	12.03	90.25	16.85	107.09	535
Admin Support	283.90	14.00	0.75	0.10	3.97	29.81	5.56	35.37	177
Medi-Cinema	195.60	14.00	0.75	0.10	2.74	20.54	3.83	24.37	122
Wards	6652.00	11.60	0.75	0.10	77.16	578.72	108.03	686.75	4807
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679
Wards	6475.00	11.60	0.75	0.10	75.11	563.33	105.15	668.48	4679

TOTAL ELECTRICAL CONSUMPTION FOR LIGHTING (kWh/Week) 113849

ANNUAL TOTAL (kWh/Year) 5920160

Notes

[1] *Intermittent departments are highlighted in yellow.*

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MECHANICAL PLANT ELECTRICAL CONSUMPTION

SUPPLY VENTILATION

The total electrical consumption per week for each air handling unit was calculated by converting the supply air volume into an estimated power value. The hourly electrical usage was then applied to a weekly usage profile for each unit and the total weekly electrical consumption for each unit were summed to produce a yearly electrical consumption value for the supply ventilation.

AHU REF		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
21AHU01		1.72	3.77	24	24	24	24	24	24	24	168	634
21AHU02		1.72	3.77	24	24	24	24	24	24	24	168	634
21AHU03		2.85	6.27	24	24	24	24	24	24	24	168	1053
21AHU04		3.11	6.83	24	24	24	24	24	24	24	168	1147
21AHU05		1.42	3.11	24	24	24	24	24	24	24	168	523
21AHU06		1.45	3.19	24	24	24	24	24	24	24	168	536
21AHU07		1.45	3.19	24	24	24	24	24	24	24	168	536
21AHU08		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU09		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU10		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU11		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU12		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU13		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU14		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU15		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU16		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU17		0.30	0.66	24	24	24	24	24	24	24	168	111
21AHU18		1.78	3.91	24	24	24	24	24	24	24	168	656
21AHU19		1.79	3.93	24	24	24	24	24	24	24	168	660
21AHU20		2.46	5.42	24	24	24	24	24	24	24	168	910
21AHU21		2.54	5.59	24	24	24	24	24	24	24	168	939
21AHU22		2.02	4.45	24	24	24	24	24	24	24	168	747
21AHU23		1.50	3.31	12	12	12	12	8	8	8	72	238
21AHU24		1.12	2.46	12	12	12	12	8	8	8	72	177
21AHU25		1.14	2.50	12	12	12	12	8	8	8	72	180
21AHU26		1.73	3.81	24	24	24	24	24	24	24	168	640
21AHU27		1.73	3.81	24	24	24	24	24	24	24	168	640
21AHU28		1.60	3.52	24	24	24	24	24	24	24	168	591
21AHU29		1.60	3.52	24	24	24	24	24	24	24	168	591
21AHU30		2.38	5.22	24	24	24	24	24	24	24	168	877
21AHU31		2.38	5.22	24	24	24	24	24	24	24	168	877
21AHU32		1.35	2.96	12	12	12	12	8	8	8	72	213
21AHU33		2.78	6.11	12	12	12	12	8	8	8	72	440
21AHU34		0.92	2.01	12	12	12	12	8	8	8	72	145
22AHU01		1.51	3.33	12	12	12	12	8	8	8	72	240
22AHU02		1.51	3.33	16	16	16	16	16	16	16	112	373
22AHU03		1.45	3.19	16	16	16	16	16	16	16	112	357
22AHU04		1.45	3.19	16	16	16	16	16	16	16	112	357
22AHU05		1.25	2.75	16	16	16	16	16	16	16	112	308
22AHU06		1.25	2.75	16	16	16	16	16	16	16	112	308
22AHU07		1.07	2.36	16	16	16	16	16	16	16	112	264
22AHU08		0.99	2.19	16	16	16	16	16	16	16	112	245
22AHU09		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU10		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU11		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU12		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU13		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU14		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU15		3.03	6.65	16	16	16	16	16	16	16	112	745
22AHU16		3.03	6.65	16	16	16	16	16	16	16	112	745

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AHU REF		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
22AHU17		3.03	6.65	8	8	8	8	8			40	266
22AHU18		1.65	3.64	8	8	8	8	8			40	145
22AHU19		1.65	3.64	12	12	12	12	8	8	8	72	262
22AHU20		2.01	4.41	15	15	15	15	15	15	15	105	463
22AHU21		1.39	3.06	24	24	24	24	24	24	24	168	513
22AHU22		0.44	0.97	8.5	8.5	8.5	8.5	8.5			43	41
22AHU23		1.87	4.12	16	16	16	16	16	16	16	112	461
31AHU01		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU02		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU03		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU04		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU05		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU06		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU07		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU08		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU09		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU10		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU11		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU12		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU13		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU14		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU15		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU16		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU17		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU18		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU19		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU20		3.03	6.65	16	16	16	16	16	16	16	112	745
31AHU21		3.15	6.92	16	16	16	16	16	16	16	112	776
31AHU22		3.22	7.08	16	16	16	16	16	16	16	112	793
31AHU25		2.00	4.39	24	24	24	24	24	24	24	168	738
31AHU26		2.02	4.45	8	8	8	8	8			40	178
31AHU27		2.53	5.55	8	8	8	8	8			40	222
31AHU28		1.66	3.66	16	16	16	16	16	16	16	112	409
31AHU29		1.66	3.66	16	16	16	16	16	16	16	112	409
31AHU30		1.84	4.04	16	16	16	16	16	16	16	112	453
31AHU36		2.84	6.25	12	12	12	12	8	8	8	72	450
31AHU37		3.03	6.65	12	12	12	12	8	8	8	72	479
31AHU38		3.03	6.65	12	12	12	12	8	8	8	72	479
31AHU39		0.99	2.19	12	12	12	12	8	8	8	72	157
31AHU40		1.90	4.18	12	12	12	12	8	8	8	72	301
31AHU41		3.47	7.62	12	12	12	12	8	8	8	72	549
31AHU42		1.99	4.37	8.5	8.5	8.5	8.5	8.5			43	186
31AHU48		1.50	3.29	24	24	24	24	24	24	24	168	552
31AHU52		1.43	3.13	12	12	12	12	8	8	8	72	226
31AHU53		2.28	5.01	12	12	12	12	8	8	8	72	361
31AHU54		1.63	3.58	12	12	12	12	8	8	8	72	258
31AHU55		1.63	3.58	12	12	12	12	8	8	8	72	258
31AHU56		1.85	4.06	12	12	12	12	12			60	244
31AHU57		1.85	4.06	12	12	12	12	12			60	244
31AHU58		2.38	5.24	12	12	12	12	12			60	315
31AHU59		1.66	3.66	12	12	12	12	12			60	219
31AHU60		0.84	1.86	12	12	12	12	12			60	111
32AHU01		5.72	12.57	24	24	24	24	24	24	24	168	2112
32AHU02		6.05	13.31	8	8	8	8	8	8	8	56	745
32AHU03		0.53	1.16	15	15	15	15	15	15	15	105	122
32AHU04		0.44	0.97	8.5	8.5	8.5	8.5	8.5	4	4	51	49
33AHU01		5.09	11.18	11.5	11.5	11.5	11.5	11.5	11.5		69	771
33AHU02		9.03	19.85	10	10	10	10	10			50	992

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AHU REF		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
33AHU03		1.87	4.10	10	10	10	10	10			50	205
33AHU04		2.68	5.90	8.5	8.5	8.5	8.5	8.5			43	251
41AHU01		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU02		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU03		3.20	7.04	24	24	24	24	24	24	24	168	1183
41AHU05		1.24	2.73	10	10	10	10	10			50	136
41AHU06		1.80	3.97	10	10	10	10	10			50	198
41AHU07		0.49	1.08	15	15	15	15	15	15	15	105	114
41AHU10		1.78	3.91	10	10	10	10	10			50	195
41AHU11		1.13	2.48	10	10	10	10	10			50	124
41AHU12		1.76	3.87	15	15	15	15	15	15	15	105	406
41AHU13		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU14		4.49	9.86	24	24	24	24	24	24	24	168	1657
41AHU15		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU16		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU17		1.31	2.88	24	24	24	24	24	24	24	168	484
41AHU18		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU19		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU20		1.83	4.02	24	24	24	24	24	24	24	168	676
41AHU21		1.05	2.30	24	24	24	24	24	24	24	168	387
41AHU22		2.04	4.49	24	24	24	24	24	24	24	168	754
41AHU23		0.30	0.66	24	24	24	24	24	24	24	168	111
41AHU24		2.38	5.22	10	10	10	10	10			50	261
41AHU25		3.32	7.29	24	24	24	24	24	24	24	168	1225
41AHU26		0.44	0.97	24	24	24	24	24	24	24	168	162
121AHU01		3.20	7.04	24	24	24	24	24	24	24	168	1183
121AHU02		3.24	7.12	24	24	24	24	24	24	24	168	1196
121AHU03		2.54	5.59	24	24	24	24	24	24	24	168	939
121AHU04		3.08	6.77	24	24	24	24	24	24	24	168	1137
121AHU05		1.71	3.75	24	24	24	24	24	24	24	168	630
121AHU06		3.20	7.04	24	24	24	24	24	24	24	168	1183
121AHU07		3.24	7.12	24	24	24	24	24	24	24	168	1196
121AHU08		2.54	5.59	24	24	24	24	24	24	24	168	939
121AHU09		3.08	6.77	24	24	24	24	24	24	24	168	1137
121AHU10		1.71	3.75	24	24	24	24	24	24	24	168	630
122AHU01		3.20	7.04	24	24	24	24	24	24	24	168	1183
122AHU02		3.24	7.12	24	24	24	24	24	24	24	168	1196
122AHU03		2.54	5.59	24	24	24	24	24	24	24	168	939
122AHU04		3.08	6.77	24	24	24	24	24	24	24	168	1137
122AHU05		1.71	3.75	24	24	24	24	24	24	24	168	630
122AHU06		3.20	7.04	24	24	24	24	24	24	24	168	1183
122AHU07		3.24	7.12	24	24	24	24	24	24	24	168	1196
122AHU08		2.54	5.59	24	24	24	24	24	24	24	168	939
122AHU09		3.08	6.77	24	24	24	24	24	24	24	168	1137
122AHU10		1.71	3.75	24	24	24	24	24	24	24	168	630

TOTAL ELECTRICAL CONSUMPTION FOR SUPPLY VENTILATION (kWh/Week)	84968
ANNUAL TOTAL (kWh/Year)	4418314

Notes

[1] *Rule of thumb calculation from BSRIA Rules of Thumb (4th ed.). Fan electrical input (kW) = 1.57 x total fan pressure (kPa) x volume flow rate (m^3/s). Assuming the total fan pressure = 1400 Pa and 1.57 = (1/(fan eff.* motor eff.)) where the fan efficiency = 75% and the motor/drive efficiency = 85%.*

Brookfield

MECHANICAL PLANT ELECTRICAL CONSUMPTION

EXTRACT VENTILATION

The total electrical consumption per week for each air handling unit was calculated by converting the extract air volumes into an estimated power value. The hourly electrical usage was then applied to a weekly usage profile for each unit and the total weekly electrical consumption for each unit were summed to produce a yearly electrical consumption value for the extract ventilation.

AHU REF.		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
21AHU01		1.72	1.61	24	24	24	24	24	24	24	168	270
21AHU02		1.72	1.61	24	24	24	24	24	24	24	168	270
21AHU03		2.85	2.67	24	24	24	24	24	24	24	168	448
21AHU04		3.11	2.91	24	24	24	24	24	24	24	168	488
21AHU05		1.42	1.33	24	24	24	24	24	24	24	168	223
21AHU06		1.45	1.36	24	24	24	24	24	24	24	168	228
21AHU07		1.45	1.36	24	24	24	24	24	24	24	168	228
21AHU08		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU09		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU10		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU11		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU12		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU13		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU14		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU15		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU16		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU17		0.30	0.28	24	24	24	24	24	24	24	168	47
21AHU18		1.78	1.66	24	24	24	24	24	24	24	168	280
21AHU19		1.79	1.67	24	24	24	24	24	24	24	168	281
21AHU20		2.46	2.31	24	24	24	24	24	24	24	168	387
21AHU21		2.54	2.38	24	24	24	24	24	24	24	168	400
21AHU22		2.02	1.89	24	24	24	24	24	24	24	168	318
21AHU23		1.50	1.41	12	12	12	12	8	8	8	72	101
21AHU24		1.12	1.05	12	12	12	12	8	8	8	72	75
21AHU25		1.14	1.06	12	12	12	12	8	8	8	72	77
21AHU26		1.73	1.62	24	24	24	24	24	24	24	168	273
21AHU27		1.73	1.62	24	24	24	24	24	24	24	168	273
21AHU28		1.60	1.50	24	24	24	24	24	24	24	168	252
21AHU29		1.60	1.50	24	24	24	24	24	24	24	168	252
21AHU30		2.38	2.22	24	24	24	24	24	24	24	168	374
21AHU31		2.38	2.22	24	24	24	24	24	24	24	168	374
21AHU32		2.23	2.08	12	12	12	12	8	8	8	72	150
21AHU33		2.78	2.60	12	12	12	12	8	8	8	72	187
21AHU34		0.92	0.86	12	12	12	12	8	8	8	72	62
22AHU01		1.51	1.42	12	12	12	12	8	8	8	72	102
22AHU02		1.51	1.42	16	16	16	16	16	16	16	112	159
22AHU03		1.47	1.38	16	16	16	16	16	16	16	112	154
22AHU04		1.47	1.38	16	16	16	16	16	16	16	112	154
22AHU05		1.25	1.17	16	16	16	16	16	16	16	112	131
22AHU06		1.25	1.17	16	16	16	16	16	16	16	112	131
22AHU07		1.07	1.00	16	16	16	16	16	16	16	112	113
22AHU08		0.99	0.93	16	16	16	16	16	16	16	112	104
22AHU09		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU10		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU11		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU12		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU13		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU14		3.03	2.83	16	16	16	16	16	16	16	112	317

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AHU REF.		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
22AHU15		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU16		3.03	2.83	16	16	16	16	16	16	16	112	317
22AHU17		3.03	2.83	8	8	8	8	8	0	0	40	113
22AHU18		1.28	1.20	8	8	8	8	8	0	0	40	48
22AHU19		1.28	1.20	12	12	12	12	8	8	8	72	87
22AHU20		2.01	1.88	15	15	15	15	15	15	15	105	197
22AHU21		1.39	1.30	24	24	24	24	24	24	24	168	219
22AHU22		0.44	0.41	8.5	8.5	8.5	8.5	8.5	0	0	43	18
22AHU23		1.87	1.75	16	16	16	16	16	16	16	112	196
31AHU01		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU02		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU03		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU04		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU05		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU06		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU07		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU08		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU09		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU10		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU11		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU12		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU13		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU14		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU15		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU16		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU17		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU18		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU19		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU20		3.03	2.83	16	16	16	16	16	16	16	112	317
31AHU21		3.15	2.95	16	16	16	16	16	16	16	112	330
31AHU22		3.22	3.01	16	16	16	16	16	16	16	112	338
31AHU25		2.39	2.24	24	24	24	24	24	24	24	168	376
31AHU26		2.02	1.89	8	8	8	8	8	0	0	40	76
31AHU27		2.10	1.97	8	8	8	8	8	0	0	40	79
31AHU28		1.17	1.10	16	16	16	16	16	16	16	112	123
31AHU29		1.17	1.10	16	16	16	16	16	16	16	112	123
31AHU30		1.84	1.72	16	16	16	16	16	16	16	112	193
31AHU36		2.84	2.66	12	12	12	12	8	8	8	72	192
31AHU37		3.03	2.83	12	12	12	12	8	8	8	72	204
31AHU38		3.03	2.83	12	12	12	12	8	8	8	72	204
31AHU39		0.99	0.93	12	12	12	12	8	8	8	72	67
31AHU40		1.90	1.78	12	12	12	12	8	8	8	72	128
31AHU41		2.82	2.64	12	12	12	12	8	8	8	72	190
31AHU42		1.99	1.86	8.5	8.5	8.5	8.5	8.5	0	0	43	79
31AHU48		1.52	1.42	24	24	24	24	24	24	24	168	239
31AHU52		1.43	1.33	12	12	12	12	8	8	8	72	96
31AHU53		2.28	2.13	12	12	12	12	8	8	8	72	154
31AHU54		1.63	1.52	12	12	12	12	8	8	8	72	110
31AHU55		1.63	1.52	12	12	12	12	8	8	8	72	110
31AHU56		1.85	1.73	12	12	12	12	12	0	0	60	104
31AHU57		1.85	1.73	12	12	12	12	12	0	0	60	104
31AHU58		2.38	2.23	12	12	12	12	12	0	0	60	134
31AHU59		1.66	1.56	12	12	12	12	12	0	0	60	93
31AHU60		0.84	0.79	12	12	12	12	12	0	0	60	47

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AHU REF.		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
32AHU01		5.72	5.35	24	24	24	24	24	24	24	168	899
32AHU02		6.05	5.67	8	8	8	8	8	8	8	56	317
32AHU03		0.53	0.49	15	15	15	15	15	15	15	105	52
32AHU04		0.44	0.41	8.5	8.5	8.5	8.5	8.5	4	4	51	21
33AHU01		5.30	4.96	11.5	11.5	11.5	11.5	11.5	11.5	0	69	342
33AHU02		9.08	8.50	10	10	10	10	10	0	0	50	425
33AHU03		1.91	1.79	10	10	10	10	10	0	0	50	89
33AHU04		3.05	2.86	8.5	8.5	8.5	8.5	8.5	0	0	43	121
41AHU01		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU02		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU03		3.04	2.85	24	24	24	24	24	24	24	168	479
41AHU05		1.24	1.16	10	10	10	10	10	0	0	50	58
41AHU06		1.80	1.69	10	10	10	10	10	0	0	50	84
41AHU07		0.00	0.00	15	15	15	15	15	15	15	105	0
41AHU10		1.78	1.66	10	10	10	10	10	0	0	50	83
41AHU11		1.13	1.05	10	10	10	10	10	0	0	50	53
41AHU12		1.76	1.65	15	15	15	15	15	15	15	105	173
41AHU13		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU14		0.00	0.00	24	24	24	24	24	24	24	168	0
41AHU15		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU16		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU17		1.31	1.23	24	24	24	24	24	24	24	168	206
41AHU18		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU19		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU20		1.83	1.71	24	24	24	24	24	24	24	168	288
41AHU21		1.05	0.98	24	24	24	24	24	24	24	168	165
41AHU22		2.04	1.91	24	24	24	24	24	24	24	168	321
41AHU23		0.30	0.28	24	24	24	24	24	24	24	168	47
41AHU24		0.00	0.00	10	10	10	10	10	0	0	50	0
41AHU25		0.00	0.00	24	24	24	24	24	24	24	168	0
41AHU26		0.00	0.00	24	24	24	24	24	24	24	168	0
121AHU01		2.81	2.63	24	24	24	24	24	24	24	168	441
121AHU02		2.05	1.92	24	24	24	24	24	24	24	168	322
121AHU03		2.37	2.22	24	24	24	24	24	24	24	168	372
121AHU04		1.43	1.34	24	24	24	24	24	24	24	168	226
121AHU05		1.67	1.56	24	24	24	24	24	24	24	168	263
121AHU06		2.81	2.63	24	24	24	24	24	24	24	168	441
121AHU07		2.05	1.92	24	24	24	24	24	24	24	168	322
121AHU08		2.37	2.22	24	24	24	24	24	24	24	168	372
121AHU09		1.43	1.34	24	24	24	24	24	24	24	168	226
121AHU10		1.67	1.56	24	24	24	24	24	24	24	168	263
122AHU01		2.81	2.63	24	24	24	24	24	24	24	168	441
122AHU02		2.05	1.92	24	24	24	24	24	24	24	168	322
122AHU03		2.37	2.22	24	24	24	24	24	24	24	168	372
122AHU04		1.43	1.34	24	24	24	24	24	24	24	168	226
122AHU05		1.67	1.56	24	24	24	24	24	24	24	168	263
122AHU06		2.81	2.63	24	24	24	24	24	24	24	168	441
122AHU07		2.05	1.92	24	24	24	24	24	24	24	168	322
122AHU08		2.37	2.22	24	24	24	24	24	24	24	168	372
122AHU09		1.43	1.34	24	24	24	24	24	24	24	168	226
122AHU10		1.67	1.56	24	24	24	24	24	24	24	168	263
31DE01		2.20	2.06	24	24	24	24	24	24	24	168	346
31DE02		2.20	2.06	24	24	24	24	24	24	24	168	346
31DE03		2.20	2.06	24	24	24	24	24	24	24	168	346
31DE04		2.20	2.06	24	24	24	24	24	24	24	168	346

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AHU REF.		AIR VOLUME (m^3/s)	ESTIMATED POWER (kW)[1]	MON. (hrs)	TUE. (hrs)	WED. (hrs)	THUR. (hrs)	FRI. (hrs)	SAT. (hrs)	SUN. (hrs)	TOTAL HRS PER WEEK	TOTAL ELEC. CONSUMPTION PER WEEK (kWh)
121CE01		2.11	1.98	24	24	24	24	24	24	24	168	332
121CE02		2.11	1.98	24	24	24	24	24	24	24	168	332
121DE01		1.32	1.24	24	24	24	24	24	24	24	168	208
121DE02		1.32	1.24	24	24	24	24	24	24	24	168	208
122CE01		2.11	1.98	24	24	24	24	24	24	24	168	332
122CE02		2.11	1.98	24	24	24	24	24	24	24	168	332
122CE03		0.88	0.82	24	24	24	24	24	24	24	168	138
122DE01		1.32	1.24	24	24	24	24	24	24	24	168	208
122DE02		1.32	1.24	24	24	24	24	24	24	24	168	208
122DE03		1.32	1.24	24	24	24	24	24	24	24	168	208
22DE01		2.20	2.06	24	24	24	24	24	24	24	168	346
22DE02		2.20	2.06	24	24	24	24	24	24	24	168	346

TOTAL ELECTRICAL CONSUMPTION FOR EXTRACT VENTILATION (kWh/Week)	33882
ANNUAL TOTAL (kWh/Year)	1761846

Notes

[1] *Rule of thumb calculation from BSRIA Rules of Thumb (4th ed.). Fan electrical input (kW) = 1.57 x total fan pressure (kPa) x volume flow rate (m3/s). Assuming the total fan pressure = 600 Pa and 1.57 = (1/(fan eff.* motor eff.)) where the fan efficiency = 75% and the motor efficiency = 85%.*

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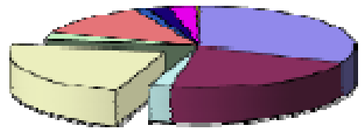
VENTILATION SUMMARY



ELECTRICAL CONSUMPTION SUMMARY OF AIR PLANTS

DESCRIPTION	WEEKLY ELECTRICAL CONSUMPTION (kWh/Week)	ANNUAL ELECTRICAL CONSUMPTION (kWh/Year)
SUPPLY VENTILATION	84967.57	4418313.82
EXTRACT VENTILATION	33881.66	1761846.32

ANNUAL TOTAL (kWh/Year)	6180160

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MECHANICAL PLANT ELECTRICAL CONSUMPTION

The electrical consumption for DX Units, HWS, Medical Gas Services and Heating equipment was calculated by determining the operational duration of the units by applying usage factors to a yearly profile which was then multiplied with the power rating of each unit to obtain the electrical consumption for the year.

HOSPITAL

DX UNITS ELECTRICAL CONSUMPTION

ROOMS	ELEC. LOAD PER UNIT (kW)	No. UNITS	U.F	YEARLY CONSUMPTION (kWh/YEAR)
Medical Cold Stores	1.5	1	0.5	6552
Catering Cold Stores	1.5	4	0.75	39312
		ANNUAL TOTAL (kWh/Year)		45864

WATER SERVICES ELECTRICAL CONSUMPTION

EQUIPMENT	ELEC. LOAD PER UNIT (kW)	No. UNITS	U.F	YEARLY CONSUMPTION (kWh/YEAR)
All HWS Pumps[2]	10	1	1	87360
Water Booster Set	40	2	1	524160
		ANNUAL TOTAL (kWh/Year)		611520

MEDICAL GAS SERVICES ELECTRICAL CONSUMPTION

EQUIPMENT	ELEC. LOAD PER UNIT (kW)	No. UNITS	U.F	YEARLY CONSUMPTION (kWh/YEAR)
MA4 Compressor	15	6	0.25	196560
Vacuum Pumps[2]	10	6	0.75	393120
SA7 Compressor	7.5	6	0.25	98280
AGSS	0.5	30	0.6	78624
		ANNUAL TOTAL (kWh/Year)		766584

HEATING (PUMPS ETC) ELECTRICAL CONSUMPTION

EQUIPMENT	ELEC. LOAD PER UNIT (kW)	No. UNITS	HEATING EQUIPMENT USAGE PROFILE (kWh)								YEARLY CONSUMPTION (kWh/YEAR)
			U.F	WINTER	U.F	SPRING	U.F	SUMMER	U.F	AUTUMN	
Boiler Pumps2	3	8	0.75	39312	0.5	26208	0.25	13104	0.5	26208	104832
Primary Pumps[2]	7.5	8	0.75	98280	0.5	65520	0.25	32760	0.5	65520	262080
All Heating Distribution Pumps[2]	100	1	0.75	163800	0.5	109200	0.25	54600	0.5	109200	436800
									ANNUAL TOTAL (kWh/Year)		803712

ELECTRICAL HUMIDIFICATION[1]

PLANT	VOLUME	MASS FLOW	STEAM USAGE	$h_f + h_{fg}$	THERMAL ENERGY	YEARLY CONSUMPTION
Notional Allowance	10.000	12.000	496119.17	2613.82	1296.77	360212.83
	0.000	0.000	0.00	2613.82	0.00	0.00
	0.000	0.000	0.00	2613.82	0.00	0.00
	0.000	0.000	0.00	2613.82	0.00	0.00
	0.000	0.000	0.00	2613.82	0.00	0.00
	0.000	0.000	0.00	2613.82	0.00	0.00
	0.000	0.000	0.00	2613.82	0.00	0.00
					ANNUAL TOTAL INCLUDING BLOWDOWN LOSSES (kWh/Year		378223

Notes

[1] The Total Steam Required to Maintain Humidity Level figure and the Air Conditioning required for this calculation has been taken from Appendix

[2] Pumps electrical loads include 70% pump efficiency and 80% motor/drive efficiency

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MECHANICAL PLANT ELECTRICAL CONSUMPTION

PNEUMATIC TUBE

The electrical consumption for the Pneumatic Tube System was calculated by applying a usage profile for each day of the week to the total system load. The weekly consumption was then used to determine the yearly electrical consumption.

INDIVIDUAL FAN POWER PER SYSTEM (kW)	2
No. OF SYSTEMS	10
TOTAL SYSTEM LOAD (kW)	20

WEEKDAY PNEUMATIC TUBE ELECTRICAL CONSUMPTION

TIME OF DAY	USAGE FACTOR[1]	DIVERSITY[2]	CONSUMPTION (kWh)
12pm-1am	0.15	1	3
1am-2am	0.15	1	3
2am-3am	0.15	1	3
3am4am	0.15	1	3
4am-5am	0.15	1	3
5am-6am	0.15	1	3
6am-7am	0.15	1	3
7am-8am	0.15	1	3
8am-9am	0.15	1	3
9am-10am	1.00	1.25	25
10am-11am	1.00	1.25	25
11am-12am	1.00	1.25	25
12am-1pm	1.00	1.25	25
1pm-2pm	1.00	1.25	25
2pm-3pm	1.00	1.25	25
3pm-4pm	1.00	1.25	25
4pm-5pm	1.00	1.25	25
5pm-6pm	0.50	1	10
6pm-7pm	0.50	1	10
7pm-8pm	0.50	1	10
8pm-9pm	0.20	1	4
9pm-10pm	0.20	1	4
10pm-11pm	0.20	1	4
11pm-12pm	0.20	1	4

WEEKDAY TOTAL (kWh/Day)	273

WEEKEND PNEUMATIC TUBE ELECTRICAL CONSUMPTION

TIME OF DAY	USAGE FACTOR[1]	DIVERSITY[2]	CONSUMPTION (kWh)
24hours	0.15	1	72

WEEKEND TOTAL (kWh/Day)	72
WEEKLY TOTAL (kWh/Week)	1509
YEARLY TOTAL (kWh/Year)	78468

[1] *The usage factor is determined from the Hourly Carrier Traffic flows of the Pneumatic Tube System from past projects*

[2] *The diversity figure allows for when the start up current of the pneumatic tube system fans will produce a higher power consumption than normal due to the on/off operation of the blowers when there is continual movement of the capsules in the system.*

Brookfield

MECHANICAL COOLING ELECTRICAL CONSUMPTION

The electrical consumption associated with the mechanical cooling equipment has been obtained by using a cooling load profile against the total cooling capacity per month which produced a monthly mechanical cooling load. This was then converted into an electrical cooling consumption (kWh) using an SEER of 4.5. The monthly totals were summed to produce an annual electrical consumption for the chillers. The electrical consumption for the primary and secondary pumps was calculated by making a monthly assessment of the usage of the pumps and applying this to the cooling profile which produced a monthly electrical energy consumption. The monthly totals were summed to obtain the annual electrical energy consumption.

MECHANICAL COOLING ELECTRICAL CONSUMPTION - HOSPITAL

TOTAL HOSPITAL COOLING CAPACITY[1] 6755 kW

CHILLERS ELECTRICAL CONSUMPTION

MONTH	AVERAGE MECH. COOLING				ELEC. COOLING CONS. (kWh)		
	DAY[1]		NIGHT[2]				
	COOLING PROFILE[3]	kW	COOLING PROFILE[3]	kW	DAY[1]	NIGHT[2]	MONTHLY
JANUARY	5	337.75	3	202.65	750.56	630.47	42811.69
FEBRUARY	10	675.50	3	202.65	1501.11	630.47	59684.18
MARCH	26	1756.30	7	472.85	3902.89	1471.09	166593.31
APRIL	32	2161.60	8	540.40	4803.56	1681.24	194544.00
MAY	37	2499.35	14	945.70	5554.11	2942.18	263384.96
JUNE	61	4120.55	21	1418.55	9156.78	4413.27	407101.33
JULY	74	4998.70	35	2364.25	11108.22	7355.44	572373.67
AUGUST	74	4998.70	35	2364.25	11108.22	7355.44	572373.67
SEPTEMBER	61	4120.55	21	1418.55	9156.78	4413.27	407101.33
OCTOBER	33	2229.15	14	945.70	4953.67	2942.18	244771.18
NOVEMBER	10	675.50	3	202.65	1501.11	630.47	63947.33
DECEMBER	5	337.75	3	202.65	750.56	630.47	42811.69

SEER 4.5

ELECTRICAL CONSUMPTION FOR CHILLERS (kWh/YEAR) 3037498

COOLING PUMPS ELECTRICAL CONSUMPTION

MONTH	PRIMARY PUMPS						SECONDARY PUMPS							
	NO. PUMPS[4]	DAY[1]		NIGHT[2]		MONTHLY (kWh)	NO. PUMPS[5]	DAY[1]			NIGHT[2]			MONTHLY (kWh)
		U.F	kWh	U.F	kWh			U.F	COOLING PROFILE[3]	kWh	U.F	COOLING PROFILE[3]	kWh	
JANUARY	1	1	75	1	105	5580	1	1	15	180	1	15	252	13392
FEBRUARY	1	1	75	1	105	5040	1	1	15	180	1	15	252	12096
MARCH	2	1	150	1	210	11160	1	1	21	252	1	15	252	15624
APRIL	2	1	150	1	210	10800	1	1	28	336	1	15	252	17640
MAY	3	1	225	1	315	16740	1	1	42	504	1	15	252	23436
JUNE	4	1	300	1	420	21600	1	1	56	672	1	21	353	30744
JULY	5	1	375	1	525	27900	1	1	69	828	1	35	588	43896
AUGUST	5	1	375	1	525	27900	1	1	69	828	1	35	588	43896
SEPTEMBER	4	1	300	1	420	21600	1	1	56	672	1	21	353	30744
OCTOBER	2	1	150	1	210	11160	1	1	28	336	1	15	252	18228
NOVEMBER	1	1	75	1	105	5400	1	1	15	180	1	15	252	12960
DECEMBER	1	1	75	1	105	5580	1	1	15	180	1	15	252	13392

PRIMARY PUMPS ANNUAL CONSUMPTION (kWh/YEAR) 170460

SECONDARY PUMPS ANNUAL CONSUMPTION (kWh/YEAR) 276048

TOTAL ANNUAL COOLING ELECTRICAL CONSUMPTION (kWh/YEAR) 3484006

Notes

[1] *Day-time operational hours are between 8am and 6pm, 7 days a week.*

[2] *Night-time hours are between 6pm and 8am, 7 days a week.*

[3] *This is the Annual Cooling Load Profile expressed as a percentage of the Total Cooling Load. Where the Annual Cooling Profile has been applied to the Secondary Cooling Pumps, a factor of 15% has been used as a minimum operating percentage.*

[4] *There are 6 No. Primary Pumps which have an electrical load of 7.5 kW per pump.*

[5] *The total electrical load for all the Secondary Pumps = 120 kW.*

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LIFTS ELECTRICAL CONSUMPTION

The lift electrical consumption has been calculated by determining how often the lift is used, and how much power is required to operate the lift during these periods. Information regarding motor ratings, loading factors and lift traffic data from past projects was used. The cycle time and motor rating were used with day-time (8 am to 6 pm) and night-time (6 pm to 8 am) usage factors (to represent the utilisation of each lift) to produce an electrical consumption for each lift. The totals from each lift were then summed to obtain an annual total for all lifts.

LIFT No.	FULL LOAD MOTOR RATING (kW)	ADJUSTED MOTOR RATING (kW)[1]	No. STARTS PER HOUR	TIME IN MOTION PER CYCLE[2]	DAY-TIME U.F[3]	NIGHT TIME U.F[3]	CONSUMPTION (kWh)
L1	17	12	240	5	0.75	0.5	58.00
L2	17	12	240	5	0.75	0.5	58.00
L3	25	8	240	5	0.5	0.25	22.67
L4	25	8	240	5	0.5	0.25	22.67
L5	25	8	240	5	0.75	0.5	38.67
L6	25	8	240	5	0.75	0.5	38.67
L7	17	6	240	5	0.75	0.5	29.00
L8	17	6	240	5	0.75	0.5	29.00
L9	25	8	240	5	0.5	0.25	22.67
L10	25	8	240	5	0.5	0.25	22.67
L11	25	8	240	5	0.75	0.5	38.67
L12	25	8	240	5	0.75	0.5	38.67
L13	15	5	180	5	0.75	0.5	18.13
L14	25	8	240	5	0.75	0.5	38.67
L15	25	8	240	5	0.75	0.5	38.67
L16	22	7	240	5	0.5	0.25	19.83
L17	22	7	240	5	0.5	0.25	19.83
L18	22	7	240	8	0.75	0.5	54.13
L19	22	7	240	8	0.75	0.5	54.13
L20	22	7	240	5	0.5	0.25	19.83
L21	22	7	240	5	0.5	0.25	19.83
L22	22	7	240	8	0.75	0.5	54.13
L23	22	7	240	8	0.75	0.5	54.13
L24	15	5	240	5	0.75	0.5	24.17
L25	15	5	240	5	0.75	0.5	24.17

DAILY TOTAL (kWh)	859
INCREASE BY 100% - P'BORO TO GLASGOW	1718
ANNUAL TOTAL (kWh/Year	627064

Notes

[1] *This figure assumes that the lift will rarely work to full capacity.*

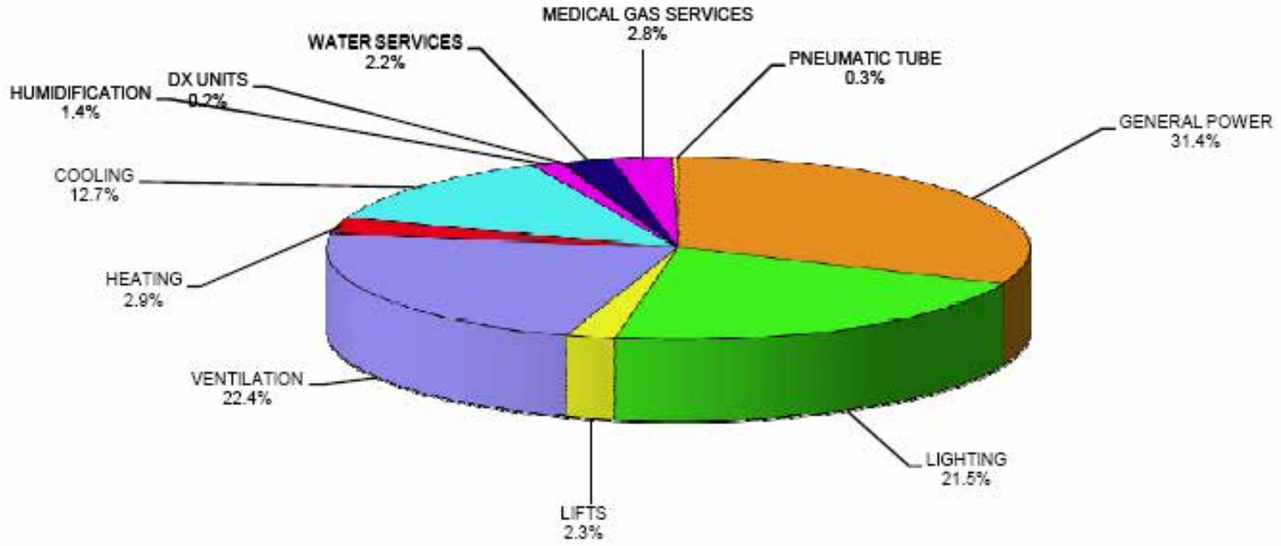
[2] *The operating cycle of the lift will include stationary time when the doors open and close. The time in motion will vary depending on the speed of the lift.*

[3] *Different usage factors have been assumed for the day-time period (8am to 6pm) and night-time period (6pm to 8am) which allows for the daily usage patterns, lifts travelling more than one floor at a time, lifts to be loaded and un-loaded and for lifts not being used. The goods lifts have a lower usage factor as it is assumed that they will not be used as much as the passenger lifts and will likely take longer to load and un-load due to the items being transported.*

Brookfield

ESTIMATED ANNUAL ELECTRICAL ENERGY CONSUMPTION SUMMARY

GENERAL POWER	8767876	kWh/Year[1]
LIGHTING	6008963	kWh/Year[1]
LIFTS	636470	kWh/Year[1]
ELECTRICAL TOTAL	15413309	kWh/Year[1]
VENTILATION	6272863	kWh/Year[1]
HEATING	815768	kWh/Year[1]
COOLING	3536266	kWh/Year[1]
HUMIDIFICATION	383897	kWh/Year[1]
DX UNITS	46552	kWh/Year[1]
WATER SERVICES	620693	kWh/Year[1]
MEDICAL GAS SERVICES	778083	kWh/Year[1]
PNEUMATIC TUBE	79645	kWh/Year[1]
MECHANICAL TOTAL	12533766	kWh/Year[1]
ANNUAL ELECTRICAL CONSUMPTION INCLUDING TRANSFORMER LOSSES (kWh/Year)	27947075	kWh/Year[1]



Notes

[1] *Electrical Energy Consumption figure allows for Transformer losses of 1.5%.*

Brookfield

B) MECHANICAL FOSSIL FUELS ENERGY USAGE

FABRIC HEATING

The energy consumption of the boilers to compensate for the losses through the fabric of the building has been calculated over two heating time periods, 24hr and 12hr, which assumes that various areas within the building will only be used for 10hours per day and other areas will be used for 24hours per day. The 12hr heating areas will have different losses during the day and at night. To obtain the total thermal energy for fabric heating per year a fabric heating load assessment figure was applied across the volume of the building associated with its time period which produced the fabric heat loss (kW).
The degree-day method was then used along with correction factors to calculate the yearly thermal energy for fabric heating for both time periods, which were then summed to obtain a combined figure. Factors for the seasonal efficiency of the boiler and the distribution losses were then incorporated into the final energy consumption figure.

	TREATED AREA (m^2)	FABRIC HEATING LOAD ASSESSMENT (W/m^2)	FABRIC HEAT LOSS (kW)
24hr/Htg	113887.70	17.00	1936.09
12hr/Htg Daytime	30360.90	17.00	516.14

TOTAL ANNUAL ENERGY REQUIREMENT FOR FABRIC HEATING

	DEGREE DAY[1]	DESIGN TEMPERATURE (°C)		TEMP. RATIO	UNCORRECTED HOURS
		INDOOR	OUTDOOR		
24hr/Htg	3517	21	-6	1	3126
12hr/Htg Daytime	3517	21	-6	1	3126

CORRECTION FACTORS FOR OPERATION HOURS

	WEEKLY FACTOR[2]	RESPONSE FACTOR[3]	DAILY FACTOR[4]	CORRECTED HOURS	NET HEAT (GJ/YEAR)
24hr/Htg	1	1	N/A	3126	21790
12hr/Htg Daytime	0.85	0.85	1.01	2281	4239

TOTAL THERMAL ENERGY FOR FABRIC HEATING (GJ/Year)	26028
TOTAL ENERGY CONSUMPTION FOR FABRIC HEATING (kWh/Year)	7230101
TOTAL INCLUDING BOILER SEASONAL AND DISTRIBUTION LOSSES (kWh/Year)[5]	9247803

Notes

[1] *Taken from CIBSE Guide A Glasgow region for base temperature of 18.5 °C.*

[2] *Weekly Factor taken from CIBSE Guide B-Table 18.11, assuming a heavyweight building.*

[3] *Response Factor taken from CIBSE Guide B-Table 18.12, assuming a heavyweight building.*

[4] *Daily Factor taken from CIBSE Guide B-Table 18.13, assuming a heavyweight building. This factor is not applicable to continuously occupied spaces.*

[5] *Factor for boiler seasonal efficiency = 86%. Distribution losses in the system = additional 10%.*

Brookfield

AIR HEATING

The air ventilation heat load for all the air handling units was calculated using the supply air volume, the temperature difference, the heat reclaim factor (derived from % of supply air lost to space, % of supply air passed through heat recovery and lost to space and % of supply air passed through heat recovery returned to plant) and a conversion factor to convert into GJ. The degree-day method was then used along with correction factors for the operating hours to calculate the yearly thermal energy for air heating. Factors for the seasonal efficiency of the boiler and the distribution losses were then incorporated into the final energy consumption figure.

TOTAL ANNUAL ENERGY REQUIREMENT FOR AIR HEATING

DEGREE DAY[1]	DESIGN TEMP. (°C)		THERMAL WHEEL EFFICIENCY[2]	PLATE HEAT EXCHANGER EFFICIENCY[2]	TEMPERATURE RATIO[3]
	INDOOR	OUTDOOR			
3517	21	-6	0.3	0.45	1

AIR VENTILATION HEAT LOAD				EQUIVALENT HOURS	NET HEAT (GJ/YEAR)
AHU UNIT		SUPPLY AIR VOL (m^3/s)	HEAT LOAD (kW)		
21AHU01		1.72	17.01	3126	191
21AHU02		1.72	17.01	3126	191
21AHU03		2.85	28.27	3126	318
21AHU04		3.11	30.80	3126	347
21AHU05		1.42	14.05	3126	158
21AHU06		1.45	14.40	3126	162
21AHU07		1.45	14.40	3126	162
21AHU08		0.30	2.97	3126	33
21AHU09		0.30	2.97	3126	33
21AHU10		0.30	2.97	3126	33
21AHU11		0.30	2.97	3126	33
21AHU12		0.30	2.97	3126	33
21AHU13		0.30	2.97	3126	33
21AHU14		0.30	2.97	3126	33
21AHU15		0.30	2.97	3126	33
21AHU16		0.30	2.97	3126	33
21AHU17		0.30	2.97	3126	33
21AHU18		1.78	17.62	3126	198
21AHU19		1.79	17.71	3126	199
21AHU20		2.46	24.43	3126	275
21AHU21		2.54	25.21	3126	284
21AHU22		2.02	20.07	3126	226
21AHU23		1.50	14.92	1340	72
21AHU24		1.12	11.08	1340	53
21AHU25		1.14	11.25	1340	54
21AHU26		1.73	17.19	3126	193
21AHU27		1.73	17.19	3126	193
21AHU28		1.60	15.88	3126	179
21AHU29		1.60	15.88	3126	179
21AHU30		2.38	23.56	3126	265
21AHU31		2.38	23.56	3126	265
21AHU32		1.35	13.35	1340	64
21AHU33		2.78	27.57	1340	133
21AHU34		0.92	9.07	1340	44
22AHU01		1.51	15.01	1340	72

Brookfield

AIR VENTILATION HEAT LOAD				EQUIVALENT HOURS	NET HEAT (GJ/YEAR)
AHU UNIT		SUPPLY AIR VOL (m^3/s)	HEAT LOAD (kW)		
22AHU02		1.51	15.01	2084	113
22AHU03		1.45	14.40	2084	108
22AHU04		1.45	14.40	2084	108
22AHU05		1.25	12.39	2084	93
22AHU06		1.25	12.39	2084	93
22AHU07		1.07	10.64	2084	80
22AHU08		0.99	9.86	2084	74
22AHU09		3.03	30.01	2084	225
22AHU10		3.03	30.01	2084	225
22AHU11		3.03	30.01	2084	225
22AHU12		3.03	30.01	2084	225
22AHU13		3.03	30.01	2084	225
22AHU14		3.03	30.01	2084	225
22AHU15		3.03	30.01	2084	225
22AHU16		3.03	30.01	2084	225
22AHU17		3.03	30.01	744	80
22AHU18		1.65	16.40	744	44
22AHU19		1.65	16.40	1340	79
22AHU20		2.01	19.89	1954	140
22AHU21		1.39	13.78	3126	155
22AHU22		0.44	4.36	791	12
22AHU23		1.87	18.58	2084	139
31AHU01		3.03	30.01	2084	225
31AHU02		3.03	30.01	2084	225
31AHU03		3.03	30.01	2084	225
31AHU04		3.03	30.01	2084	225
31AHU05		3.03	30.01	2084	225
31AHU06		3.03	30.01	2084	225
31AHU07		3.03	30.01	2084	225
31AHU08		3.03	30.01	2084	225
31AHU09		3.03	30.01	2084	225
31AHU10		3.03	30.01	2084	225
31AHU11		3.03	30.01	2084	225
31AHU12		3.03	30.01	2084	225
31AHU13		3.03	30.01	2084	225
31AHU14		3.03	30.01	2084	225
31AHU15		3.03	30.01	2084	225
31AHU16		3.03	30.01	2084	225
31AHU17		3.03	30.01	2084	225
31AHU18		3.03	30.01	2084	225
31AHU19		3.03	30.01	2084	225
31AHU20		3.03	30.01	2084	225
31AHU21		3.15	31.23	2084	234
31AHU22		3.22	31.93	2084	240
31AHU25		2.00	19.81	3126	223
31AHU26		2.02	20.07	744	54
31AHU27		2.53	25.04	744	67
31AHU28		1.66	16.49	2084	124
31AHU29		1.66	16.49	2084	124

Brookfield

AIR VENTILATION HEAT LOAD				EQUIVALENT HOURS	NET HEAT (GJ/YEAR)
AHU UNIT		SUPPLY AIR VOL (m^3/s)	HEAT LOAD (kW)		
31AHU30		1.84	18.23	2084	137
31AHU36		2.84	28.18	1340	136
31AHU37		3.03	30.01	1340	145
31AHU38		3.03	30.01	1340	145
31AHU39		0.99	9.86	1340	48
31AHU40		1.90	18.85	1340	91
31AHU41		3.47	34.38	1340	166
31AHU42		1.99	19.72	791	56
31AHU48		1.50	14.83	3126	167
31AHU52		1.43	14.13	1340	68
31AHU53		2.28	22.60	1340	109
31AHU54		1.63	16.14	1340	78
31AHU55		1.63	16.14	1340	78
31AHU56		1.85	18.32	1117	74
31AHU57		1.85	18.32	1117	74
31AHU58		2.38	23.64	1117	95
31AHU59		1.66	16.49	1117	66
31AHU60		0.84	8.38	1117	34
32AHU01		5.72	56.71	3126	638
32AHU02		6.05	60.03	1042	225
32AHU03		0.53	5.23	1954	37
32AHU04		0.44	4.36	940	15
33AHU01		5.09	50.43	1284	233
33AHU02		9.03	89.52	930	300
33AHU03		1.87	18.50	930	62
33AHU04		2.68	26.61	791	76
41AHU01		0.30	2.97	3126	33
41AHU02		0.30	2.97	3126	33
41AHU03		3.20	31.76	3126	357
41AHU05		1.24	12.30	930	41
41AHU06		1.80	17.89	930	60
41AHU07		0.49	4.89	1954	34
41AHU10		1.78	17.62	930	59
41AHU11		1.13	11.17	930	37
41AHU12		1.76	17.45	1954	123
41AHU13		0.30	2.97	3126	33
41AHU14		4.49	44.50	3126	501
41AHU15		0.30	2.97	3126	33
41AHU16		0.30	2.97	3126	33
41AHU17		1.31	13.00	3126	146
41AHU18		0.30	2.97	3126	33
41AHU19		0.30	2.97	3126	33
41AHU20		1.83	18.15	3126	204
41AHU21		1.05	10.38	3126	117
41AHU22		2.04	20.24	3126	228
41AHU23		0.30	2.97	3126	33
41AHU24		2.38	23.56	930	79
41AHU25		3.32	32.89	3126	370
41AHU26		0.44	4.36	3126	49
121AHU01		3.20	47.64	3126	536
121AHU02		3.24	48.16	3126	542

Brookfield

AIR VENTILATION HEAT LOAD				EQUIVALENT HOURS	NET HEAT (GJ/YEAR)
AHU UNIT		SUPPLY AIR VOL (m^3/s)	HEAT LOAD (kW)		
121AHU03		2.54	37.82	3126	426
121AHU04		3.08	45.80	3126	516
121AHU05		1.71	25.39	3126	286
121AHU06		3.20	47.64	3126	536
121AHU07		3.24	48.16	3126	542
121AHU08		2.54	37.82	3126	426
121AHU09		3.08	45.80	3126	516
121AHU10		1.71	25.39	3126	286
122AHU01		3.20	47.64	3126	536
122AHU02		3.24	48.16	3126	542
122AHU03		2.54	37.82	3126	426
122AHU04		3.08	45.80	3126	516
122AHU05		1.71	25.39	3126	286
122AHU06		3.20	47.64	3126	536
122AHU07		3.24	48.16	3126	542
122AHU08		2.54	37.82	3126	426
122AHU09		3.08	45.80	3126	516
122AHU10		1.71	25.39	3126	286

TOTAL THERMAL ENERGY FOR AIR HEATING (GJ/Year)	28748
TOTAL ENERGY CONSUMPTION FOR AIR HEATING (kWh/Year)	7985571
TOTAL INCLUDING BOILER SEASONAL AND DISTRIBUTION LOSSES (kWh/Year)[7]	9749825

Notes

[1] *Taken from CIBSE Guide A Glasgow region for base temperature of 18.5 °C.*

[2] *The Heat Reclaim Factor is the amount of heating required for ventilation air following recovery of heat from exhaust system. These factors have been derived from a 70% efficiency of a thermal wheel and 55% efficiency of a plate heat exchanger*

[3] *Temperature Ratio taken from CIBSE Guide B-Table 18.9 (from base temp of 15.5 °C).*

[4] *Weekly Factor taken from CIBSE Guide B-Table 18.11, assuming a heavyweight building.*

[5] *Response Factor taken from CIBSE Guide B-Table 18.12, assuming a heavyweight building.*

[6] *Daily Factor taken from CIBSE Guide B-Table 18.13, assuming a heavyweight building. This factor is not applicable to continuously occupied spaces (24 hour).*

[7] *Factor for boiler seasonal efficiency = 86%. Distribution losses in the system = additional 5%.*

Brookfield

HOT WATER SERVICES

The total yearly hot water services heat load was derived from obtaining the total hot water consumption per year. This figure was achieved by applying a consumption figure for each bed then multiplying this figure by the total number of beds within the hospital. A conversion factor was applied to the yearly consumption figure to convert this into kWh per year. Factors for the seasonal efficiency of the boiler and the distribution losses was then incorporated into the final energy consumption figure.

HWS HEAT LOAD

CONSUMPTION (LITRES/BED/DAY)[1]	NO. OF BEDS	ANNUAL CONSUMPTION (LITRES)	TOTAL (kJ/YEAR)[2]	TOTAL ENERGY CONSUMPTION (kWh/YEAR)
135	1435	70709625	14778311.63	4105087

TOTAL INCLUDING +30% FOR NON-BEDDED AREAS (kWh/Year)	5336613
TOTAL INCLUDING BOILER SEASONAL EFFICIENCY AND DISTRIBUTION LOSSES (kWh/Year)[3]	6988421

Notes

[1] *Based on CIBSE Guide G*

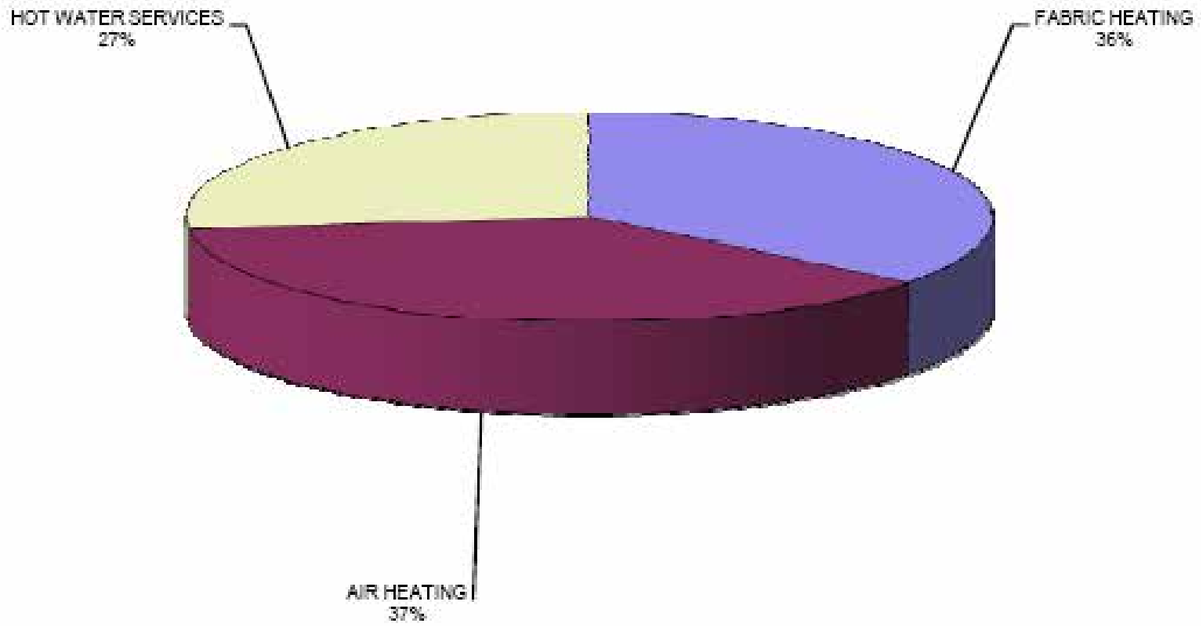
[2] *The total energy per year required raise the water temperature from 10°C and distribute at 60°C.*

[3] *Factor for boiler seasonal efficiency = 84%. Distribution losses in the system = additional 10%.*

Brookfield

ESTIMATED ANNUAL FOSSIL FUEL ENERGY CONSUMPTION SUMMARY

FABRIC HEATING	9247803	kWh/Year
AIR HEATING	9749825	kWh/Year
HOT WATER SERVICES	6988421	kWh/Year
FOSSIL FUEL ENERGY CONSUMPTION TOTAL	25986050	kWh/Year



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Brookfield

APPENDIX A - SUMMARY OF DEPARTMENT AREAS

DEPARTMENT	FLOOR	FLOOR AREA (m^2)		
		24HR	12HR	TOTAL
Basement	B	4329		4329.00
NCH Entrance	G	1483		1483.00
NCH Entrance Support	G		385.1	385.10
NCH OPD 1	G		561.3	561.30
NCH OPD 2	G		335.5	335.50
NCH OPD 3	G		222	222.00
NCH OPD 4	G		300.7	300.70
NCH OPD 5	G		478	478.00
NCH OPD 6	G		311.4	311.40
NCH OPD 7	G		448	448.00
NCH OPD 8	G		308.6	308.60
NCH Child Protection	G	121.8		121.80
NCH Observation Ward	G	849.2		849.20
NCH Emercency Department	G	1995.2		1995.20
NCH Radiology	G		1851.9	1851.90
NCH Rehabilitation	G		955.8	955.80
NCH Atrium	G	Part of Entrance		
NSGH Main Entrance	G	1225		1225.00
NSGH Retail / Cores	G		3665.6	3665.60
Local Pharmacy	G		284.4	284.40
NSGH Rehab & Therapies	G		1009	1009.00
NSGH OPD	G		1449	1449.00
NSGH Discharge Lounge	G		185	185.00
NSGH Acute Assessment	G	5645.7		5645.70
NSGH Emergency Department	G	2638.4		2638.40
NSGH Radiology	G		2070.9	2070.90
Circulation / Cores	G	2287		2287.00
NCH Critical Care (PICU)	1	1686.3		1686.30
NCH PICU Support 1	1	179.6		179.60
NCH PICU Support 2	1	319		319.00
NCH MDU	1		454.1	454.10
NCH 23 Hr Unit	1	967.2		967.20
NCH Cardiology Ward	1	861.8		861.80
NCH Special Needs	1		33.3	33.30
NCH Theatres	1	3191.8		3191.80
NCH Radiology	1		1150.7	1150.70
NSGH Critical Care	1	6283.1		6283.10
NSGH Radiology	1		2471.4	2471.40
Nuclear Medicine	1		834.2	834.20
Chapel	1		152.2	152.20
Restaurant/Visitor Dining/WCs	1		1067.3	1067.30
NSGH OPD	1		2460	2460.00
NSGH MDU	1		849.1	849.10
NSGH Stroke Ward	1	1422.4		1422.40
Circulation / Cores	1	3727		3727.00
NCH Acute Receiving Ward	2	1681		1681.00
Aseptic Suite	2	498.7		498.70
Ward Support 1	2	160		160.00
Ward Support 2	2	228.3		228.30
NCH Teenager Cancer Trust	2		89.1	89.10
NCH Schiehallion Ward	2	1105		1105.00
Ward Support 3	2	59		59.00

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DEPARTMENT	FLOOR	FLOOR AREA (m^2)		
		24HR	12HR	TOTAL
NCH Day Case Unit	2		423.2	423.20
Equipment Store	2	230.8		230.80
Sterile Store	2	188.4		188.40
Medical Physics	2		812.4	812.40
NSGH Endoscopy	2		441.8	441.80
Decontamination	2	452.8		452.80
NSGH Theatres	2	6793.6		6793.60
Telephone Services	2	151		151.00
NSGH Renal	2		1480	1480.00
NSGH Dermatology	2		754	754.00
Hotel Services	2	665		665.00
Health Records / Library / Meeting Rooms	2		605	605.00
Circulation / Cores	2	3151		3151.00
NCH In-Patient Ward 1	3	1218.4		1218.40
NCH Ward Support 1	3	502.9		502.90
NCH Ward Support 2	3	544.6		544.60
NCH In-Patient Ward 2	3	1136.4		1136.40
NCH Ward Support 3	3	212.1		212.10
NCH In-Patient Ward 3	3	1072.5		1072.50
NCH Nephrology / Renal	3		121.9	121.90
Kitchen	3		953.7	953.70
Staff Areas (Change, Accom, Stores)	3	846.7		846.70
Circulation / Cores	3	1800		1800.00
NCH DCFP	4		859.5	859.50
Admin Support	4		283.9	283.90
Medi-Cinema	4		195.6	195.60
Wards	4	6652		6652.00
Wards	5	6475		6475.00
Wards	6	6475		6475.00
Wards	7	6475		6475.00
Wards	8	6475		6475.00
Wards	9	6475		6475.00
Wards	10	6475		6475.00
Wards	11	6475		6475.00
TOTALS		113887.70	30360.90	

GROSS OCCUPIED FLOOR AREA	145202.30	m^2
LESS 6% ALLOWANCE FOR INTERNAL WALLS	8712.14	m^2
NET OCCUPIED FLOOR AREA	136490.16	m^2

Notes

[1] *The above 24hr and 12hr floor areas are used for the calculation of Electrical and Mechanical energy consumption.*

[2] *See Appendix D - Department Operating Hours for further information on the 24/12 hour department splits.*

[3] *The departmental areas have been taken from the Schedule Of Accommodation spreadsheet and NA 1:500 plans*

Brookfield

APPENDIX B - SUMMARY OF DEPARTMENT VOLUMES

LEVEL	GROSS INTERNAL AREA	LESS 6% FOR INTERNAL WALLS	HEATED INTERNAL AREA	STOREY HEIGHT	HEATED VOLUME
Basement	4329	260	4069	3.6	14649
Ground Floor	31067.50	1864	29203	4.2	122654.49
First Floor	28110.50	1687	26424	4.2	110980.254
Second Floor	19970.10	1198	18772	4.2	78841.9548
Third Floor	8409.20	505	7905	3.5	27666.268
Fourth Floor	7991.00	479	7512	3.5	26290.39
Fifth Floor	6475.00	389	6087	3.5	21302.75
Sixth Floor	6475.00	389	6087	3.5	21302.75
Seventh Floor	6475.00	389	6087	3.5	21302.75
Eighth Floor	6475.00	389	6087	3.5	21302.75
Nineth Floor	6475.00	389	6087	3.5	21302.75
Tenth Floor	6475.00	389	6087	3.5	21302.75
Eleventh Floor	6475.00	389	6087	3.5	21302.75

TOTAL VOLUME 530202 m^3

Brookfield

APPENDIX C - AHU OPERATING HOURS

AHU REF.[1]	MON.	TUE.	WED.	THUR.	FRI.	SAT.	SUN.	Department
21AHU01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 10 Bed Unit
21AHU02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 10 Bed Unit
21AHU03	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 10 Bed Unit
21AHU04	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 10 Bed Unit
21AHU05	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Support
21AHU06	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 9 Bed Unit
21AHU07	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 9 Bed Unit
21AHU08	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU09	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU10	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU11	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU12	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU13	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU14	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU15	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU16	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU17	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU Isolation Room
21AHU18	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 10 Bed Unit
21AHU19	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU 10 Bed Unit
21AHU20	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU
21AHU21	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU
21AHU22	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	CCU
21AHU23	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	MRI Suite
21AHU24	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Acute Assessment
21AHU25	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Acute Assessment
21AHU26	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Emergency Dept
21AHU27	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Emergency Dept
21AHU28	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Emergency Dept
21AHU29	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Emergency Dept
21AHU30	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Emergency Dept
21AHU31	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Emergency Dept
21AHU32	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	NCH Radiology
21AHU33	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	NCH Radiology
21AHU34	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Emergency Resus
22AHU01	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Interventional Radiology/ Cath Lab
22AHU02	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Interventional Radiology/ Cath Lab
22AHU03	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	NCH Theatres Prep & Holding
22AHU04	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	NCH Theatres Prep & Holding
22AHU05	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	NCH Theatres Recovery
22AHU06	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	NCH Theatres Recovery
22AHU07	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	NCH Theatres Recovery
22AHU08	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	NCH Theatres Support
22AHU09	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Cardiac Theatre
22AHU10	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Cardiac Theatre
22AHU11	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Ultra Clean Theatre
22AHU12	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Ultra Clean Theatre
22AHU13	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	UC Theatre
22AHU14	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Theatre
22AHU15	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Theatre
22AHU16	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Theatre
22AHU17	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Theatre
22AHU18	0830-1630	0830-1630	0830-1630	0830-1630	0830-1630			NCH Rehab
22AHU19	0830-1630	0830-1630	0830-1630	0830-1630	0830-1630			NCH Rehab

Brookfield

AHU REF.[1]	MON.	TUE.	WED.	THUR.	FRI.	SAT.	SUN.	Department
22AHU20	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	NCH Radiology Admin
22AHU21	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	Retail/ Entrance Support/ Café
22AHU22	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Sterile Store
22AHU23	0830-1700	0830-1700	0830-1700	0830-1700	0830-1700			Medical Physics
31AHU01	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU02	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU03	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU04	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU05	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU06	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU07	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU08	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU09	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU10	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU11	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU12	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU13	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU14	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU15	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU16	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU17	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU18	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU19	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU20	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU21	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU22	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre
31AHU25	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Decontamination
31AHU26	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700			Endoscopy
31AHU27	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700			Addos
31AHU28	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre Support/ Staff Change
31AHU29	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre Support/ Staff Change
31AHU30	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	Theatre Support/ Staff Change
31AHU36	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology Support
31AHU37	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology-Intervential Imaging Theatre 1
31AHU38	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology-Intervential Imaging Theatre 2
31AHU39	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	CT Suite
31AHU40	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology- General X-Ray & CT Suites
31AHU41	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology Recovery
31AHU42	0830-1700	0830-1700	0830-1700	0830-1700	0830-1700			Nuclear Medicine
31AHU48	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	NSGH Stroke Ward
31AHU52	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology Support
31AHU53	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology (MRI?)
31AHU54	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology- General X-Ray & CT Suites
31AHU55	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700	Radiology- General X-Ray & CT Suites
31AHU56	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000			Acute Assessment- Area 3
31AHU57	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000			Acute Assessment- Area 3
31AHU58	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000			Acute Assessment- Area 4
31AHU59	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000			Acute Assessment- Area 5
31AHU60	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000			Acute Assessment- Area 6
32AHU01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Hotel Services/ Health Records/ Staff Accommodation
32AHU02	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	Visitor Dining
32AHU03	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	Retail
32AHU04	0830-1700	0830-1700	0830-1700	0830-1700	0830-1700	0900-1300	0900-1300	Local Pharmacy
33AHU01	0830-2000	0830-2000	0830-2000	0830-2000	0830-2000	0830-2000		Renal Dialysis
33AHU02	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			NSGH OPD
33AHU03	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			NSGH MDU
33AHU04	0830-1630	0830-1630	0830-1630	0830-1630	0830-1630			NSGH Rehab & Therapies/ Dermatology
41AHU01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room

Brookfield

AHU REF.[1]	MON.	TUE.	WED.	THUR.	FRI.	SAT.	SUN.	Department
41AHU02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU03	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Ward Areas
41AHU05	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			OPD
41AHU06	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			OPD
41AHU07	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	Entrance Support
41AHU10	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			OPD
41AHU11	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			OPD
41AHU12	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	Retail
41AHU13	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU14	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Critical Care
41AHU15	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU16	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU17	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
41AHU18	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU19	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU20	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
41AHU21	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	Medi Cinema
41AHU22	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	Concourse
41AHU23	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
41AHU24	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			Day Case Unit
41AHU25	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Accommodation
41AHU26	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800			Renal Unit
121AHU01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU03	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU04	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU05	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU06	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU07	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU08	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU09	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
121AHU10	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU03	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU04	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU05	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU06	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU07	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU08	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU09	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
122AHU10	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Wards
31AHU03A	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
31AHU04A	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
31AHU05A	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
31AHU06A	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
31AHU07A	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	Isolation Room
31DE01	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Dirty Extract
31DE02	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Dirty Extract
31DE03	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Dirty Extract
31DE04	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	General Dirty Extract
121CE01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Clean Extract
121CE02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Clean Extract
121DE01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract
121DE02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract
122CE01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Clean Extract
122CE02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Clean Extract
122CE03	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Clean Extract
122DE01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract
122DE02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract
122DE03	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract
22DE01	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract
22DE02	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	General Dirty Extract

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APPENDIX D - DEPARTMENT OPERATING HOURS

FLOOR	DEPARTMENT	MON.	TUE.	WED.	THUR.	FRI.	SAT.	SUN.
B	Basement	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
G	NCH Entrance	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200
G	NCH Entrance Support	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200
G	NCH OPD 1	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 2	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 3	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 4	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 5	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 6	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 7	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH OPD 8	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NCH Child Protection	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400		
G	NCH Observation Ward	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400		
G	NCH Emercency Department	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
G	NCH Radiology	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700
G	NCH Rehabilitation	0830-1630	0830-1630	0830-1630	0830-1630	0830-1630		
G	NCH Atrium	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200
G	NSGH Main Entrance	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200
G	NSGH Retail / Cores	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200	0700-2200
G	Local Pharmacy	0830-1700	0830-1700	0830-1700	0830-1700	0830-1700	0900-1300	0900-1300
G	NSGH Rehab & Therapies	0830-1630	0830-1630	0830-1630	0830-1630	0830-1630		
G	NSGH OPD	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NSGH Discharge Lounge	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
G	NSGH Acute Assessment	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000		
G	NSGH Emergency Department	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
G	NSGH Radiology	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700
G	Circulation / Cores	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NCH Critical Care (PICU)	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NCH PICU Support 1	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NCH PICU Support 2	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NCH MDU	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000		
1	NCH 23 Hr Unit	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NCH Cardiology Ward	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NCH Special Needs	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000		
1	NCH Theatres	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700
1	NCH Radiology	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700
1	NSGH Critical Care	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	NSGH Radiology	0800-2000	0800-2000	0800-2000	0800-2000	0900-1700	0900-1700	0900-1700
1	Nuclear Medicine	0830-1700	0830-1700	0830-1700	0830-1700	0830-1700		
1	Chapel	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
1	Restaurant/Visitor Dining/WCs	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700
1	NSGH OPD	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
1	NSGH MDU	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000		
1	NSGH Stroke Ward	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
1	Circulation / Cores	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	NCH Acute Receiving Ward	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	Aseptic Suite	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	Ward Support 1	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	Ward Support 2	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	NCH Teenager Cancer Trust	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
2	NCH Schiehallion Ward	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	Ward Support 3	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	NCH Day Case Unit	0800-1800	0800-1800	0800-1800	0800-1800	0800-1800		
2	Equipment Store	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400

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FLOOR	DEPARTMENT	MON.	TUE.	WED.	THUR.	FRI.	SAT.	SUN.
2	Sterile Store	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	Medical Physics	0830-1700	0830-1700	0830-1700	0830-1700	0830-1700		
2	NSGH Endoscopy	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
2	Decontamination	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	NSGH Theatres	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700	0800-1700
2	Telephone Services	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	NSGH Renal	0830-2000	0830-2000	0830-2000	0830-2000	0830-2000	0830-2000	
2	NSGH Dermatology	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
2	Hotel Services	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
2	Health Records / Library / Meeting Rooms	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
2	Circulation / Cores	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH In-Patient Ward 1	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH Ward Support 1	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH Ward Support 2	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH In-Patient Ward 2	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH Ward Support 3	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH In-Patient Ward 3	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	NCH Nephrology / Renal	0830-2000	0830-2000	0830-2000	0830-2000	0830-2000	0830-2000	
3	Kitchen	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700
3	Staff Areas (Change, Accom, Stores)	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
3	Circulation / Cores	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
4	NCH DCFP	0800-2000	0800-2000	0800-2000	0800-2000	0800-2000		
4	Admin Support	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
4	Medi-Cinema	0900-1700	0900-1700	0900-1700	0900-1700	0900-1700		
4	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
5	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
6	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
7	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
8	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
9	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
10	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400
11	Wards	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400	0000-2400

Brookfield

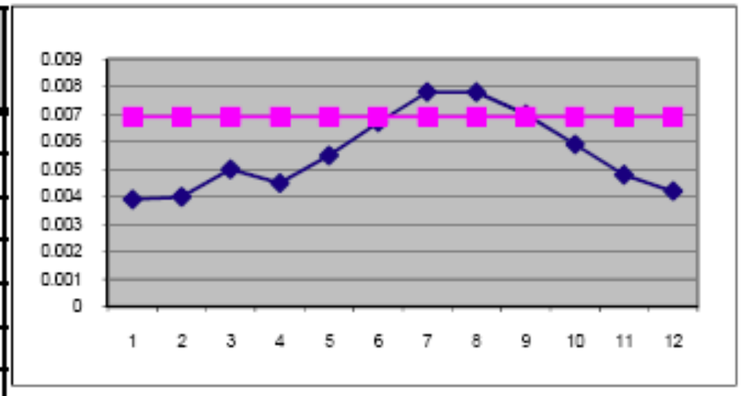
APPENDIX E - STEAM DATA

HUMDIFICATION

Using the dry-bulb and wet bulb data for the average temperature (°C) over 24 hours taken from Table 3.11 of CIBSE Guide J, the Moisture Content of Dry Air (kJ/kg3) was extracted from the CIBSE Psychrometric Chart (10 to +60oC), figure 1.2 in CIBSE Guide C. Using the yearly profile for the Moisture Content, the days which were below 0.008339 kg/kg3 (the moisture content for 45% relative humidity at 21oC) are the days which require the addition of moisture. The total steam required to maintain the humidity level was calculated by multiplying the difference in moisture content with time that the moisture content is below that of 45% relative humidity at 21oC. Using the total steam required to maintain the humidity level, the humidification load was calculated by determining the steam usage for each air handling unit associated with the steam system. The total yearly thermal energy was then determined by multiplying the steam usage by the sum of the enthalpy of steam and the enthalpy of saturated steam.

AVERAGE EXTERNAL AIR CONDITION

MONTH	AVERAGE TEMP (°C) OVER 24 HOURS		% SAT.	MOISTURE CONTENT (kg/kg^3)
	DRY-BULB	WET-BULB		
January	3.3	2.3		0.0039
February	3.6	2.5		0.004
March	5.3	3.9		0.005
April	7	5.3		0.0045
May	9.9	7.9		0.0055
June	12.8	10.6		0.0067
July	14.7	12.5		0.0078
August	14.4	12.3		0.0078
September	12.1	10.4		0.007
October	9.3	8		0.0059
November	6.1	5		0.0048
December	4	3.1		0.0042



Brookfield

AVERAGE MONTHLY MOISTURE ADDITION

MONTH	DAYS	g_o	TIME ADDITIONAL MOISTURE IS REQUIRED (SECONDS)	g AT 21°C & 45% R.H	DELTA g	STEAM REQUIRED (kg_{steam}/kg_{air}/month)
January	31	0.0039	2678400	0.006914	0.003014	8072.70
February	28	0.004	2419200	0.006914	0.002914	7049.55
March	31	0.005	2678400	0.006914	0.001914	5126.46
April	30	0.0045	2592000	0.006914	0.002414	6257.09
May	31	0.0055	2678400	0.006914	0.001414	3787.26
June	30	0.0067	2592000	0.006914	0.000214	554.69
July	31	0.0078	2678400	0.006914	-0.000886	-2373.06
August	31	0.0078	2678400	0.006914	-0.000886	-2373.06
September	30	0.007	2592000	0.006914	-8.6E-05	-222.91
October	31	0.0059	2678400	0.006914	0.001014	2715.90
November	30	0.0048	2592000	0.006914	0.002114	5479.49
December	31	0.0042	2678400	0.006914	0.002714	7269.18

TOTAL STEAM REQUIRED TO MAINTAIN HUMIDITY LEVEL (kg_{steam}/kg_{air}/year)	41343.26

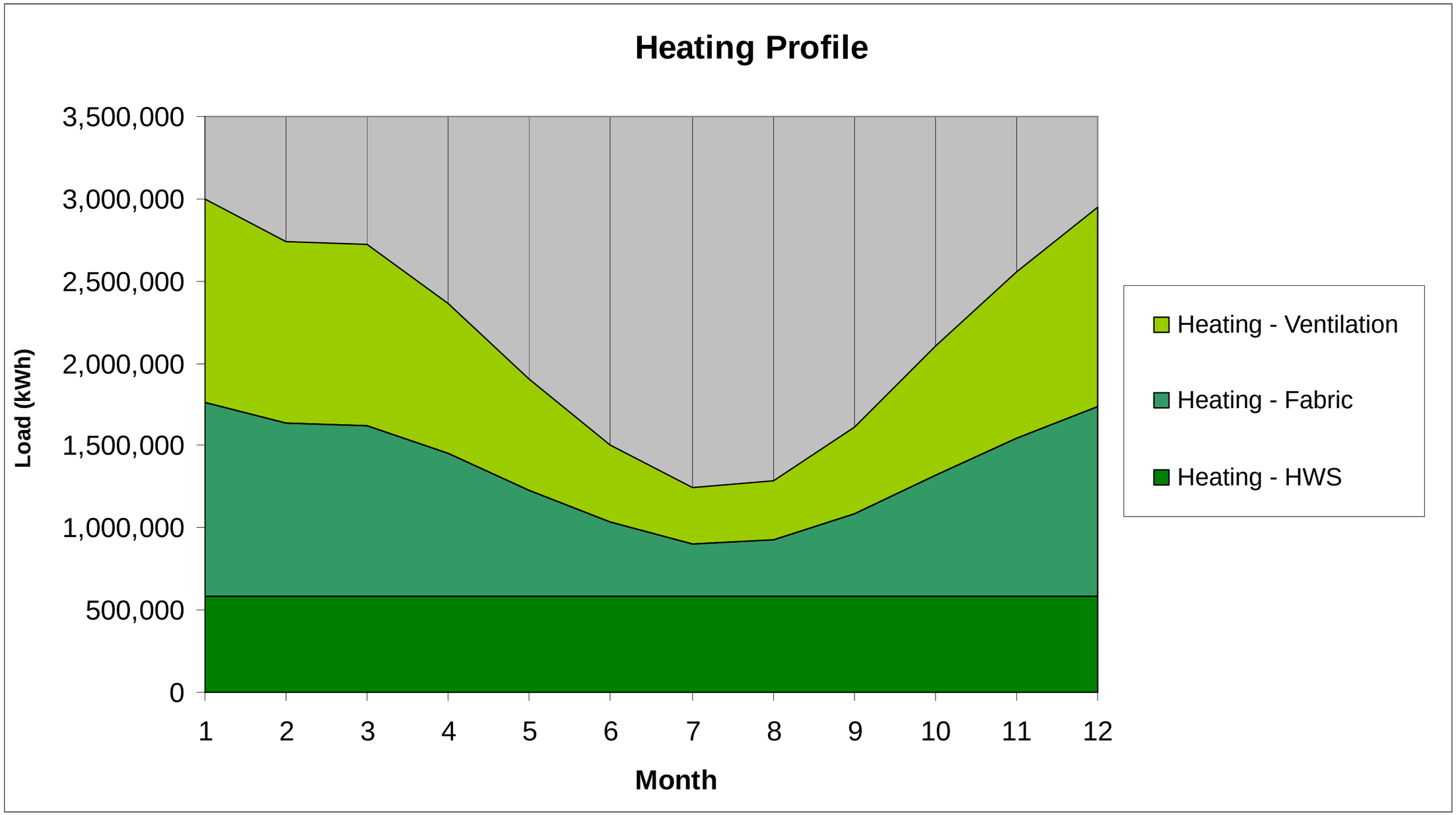
Brookfield

APPENDIX B

CALCULATION RESULTS

Brookfield

Building Heat Load Profile



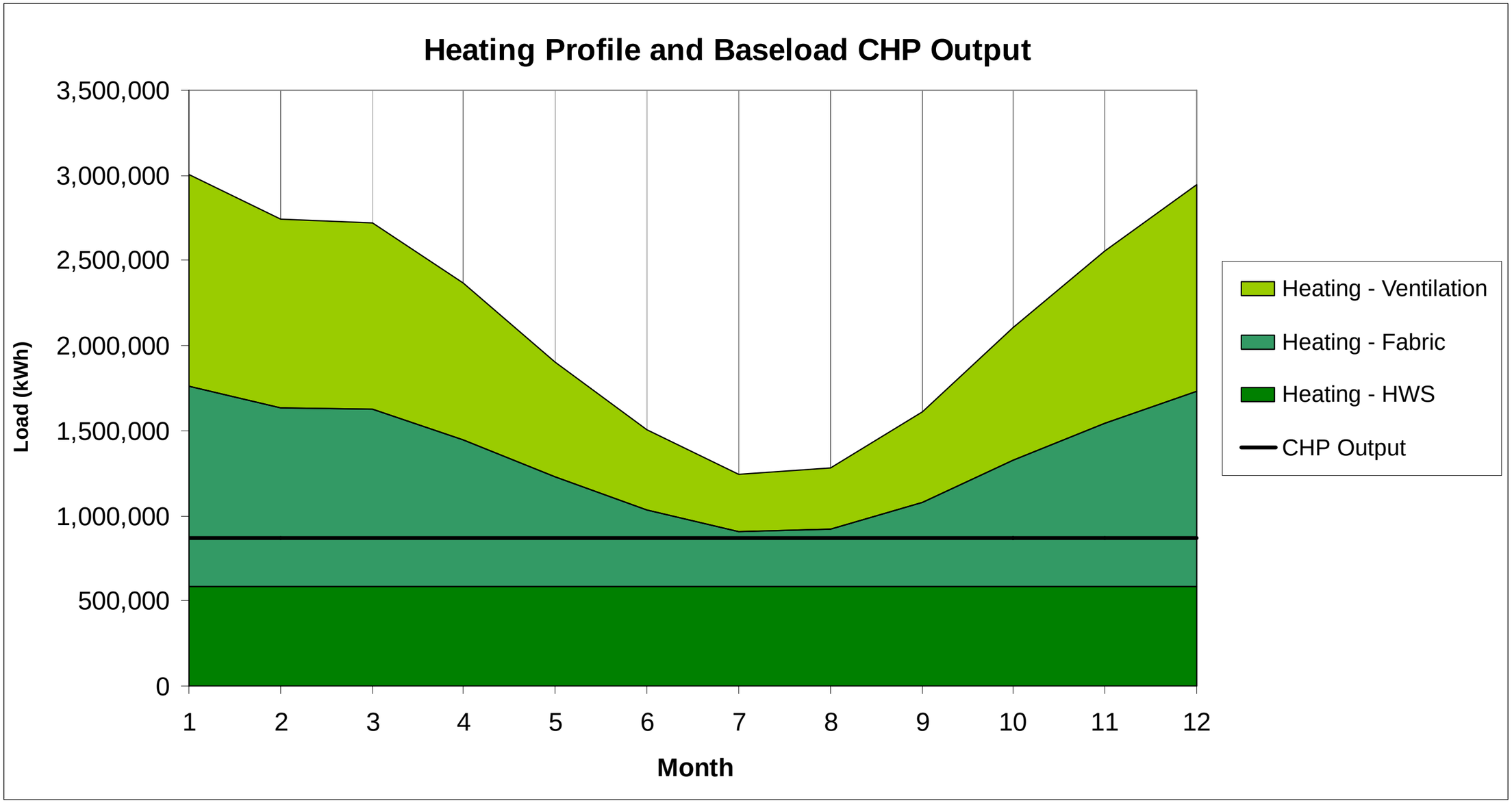
Brookfield

Heat Load

Month	Degree Days	% Total	Heat Demand as % of Total			Total Heat Load kWh
			Heating kWh	Air Heating kWh	Hot Water kWh	
Jan	448	13%	1,177,997	1,241,945	582,368	3,002,311
Feb	400	11%	1,051,783	1,108,880	582,368	2,743,031
Mar	396	11%	1,041,265	1,097,791	582,368	2,721,425
Apr	330	9%	867,721	914,826	582,368	2,364,915
May	245	7%	644,217	679,189	582,368	1,905,774
Jun	171	5%	449,637	474,046	582,368	1,506,052
Jul	122	3%	320,794	338,208	582,368	1,241,371
Aug	130	4%	341,830	360,386	582,368	1,284,584
Sep	190	5%	499,597	526,718	582,368	1,608,683
Oct	282	8%	741,507	781,760	582,368	2,105,636
Nov	365	10%	959,752	1,011,853	582,368	2,553,973
Dec	438	12%	1,151,703	1,214,223	582,368	2,948,294

Brookfield

CHP Unit Sized to Base Load



Brookfield

CHP unit

Size	1,250	kWe
Gives	1,385	kWt
Running	7,500	hours per year
	625	hours per month
Output	865,709	kWht per month

Elec	37.0%
Mech	41.0%
Waste	22.0%

Carbon Reduction - Heating

Month	Total Heat Load kWh	CHP Output kWh	CO_2 Offset (Heat) Kg (inc. Boiler Efficiency)
Jan	3,002,311	865,709	204,814
Feb	2,743,031	865,709	204,814
Mar	2,721,425	865,709	204,814
Apr	2,364,915	865,709	204,814
May	1,905,774	865,709	204,814
Jun	1,506,052	865,709	204,814
Jul	1,241,371	865,709	204,814
Aug	1,284,584	865,709	204,814
Sep	1,608,683	865,709	204,814
Oct	2,105,636	865,709	204,814
Nov	2,553,973	865,709	204,814
Dec	2,948,294	865,709	204,814

Carbon Offset - Electricity

Month	Electrical Generation kWh	CO_2 Offset Kg
Jan	781,250	443,750
Feb	781,250	443,750
Mar	781,250	443,750
Apr	781,250	443,750
May	781,250	443,750
Jun	781,250	443,750
Jul	781,250	443,750
Aug	781,250	443,750
Sep	781,250	443,750
Oct	781,250	443,750
Nov	781,250	443,750
Dec	781,250	443,750

Input Power - Gas

Month	Input Power kWh	CO_2 Produced Kg
Jan	2,111,486	409,628
Feb	2,111,486	409,628
Mar	2,111,486	409,628
Apr	2,111,486	409,628
May	2,111,486	409,628
Jun	2,111,486	409,628
Jul	2,111,486	409,628
Aug	2,111,486	409,628
Sep	2,111,486	409,628
Oct	2,111,486	409,628
Nov	2,111,486	409,628
Dec	2,111,486	409,628

Brookfield

Carbon Saved

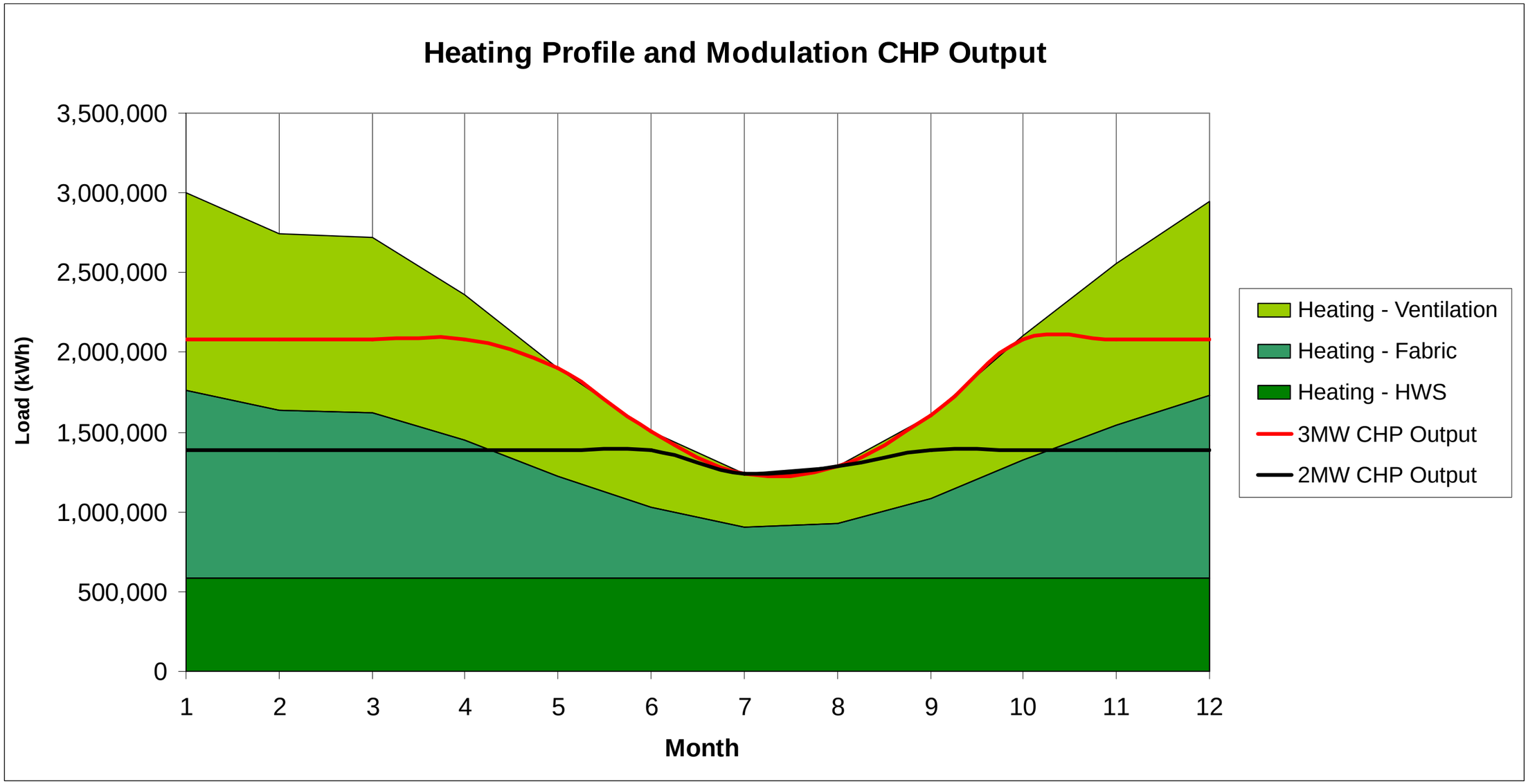
Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	409,628	204,814	443,750	-238,936
Feb	409,628	204,814	443,750	-238,936
Mar	409,628	204,814	443,750	-238,936
Apr	409,628	204,814	443,750	-238,936
May	409,628	204,814	443,750	-238,936
Jun	409,628	204,814	443,750	-238,936
Jul	409,628	204,814	443,750	-238,936
Aug	409,628	204,814	443,750	-238,936
Sep	409,628	204,814	443,750	-238,936
Oct	409,628	204,814	443,750	-238,936
Nov	409,628	204,814	443,750	-238,936
Dec	409,628	204,814	443,750	-238,936
				-2,867,230

Building Carbon Target

Gross Building Floor Area	136,490	m^2
Total Emissions	16,834,959	Kg CO_2 per year
Gives	123	Kg CO_2 per m^2 per year
With CHP, emissions drop to	13,967,730	Kg CO_2 per year
Which Gives	102	Kg CO_2 per m^2 per year

Brookfield

Modulating CHP Units



Brookfield

2MWe CHP Unit

CHP unit

Size	2,000	kWe	Elec	37.0%
			Mech	41.0%
Gives	2,216	kWt	Waste	22.0%
Running	7,500	hours per year		
	625	hours per month		
Output	1,385,135	kWht per month		

Carbon Reduction - Heating

Month	Total Heat Load kWh	CHP Output kWh	CO_2 Offset (Heat) Kg (inc. Boiler Efficiency)
Jan	3,002,311	1,385,135	327,703
Feb	2,743,031	1,385,135	327,703
Mar	2,721,425	1,385,135	327,703
Apr	2,364,915	1,385,135	327,703
May	1,905,774	1,385,135	327,703
Jun	1,506,052	1,385,135	327,703
Jul	1,241,371	1,241,371	293,690
Aug	1,284,584	1,284,584	303,914
Sep	1,608,683	1,385,135	327,703
Oct	2,105,636	1,385,135	327,703
Nov	2,553,973	1,385,135	327,703
Dec	2,948,294	1,385,135	327,703

Brookfield

Carbon Offset - Electricity

Month	Electrical Generation kWh	CO_2 Offset Kg
Jan	1,250,000	710,000
Feb	1,250,000	710,000
Mar	1,250,000	710,000
Apr	1,250,000	710,000
May	1,250,000	710,000
Jun	1,250,000	710,000
Jul	1,120,261	636,308
Aug	1,159,259	658,459
Sep	1,250,000	710,000
Oct	1,250,000	710,000
Nov	1,250,000	710,000
Dec	1,250,000	710,000

Input Power - Gas

Month	Input Power kWh	CO_2 Produced Kg
Jan	3,378,378	655,405
Feb	3,378,378	655,405
Mar	3,378,378	655,405
Apr	3,378,378	655,405
May	3,378,378	655,405
Jun	3,378,378	655,405
Jul	3,027,733	587,380
Aug	3,133,131	607,827
Sep	3,378,378	655,405
Oct	3,378,378	655,405
Nov	3,378,378	655,405
Dec	3,378,378	655,405

Brookfield

Carbon Saved

Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	655,405	327,703	710,000	-382,297
Feb	655,405	327,703	710,000	-382,297
Mar	655,405	327,703	710,000	-382,297
Apr	655,405	327,703	710,000	-382,297
May	655,405	327,703	710,000	-382,297
Jun	655,405	327,703	710,000	-382,297
Jul	587,380	293,690	636,308	-342,618
Aug	607,827	303,914	658,459	-354,545
Sep	655,405	327,703	710,000	-382,297
Oct	655,405	327,703	710,000	-382,297
Nov	655,405	327,703	710,000	-382,297
Dec	655,405	327,703	710,000	-382,297
				-4,520,136

Building Carbon Target

Gross Building Floor Area	136,490	m^2
Total Emissions	16,834,959	Kg CO_2 per year
Gives	123	Kg CO_2 per m^2 per year
With CHP, emissions drop to	12,314,823	Kg CO_2 per year
Which Gives	90	Kg CO_2 per m^2 per year

Brookfield

3MWe CHP Unit

CHP unit

Size	3,000	kWe	Elec	37.0%
			Mech	41.0%
Gives	3,324	kWt	Waste	22.0%
Running	7,500	hours per year		
	625	hours per month		
Output	2,077,703	kWht per month		

Carbon Reduction - Heating

Month	Total Heat Load kWh	CHP Output kWh	CO_2 Offset (Heat) Kg (inc. Boiler Efficiency)
Jan	3,002,311	2,077,703	491,554
Feb	2,743,031	2,077,703	491,554
Mar	2,721,425	2,077,703	491,554
Apr	2,364,915	2,077,703	491,554
May	1,905,774	1,905,774	450,878
Jun	1,506,052	1,506,052	356,310
Jul	1,241,371	1,241,371	293,690
Aug	1,284,584	1,284,584	303,914
Sep	1,608,683	1,608,683	380,591
Oct	2,105,636	2,077,703	491,554
Nov	2,553,973	2,077,703	491,554
Dec	2,948,294	2,077,703	491,554

Brookfield

Carbon Offset - Electricity

Month	Electrical Generation kWh	CO_2 Offset Kg
Jan	1,875,000	1,065,000
Feb	1,875,000	1,065,000
Mar	1,875,000	1,065,000
Apr	1,875,000	1,065,000
May	1,719,845	976,872
Jun	1,359,120	771,980
Jul	1,120,261	636,308
Aug	1,159,259	658,459
Sep	1,451,739	824,588
Oct	1,875,000	1,065,000
Nov	1,875,000	1,065,000
Dec	1,875,000	1,065,000

Input Power - Gas

Month	Input Power kWh	CO_2 Produced Kg
Jan	5,067,568	983,108
Feb	5,067,568	983,108
Mar	5,067,568	983,108
Apr	5,067,568	983,108
May	4,648,230	901,757
Jun	3,673,297	712,620
Jul	3,027,733	587,380
Aug	3,133,131	607,827
Sep	3,923,618	761,182
Oct	5,067,568	983,108
Nov	5,067,568	983,108
Dec	5,067,568	983,108

Brookfield

Carbon Saved

Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	983,108	491,554	1,065,000	-573,446
Feb	983,108	491,554	1,065,000	-573,446
Mar	983,108	491,554	1,065,000	-573,446
Apr	983,108	491,554	1,065,000	-573,446
May	901,757	450,878	976,872	-525,994
Jun	712,620	356,310	771,980	-415,670
Jul	587,380	293,690	636,308	-342,618
Aug	607,827	303,914	658,459	-354,545
Sep	761,182	380,591	824,588	-443,997
Oct	983,108	491,554	1,065,000	-573,446
Nov	983,108	491,554	1,065,000	-573,446
Dec	983,108	491,554	1,065,000	-573,446
				-6,096,946

Building Carbon Target

Gross Building Floor Area	136,490	m^2
Total Emissions	16,834,959	Kg CO_2 per year
Gives	123	Kg CO_2 per m^2 per year
With CHP, emissions drop to	10,738,014	Kg CO_2 per year
Which Gives	79	Kg CO_2 per m^2 per year

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Brookfield

3MWe Biofuel CHP Unit

Alternative Input Fuels - RME Biodiesel

Month	Input Power kWh	CO_2 Produced Kg	% Biodiesel
Jan	5,067,568	837,162	30%
Feb	5,067,568	837,162	30%
Mar	5,067,568	837,162	30%
Apr	5,067,568	837,162	30%
May	4,648,230	767,888	30%
Jun	3,673,297	606,829	30%
Jul	3,027,733	500,182	30%
Aug	3,133,131	517,593	30%
Sep	3,923,618	648,182	30%
Oct	5,067,568	837,162	30%
Nov	5,067,568	837,162	30%
Dec	5,067,568	837,162	30%

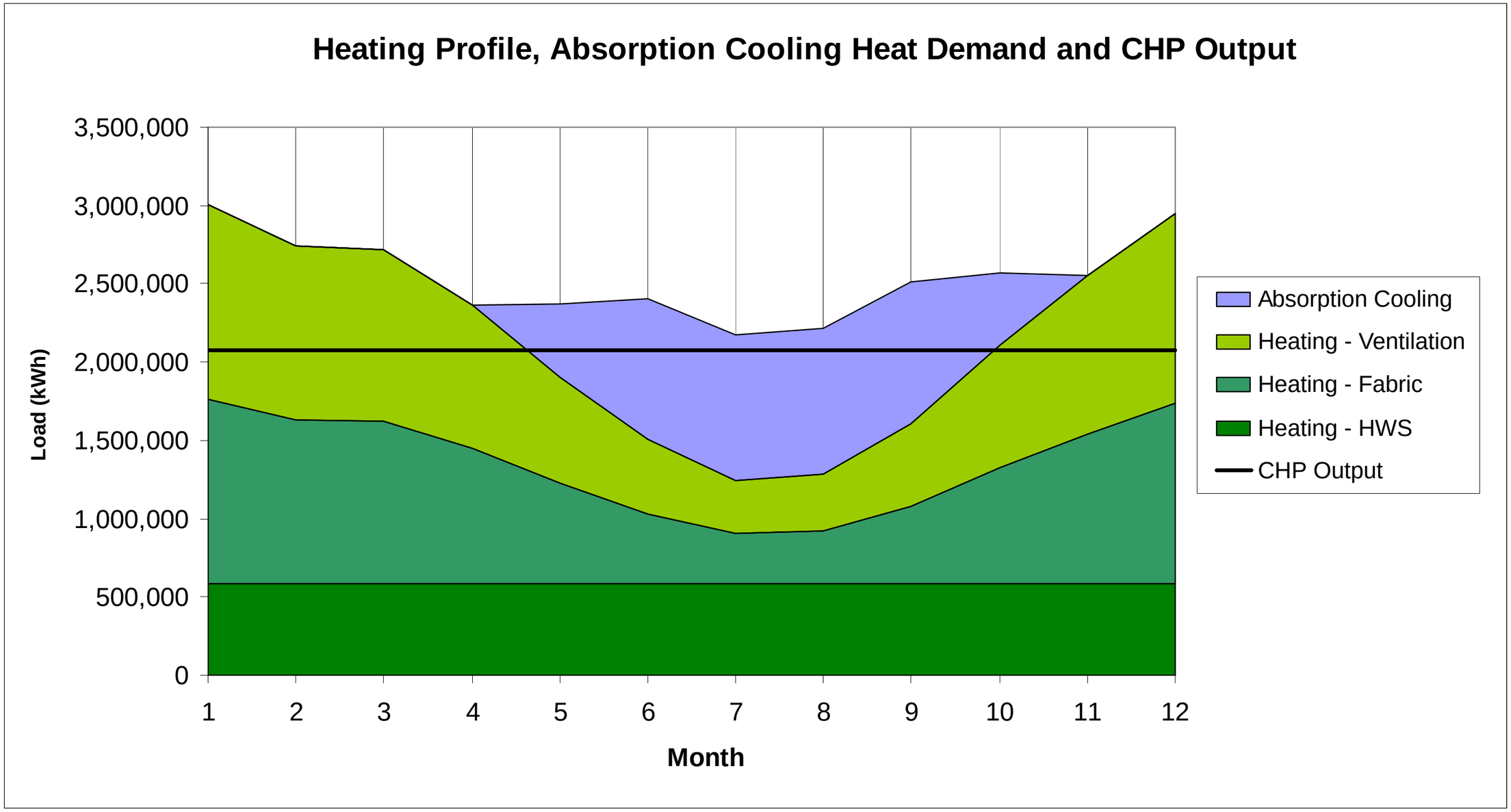
Carbon Saved

Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	837,162	491,554	1,065,000	-719,392
Feb	837,162	491,554	1,065,000	-719,392
Mar	837,162	491,554	1,065,000	-719,392
Apr	837,162	491,554	1,065,000	-719,392
May	767,888	450,878	976,872	-659,863
Jun	606,829	356,310	771,980	-521,461
Jul	500,182	293,690	636,308	-429,817
Aug	517,593	303,914	658,459	-444,779
Sep	648,182	380,591	824,588	-556,997
Oct	837,162	491,554	1,065,000	-719,392
Nov	837,162	491,554	1,065,000	-719,392
Dec	837,162	491,554	1,065,000	-719,392
				-7,648,660

Gives 67 Kg CO_2 per m^2 per year

Brookfield

CHP Units and Absorption Cooling



Brookfield

Cooling Load

Size	1000	kW
Efficiency	0.8	

Month	Running Hours	Cooling Load kWh	Heat Required kWh
Jan	0	0	0
Feb	0	0	0
Mar	0	0	0
Apr	0	0	0
May	372	372,000	465,000
Jun	720	720,000	900,000
Jul	744	744,000	930,000
Aug	744	744,000	930,000
Sep	720	720,000	900,000
Oct	372	372,000	465,000
Nov	0	0	0
Dec	0	0	0

CHP unit

Size	3,000	kWe	Elec	37.0%
			Mech	41.0%
Gives	3,324	kWt	Waste	22.0%
Running	7,500	hours per year	Chiller SEER	4.5
	625	hours per month		
Output	2,077,703	kWht per month		

Brookfield

Carbon Reduction - Cooling

Month	Heat Required For Cooling Load kWh	CHP Picks Up kWh	CO_2 Offset Kg (Offsetting main chiller input)
Jan	0	0	0
Feb	0	0	0
Mar	0	0	0
Apr	0	0	0
May	465,000	465,000	43,607
Jun	900,000	900,000	84,400
Jul	930,000	930,000	87,213
Aug	930,000	930,000	87,213
Sep	900,000	900,000	84,400
Oct	465,000	465,000	43,607
Nov	0	0	0
Dec	0	0	0

Carbon Reduction - Heating

Month	Total Heat Load kWh	Plus Cooling Load kWh	CHP Output kWh	CHP Picks Up kWh (Heat)	CO_2 Offset (Heat) Kg (inc. Boiler Efficiency)
Jan	3,002,311	3,002,311	2,077,703	2,077,703	491,554
Feb	2,743,031	2,743,031	2,077,703	2,077,703	491,554
Mar	2,721,425	2,721,425	2,077,703	2,077,703	491,554
Apr	2,364,915	2,364,915	2,077,703	2,077,703	491,554
May	1,905,774	2,370,774	2,077,703	1,612,703	381,542
Jun	1,506,052	2,406,052	2,077,703	1,177,703	278,627
Jul	1,241,371	2,171,371	2,077,703	1,147,703	271,530
Aug	1,284,584	2,214,584	2,077,703	1,147,703	271,530
Sep	1,608,683	2,508,683	2,077,703	1,177,703	278,627
Oct	2,105,636	2,570,636	2,077,703	1,612,703	381,542
Nov	2,553,973	2,553,973	2,077,703	2,077,703	491,554
Dec	2,948,294	2,948,294	2,077,703	2,077,703	491,554

Brookfield

Carbon Offset - Electricity

Month	Electrical Generation kWh	CO_2 Offset Kg
Jan	1,875,000	1,065,000
Feb	1,875,000	1,065,000
Mar	1,875,000	1,065,000
Apr	1,875,000	1,065,000
May	1,875,000	1,065,000
Jun	1,875,000	1,065,000
Jul	1,875,000	1,065,000
Aug	1,875,000	1,065,000
Sep	1,875,000	1,065,000
Oct	1,875,000	1,065,000
Nov	1,875,000	1,065,000
Dec	1,875,000	1,065,000

Input Power - Gas

Month	Input Power kWh	CO_2 Produced Kg
Jan	5,067,568	983,108
Feb	5,067,568	983,108
Mar	5,067,568	983,108
Apr	5,067,568	983,108
May	5,067,568	983,108
Jun	5,067,568	983,108
Jul	5,067,568	983,108
Aug	5,067,568	983,108
Sep	5,067,568	983,108
Oct	5,067,568	983,108
Nov	5,067,568	983,108
Dec	5,067,568	983,108

Brookfield

Carbon Saved

Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Cooling) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	983,108	491,554	0	1,065,000	-573,446
Feb	983,108	491,554	0	1,065,000	-573,446
Mar	983,108	491,554	0	1,065,000	-573,446
Apr	983,108	491,554	0	1,065,000	-573,446
May	983,108	381,542	43,607	1,065,000	-507,040
Jun	983,108	278,627	84,400	1,065,000	-444,919
Jul	983,108	271,530	87,213	1,065,000	-440,635
Aug	983,108	271,530	87,213	1,065,000	-440,635
Sep	983,108	278,627	84,400	1,065,000	-444,919
Oct	983,108	381,542	43,607	1,065,000	-507,040
Nov	983,108	491,554	0	1,065,000	-573,446
Dec	983,108	491,554	0	1,065,000	-573,446
					-6,225,865

Building Carbon Target

Gross Building Floor Area	136,490	m^2
Total Emissions	16,834,959	Kg CO_2 per year
Gives	123	Kg CO_2 per m^2 per year
With CHP, emissions drop to	10,609,095	Kg CO_2 per year
Which Gives	78	Kg CO_2 per m^2 per year

Brookfield

Biofuel CHP Unit and Absorption Cooling

Alternative Input Fuels - RME Biodiesel

Month	Input Power kWh	CO_2 Produced Kg	% Biodiesel
Jan	5,067,568	837,162	30%
Feb	5,067,568	837,162	30%
Mar	5,067,568	837,162	30%
Apr	5,067,568	837,162	30%
May	5,067,568	837,162	30%
Jun	5,067,568	837,162	30%
Jul	5,067,568	837,162	30%
Aug	5,067,568	837,162	30%
Sep	5,067,568	837,162	30%
Oct	5,067,568	837,162	30%
Nov	5,067,568	837,162	30%
Dec	5,067,568	837,162	30%

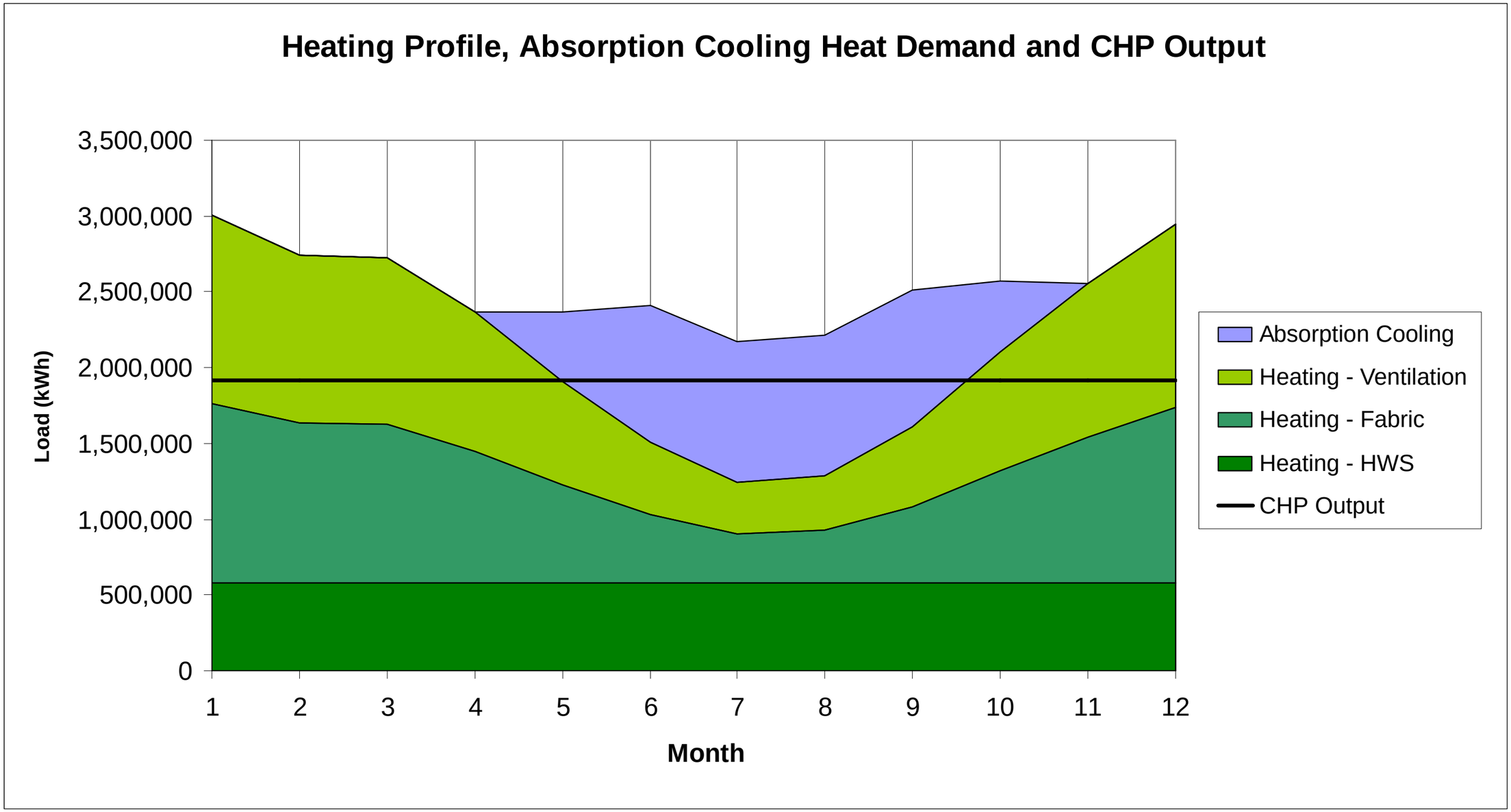
Carbon Saved

Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Cooling) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	837,162	491,554	0	1,065,000	-719,392
Feb	837,162	491,554	0	1,065,000	-719,392
Mar	837,162	491,554	0	1,065,000	-719,392
Apr	837,162	491,554	0	1,065,000	-719,392
May	837,162	381,542	43,607	1,065,000	-652,986
Jun	837,162	278,627	84,400	1,065,000	-590,865
Jul	837,162	271,530	87,213	1,065,000	-586,581
Aug	837,162	271,530	87,213	1,065,000	-586,581
Sep	837,162	278,627	84,400	1,065,000	-590,865
Oct	837,162	381,542	43,607	1,065,000	-652,986
Nov	837,162	491,554	0	1,065,000	-719,392
Dec	837,162	491,554	0	1,065,000	-719,392
					-7,977,216

Gives 65 Kg CO_2 per m^2 per year

Brookfield

CHP Units with Higher Electrical Output and Absorption Cooling



Brookfield

Cooling Load

Size	1000	kW
Efficiency	0.8	

Month	Running Hours	Cooling Load kWh	Heat Required kWh
Jan	0	0	0
Feb	0	0	0
Mar	0	0	0
Apr	0	0	0
May	372	372,000	465,000
Jun	720	720,000	900,000
Jul	744	744,000	930,000
Aug	744	744,000	930,000
Sep	720	720,000	900,000
Oct	372	372,000	465,000
Nov	0	0	0
Dec	0	0	0

CHP unit

Size	3,000	kWe	Elec	43.0%
			Mech	44.0%
Gives	3,070	kWt	Waste	13.0%
Running	7,500	hours per year	Chiller SEER	4.5
	625	hours per month		
Output	1,918,605	kWht per month		

Brookfield

Carbon Reduction - Cooling

Month	Heat Required For Cooling Load kWh	CHP Picks Up kWh	CO_2 Offset Kg (Offsetting main chiller input)
Jan	0	0	0
Feb	0	0	0
Mar	0	0	0
Apr	0	0	0
May	465,000	465,000	43,607
Jun	900,000	900,000	84,400
Jul	930,000	930,000	87,213
Aug	930,000	930,000	87,213
Sep	900,000	900,000	84,400
Oct	465,000	465,000	43,607
Nov	0	0	0
Dec	0	0	0

Carbon Reduction - Heating

Month	Total Heat Load kWh	Plus Cooling Load kWh	CHP Output kWh	CHP Picks Up kWh (Heat)	CO_2 Offset (Heat) Kg (inc. Boiler Efficiency)
Jan	3,002,311	3,002,311	1,918,605	1,918,605	437,893
Feb	2,743,031	2,743,031	1,918,605	1,918,605	437,893
Mar	2,721,425	2,721,425	1,918,605	1,918,605	437,893
Apr	2,364,915	2,364,915	1,918,605	1,918,605	437,893
May	1,905,774	2,370,774	1,918,605	1,453,605	331,764
Jun	1,506,052	2,406,052	1,918,605	1,018,605	232,482
Jul	1,241,371	2,171,371	1,918,605	988,605	225,634
Aug	1,284,584	2,214,584	1,918,605	988,605	225,634
Sep	1,608,683	2,508,683	1,918,605	1,018,605	232,482
Oct	2,105,636	2,570,636	1,918,605	1,453,605	331,764
Nov	2,553,973	2,553,973	1,918,605	1,918,605	437,893
Dec	2,948,294	2,948,294	1,918,605	1,918,605	437,893

Brookfield

Carbon Offset - Electricity

Month	Electrical Generation kWh	CO_2 Offset Kg
Jan	1,875,000	1,065,000
Feb	1,875,000	1,065,000
Mar	1,875,000	1,065,000
Apr	1,875,000	1,065,000
May	1,875,000	1,065,000
Jun	1,875,000	1,065,000
Jul	1,875,000	1,065,000
Aug	1,875,000	1,065,000
Sep	1,875,000	1,065,000
Oct	1,875,000	1,065,000
Nov	1,875,000	1,065,000
Dec	1,875,000	1,065,000

Input Power - Gas

Month	Input Power kWh	CO_2 Produced Kg
Jan	4,360,465	845,930
Feb	4,360,465	845,930
Mar	4,360,465	845,930
Apr	4,360,465	845,930
May	4,360,465	845,930
Jun	4,360,465	845,930
Jul	4,360,465	845,930
Aug	4,360,465	845,930
Sep	4,360,465	845,930
Oct	4,360,465	845,930
Nov	4,360,465	845,930
Dec	4,360,465	845,930

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Carbon Saved

Month	CO_2 Produced Kg	CO_2 Offset (Heat) Kg	CO_2 Offset (Cooling) Kg	CO_2 Offset (Elec) Kg	Net CO_2 Emissions Kg
Jan	845,930	437,893	0	1,065,000	-656,963
Feb	845,930	437,893	0	1,065,000	-656,963
Mar	845,930	437,893	0	1,065,000	-656,963
Apr	845,930	437,893	0	1,065,000	-656,963
May	845,930	331,764	43,607	1,065,000	-594,440
Jun	845,930	232,482	84,400	1,065,000	-535,951
Jul	845,930	225,634	87,213	1,065,000	-531,918
Aug	845,930	225,634	87,213	1,065,000	-531,918
Sep	845,930	232,482	84,400	1,065,000	-535,951
Oct	845,930	331,764	43,607	1,065,000	-594,440
Nov	845,930	437,893	0	1,065,000	-656,963
Dec	845,930	437,893	0	1,065,000	-656,963
					-7,266,397

Building Carbon Target

Gross Building Floor Area	136,490	m^2
Total Emissions	16,834,959	Kg CO_2 per year
Gives	123	Kg CO_2 per m^2 per year
With CHP, emissions drop to	9,568,563	Kg CO_2 per year
Which Gives	70	Kg CO_2 per m^2 per year

Brookfield

Wind, Solar Thermal, Photovoltaics and Ground Source Cooling

Wind Energy

Windprospect.com - wind turbine installers		
Quoted annual output from 2MW turbine	5,000,000	kWh per year
This is equivalent to	2,840,000	Kg CO_2 per year
	21	Kg CO_2 per m^2 per year
Quietrevolution qr5 - quoted output	4,000 - 10,000	kWh per year
For this calculations, say	8,000	kWh per year
Number of turbines	12	
Carbon Saved	54,528	Kg CO_2 per year
	0.40	Kg CO_2 per m^2 per year

Solar Hot Water

Calculated from Viessmann quotation	465	Annual heat output (kWh) per m^2 of panel
Assume	200	m^2 of panels (1 panel is approx 4.3m^2)
Gives	93,000	kWh hot water generated per year
	18,042	Kg CO_2 per year
	0.13	Kg CO_2 per m^2 per year

Brookfield

Groundwater Cooling

Total Cooling Capacity	5500	kW
Chilled Beam Capacity	550	kW
Percentage of total taken from groundwater	10%	
Energy Saved	247,317	kWh per year
Carbon Saved	104,368	Kg CO_2 per year
	0.76	Kg CO_2 per m^2 per year

PV Cells

Area	6	m^2 required per kWp
Generation	810	kWh per 1kWp of pv installed
Size of PV Array	200	m^2
Raing of Array	33	kW
Power Generated	27,000	kWh per year
Carbon Saved	15,336	Kg CO_2 per year
	0.11	Kg CO_2 per m^2 per year

Brookfield

BREEAM Scoring Schedule

BREEAM Excellent – Scoring Summary

Achieving BREEAM Excellent has meant evaluating design proposals with the design team in order to ensure that the maximum possible number of credits is scored in the different BREEAM categories. The integration of the BREEAM assessment early on in the design process resulted in a BREEAM responsibility matrix being circulated at a point where the different members of the design team could ensure that the BREEAM action and supporting evidence can be easily accommodated into their work. Individual meetings with all BREEAM responsibility holders were held so that the detail of the credits could be discussed and that the requirements for the evidence are known, to avoid extra work at a later date. This approach means that the pre-assessment presented here is as an accurate reflection of the final BREEAM score, as deemed possible at this stage in the design. Details of how the credits will be scored are given within the pre-assessment, with the following table showing the overall summary:

BREEAM Section	Score
Management	12%
Health and Wellbeing	11.67%
Energy	13.15%
Transport	6.29%
Water	2.67%
Materials	5.83%
Waste	4.69%
Land Use and Ecology	7%
Pollution	6.15%
Innovation	2%
Final Score	71.45%

The BREEAM Assessor (appointed from WSP) will start to collate evidence as soon as possible, whilst providing ongoing advice and support to the design and construction team in order to ensure that the predicted Excellent rating becomes reality.

To achieve an Excellent rating in BREEAM Healthcare, there are a number of mandatory credits as well as additional credits for the low carbon design requirements, identified by the Greater Glasgow and Clyde NHS Board. These are shown in the following tables, with commentary on how they are achieved.

Mandatory BREEAM Healthcare Credits for Excellent

BREEAM Ref.	Credit Name	Commentary	Scored?
Man1	Commissioning	Brookfield have appointed a commissioning manager for the entire development, whose responsibility will include fulfilling this credit.	✓
Man2	Considerate Contractors	Brookfield and Dunne have a strong track record with the Considerate Contractors scheme and are confident of achieving this.	✓
Man4	Building User Guide	A building user guide will be developed by Brookfield in conjunction with ZBP, Mercury and the rest of the design team.	✓
Hea4	High Frequency Lighting	ZBP are specifying this as standard throughout the building.	✓
Hea12	Microbial Contamination	This is now a standard requirement due to Health and Safety requirements for ZBP in healthcare design.	✓
Ene1	Reduction of CO_2 emissions	The predicted EPC rating is 22, which will result in 11 points being scored under this credit.	✓
Ene2	Sub-metering	ZBP have included sub-metering for all relevant areas of the building, linked directly to the BMS.	✓
Ene5	LZC technologies	The energy strategy includes a natural gas CHP supplemented by wind power, allowing maximum points to be scored.	✓
Wat1	Water Consumption	Water efficient fittings have been specified throughout in accordance with the Board's stipulations.	✓
Wat2	Water meter	A mains water meter will be fitted as well as sub-water metering, linked to the BMS	✓
Wst3	Recyclable Waste Storage	This requirement has been designed into the main hospital building with complimentary space in the facilities management area.	✓
Le4	Mitigating Ecological Impact	Gillespies has used the Ecologist's feedback to inform their landscaping strategy and will continue to work with them to maximise the ecological potential of the site.	✓

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Additional Low Carbon Design Credits, as specified in Vol. 2/1, App. M&E.4: Sustainable Design Considerations.

BREEAM Ref.	Credit Name	Commentary	Scored?
Man12	Whole Life Cycle Costing	Doig and Smith are completing this as part of the Life Cycle Costing required within the bid submission.	✓
Hea1	Daylighting	Daylight levels have been maximised in all areas of the hospital, allowing good levels within the wards in particular. Due to the necessary design of the podium and the tower, this credit has not been able to be scored however.	
Hea7	Potential for Natural Ventilation	Operable windows have been provided for all patient areas however this has not been due to the necessary design of the podium and the tower.	
Hea10	Thermal Comfort	The thermal comfort assessment has been conducted using thermal building modelling to understand how the buildings'' internal temperatures will change through the course of a year.	✓
Ene3	Sub-metering of further areas	ZBP have included sub-metering for all relevant areas of the building, linked directly to the BMS.	✓
Ene4	External lighting	ZBP and Gillespies have worked together to ensure that energy efficient lamps are specified and also fit with the landscaping strategy.	✓
Ene8	Lifts	Schindler are well acquainted with the BREEAM requirements and are providing energy efficient lifts as required by BREEAM.	✓
Ene15	Energy Efficient Equipment	This credit has not been scored on the basis of feedback from the NHS Board.	

Brookfield

breeam

BREEAM Healthcare 2008 Pre-Assessment Estimator

Indicative Overall BREEAM Score
71.45%

BREEAM Rating Benchmarks	
PASS	≥30
GOOD	≥45
VERY GOOD	≥55
EXCELLENT	≥70
OUTSTANDING*	≥85

Ref	BREEAM Issue Title	BREEAM Healthcare - Issue Criteria	Number of BREEAM credits available	Total predicted BREEAM credits achieved	Minimum BREEAM Standards: Pass	Good	Very Good	Excellent	Outstanding	Notes
					YES	YES	YES	YES	NO	
					Minimum required credits by BREEAM issue and rating					
Management										
Man 1	Commissioning	One credit where evidence provided demonstrates that an appropriate project team member has been appointed to monitor commissioning on behalf of the client to ensure commissioning will be carried out in line with current best practice. Two credits where, in addition to the above, evidence provided demonstrates that seasonal commissioning will be carried out during the first year of occupation, post construction (or post fit out).	2	2	1	1	1	1	2	Brookfield Commissioning Manager is lead, supported by Mercury, ZBP, Schindler, Swiss Log etc as appropriate
Man 2	Considerate Constructors	One credit where evidence provided demonstrates that there is a commitment to comply with best practice site management principles. Two credits where evidence provided demonstrates that there is a commitment to go beyond best practice site management principles.	2	2	-	-	-	1	2	Joint responsibilty between Dunne and Brookfield.
Man 3	Construction Site Impacts	One credit where evidence provided demonstrates that 2 or more of items a-g (listed below) are achieved. Two credits where evidence provided demonstrates that 4 or more of items a-g (listed below) are achieved. Three credits where evidence provided demonstrates that 6 or more of items a-g are achieved: a. Monitor, report and set targets for CO2 or energy arising from site activities b. Monitor, report and set targets for CO2 or energy arising from transport to and from site c. Monitor, report and set targets for water consumption arising from site activities d. Implement best practice policies in respect of air (dust) pollution arising from the site e. Implement best practice policies in respect of water (ground and surface) pollution occurring on the site f. Main contractor has an environmental materials policy, used for sourcing of construction materials to be utilised on site g. Main contractor operates an Environmental Management System. One additional credit where evidence provided demonstrates that at least 80% of site timber is responsibly sourced and 100% is legally sourced.	4	4	-	-	-	-	-	To be formulated by Brookfield.
Man 4	Building user guide	One credit where evidence provided demonstrates the provision of a simple guide that covers information relevant to the tenant/occupants and non-technical building manager on the operation and environmental performance of the building.	1	1	-	-	-	1	1	With input from Mercury, Schindler, Swiss log, BSL - FM
Man 6	Consultation	One credit where evidence provided demonstrates that consultation has been, or is being, undertaken and feedback given to the local community and building users. In addition, advice should also have been sought from any relevant national and local history, archaeological bodies or military history groups regarding the heritage value of the building/site/surroundings. Two credits where, in addition to the above, evidence provided demonstrates that changes to the design and/or action has been taken as a result of the above consultation process. This should include the protection of any parts of the building (or site) having historic or heritage value in accordance with independent advice from the relevant body.	2	2	-	-	-	-	-	Consultation has been undertaken by the Board already, with relevant details fed back to the Brookfield design team
Man 8	Security	One credit where evidence provided demonstrates that an Architectural Liaison Officer (ALO) or Crime Prevention Design Advisor (CPDA) from the local police force has been consulted at the design stage and their recommendations incorporated into the design of the building and its parking facilities (if relevant).	1	1	-	-	-	-	-	Nightingale Associates has undertaken this credit

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Man 11	Ease of Maintenance	One credit where evidence provided demonstrates that specifications for the building and the building services/systems and landscaping have considered ease and efficiency of maintenance in line with best practice.	1	1	-	-	-	-	-	ZBP's responsibilty with input from Mercury and Nightingale Associates.
Man 12	Life Cycle Costing	One credit where evidence provided demonstrates that a Life Cycle Cost (LCC) analysis based on the feasibility study proposals has been undertaken on the building design at a strategic and system level. Two credits where, in addition to the above, evidence provided demonstrates that the results of the feasibility study and consideration of LCC have been implemented.	2	2	-	-	-	-	-	Mandatory in NHS Board Employers Requirements and to be undertaken by Doig and Smith.

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Man 13	Good Corporate Citizen	One credit where evidence provided demonstrates that the Good Corporate Citizen model has been used to assess the development and that there is a commitment to continue to use the model to re-assess the development regularly.	1	1	-	-	-	-	-	Managed by Brookfield, however commitment from the NHS Board also required.
		Indicative Management (weighted) Section Score	**12.00%**							
Health & Wellbeing										
Hea 1	Daylighting	Two credits where at least 80% by floor area of occupied staff and public spaces have an average daylight factor of 2% or more. And at least 80% by floor area of occupied patient spaces (dayrooms, wards) and consulting rooms have an average daylight factor of 3% or more.	2	0	-	-	-	-	-	Mandatory in NHS Board Employers Requirements. ZBP to conduct daylighting assessment to assess compliance.
Hea 2	View Out	One credit where evidence provided demonstrates that all workstations/benches and desks and at least 80% by floor area of public areas have an adequate view out. One credit where evidence provided demonstrates that all patient-occupied spaces have an adequate view out.	2	2	-	-	-	-	-	Nightingale Associates - as illustrated in hospital drawings
Hea 3	Glare Control	One credit where evidence provided demonstrates that an occupant-controlled shading system (e.g. internal or external blinds) is fitted in relevant building areas.	1	1	-	-	-	-	-	Nightingale Associates - part of ward designs
Hea 4	High frequency lighting	One credit where evidence provided demonstrates that high frequency ballasts are installed on all fluorescent and compact fluorescent lamps.	1	1	1	1	1	1	1	ZBP
Hea 5	Internal and external lighting levels	One credit where evidence provided demonstrates that all internal and external lighting, where relevant, is specified in accordance with the appropriate maintained illuminance levels (in lux) recommended by CIBSE.	1	1	-	-	-	-	-	ZBP
Hea 6	Lighting zones & controls	One credit where evidence provided demonstrates that, in all relevant building areas, lighting is appropriately zoned and occupant controllable.	1	1	-	-	-	-	-	ZBP
Hea 7	Potential for natural ventilation	One credit where evidence provided demonstrates that fresh air is capable of being delivered to the occupied spaces of the building via a natural ventilation strategy, and there is sufficient user-control of the supply of fresh air.	1	0	-	-	-	-	-	
Hea 8	Indoor air quality	One credit where air intakes serving occupied areas avoid major sources of external pollution and recirculation of exhaust air.	1	1	-	-	-	-	-	ZBP - as demonstrated in the building services drawings
Hea 9	Volatile Organic Compounds	One credit where evidence provided demonstrates that the emissions of VOCs and other substances from key internal finishes and fittings comply with best practice levels.	1	1	-	-	-	-	-	Nightingale Associates
Hea 10	Thermal comfort	One credit where evidence provided demonstrates that thermal comfort levels in occupied spaces of the building are assessed at the design stage to evaluate appropriate servicing options, ensuring appropriate thermal comfort levels are achieved.	1	1	-	-	-	-	-	Mandatory in NHS Board Employers Requirements - ZBP

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Hea 11	Thermal zoning	One credit where evidence provided demonstrates that local occupant control is available for temperature adjustment in each occupied space to reflect differing user demands.	1	0	-	-	-	-	-	
Hea 12	Microbial contamination	One credit where evidence provided demonstrates that the risk of waterborne and airborne legionella contamination has been minimised.	1	1	1	1	1	1	1	ZBP
Hea 13	Acoustic Performance	One credit where evidence provided demonstrates that indoor ambient noise levels and airborne and impact sound insulation levels achieve the recommended performance benchmarks outlined HTM 08-01 Part A. One credit where evidence provided demonstrates that reverberation times are compliant with the recommended performance benchmarks outlined HTM 08-01 Part A.	2	2	-	-	-	-	-	Acoustic Logic
Hea 15	Outdoor Space	One credit where evidence provided demonstrates the provision of an adequate outdoor amenity space accessible for use by the building's occupants.	1	1	-	-	-	-	-	Gillespies to provide evidence
Hea 19	Arts in health	One credit where evidence provided demonstrates that an art co-ordinator has been appointed or an art strategy and policy have been prepared for the development.	1	1	-	-	-	-	-	Gillespies and Nightingale Associates producing Arts Strategy
		Indicative Health & Wellbeing (weighted) Section Score	**11.67%**							

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Energy

Ene 1	Reduction of CO2 Emissions	Up to fifteen credits where evidence provided demonstrates an improvement in the energy efficiency of the building's fabric and services and therefore achieves lower building operational related CO2 emissions (refer to the BREEAM manual for benchmarks)	**15**	**8**	-	-	-	6	10	**Predicted EPC ratings indicate at least 31 points is possible.**
Ene 2	Sub-metering of Substantial Energy Uses	One credit where evidence provided demonstrates the provision of direct sub-metering of energy uses within the building. Two credits where, in addition to the above, evidence provided demonstrates that sub meters are connected to a BMS or other type of automated control device.	**2**	**2**	-	-	1	1	1	**ZBP have designed a full metering strategy**
Ene 3	Sub-metering of high energy load Areas and Tenancy	One credit where evidence provided demonstrates sub-metering of energy consumption by tenancy/building function area is installed within the building.	**1**	**1**	-	-	-	-	-	**ZBP have designed a full metering strategy**
Ene 4	External Lighting	One credit where energy-efficient external lighting is specified and all light fittings are controlled for the presence of daylight.	**1**	**1**	-	-	-	-	-	**ZBP**
Ene 5	Low zero carbon technologies	One credit where evidence provided demonstrates that a feasibility study considering local (on-site and/or near site) low or zero carbon (LZC) technologies has been carried out and the results implemented. Two credits where evidence provided demonstrates that the first credit has been achieved and there is a 10% reduction in the building's CO2 emissions as a result of the installation of a feasible local LZC technology. Three credits where evidence provided demonstrates that the first credit has been achieved and there is a 15% reduction in the building's CO2 emissions as a result of the installation of a feasible local LZC technology. Or alternatively: A maximum of one credit where evidence provided demonstrates that a contract with an energy supplier is in place to provide sufficient electricity used within the assessed building/development to meet the above criteria from a 100% renewable energy source. (Note: a standard Green Tariff will not comply)	**3**	**3**	-	-	-	1	1	**An onsite natural gas CHP is an acceptable LZC technology and will provide the majority of the power and heat for the buildings.**
Ene 8	Lifts	Up to two credits are available where evidence provided demonstrates the installation of energy-efficient lift(s).	**2**	**2**	-	-	-	-	-	**Schindler**
Ene 15	Provision of Energy Efficient Equipment	One credit where evidence provided demonstrates procurement of office and domestic scale equipment on the basis of energy-efficient performance over the product life cycle.	**1**	**0**	-	-	-	-	-	**Advised as not possible by NHS Board**
Ene 16	CHP Community Energy	One credit where evidence provided demonstrates that a feasibility study has been carried out on the potential for the building to set up, contribute to or benefit from a local CHP community energy scheme.	**1**	**1**	-	-	-	-	-	**WSP Sustainability - meetings with Sustainable Glasgow Initiative and SSE completed, to be written up.**
		Indicative Energy (weighted) Section Score	**13.15%**							

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Transport

Tra 1	Provision of public transport	Up to five credits are awarded on a sliding scale based on the assessed buildings' accessibility to the public transport network.	5	3	-	-	-	-	-	**Currently indicative score, potential to score more once full assessment complete.**
Tra 2	Proximity to amenities	One credit where evidence provided demonstrates that the building is located within 500m of accessible local amenities appropriate to the building type and its users.	1	1	-	-	-	-	-	**As stated within the NHS Board's documentation**
Tra 3	Cyclist Facilities	One credit where evidence provided demonstrates that covered, secure and well-lit cycle storage facilities are provided for all building users. Two credits where, in addition to the above, adequate changing facilities are provided for staff use.	2	2	-	-	-	-	-	**Gillespies - cycle storage; Nightingale Associates - cyclist facilities.**
Tra 4	Pedestrian and cycle safety	**Medium/Large developments** e.g. acute, teaching, specialist and mental health hospitals One credit where evidence provided demonstrates that the site layout has been designed in accordance with best practice to ensure safe and adequate cycle access. One credit where evidence provided demonstrates that the site layout has been designed in accordance with best practice to ensure safe and adequate pedestrian access.	2	2	-	-	-	-	-	**Gillespies**
Tra 5	Travel plan	One credit where evidence is provided to demonstrate that a travel plan has been developed and tailored to the specific needs of the building users.	1	1	-	-	-	-	-	**Gillespies to produce marked up site plan**
Tra 6	Maximum car parking capacity	One credit where evidence provided demonstrates that the number of parking spaces provided for the building has been limited.	1	0	-	-	-	-	-	**Advised as unlikely by NHS Board - to be fully investigated when finalised.**
Tra 7	Travel information point	One credit where evidence provided demonstrates there is a dedicated space within the development for the provision of real-time public transport information.	1	1	-	-	-	-	-	**Gillespies to incorporate into site master plan**
Tra 8	Deliveries & manoeuvring	One credit where evidence provided demonstrates that vehicle access areas have been designed to ensure adequate space for manoeuvring delivery vehicles and provide space away from manoeuvring area for storage of refuse skips and pallets.	1	1	-	-	-	-	-	**Gillespies/WSP C&S**
		Indicative Transport (weighted) Section Score	**6.29%**							

Water

Wat 1	Water Consumption	Up to three credits where evidence provided demonstrates that the specification includes taps, urinals, WCs and showers that consume less potable water in use than standard specifications for the same type of fittings.	3	1	-	1	1	1	2	**The Board has confirmed that flush volumes of 4.5litres are unacceptable, therefore only able to score credit for flow rate on taps.**
Wat 2	Water meter	One credit where evidence provided demonstrates that a water meter with a pulsed output will be installed on the mains supply to each building/unit.	1	1	-	1	1	1	1	**ZBP**
Wat 3	Major leak detection	One credit where evidence provided demonstrates that a leak detection system is specified or installed on the building's water supply.	1	1	-	-	-	-	-	**ZBP**

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Wat 4	Sanitary supply shut off	One credit where evidence provided demonstrates that proximity detection shut-off is provided to the water supply to all toilet areas.	1	0	-	-	-	-	-	
Wat5	Water recycling	Up to two credits where evidence provided demonstrates the specification of systems that collect, store and, where necessary treat, rainwater or greywater for WC and urinal flushing purposes.	2	0	-	-	-	-	-	
Wat 6	Irrigation systems	One credit where evidence provided demonstrates that a low-water irrigation strategy/system has been installed, or where planting and landscaping is irrigated via rainwater or reclaimed water.	1	1	-	-	-	-	-	Gillespies (with liaison with ZBP if green roof irrigation is needed)
		Indicative Water (weighted) Section Score	**2.67%**							
Materials										
Mat 1	Materials Specification (major building elements)	Up to six credits are available, determined by the Green Guide to Specification ratings for the following major building/finishing elements: 1. External Walls 2. Windows 3. Roof 4. Upper Floor Slabs 5. Internal Walls 6. Floor Finishes / Coverings	6	3	-	-	-	-	-	Nightingales - estimated score, to be revised when final materials choice completed
Mat 2	Hard landscaping and boundary protection	One credit where evidence provided demonstrates that at least 80% of the combined area of external hard landscaping and boundary protection specifications achieve an A or A+ rating, as defined by the Green Guide to Specification.	1	1	-	-	-	-	-	Gillespies
Mat 3	Re-use of building façade	One credit is awarded where evidence provided demonstrates that at least 50% of the total façade (by area) is reused and at least 80% of the reused façade (by mass) comprises in-situ reused material.	1	0	-	-	-	-	-	
Mat 4	Re-use of building structure	One credit is awarded where evidence provided demonstrates that a design reuses at least 80% of an existing primary structure and for part refurbishment and part new build, the volume of the reused structure comprises at least 50% of the final structure's volume.	1	0	-	-	-	-	-	
Mat 5	Responsible sourcing of materials	Up to 3 credits are available where evidence provided demonstrates that 80% of the assessed materials in the following building elements are responsibly sourced: a. Structural Frame b. Ground floor c. Upper floors (including separating floors) d. Roof e. External walls f. Internal walls g. Foundation/substructure h. Staircase Additionally 100% of any timber must be legally sourced.	3	1	-	-	-	-	-	Brookfield Procurement - to be included in contract documents
Mat 6	Insulation	One credit where evidence provided demonstrates that thermal insulation products used in the building have a low embodied impact relative to their thermal properties, determined by the Green Guide to Specification ratings. One credit where evidence provided demonstrates that thermal insulation products used in the building have been responsibly sourced.	2	1	-	-	-	-	-	Nightingale Associates/ Brookfield Procurement
Mat 7	Designing For Robustness	One credit where protection is given to vulnerable parts of the building such as areas exposed to high pedestrian traffic, vehicular and trolley movements.	1	1	-	-	-	-	-	Nightingale Associates
		Indicative Materials (weighted) Section Score	**5.83%**							
Waste										

Brookfield

Wst 1	Construction Site Waste Management	Up to three credits are available where evidence provided demonstrates that the amount of non-hazardous construction waste (m3/100m2 or tonnes100m2) generated on site by the development is the same as or better than good or best practice levels. One credit where evidence provided demonstrates that a significant majority of non-hazardous construction waste generated by the development will be diverted from landfill and reused or recycled.	4	3	-	-	-	-	-	Brookfield
Wst 2	Recycled aggregates	One credit where evidence provided demonstrates the significant use of recycled or secondary aggregates in 'high-grade' building aggregate uses.	1	0	-	-	-	-	-	Dunne - Recycled aggregates will be used where possible but need to assess if 25% possible.
Wst 3	Recyclable waste storage	One credit where a central, dedicated space is provided for the storage of the building's recyclable waste streams.	1	1	-	-	-	1	1	Nightingale Associates - this will be part of the facilities compound
Wst 4	Compactor / Baler	One credit where evidence provided demonstrates that either an industrial waste compactor or baler is installed for compacting/baling waste materials generated on site and a. A water outlet is provided for cleaning b. The development achieves the BREEAM credit for storage of recyclable waste.	1	1	-	-	-	-	-	Brookfield - this will be part of the facilities compound
Wst 5	Composting	One credit w here evidence provided demonstrates there is a vessel on site for composting food waste, and adequate storage for such waste generated by the building's users and operation. OR Where space or access is limited, there is a dedicated space for compostable food waste to be stored prior to removal and composting at an alternative site.	1	0	-	-	-	-	-	Possibly - dependent on how food waste collected on site is disposed of.
		Indicative Waste (weighted) Section Score	**4.69%**							
Land Use & Ecology										
LE1	Re-use of land	One credit where evidence provided demonstrates that the majority of the footprint of the proposed development falls within the boundary of previously developed land.	1	0	-	-	-	-	-	Advised by NHS Board not possible
LE2	Contaminated land	One credit is awarded where evidence provided demonstrates that the land used for the new development has, prior to development, been defined as contaminated and where adequate remedial steps have been taken to decontaminate the site prior to construction.	1	0	-	-	-	-	-	
LE3	Ecological value of site AND Protection of ecological features	One credit is awarded where evidence provided demonstrates that the construction zone is defined as land of low ecological value and all existing features of ecological value will be fully protected from damage during site preparation and construction works.	1	1	-	-	-	-	-	Dunne - with input from appointed ecologist
LE4	Mitigating Ecological impact	One credit where evidence provided demonstrates that the change in the site's existing ecological value, as a result of development, is minimal. Two credits where evidence provided demonstrates that there is no negative change in the site's existing ecological value as a result of development.	2	2	-	-	1	1	1	Gillespies - with input from appointed ecologist
LE5	Enhancing Site Ecology	One credit where the design team (or client) has appointed a suitably qualified ecologist to advise and report on enhancing and protecting the ecological value of the site; and implemented the professional's recommendations for general enhancement and protection of site ecology. Two credits where, in addition to the above, there is a positive increase in the ecological value of the site of up to (but not including) 6 species. Three credits where, in addition to the above, evidence is provided to demonstrate a positive increase in the ecological value of the site of 6 species or greater.	3	2	-	-	-	-	-	Gillespies - with input from appointed ecologist. Possibiltiy for more credits to be scored.

Brookfield

LE6	Long term impact on biodiversity	One credit where the client has committed to achieving the mandatory requirements listed below and at least two of the additional requirements. Two credits where the client has committed to achieving the mandatory requirements listed below and at least four of the additional requirements.	2	2	-	-	-	-	-	Brookfield
		Indicative Land Use & Ecology (weighted) Section Score	**7.00%**							
Pollution										
Pol 1	Refrigerant GWP - Building services	One credit where evidence provided demonstrates the use of refrigerants with a global warming potential (GWP) of less than 5 or where there are no refrigerants specified for use in building services.	1	0	-	-	-	-	-	
Pol 2	Preventing refrigerant leaks	One credit where evidence provided demonstrates that refrigerant leaks can be detected or where there are no refrigerants specified for the development. One credit where evidence provided demonstrates that the provision of automatic refrigerant pump down is made to a heat exchanger (or dedicated storage tanks) with isolation valves. Or where there are no refrigerants specified for the development.	2	1	-	-	-	-	-	ZBP
Pol 3	Refrigerant GWP - Cold storage	One credit where evidence provided demonstrates the use of refrigerants within cold storage systems with a global warming potential (GWP) of less than 5.	1	0	-	-	-	-	-	
Pol 4	NOx emissions from heating source	One credit where evidence provided demonstrates that the maximum dry NOx emissions from delivered space heating energy are ≤100 mg/kWh (at 0% excess O2). Two credits where evidence provided demonstrates that the maximum dry NOx emissions from delivered space heating energy are ≤70 mg/kWh (at 0% excess O2). Three credits where evidence provided demonstrates that the maximum dry NOx emissions from delivered space heating energy are ≤40 mg/kWh (at 0% excess O2) and emissions from delivered water heating energy are 100 mg/kWh or less (at 0% excess O2).	3	1	-	-	-	-	-	Mercury
Pol 5	Flood risk	Two credits where evidence provided demonstrates that the assessed development is located in a zone defined as having a low annual probability of flooding. One credit where evidence provided demonstrates that the assessed development is located in a zone defined as having a medium or high annual probability of flooding AND the ground level of the building, car parking and access is above the design flood level for the site's location. One further credit where evidence provided demonstrates that surface water run-off attenuation measures are specified to minimise the risk of localised flooding, resulting from a loss of flood storage on site due to development.	3	3	-	-	-	-	-	WSP C&S
Pol 6	Minimising watercourse pollution	One credit here evidence provided demonstrates that effective on site treatment such as Sustainable Drainage Systems (SUDs) or oil separators have been specified in areas that are or could be a source of watercourse pollution.	1	1	-	-	-	-	-	WSP C&S
Pol 7	Reduction of Night Time Light Pollution	One credit where evidence provided demonstrates that the external lighting design is in compliance with the guidance in the Institution of Lighting Engineers (ILE) Guidance notes for the reduction of obtrusive light, 2005.	1	1	-	-	-	-	-	ZBP

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Pol 8	Noise Attenuation	One credit where evidence provided demonstrates that new sources of noise from the development do not give rise to the likelihood of complaints from existing noise-sensitive premises and amenity or wildlife areas that are within the locality of the site.	1	1	-	-	-	-	-	Acoustic Logic
		Indicative Pollution (weighted) Section Score	**6.15%**							

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Innovation

Man 2	Considerate Constructors	Where post construction, a Considerate Constructors Scheme certificate can be provided demonstrating that the site achieved CCS Code of Considerate Practice with a score of at least 36. OR Where post construction, the site has complied in full with the alternative, independently assessed scheme, and the alternative scheme addresses all the mandatory and optional items in Checklist A2.	**1**	**1**	**Scored through Brookfield and Dunne, based on past performance**
Hea 1	Daylighting	At least 80% of the floor area (for the building spaces/room identified above in the standard requirements) has an average daylight factor of 3% in multi-storey buildings and 4% in single-storey buildings.	**1**		
Ene 1	Reduction of CO2 emissions	One additional innovation credit can be awarded where evidence provided demonstrates the building is designed to be a carbon neutral building as defined by the NCM (i.e. in terms of building services energy demand), as follows: a. A new building achieves a CO2 index less than 0 on the benchmark scale. b. A refurbished building achieves a CO2 index equal to or less than 0 on the benchmark scale. Two additional innovation credits can be awarded where evidence provided demonstrates the building is designed to be a True zero carbon building (in terms of building services and operational energy demand).	**2**		
Ene 5	Low or Zero Carbon Technologies	A local LZC energy technology has been installed in line with the recommendations of a compliant feasibility study and this method of supply results in a 20% reduction in the building's CO2 emissions.	**1**	**1**	**Scored through CHP solution, devised by ZBP**
Wat 2	Water Meter	Where sub meters are fitted to allow individual water-consuming plant or building areas to be monitored such as cooling towers, car washes, catering areas, etc. If the building does not have any major water consuming plant this exemplar credit is not available. Each sub meter has a pulsed output to enable connection to a Building Management System (BMS) for the monitoring of water consumption. In addition to the above, for sites with multiple departments e.g. large health centres or acute hospitals, separate pulsed sub meters are fitted on the supply to the following areas where present: a. Staff and public areas b. Clinical areas and wards c. Letting areas: On the water supply to each tenant unit d. Laundries e. Main production kitchen f. Hydrotherapy pools g. Laboratories h. CSSD/HSDU, pathology, pharmacy, mortuary and any other major process water user.	**1**		
Mat 1	Materials Specification	One exemplary BREEAM credit can be awarded as follows: a. Where assessing four or more applicable building elements, the building achieves at least two points additional to the total points required to achieve maximum credits under the standard BREEAM requirements. b. Where assessing fewer than four applicable building elements, the building achieves at least one point additional to the total points required to achieve maximum credits under the standard BREEAM requirements.	**1**		
Mat 5	Responsible Sourcing of Materials	Where, in addition to the standard BREEAM requirements, 95% of the applicable materials, comprised within the applicable building elements, have been responsibly sourced.	**1**		

Brookfield

Wst 1	Construction Site Waste Management	Where non-hazardous construction waste generated by the building's development meets or exceeds the resource efficiency benchmark required to achieve three credits (as outlined in the guidance). Where at least 90% by weight (80% by volume) of non-hazardous construction waste and 95% of demolition waste by weight (85% by volume) (if applicable) generated by the build has been diverted from landfill and either: a. Reused on site (in-situ or for new applications) b. Reused on other sites c. Salvaged/reclaimed for reuse d. Returned to the supplier via a 'take-back' scheme e. Recovered from site by an approved waste management contractor and recycled. Where all key waste groups are identified for diversion from landfill at pre-construction stage SWMP.	1		
		Indicative Innovation (weighted) Section Score	**2.00%**		

Brookfield

Helipad M&E Services Design Strategy

General

The Mechanical and Electrical Engineering requirements for the helipad will be as detailed in HBN 15-03.

Special consideration will be given to the position of adjacent intake or exhaust vents, which may be influenced by the location of the helipad.

Helipad lighting will provide reliable illumination in exposed conditions, including the strong winds caused by helicopter downwash. The lighting will meet the chromaticity and illumination levels specified in ICAO Annex 14. The luminaires will be supplied by accredited aviation suppliers.

All helipad guidance and obstacle lighting will be operated by a single switch near the helipad.

Brookfield

LIGHTING

Lighting for Night Operations

A locating beacon, approach lights, and visual alignment and approach slope indicators will be provided as necessary.

The windsock will be illuminated.

The Energy Centre Flue will carry a light.

Helipad Lighting

The helipad will be lit by:-

- Omni-directional green lights in straight lines off each side of the helipad but within 1.5m of the perimeter. The lights will not project more than 25cm above the helipad, and the light sources will not be visible from below the helipad level. There will be one light at each corner and others evenly spaced in between at intervals of not more than 3m.
- Four low-level (25cm) Xenon floodlights to illuminate the landing surface, well-shielded so as not to dazzle pilots.

Drainage

Fire-resistant guttering will be provided around the perimeter of the helipad to carry rainwater, fuel and fire-fighting media into the drainage system. Rain water will be directed into the foul water sewage system. In the event of a fire, a valve will divert aircraft fuel, fire-fighting media, and all other fluids to an oil/water separator. The capacity of the separator will be suitable for the size of the helicopter. The down-pipes will be fire-resistant and will include a system to exclude air (sufficient to extinguish burning fuel).

Water

The water for extinguishing and for making foam will be supplied from tanks immediately below the helipad level, pressurised by an inert gas to propel the water to the nozzles when activated. The delivery pipe for the system will be inside the building. Tanks will also be provided for the foam concentrate. A break tank and pumps with hose will be provided for washing the helipad surface to remove routine dirt and bird droppings in order to retain the friction characteristics of the surface.

Ventilation

Consideration will be given to:-

- Hot air from exhaust vents and flues which might disrupt the airflows around the helicopter
- Roof-level ventilation intakes; any fumes from the helicopter are likely to be dispersed, but could be mistaken for the smell of fire by hospital staff, who might then sound the alarm.

Brookfield

Maintenance and Major Plant and Equipment Replacement Strategy

General

The engineering services will be designed to allow safe and satisfactory access for routine maintenance activities, and provide means of carrying out future major plant replacement without causing significant disruption to the general operation of the hospital, in line with the requirements of the Construction, Design and Management (CDM) Regulations 2007.

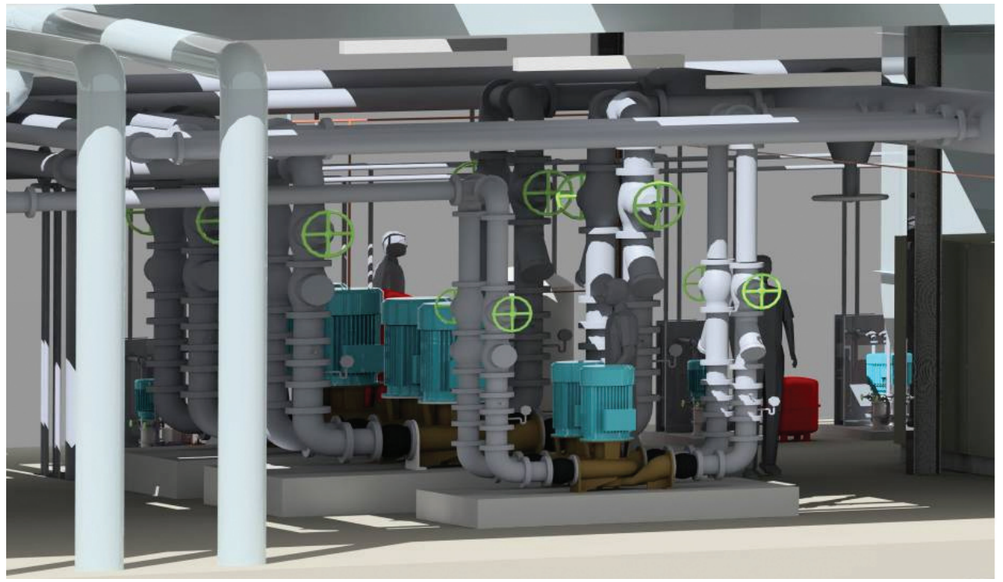
Whenever possible, engineering services plant and components which require regular inspection and maintenance, will be provided with access from floor level, without the use of steps and ladders or access towers.

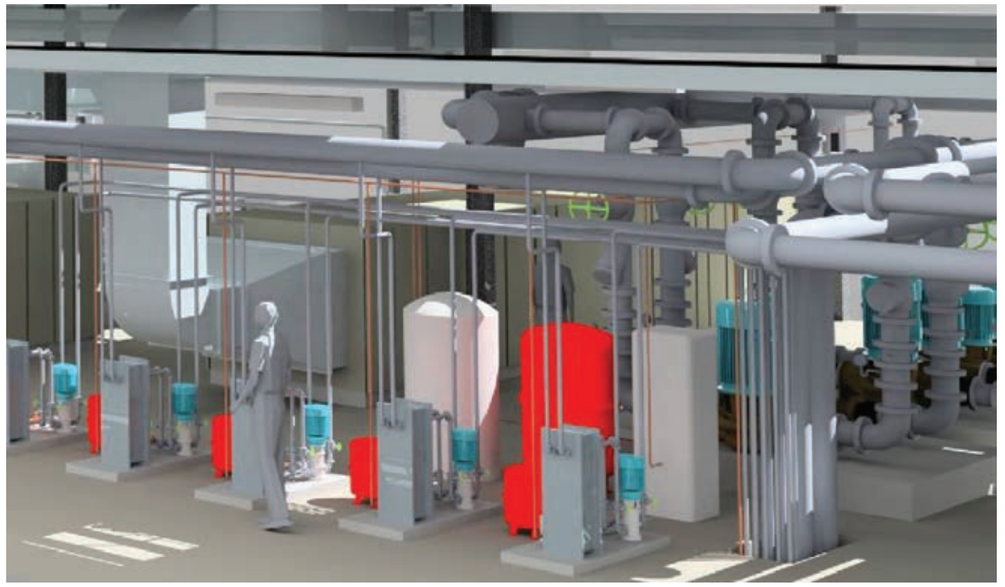
Access routes through plantrooms will be designated on the design drawings, and have a clear width suitable for personnel and equipment passage. The Goods Lifts serving plantroom levels will be maximised in their use for transporting of items such as filters, motors, AHU internal components, etc. Limitation on the use of the lifts will generally be on weight and door opening restrictions.

Space for component withdrawal will be identified. In some cases, due to the infrequent use of such spaces, these may be shared with general access provisions.

It is envisaged that for air handling units internal components will be replaced during the life of the plant, rather than complete units.

The following describes specific allowances in key areas for engineering services maintenance and replacement.





Plantrooms will be arranged to provided satisfactory access for maintenance and plant replacement

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Maintenance

Refer to drawing numbers ZBP-XX-ML-PL-520-010, ZBP-XX-ML-SE-520-011 & 012, ZBP-XX-02-PL-520-021 & 022, ZBP-XX-03-PL-520-023 & 024, ZBP-XX-04-PL-520-025 and ZBP-XX-12-PL-520-026 & 027.

The above drawings of the plantroom layouts show that space has been afforded around and adjacent to all the major items of equipment. This space is for both general maintenance and the removal and replacement of both small and large items of equipment.

Atria

Wherever possible, luminaires in high ceiling spaces, such as the atria, will be of a type that can be accessed from floor level without the need for ladders and steps or access towers.

However, in some instances this may not be practical. In these cases, the luminaires will be maintained using cherry pickers, which are also used for building fabric maintenance. When in use, certain areas of the space may be restricted and cordoned off to avoid public access.

In all cases, low maintenance luminaires with long life light sources will be used to minimise the need for frequent access.

Ductwork Cleaning

In order to maintain hygiene in ventilation systems, it is necessary to carry out regular inspections of ductwork interior surfaces and occasionally undertake extensive cleaning.

To undertake this, access doors are provided on ductwork system at interval recommended by HVCA document TR19.

Since ductwork is located within ceiling voids and high level within plant areas, the use of mobile access platforms will be required. Wherever practical, access doors will be positioned in conveniently accessible areas, but it is likely that some disruption will occur in spaces where cleaning is necessary.

These cleaning activities will need to be coordinated between the Facilities Management and the Hospital Board to minimise disruption to hospital activities.

Major Plant and Equipment Replacement

Energy Centre

Refer to drawing numbers ZBP-XX-00-PL-525-104, ZBP-XX-01-PL-525-105, ZBP-XX-02-PL-525-106, and ZBP-XX-RF-PL-525-107.

The Energy Centre houses major generation plant for electricity, heat and cooling, and is divided over three floors and roof.

Generally small items of plant and consumables will be conveyed via the main personnel access and the good lift serving all floors. This should cover all but the major plant items of replacement.

The ground floor houses the bulk oil storage tanks and oil transfer plant. Plant removal/ replacement will be via doors direct to outside above bund level.

The first floor houses the generators, transformers and electrical equipment. Plant replacement will be via removable louvres which enable the plant to be withdrawn from the building onto a temporary platform from where it can be craned away.

The second floor houses the boilers and water services equipment. Plant replacement will also be via removable louvre panels which enable the plant to be withdrawn from the building onto a temporary platform from where it can be craned away.

It is envisaged that the major plant items, e.g. boilers and generators, will be removed/ replaced through these openings by the use of rollers and heavy lifting equipment for loading onto transport vehicles.

The transformers are readily accessible from the roadway. Electrical switchgear will be cubicalised to allow for dismantling and replacement.

The main chillers on the roof of the Energy Centre will be craned from their permanent location directly onto transport vehicles.

These activities may require closure of parts of the adjacent service road.

Brookfield

Basement Acute Hospital
All services will be accessed and removed via the FM tunnels and FM lifts to outside.

Plantroom 21 (Second Floor Acute Hospital)
Refer to drawing numbers ZBP-XX-02-PL-525-100.

This plantroom is located at second floor level and is served by one of the FM lift in the Central Core.

This plantroom houses air handling and water services plant, as well as electrical substations and switchrooms.

The only items of the electrical sub-stations that will not follow the general plant replacement principles are the transformers, each weighing in the order of 5,000 kg.

The transformer bays are located on the perimeter of the building and have demountable louvres for access for replacement and to allow the transformer to be removed and craned from plant level down to ground level.

The air handling equipment will be dismantled into sections, and along with other plant items, will be taken to the designated access point for craning down to ground level.

Small items of equipment of a suitable size and weight, e.g. pumps, coils and filters, will be taken from the plantroom via FM lifts in the Central Core.

The erection of a scaffold platform will provide a landing platform and permit safe personnel access for manoeuvring activities.

Craning activities will require partial closure of the service road adjacent to the plantrooms, and alternative traffic management arrangement will need to be put in place during these times.

Plantroom 22(Second Floor Acute Hospital)
Refer to drawing numbers ZBP-XX-02-PL-525-100.

This plantroom is located at second floor level and are served by one of the FM lift in the Central Core.

This plantroom houses air handling and water services plant.

The air handling equipment will be dismantled into sections, and along with other plant items, will be taken to the designated access point for craning down to ground level.

Small items of equipment of a suitable size and weight, e.g. pumps, coils and filters, will be taken from the plantroom via FM lifts in the Central Core.

The erection of a scaffold platform will provide a landing platform and permit safe personnel access for manoeuvring activities.

Craning activities may require partial closure of the service road adjacent to the plantrooms, and alternative traffic management arrangement may need to be put in place during these times.

Brookfield

Plantroom 31(Third Floor Acute Hospital)
Refer to drawing numbers ZBP-XX-03-PL-525-101.

This plantroom is located at third floor level and is served by one of the FM lift in the Central Core.

This plantroom houses air handling and water services plant, as well as electrical substations and switchrooms.

The only items of the electrical sub-stations that will not follow the general plant replacement principles are the transformers, each weighing in the order of 5,000 kg.

The transformer bay adjacent to the service road is located on the perimeter of the building will have demountable louvres for access for replacement and to allow the transformer to be removed and craned from plant level down to ground level.

The transformer bay adjacent to the children's roof garden is located on the perimeter of the building will have demountable louvres for access for replacement and to allow the transformer to be removed. The transformer will have to be moved on spreader plates across the roof to a designated landing point and craned down to ground level.

The air handling equipment will be dismantled into sections, and along with other plant items, will be taken to the designated 'plant landing' zone for craning down to ground level.

Small items of equipment of a suitable size and weight, e.g. pumps, coils and filters, will be taken from the plantroom via FM lifts in the Central Core.

The erection of a scaffold platform will provide a landing platform and permit safe personnel access for manoeuvring activities.

Craning activities may require partial closure of the service road adjacent to the plantrooms, and alternative traffic management arrangement may need to be put in place during these times.

Plantroom 32 & 33 (Third Floor Acute Hospital)
Refer to drawing numbers ZBP-XX-03-PL-525-101.

This plantroom is located at third floor level and is served by one of the FM lift in the Central Core.

This plantroom houses air handling and water services plant, as well as electrical substations and switchrooms.

The only items of the electrical sub-stations that will not follow the general plant replacement principles are the transformers, each weighing in the order of 5,000 kg.

The transformer bays are located on the perimeter of the building and have demountable louvres for access for replacement and to allow the transformer to be removed and positioned on designated 'plant landing' zone and craned from plant level down to ground level.

The air handling equipment will be dismantled into sections, and along with other plant items, will be taken to the designated 'plant landing' zone for craning down to ground level.

Small items of equipment of a suitable size and weight, e.g. pumps, coils and filters, will be taken from the plantroom via FM lifts in the Central Core.

Craning activities will require partial closure of the service road adjacent to the plantrooms, and alternative traffic management arrangement will need to be put in place during these times.

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Plantroom 41 (NCH Fourth Floor)
Refer to drawing numbers ZBP-XX-04-PL-525-102.

This plantroom is located at fourth floor level and is served by one of the FM lift in the Childrens Hospital Core.

This plantroom houses air handling and water services plant, as well as electrical substations and switchrooms.

The only items of the electrical sub-stations that will not follow the general plant replacement principles are the transformers, each weighing in the order of 5,000 kg.

The transformer bay is located on the perimeter of the building will have demountable louvres for access for replacement and to allow the transformer to be removed and craned from plant level down to ground level.

The air handling equipment will be dismantled into sections, and along with other plant items, will be taken to the designated ‘plant landing’ zone for craning down to ground level.

Small items of equipment of a suitable size and weight, e.g. pumps, coils and filters, will be taken from the plantroom via FM lifts in the Central Core.

The erection of a scaffold platform will provide a landing platform and permit safe personnel access for manoeuvring activities.

Craning activities will require partial closure of the service road adjacent to the plantrooms, and alternative traffic management arrangement will need to be put in place during these times.

Plantrooms 121 & 122 (Twelfth Floor Acute Hospital)
Refer to drawing numbers ZBP-XX-12-PL-525-103.

These plantrooms are located at twelfth floor level and are served by one of the FM lift in the Central Core.

These plantrooms house air handling plant.

The air handling equipment will be dismantled into sections, will be taken to the designated ‘plant landing’ zone designated for craning down to ground level.

Small items of equipment of a suitable size and weight, e.g. coils and filters, will be taken from the plantroom via FM lifts in the Central Core.

Craning activities will require partial closure of the service road adjacent to the plantrooms, and alternative traffic management arrangement will need to be put in place during these times.

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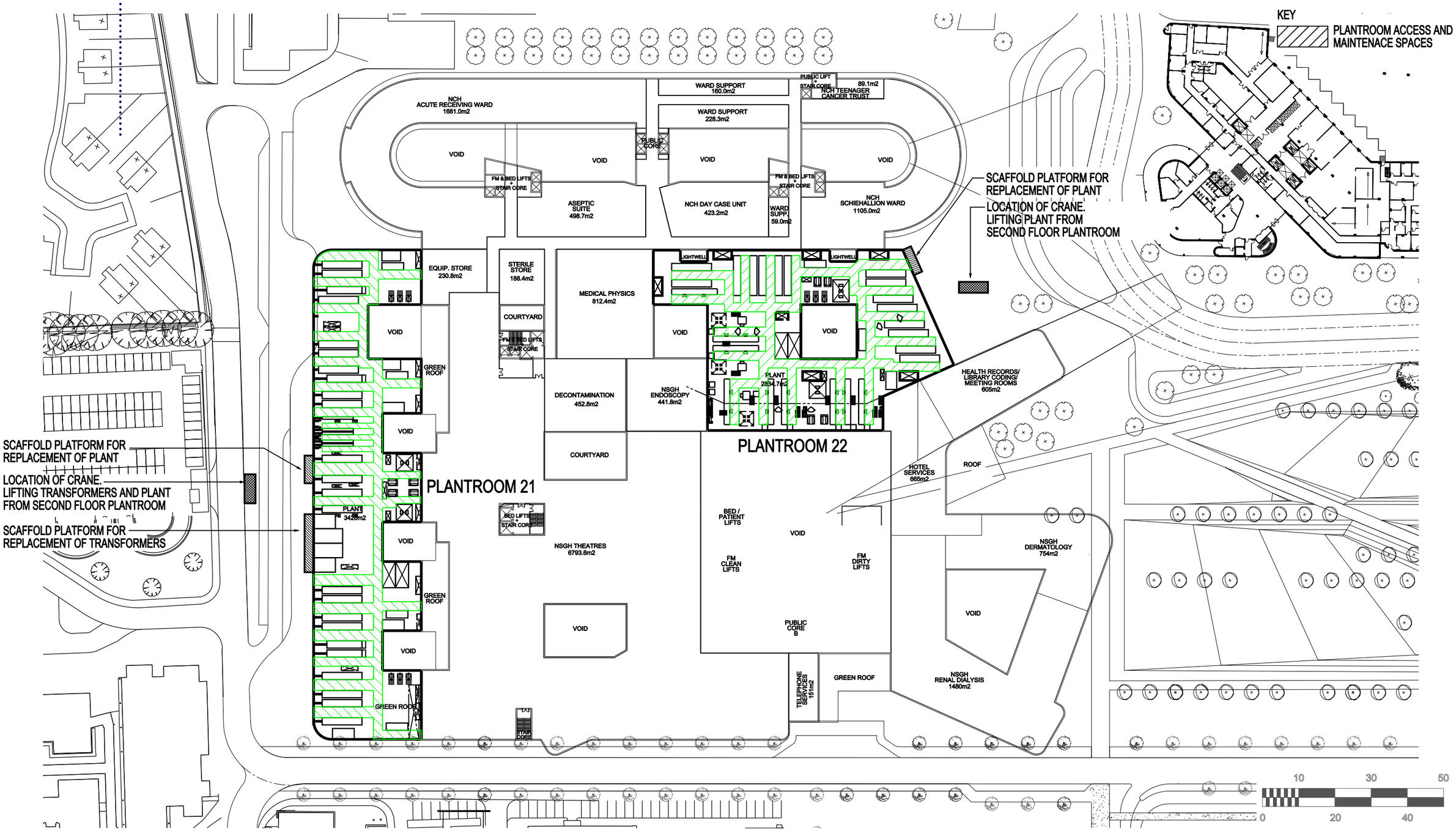

ITPD Reference:
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Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY SECOND FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

Date: JULY '09
Scale @A3: 1:1000
Drawing Number: ZBP-XX-02-PL-525-100
Revision:

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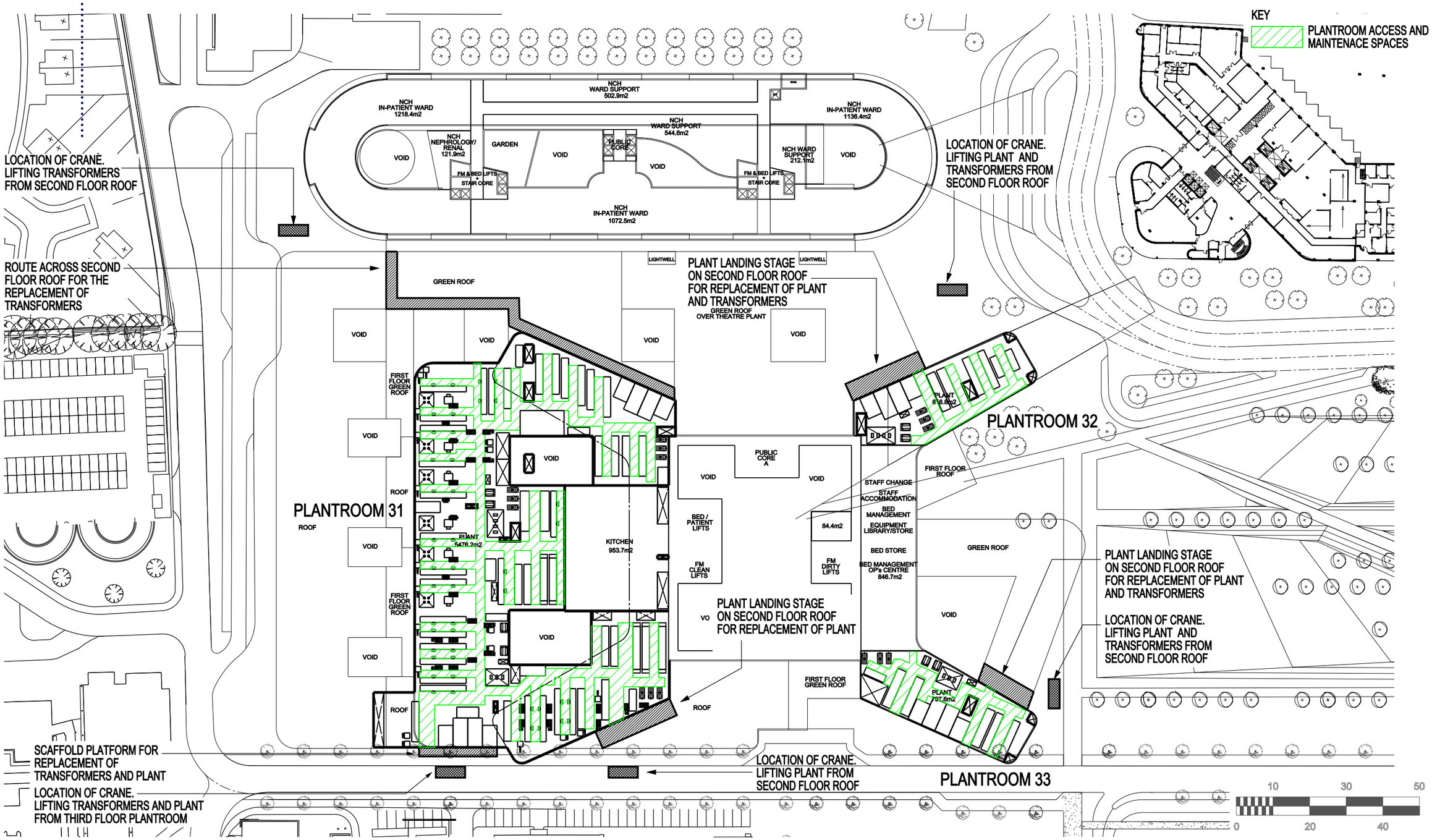

ITPD Reference:
VOLUME 3
Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY THIRD FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

Date: JULY '09
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Drawing Number: ZBP-XX-03-PL-525-101
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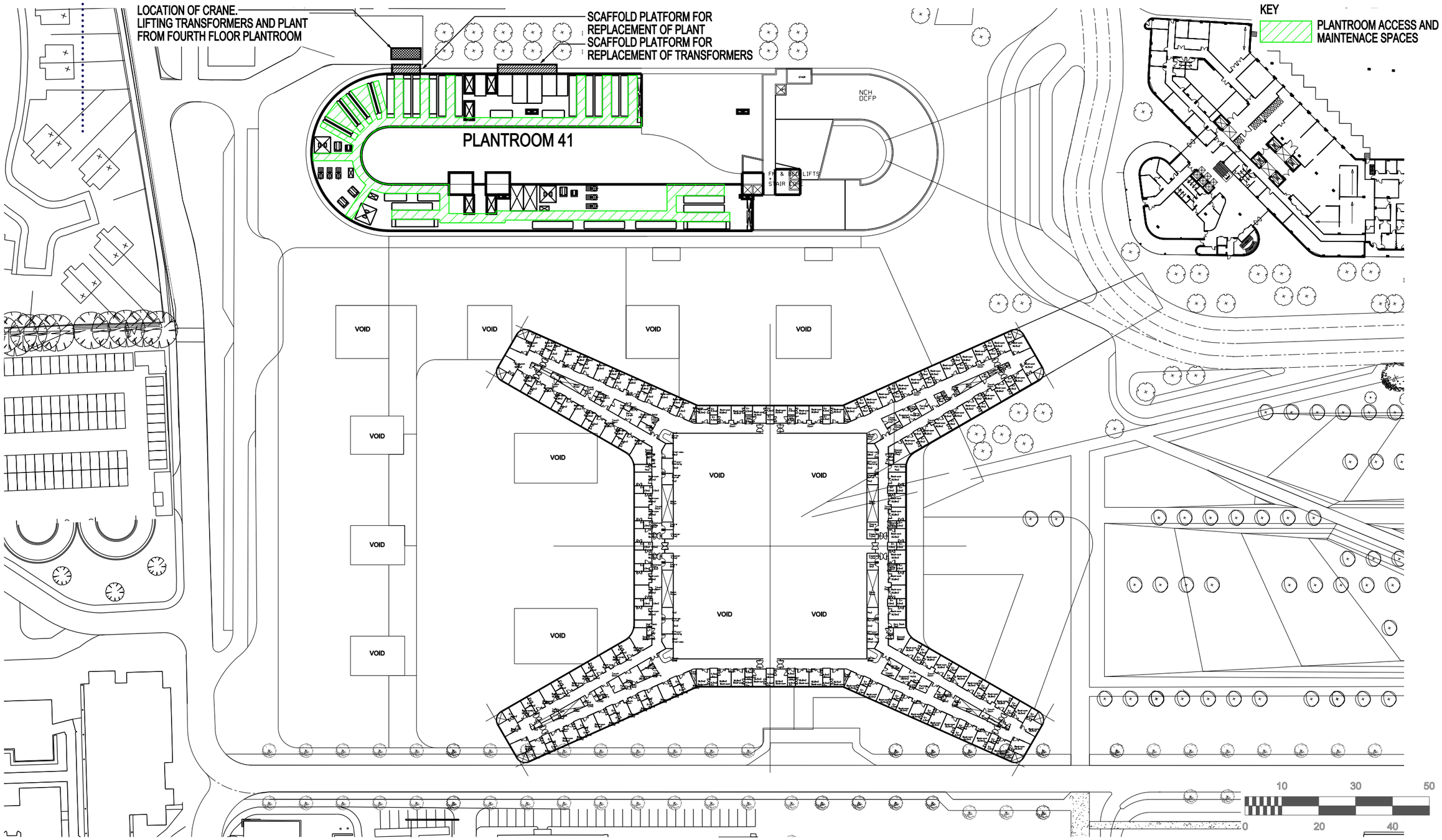

ITPD Reference:
VOLUME 3
Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY FOURTH FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

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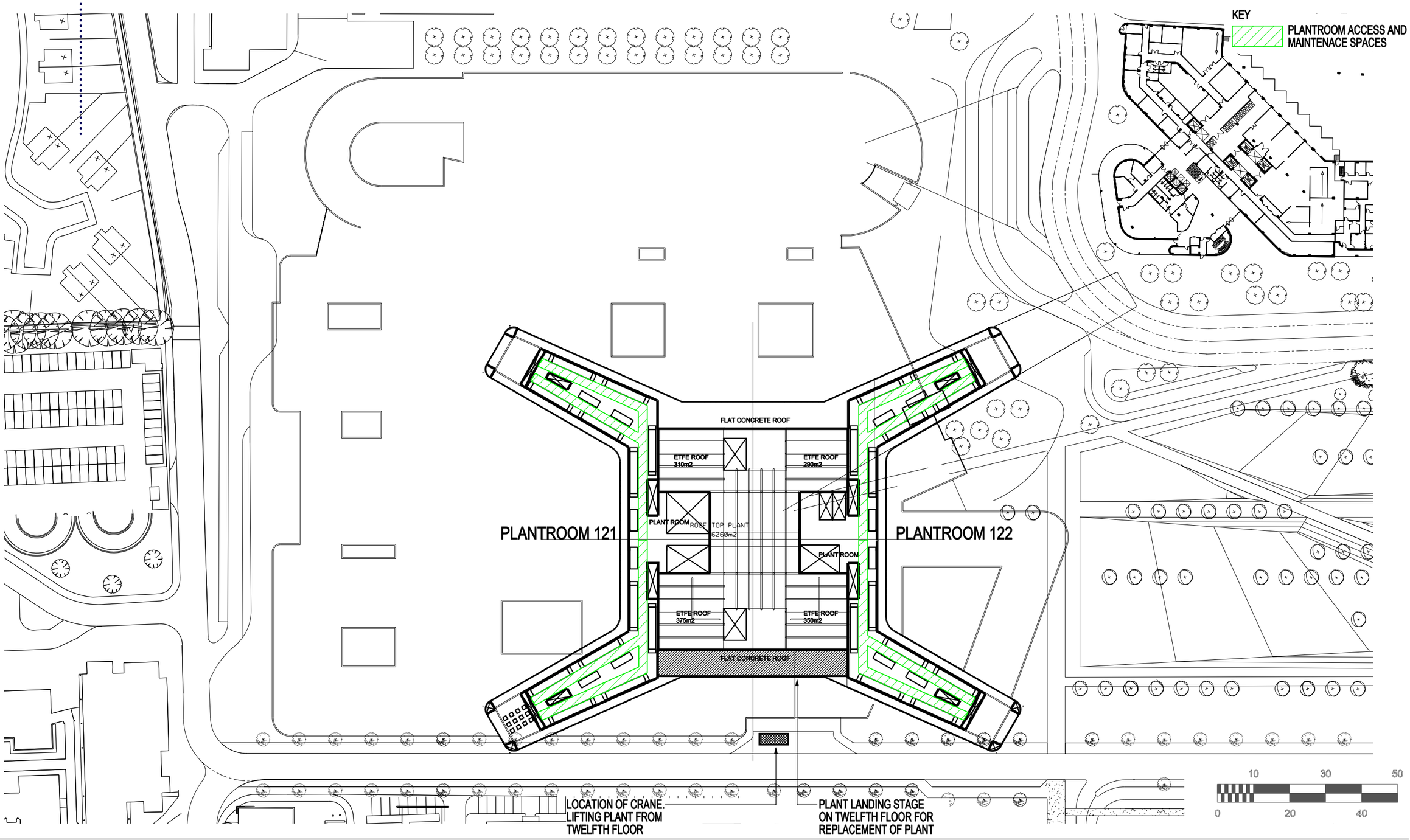

ITPD Reference:
VOLUME 3
Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY TWELFTH FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

Date: JULY '09
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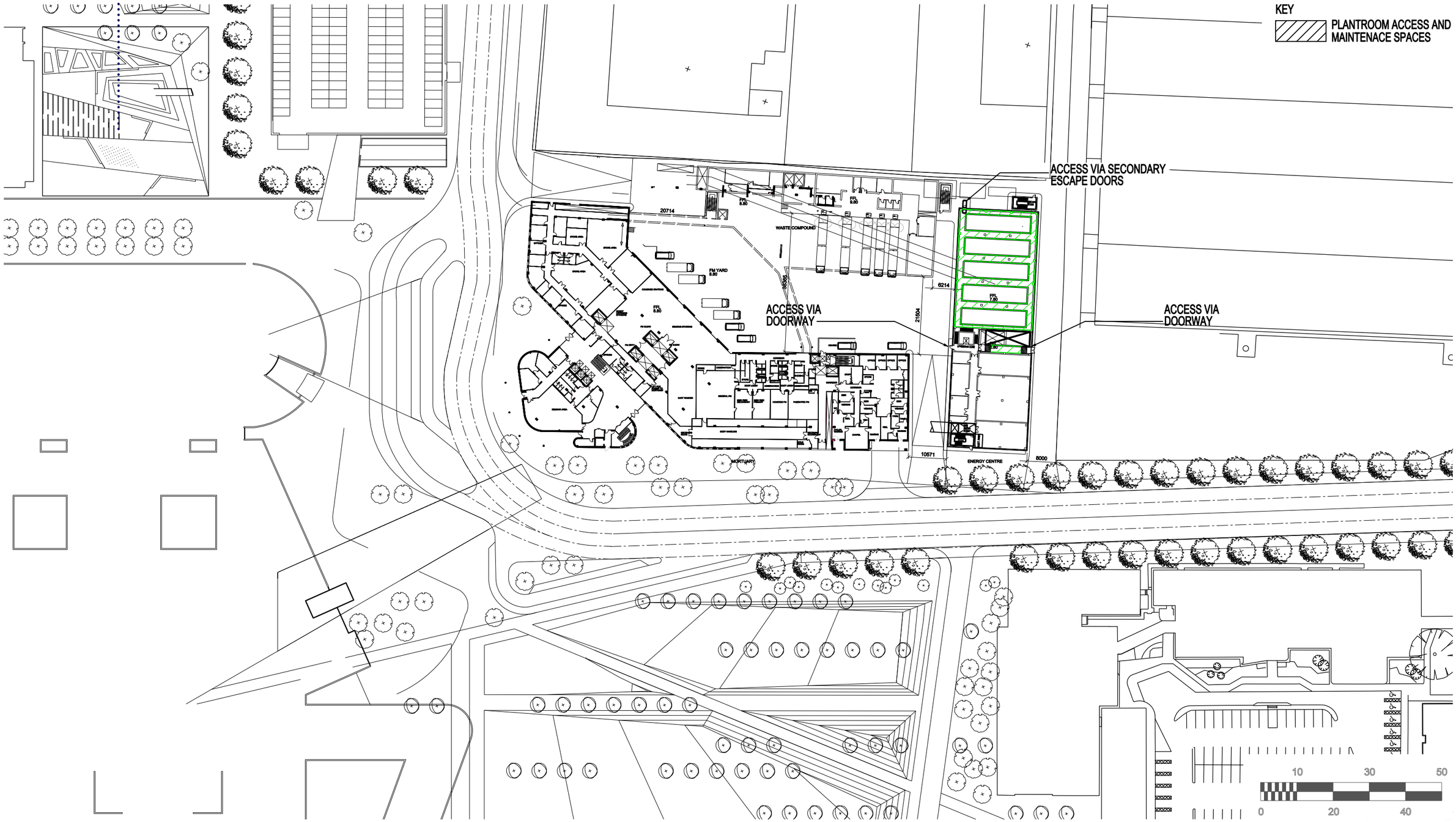

ITPD Reference:
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Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY ENERGY CENTRE GROUND FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

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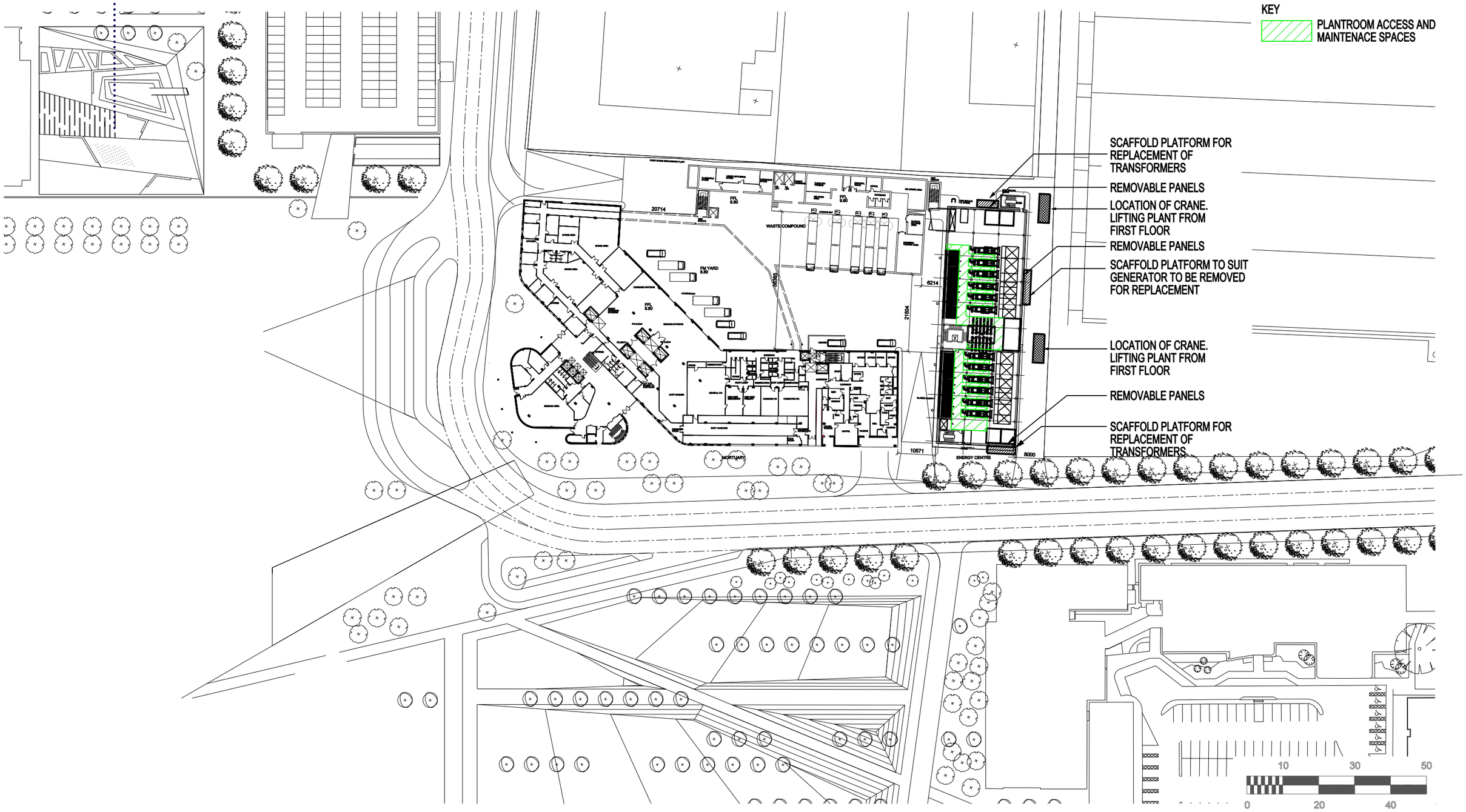

ITPD Reference:
VOLUME 3
Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY ENERGY CENTRE FIRST FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

Date: JULY '09
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Drawing Number: ZBP-XX-01-PL-525-105
Revision:

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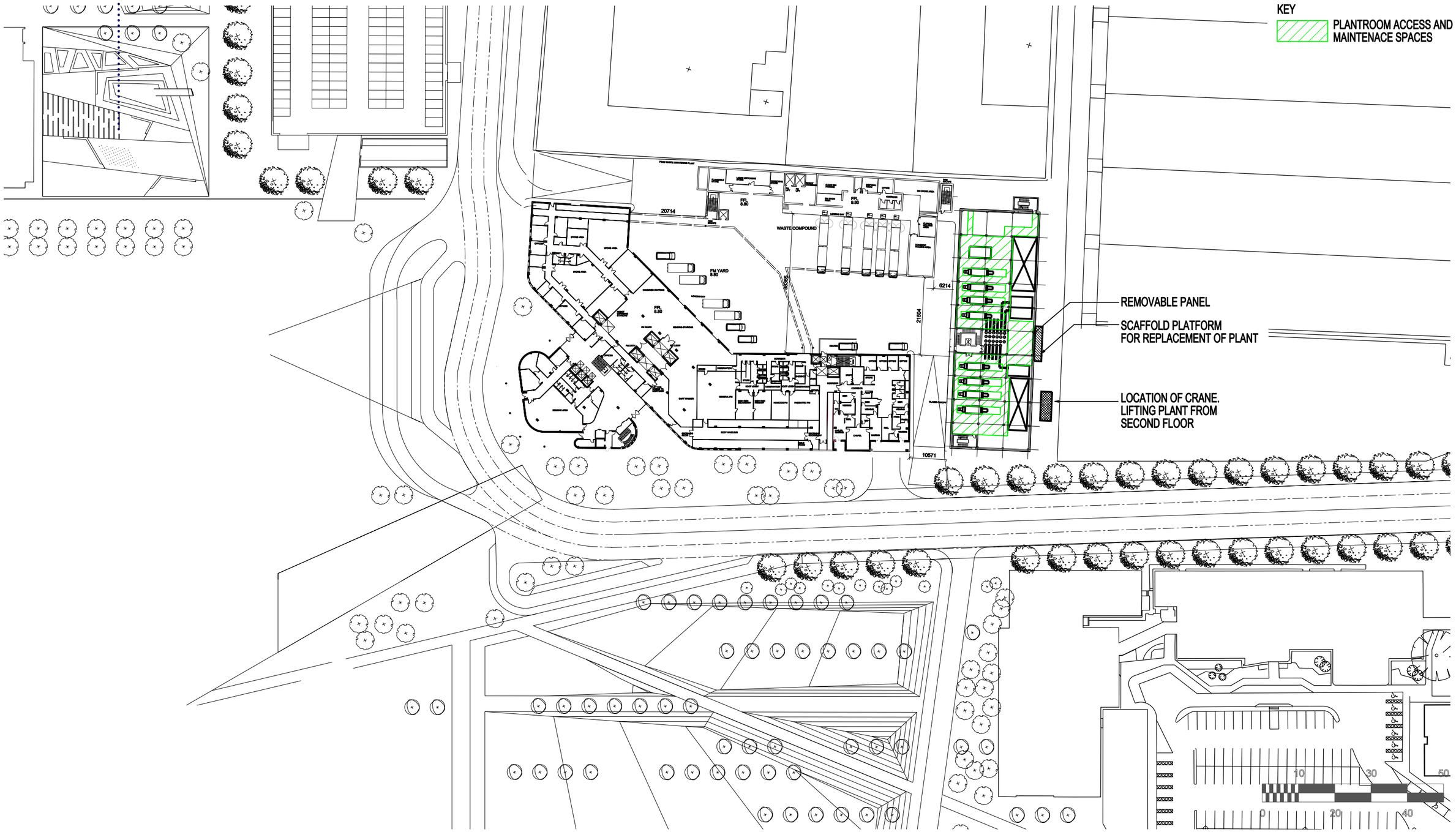

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VOLUME 3
Section 3.23

PLANT REPLACEMENT AND MAINTENANCE STRATEGY ENERGY CENTRE SECOND FLOOR

New South Glasgow Hospitals (NSGH) Project ITPD

Date: JULY '09
Scale @A3: 1:1000
Drawing Number: ZBP-XX-02-PL-525-106
Revision:

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NHS Greater Glasgow and Clyde

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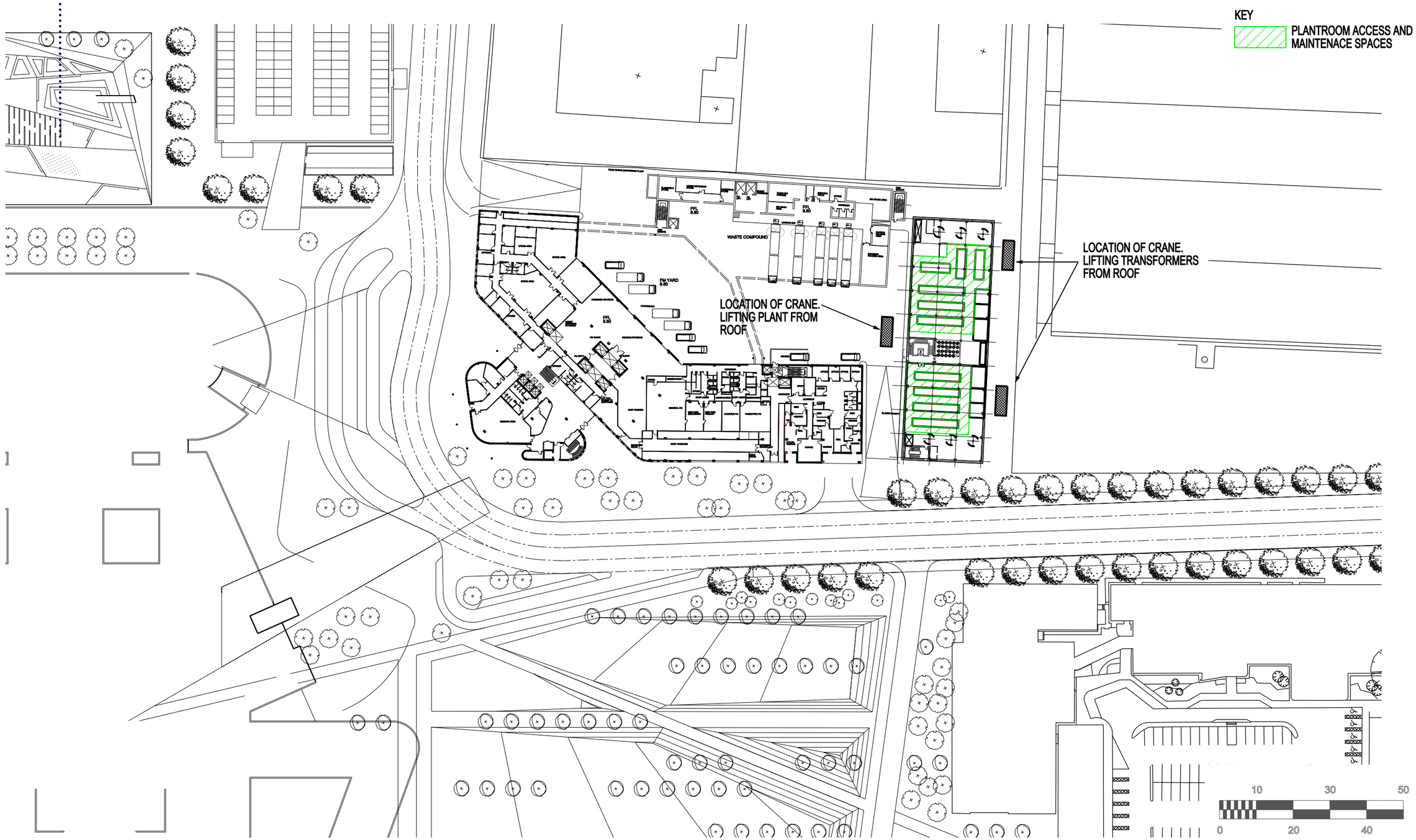

ITPD Reference:
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PLANT REPLACEMENT AND MAINTENANCE STRATEGY ENERGY CENTRE ROOF

New South Glasgow Hospitals (NSGH) Project ITPD

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A48235836

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Building Services Commissioning, Handover And Training Strategy

1.0 BUILDING SERVICES COMMISSIONING STRATEGY.

Purpose of the Document.

The purpose of this document is to explain the Brookfield plan for MEP testing & commissioning strategy being proposed for the New South Glasgow Hospitals Project, how the individual suppliers will be managed in regards to the commissioning process, and to demonstrate how Brookfield intend to successfully deliver the commissioning of systems and the hand-over to operational readiness prior to public opening.

What the Strategy Covers.

Brookfield will approach the delivery and management of commissioning internally and through the suppliers engaged by Brookfield to test and commission the systems within the hospital, in order to prove to the stakeholders, both client & design team that the integrated design meets the requirements of the hospital.

How the Strategy will be Delivered

Delivery of the hospital services commissioning is dependent on the integration and cooperative working of the various supplier teams. The QITP strategy covers the off-site testing and pre-commissioning (where applicable), on-site pre-commissioning, commissioning and acceptance of systems and the integration tests leading to handover to operational readiness; ACHP completion.

The QA processes Brookfield and their suppliers will follow throughout the project shall outline the interface boundaries and requirements regarding 3rd party teams for validation and independent certification.

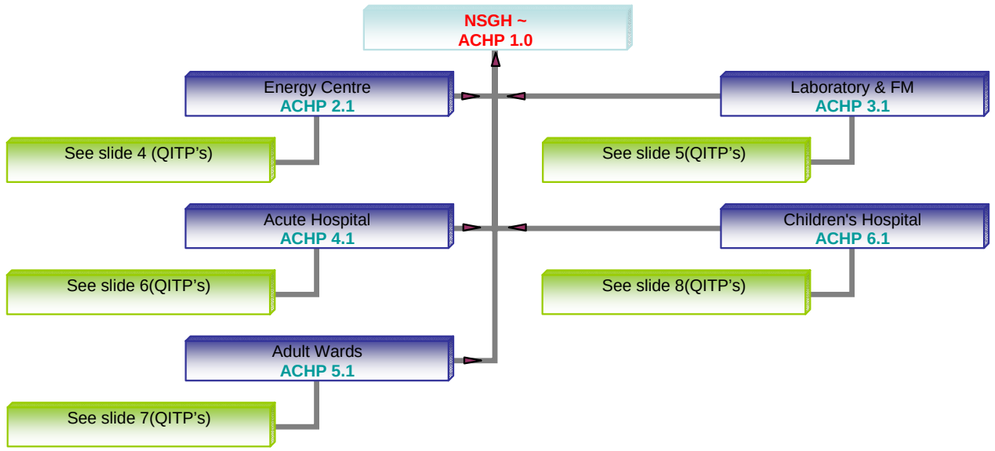

Fig 1; Asset Commissioning & Hand Over Plan

The diagram above demonstrates a high level overview of the Brookfield approach to the commissioning process using the Asset Commissioning & Handover Plan (ACHP) system:

Developing the Outline Commissioning Plan.

For this project this document will define the scope and detail of the commissioning process. This deliverable is created during the design stage by the Brookfield commissioning manager with input from the design team, subcontractors and will serves as a guideline for team members to follow. It will identify the processes and procedures that will be undertaken, including schedule of all activities, and the roles and responsibilities of each team member.

The Commissioning Plan is an evolving document that defines the project's commissioning activities, schedule, documentation requirements, and the roles and responsibilities of team members.

The final Commissioning Plan will include:

- General building information and contact information
- Project objectives.
- An overview of the commissioning process ~ FAT, SAT and IST protocols including the O&M delivery.
- Building and systems description, including a list of components and systems that will be commissioned.
- Develop the scope of commissioning QITP's and the Hand over procedure.
- List of team members, their responsibilities, and expected deliverables
- Description of communications, reporting, and management protocols
- Detailed description of power monitoring procedures ~ specifically for the periods up to PC and during the 36 month DLP.
- Recommended training activities

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Perform Commissioning-Focused Design Review.

During the stage review Brookfield will review with our design team to further understand their reasoning and assumptions for choices made about how to accomplish the project goals. The Brookfield commissioning manager will review design documents for clarity, completeness and compliance.

The design review process has several steps and takes place throughout the pre construction phase of the project:

- Next, the lead examines the implications of system choices to ensure that the design will meet the project requirements. At this stage of the development of the project this general review would be carried out as a concerted effort with the design team.
- A coordination review to examine how systems will interact and whether there are any potential conflicts.
- When the specifications are drafted, the lead will carry out a final sweep up review for anomalies.

Some of the most important decisions for the commissioning manager to review during the design phase include:

- Sizing and selection of building systems and equipment accessibility of equipment for operations and maintenance
- Sustainability objectives such as target emission reduction.
- Details of the controls design relative to equipment being controlled & monitored.
- Ability of controls interface to facilitate trending and identification of equipment faults during functional testing.
- Identification and access of test ports, sensors, and in-situ measurement devices for use in functional testing & analysing performance

Brookfield Commissioning Team Structure

It is important to note that the commissioning process will be adapted to meet the needs of this building project. During all phases of commissioning, the Brookfield commissioning manager will be interacting with members of the design, construction, and operations teams. The Brookfield team will develop and establish a clear and pragmatic process for sharing information early in the project in order to get the full benefit from the Brookfield commissioning process.

Our suppliers will have a commissioning manager/supervisor (as appropriate) who shall be accountable for their commissioning plan/deliverables and its integration into the overall project wide commissioning plan. These commissioning managers/supervisors will be accountable for the detailed commissioning planning and activities at sub-project level, this detail will be fed back into the Integrated commissioning programme.

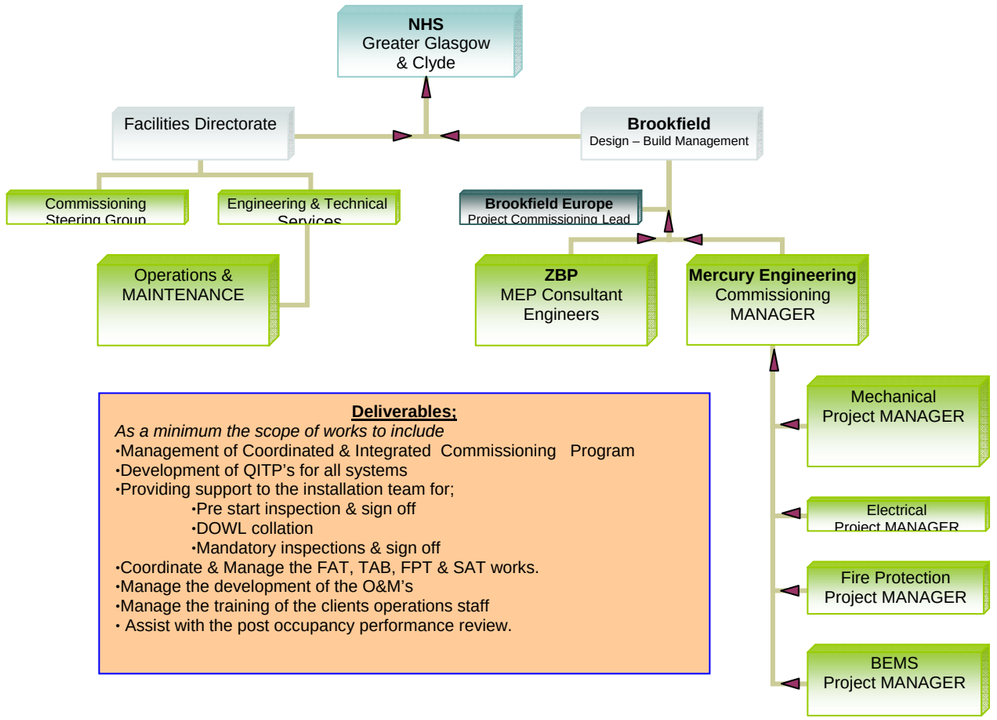

Fig 2; MEP Commissioning Team

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Who will be involved in delivering the commissioning

In order that commissioning can succeed (and in turn that operational readiness and handover can be achieved), it is vital that handover from construction / installation to commissioning is carried out strictly in accordance with the integrated commissioning programme.

To overcome the time schedule issues between construction / installation / fit-out / commissioning, a co-ordinated time schedule will be produced by Brookfield that highlights the dependencies that the systems have upon each other and the impact that they can have.

Commissioning periods cannot be permitted to be viewed as “float” for construction activities

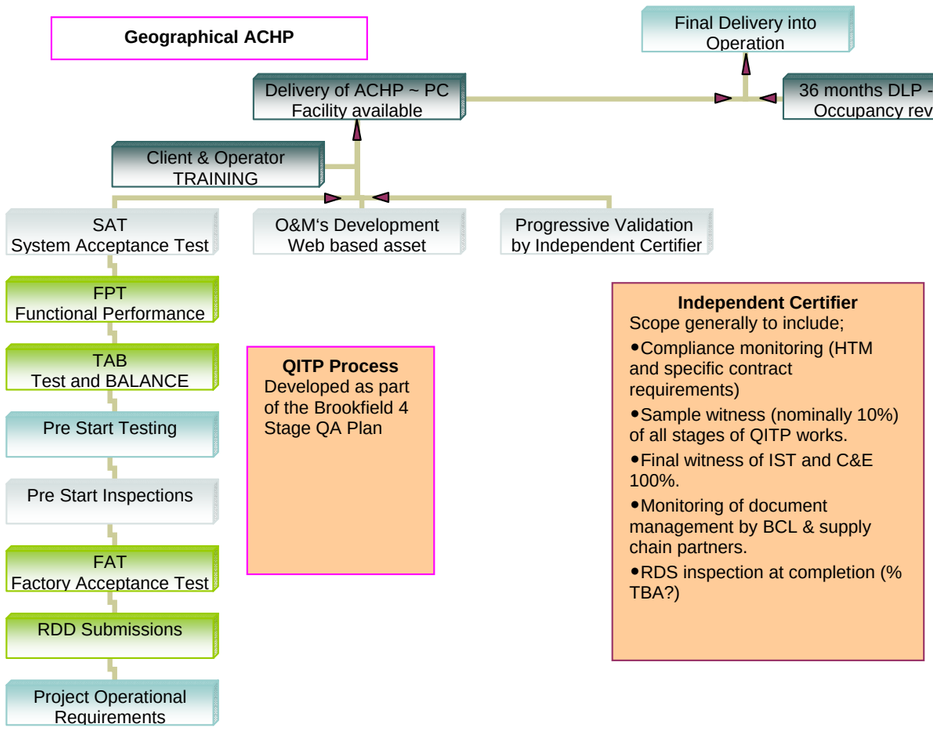

Fig 3; Assurance PROCESS diagram

Perform Functional Tests (System Acceptance Test)

The development of SAT procedures assists in practical levels of % witness validation of the system operation. In many cases it is impractical to naturally observe every possible operating regime. The Brookfield commissioning manager will agree protocols for the witnessing and documentation to be conducted by the contractors.

The commissioning manager and contractors schedule the testing and make any necessary preparations, such as checking and calibrating control points or temperature sensors.

Functional tests typically involve forcing the system into a series of operating modes, and observing the system’s response. The commissioning manager will ensure that all data is meticulously recorded and observations noted on a pre-defined data sheet, and then ensure that all systems are returned to a “normal” state.

During functional testing, the commissioning manager uses an Issues log to track any performance issues that may arise, and their resolutions.

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Systems that we would define for specific review include:

No;	Discipline	Detail	% Sample Witness
1	HV operation	Normal and alternate demand for EDF supply and generator back up.	25%
2	LV operation	Essential power feed ACO functionality and demand.	10%
	UPS/IPS	Normal and autonomy testing for the IT hub rooms & Endoscopy / Recovery rooms.	10%
	Fire Alarm & Detection & Life Safety	Fire detection and suppression and interfaces detailed in C&E matrix	100%
	Stair Pressurisation and smoke extract ventilation	Functional testing and interfacing of SFD/FD scenario requirements. (see C&E)	100%
	Lighting	Normal control & emergency functionality	10% & 100%
	BEMS	System management & functionality tests including status monitoring & telemetry	20% - 50%
	Security / Access Control	System functionality and resilience under power failure.	10%
	Nurse Call / Alarm systems	System functionality and resilience under power failure.	10%
	IT and communication systems	System functionality and resilience under power failure.	10%
	CHW	System functionality and resilience under power failure	10%
	LTHW	System functionality with the operational sequencing of the CHP lead and Biomass boiler	10%
	PHE	Operational tests of the HWS/BCWS and the SVP/RWP systems. This should include the surge protection, PRV setting, temperature blending & the leak detection system.	10%
	Medical Gas	Integrity and functionality checks in readiness for the Clinical team Pharmacist validation and setting to work.	20% - 50%
	General Ventilation	Functional Testing and balancing of comfort cooled areas and the dirty extract systems. FD drop test demonstration to BCO	10% & 100%
	Clinical area ventilation	In particular the pre testing of the departments with close controlled operation - pressure and temperature regime areas such as the Aseptic suite and Isolation rooms& including the setting up of the fume cupboard extracts	20% - 50%
		The final set up by the Clinical team Pharmacist validation and setting to work to be agreed	

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Integrated Systems Test

The Integrated Systems Test is the ultimate shakedown demonstration of the commissioned building performance. This test can only occur after all individual SAT's have been successfully verified and documented to function according to their respective design intent. The goal of the Integrated Systems is to finally verify the overall reliable functional interactivity of the MEP systems for the whole building during normal, emergency, and other failure scenarios.

The diagram below is indicative of the approach that Brookfield will use on the NSGH project. The QITP's are integral to the milestone process regime that will culminate in the final system functional performance tests that are required to complete the ACHP. This plan provides flexibility and ongoing assurance that the works and systems will deliver the requirements of the project.

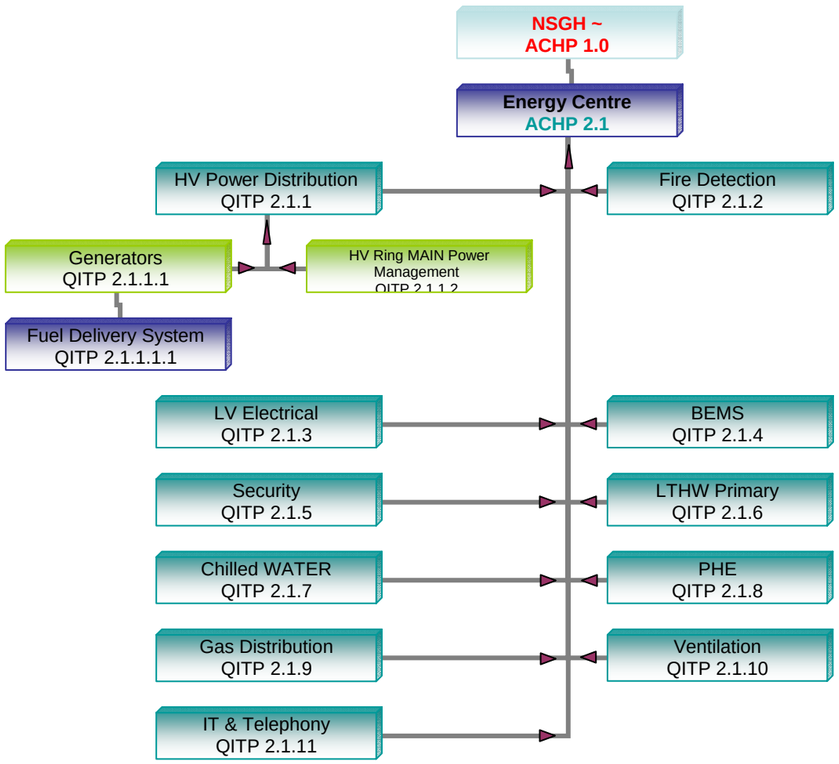

Fig 4; QITP process diagram

Documentation

As part of the final hand over procedure the documentation that would traditionally populate the O&M's will be updated into the digital web based asset management system.

This database will be in use from the project design commencement until handover to NSGH operational use.

Brookfield will during the course of the contract maintain online access to the system and will provide at the time of handover a computer complete with hard drive containing all completed information.

NSGH may wish to consider the offer provided by Zutec for extended use of the online system after expiration of Brookfield defects liability period.

Verify Training of Client Staff and Review.

Brookfield realise the importance of these activities and will ensure that this phase of the delivery is not underestimated because of its role in assuring long term benefits for the operational health of the facility. The Brookfield commissioning manager will verify that they are carried out to the operator's satisfaction.

Post Occupancy DLP period

The requirement within the outline brief to verify the systems conditions at the end of the extended defects liability period will necessitate sample readings of all systems.

At the handover the building will be taken over by the hospital Board and operation staff, although the Project will have achieved practical completion, Brookfield will continue to monitor the power consumption of the facility in normal operation for the defects liability period.

Brookfield commissioning manager will develop ongoing review and feedback with the hospital operations management staff regarding system performance. Fundamental building commissioning will have been completed, witnessed and recorded, further fine tune commissioning ,may be required post practical completion during the defects liability period.

This will include as an example; the setting of ambient lighting control post FFE completion and post occupancy seasonal testing, calibration checks of control systems.

Brookfield experience that the post construction period environmental checks on the performance of systems is beneficial to making sure that the energy efficiency objective is maintained; monitoring during operational conditions usually provides more reliable data to make adjustments and provides key information to the hospital operation & maintenance staff.

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Brookfield will ensure that this is a coordinated monitoring regime with the operational staff to verify system performance during different seasons – as a minimum winter and summer. Upon completion the data would then be reviewed with a concerted issue log developed as appropriate.

Towards the end of the 24 months defects liability period, initially this will follow specific periods (1 month/3 month post PC) whereby Brookfield will address comments from the operators and address any adverse data from the building energy management system. The Brookfield commissioning manager will review and update the issues log and assist in updating the electronic asset management system with the revised information.

Additional Training During Handover

It is proposed that during the construction period a number of locally sourced junior engineers will be employed and trained on the project. These engineers will form a critical part of the final commissioning teams.

During the commissioning period these engineers will be involved with every aspect of the setting to work of all of the mechanical and electrical systems. This will provide a resource to the hospital at handover stage of personnel who will be fully conversant with the systems and who will have had an active part in the commissioning of this system. These engineers can eventually work directly within the FM department of the hospital.

Definitions of Testing & Commissioning

The meaning of the terms “testing” and “commissioning” used in this document are those defined in the acknowledged standards published by BSRIA, CIBSE, IEE 17th edition and requirements of NSGH, SHTM’s and HTM’s.

The activity “Handover”, which is linked to commissioning, is not specifically covered in this strategy but is recognised as a key output from the successful commissioning of systems.

The precise sequence and processes for handover are yet to be defined; this strategy will be amended to incorporate the specific details once they are made available.

Due to the significant quantity of system and items required to be witnessed by the client’s representative, the standard industry practice of 10% of each system type will be offered.

After all systems are put into use, a final inspection of the power quality will be made and should adjustments be required these will be undertaken during the defects period.

Definition of Systems.

Systems are generally defined by the typical functional groups such as Chilled Water & LTHW. Systems will be split into a component level of detail that may be used in the method statements and commissioning programmes to further identify interfaces between systems.

2.0 HANDOVER STRATEGY.

Asset Management System.

Brookfield hand over procedure will be based on the use of digital web based asset management system that will be populated from the project design stage until final handover to New South Glasgow Hospitals for operational use.

Brookfield will during the course of the contract maintain online access to the system for continual review and comment of all information to ensure that a very smooth and efficient handover process is completed.

Brookfield will provide at the time of handover a computer complete with hard drive containing all completed information.

The hospital Board may wish to consider the offer provided by Zutec for extended use of the online system after expiration of Brookfield defects liability period.

The reason why Brookfield use a digital web based technology for asset and handover management is that it provides a complete user friendly collaborative tool that is progressively used to development all data and information required for a successful handover and operation of the hospital. This system provides the client with the benefit of full participation with the joint development of the right information for hospital operation use commencing from the design phase until handover.

The result is that the information contained in the asset management system is exactly what the client requires including staff that participate with the system development are fully trained to use the system. The result of this collaborative approach means access to vital information can be found in an instance as required for operation and or crises management.

The system provides a seamless tool that enables successful handover of all necessary documentation including an instant process for operational and maintenance use.

The online asset system includes:

- Room data sheets.
- Construction period online snagging system.
- Design data and design functional descriptions.
- Technical submissions.
- Energy Performance model calculation data sheet.
- BREEAM rating schedule.
- Whole Life Cycle Cost Plan
- Operating and maintenance manuals.
- Commissioning records.
- As-built drawings.
- Plant replacement strategy.
- Training manuals (Documents that we use for handover training)
- Building Log book.
- High level control interface with energy monitoring system to provide instantaneous energy consumption data.
- Health & safety residual risk assessments. (CDM)
- Maintenance service log book.
- Call out log book.
- Observations report system.
- PPM system.
- Maintenance calendar.
- Interface with Maximo.

User features include instant access from any location enabling online review and comment of all data loaded on to the system; starting from design details through construction, commissioning, operation and maintenance, reducing the risk of data being lost, providing quick access to any item of information to all authorized parties.

The application includes direct data input of design details on equipment scheduling, asset tagging and provides a methodology for tracking sustainable assets.

The following captions outline the Asset Management System.

We have set up a sample demonstration home page for the New South Glasgow Hospital as outlined in Figure 1 below

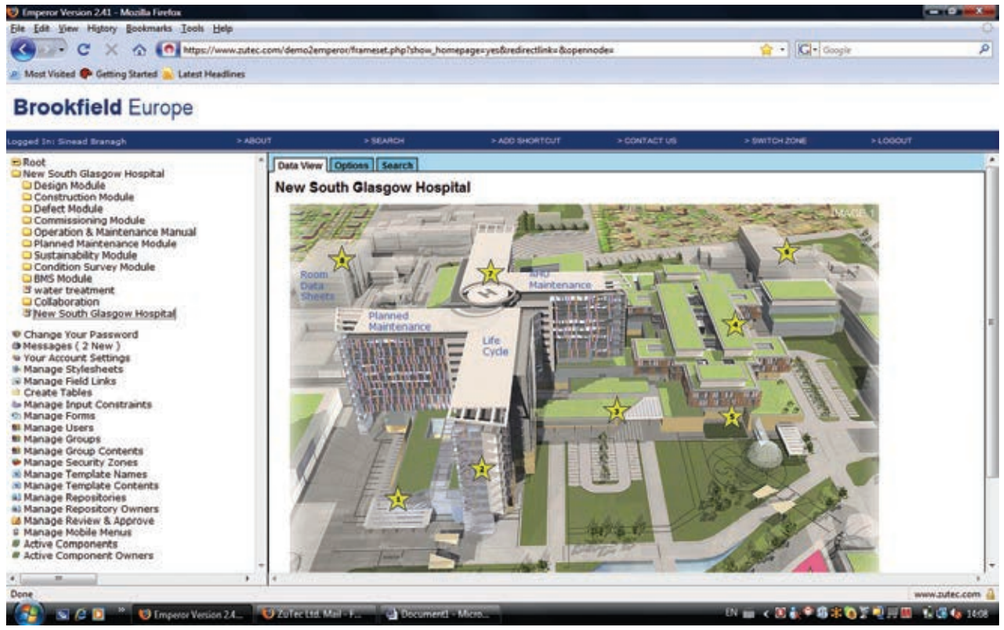

Figure 1 – Zutec Home Page

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The asset system includes the facility to capture actual Kilowatt Hour data from equipment schedules for comparison with construction submittals / commissioning test sheets and actual meter readings taken from energy metering management control system, thus giving an accurate picture of the changes which may occur throughout the building lifecycle.

By capturing all the major components of the maintainable assets using the online database approach, we are ensuring that these assets are logged and tagged in a manner that is both effective and efficient in a modern hospital facility. Completing this exercise from design stage and using an online system saves time and massively improves the quality of information provided to the operators.

Project Process

Described below is a brief detail explaining how the process for the asset management system evolves from the design stage in to operational use.

Stage 1 – Design

During this stage, the design team creates and uploads the room data schedules, equipment schedules, technical submissions, functional design descriptions and asset tags all the major maintainable assets.

The room data sheets can then be modified during the course of the project and handed over accurately completed.

This is shown in the screen shots below;

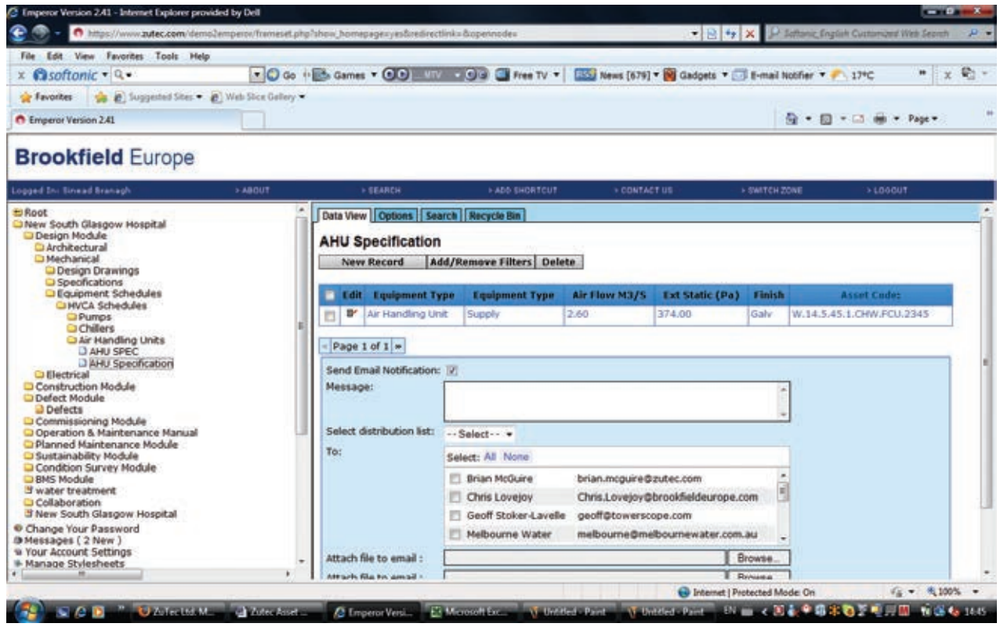

Figure 2 Design Schedule – (showing equipment schedule e.g. Mechanical Air Handling Plant)

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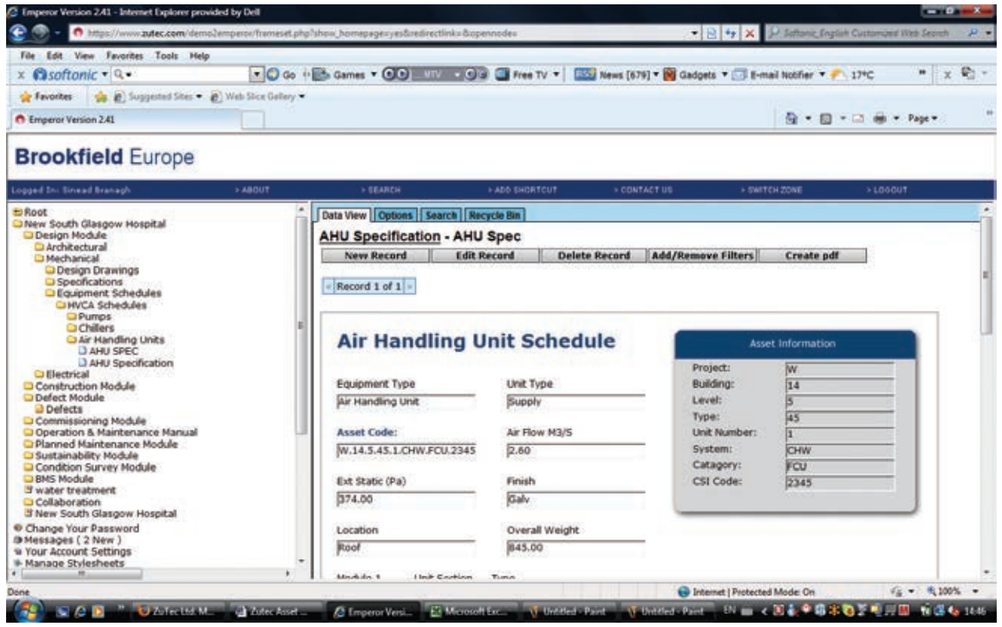

Figure 3 The Inclusion of Asset Registering as Part of Design Data Input

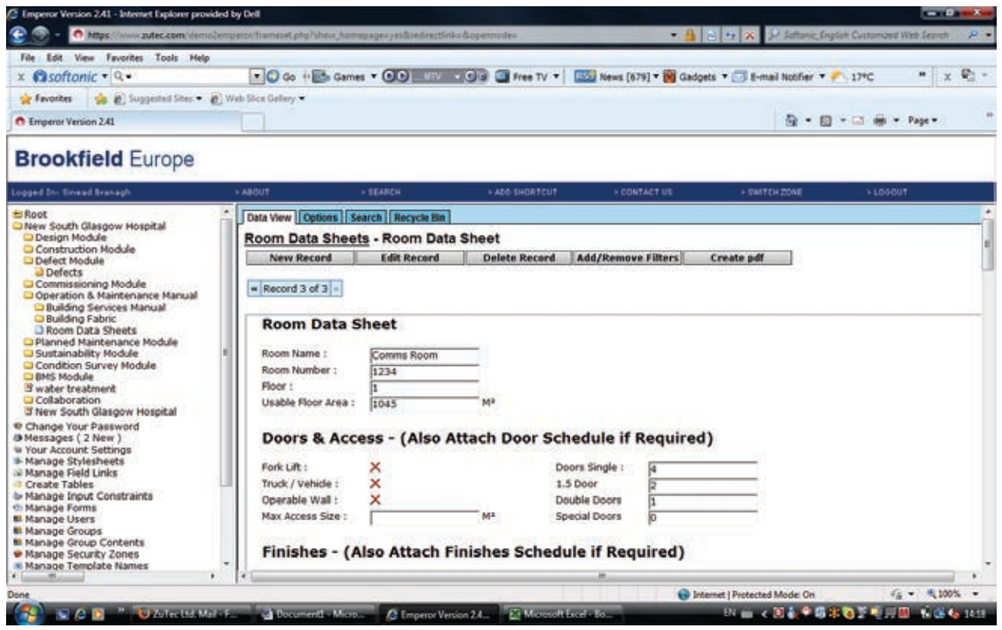

Figure 4 Room Data Sheets

Stage 2 – Construction

This stage moves from design to construction, using the already loaded Asset Tag Numbers we can ensure there is a direct link between the design equipment schedule and the construction submittal schedule – (ensuring no deviations from the BREEAM requirements).

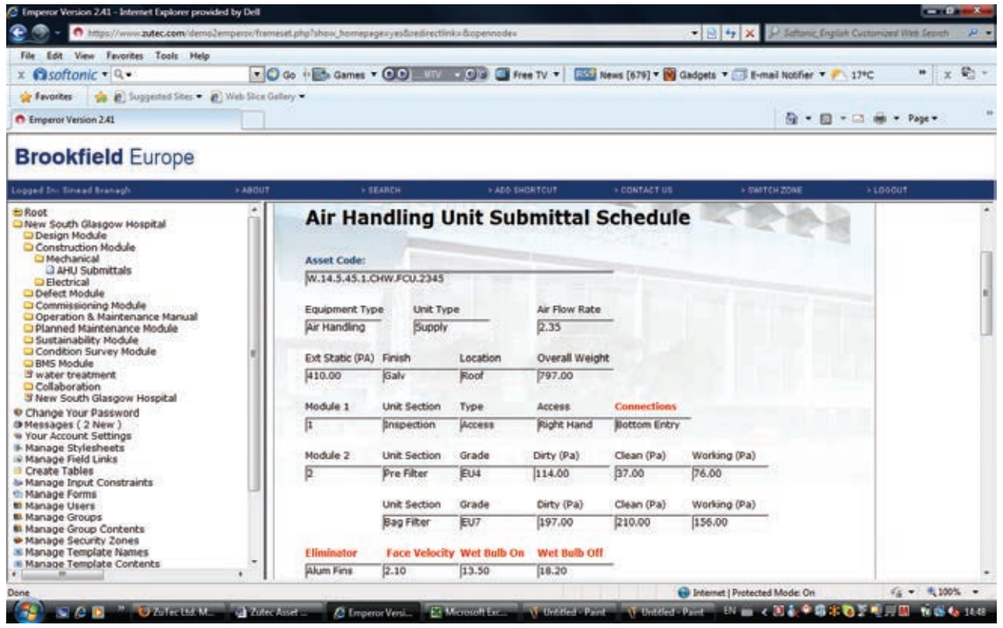

Figure 5 AHU Submittals

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Stage 3 – Commissioning Management

The commissioning management section of the system is based on BISRIA, CIBSE and IEE commissioning templates.

During this stage commissioning data is loaded directly into the required templates again under the direct data input model – the example below shows a duct traverse reading recording ductwork velocities. The system in this instance has an algorithm to calculate the average velocity in a given duct traverse reading. Using this method will ensure a major productivity gain for the commissioning company as this avoids double handling of information.

All specialist plant commissioning records are also recorded on the system.

In addition we will record actual kilowatt readings on each of the sustainable assets for design / construction and commissioning, again ensuring at an early stage that we stay within the BREEAM requirements on sustainable development.

The system enables drawings to loaded on to the system with commissioning tag points set that enables the user to click on an icon and open to see commissioning results recorded on any system of component such as individual grills, duct system and or plant item.

Remote checking of progress by authorised users from any location is available and up to date status can easily be established.

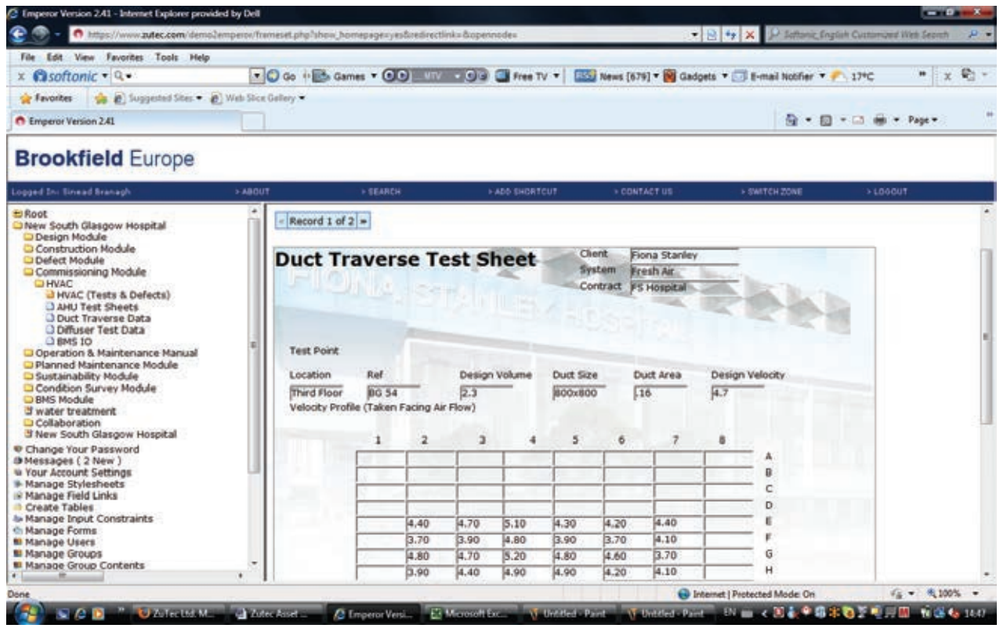

Figure 6 Commissioning Management Module

Stage 4 – Handover

In this stage we will compile the As Built Asset Register / Operation and Maintenance Manuals / As-Built Drawings / Health and Safety Files (including residual risks), client training manuals including attendance schedules and training feedback questionnaires.

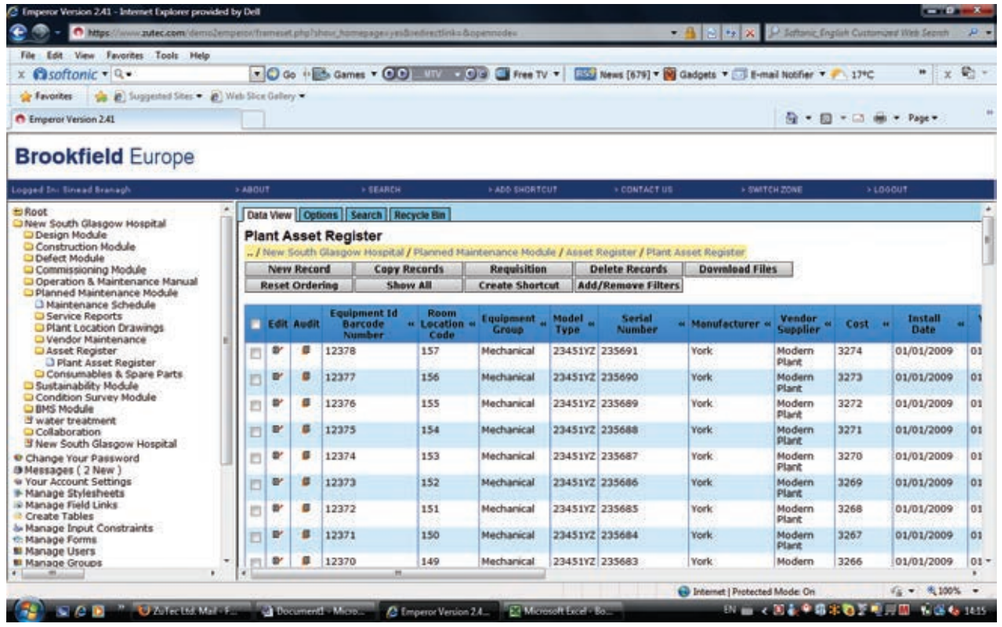

Figure 7 Asset Register

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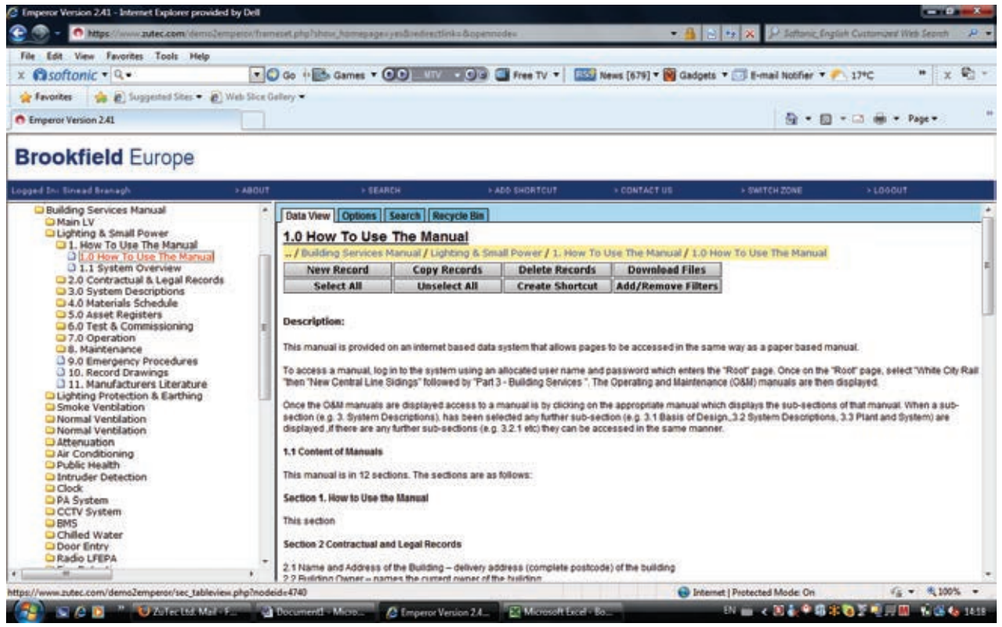

Figure 8 Operation and Maintenance Manuals

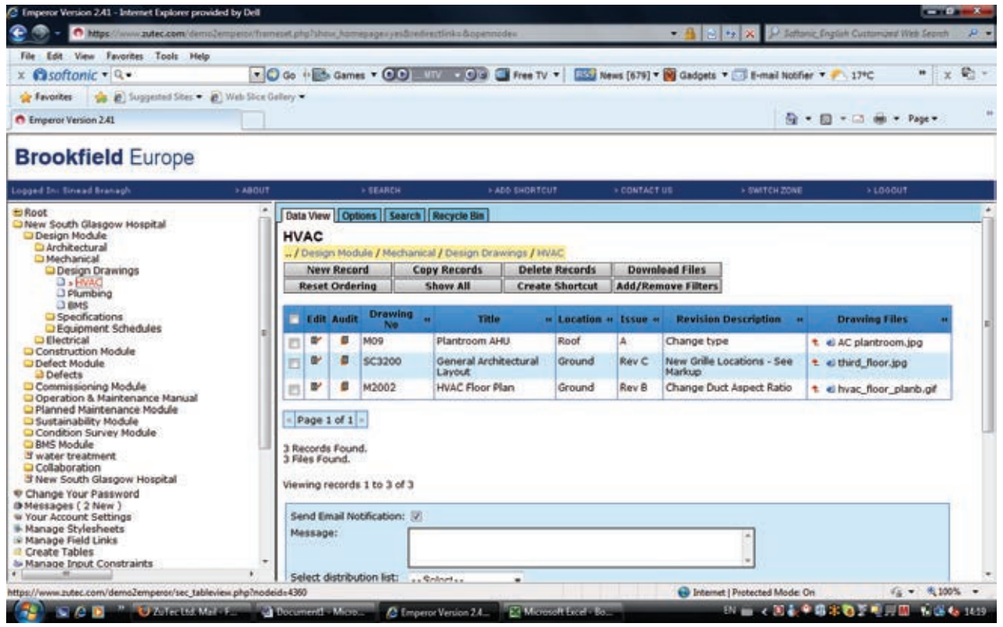

Figure 9 Drawing Register

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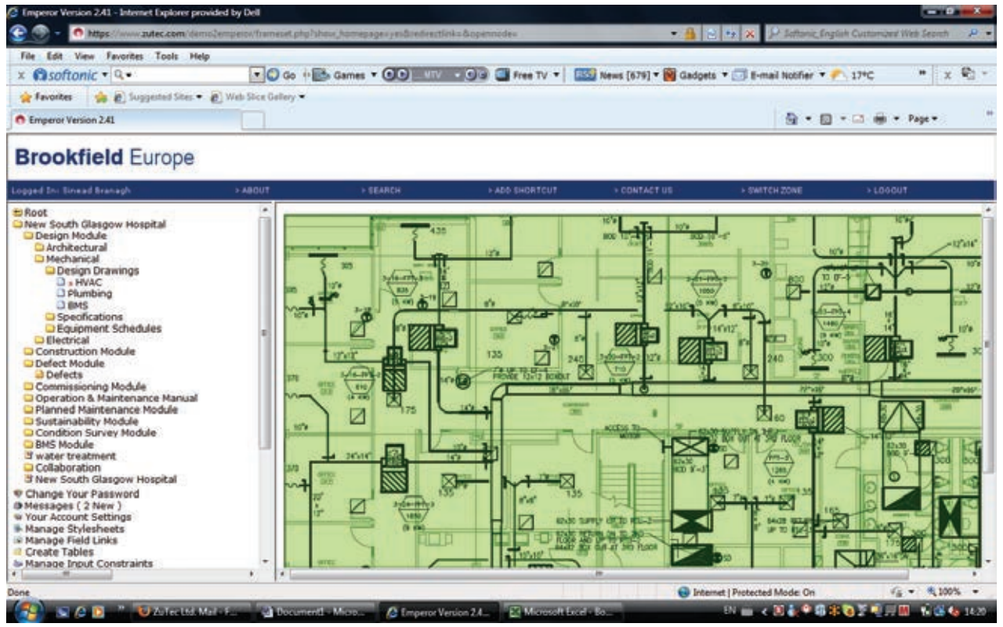

Figure 10 Drawing Detail

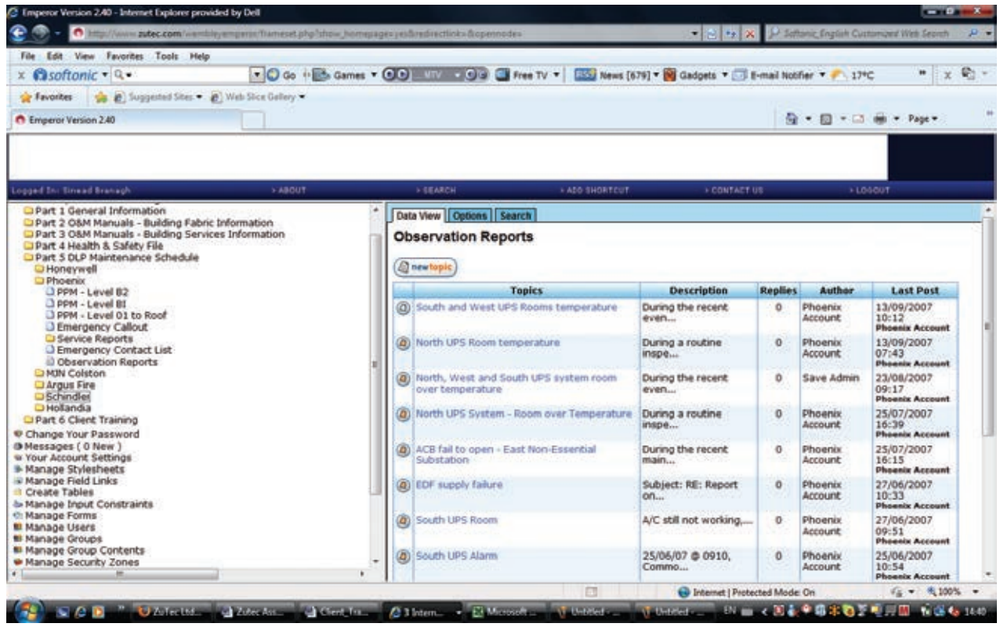

Figure 11- Observation Reports

Stage 5 – Operations

During this phase the data collected during the previous stages can be used to set up planned preventative maintenance calendar and linked to service reports (either directly or by way of drawings showing plant location.

The system includes a maintenance service log book that enables all maintenance technicians attending any equipment item or system to record materials, labour and time used. This can be picked up instantly by accounts departments.

To optimize preventative maintenance a discussion thread module is used to provide an observation report system that can be used to identify potential maintenance issues feed back directly to the maintenance management. Some of the benefit provided by this facility is to identify items that have been observed that may not need immediate attendance but only need to be dealt with at the next scheduled routine maintenance.

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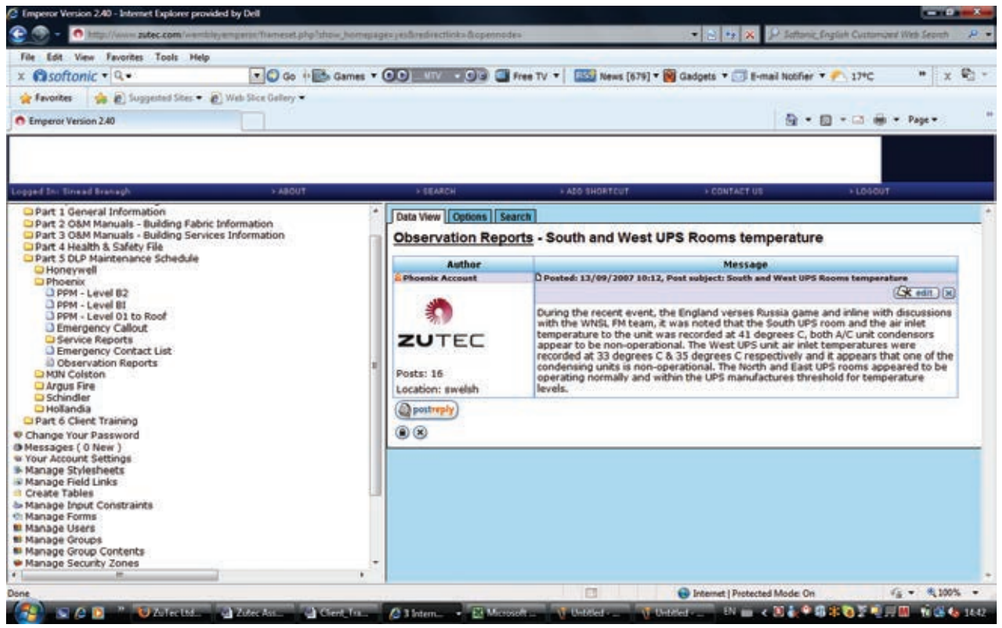

Figure 12 Observation Reports

Snagging / Defecting Tool (Please see the screen shot below).

The online snagging record tool is a natural addition to the suite of handover modules. The module allows Brookfield and the client to capture defects on a mobile camera phone, and upload the image complete with a snag description immediately into system. The system enables the inspector to superimpose the snag request by clicking on the image and send it as an email to the relevant party.

The relevant party can respond to the request with a link directly back to the module to confirm the status of the snag. The system will automatically update the defect module to reflect the status of any snag as either “Open or Closed” The application is Blackberry enabled which means that the system can be updated remotely without the need to have system access. A management report can be created listing all building trade snags and their status.

Status of defects for a typical floor or room can be accessed quickly by clicking on a tag marking the snag within a room or an area. This provides a simple user friendly methodology of clearing defects for handover and provides a precise record of all defects to be cleared during the defects liability period.

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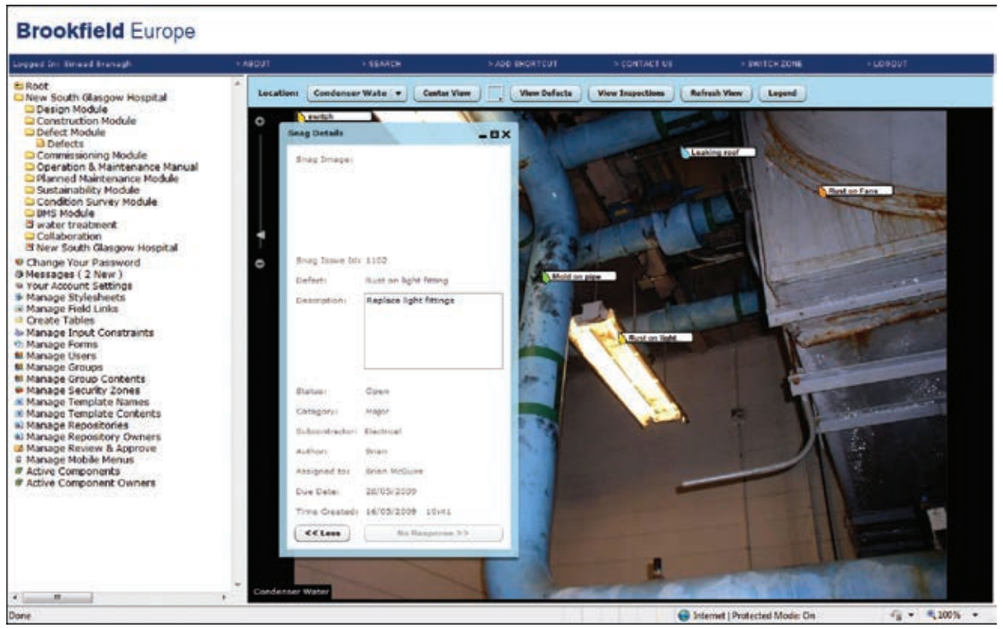

Figure 13 - Snagging / Defecting

Sustainability Module

The following screenshot is a replica of the TM31 format at recommended by CIBSE as part of the overall sustainability module. This module can be enhanced and modified to suit the complexity of the building services energy profile.

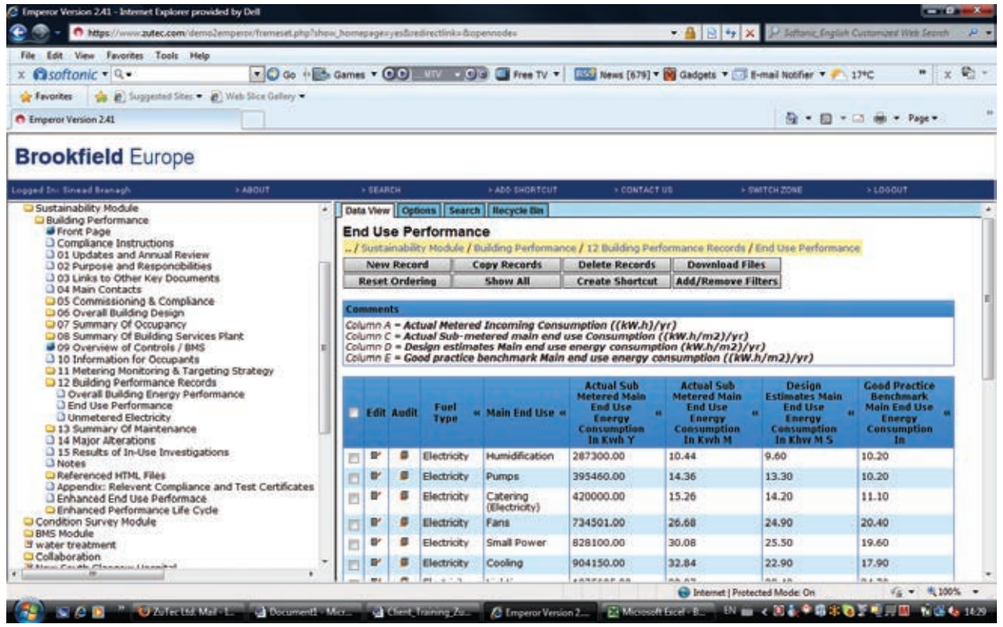

Figure 14 Building Log-Book – showing end use performance

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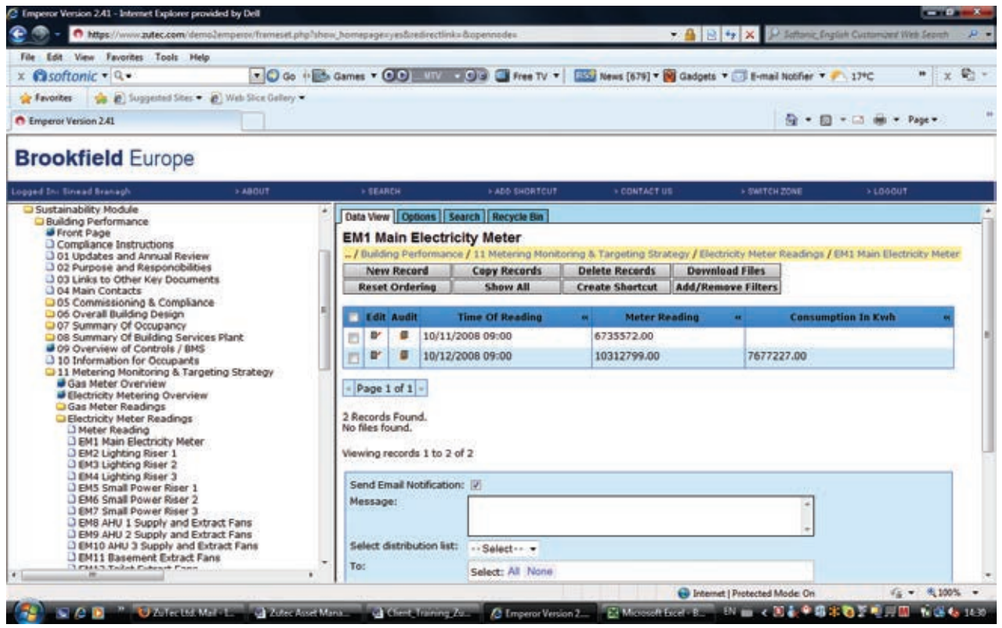

Figure 15 - Control Interface with Energy Monitoring System – showing live data input from BMS meter readings

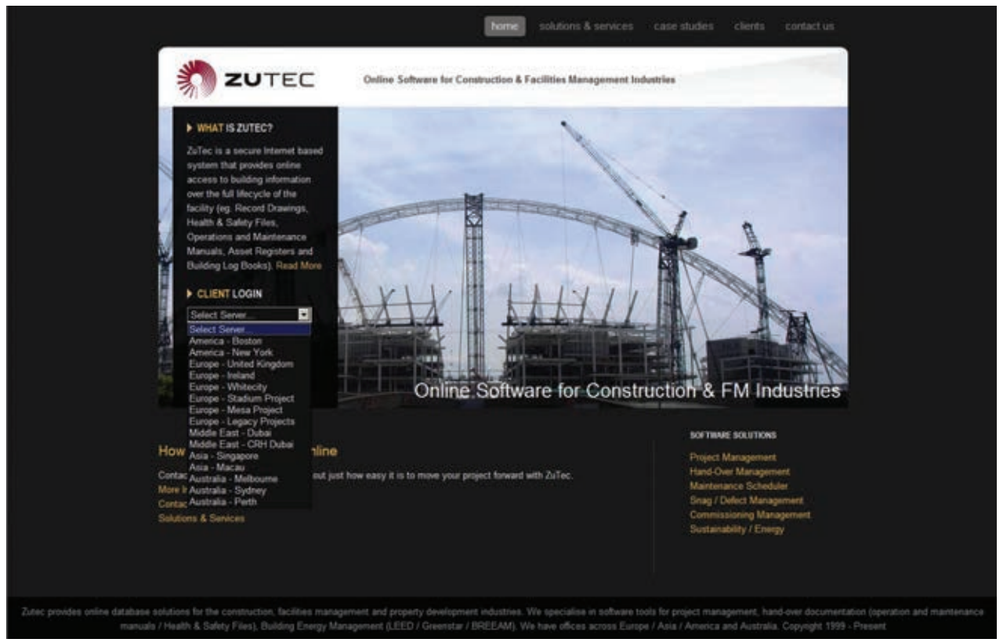

Figure 16 – www.zutec.com

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3.0 TRAINING STRATEGY.

Brookfield client training program is be based on a five stage process.

The first activity the Brookfield training facilitator will establish with the client is a detail calendar training program to ensure that all types of hospital staff required to be trained is planned in advance but spread of a reasonable period of time to enable there work commitments implemented as well as the demand for training on the facility

The five stage training process enables each staff member being trained on a specific topic to fully understand the training stage before moving on the next stage, this process is managed by a feed back questionnaire issued to all individuals attending the relevant stage who are required to identify if they are “Satisfied or Not Satisfied”

- Status “Satisfied” trainee to sign off accepting that the stage has been completed and understood.
- Status “Not Satisfied”, Brookfield training facilitator is to immediately discuss with trainee and establish the items that need to be changed or improved to meet an acceptable requirement.

Once all five stages have been completed and signed off “Satisfied”. The client will be required to provide final sign off “A” status concluding the training program for the specific package is completed.

Final sign off will confirm that the training requirements for the particular trade package presented has been completed in accordance with contract conditions and client requirements.

Information required to be provided by client.

Client to confirm:

- Quantity of personal to be trained.
- Employment role & responsibility of each individual / group required to be trained.
- User level training requirement.

Brookfield and client will jointly develop the user group training schedule so that the right level of training is provided to the relevant user level.

Five stages of training:

- Stage 1. Sub-Contractor introduction.
- Stage 2. Classroom training.
- Stage 3. Site geographic familiarization.
- Stage 4. Site hands on user training.
- Stage 5. Control systems head end user training.

Example of User Group Training Schedule

USER LEVEL	CLIENT TRAINEE / GROUP	TRAINING STAGE	PRIORITY TOPICS
Level 1.	Building manager.	Stage 1. Stage 2.	Overview of all systems. Emergency procedures. Emergency contacts.
Level 2.	Building manager.	Stage 1. Stage 2. Stage 3. Stage 5.	Overview of all systems. Emergency procedures. Emergency contacts. Security systems. Maintenance plan. Site geographic familiarisation. User level of all control systems.
Level 3.	Control systems operator.	Stage 1. Stage 2. Stage 3. Stage 5.	Overview of all systems. Emergency Procedures. Emergency Contacts. Site geographic familiarisation User level of all control systems.
Level 4.	Maintenance technicians.	Stage 1. Stage 2. Stage 3. Stage 4.	Overview of all systems. Emergency procedures. Planned preventative maintenance. Site geographic familiarization Site Hands-on User training.
Level 5.	Building manager.	Stage 3.	Emergency procedures. Site geographic familiarization.

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Priority topics listed in the table above identify the critical elements that the training program will ensure that the relevant user level will fully understand and be able to implement.

Client representatives who will participate in the training program need to have suitable skills, abilities, traits, knowledge and a level of experience for the user level defined.

Community training.

In addition to the training of staff necessary to successfully operate the hospital systems Brookfield will as part of the community commitment train entrant level persons.

The training of entrant level person is detailed in the Brookfield Community Engagement and Benefits deliverable documentation.

The content and requirements of each stage will include:

Stage 1. Sub-Contractor Introduction.

Brookfield will arrange for each subcontractor and specialist to introduce their company and include in their presentation the following key points:

- Organisation chart of the company.
- Brief background of key personnel.
- Any special services that company can provide.
- Maintenance operations of the company and emergency contact personnel / contact details.
- Subcontractor will briefly explain what services and specific packages of work they have provided on the project.
- Subcontractor will briefly describe the role and support services provided by key suppliers & specialist's contractors used on the project.

Stage 2. Classroom Training.

Classroom training will be based on using the web based asset management system.

Training will demonstrate how to navigate through the asset management system and all necessary documentation, locate key sections and information that the client facility operators & maintenance technicians will need.

Key sections that will be studied during the training sessions will include:

- Operator user information & details.
- Emergency procedures.
- Asset register.
- CDM residual risks register.
- Commissioning records.
- Building log book and energy performance information
- Planned preventative maintenance calendar and requirements of each system, item of plant & equipment.
- Service log book.
- Call out system.
- Observation reporting.
- Specialist companies required to attend and their function.
- Review of the spares shopping list, including supply sources and lead times.

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Stage 3. Site Geographic Familiarisation.

Site familiarization will require all attendants to learn the geographic location of each key system, plant and equipment.

As-Built drawings will be used as part of the geographic training.

The training session will include locating and identifying various key elements of the systems installed on site within each building, department etc.

Specific key items will include:

- Building locations and all main plant areas.
- Major system isolation points.
- Plant room locations.
- Specialist systems such as medical gas, renal water, etc.
- Specific system and the areas they serve.
- Electrical power & lighting distribution switchboards and mechanical motor control panels.
- Communications key equipment locations.
- Various control systems such as BMS, fire alarm, nurse call, IT/Data network, security communications systems, etc and all key equipment locations.
- Control rooms and control system head ends.
- Fire control centre.

Stage 4. Site Hands-On User Training.

Each Sub-contractor will demonstrate how to operate the (user level) on site plant, equipment and local control systems that they have installed for the purposes of maintenance or to enable any system to operate in a manual mode in the event of a failure.

Example of key equipment user level training will include:

Energy centre plant and equipment

Control room systems.

Mechanical Motor Control Panels.

LV switchboards.

Demonstrate access to plant and equipment.

Drain down & system venting points.

Medical Gas.

Pneumatic tube.

Chemical treatment dosing facilities.

Domestic CWS water treatment plant.

Change air handling unit filters.

Specialist equipment and systems.

Stage 5. Control System Head End User Training.

The objective of this training stage is to teach the operators and technicians how to use all of the IT / data, hospital electronic systems and building services control systems to a level of competence that enable the successful operation of each system to a user level.

Each user will be trained on how to change control set points, set up trend log information, fault finding etc

The training will not include teaching to program or system author / architecture level, or how to change the cause and effects data.

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Drainage Strategy

Section
3.25

Deliverable
Drainage strategy including:-

Methodology for Addressing the requirements of the Hydraulic Assessment and Flood Risk assessment as scoped out on the Drainage Impact Assessment and Strategy Report

SUDS and Drainage Strategy statement which recognises the requirements as outlined in the Drainage Impact and Strategy Report

The below ground drainage design strategy report has been prepared to demonstrate a thorough understanding of the situation and condition of the existing site and the complexities of addressing the limitations of the existing drainage infrastructure adjacent to and on the main site. The report also demonstrates that the design issues specific to the NSGH site adopting best practice and in accordance with URS DIA report and dialogue with the relevant statutory authorities.

1 Introduction

2 Foul Drainage

3 Surface Water Drainage

4 Summary

Appendix A

Appendix B

Appendix C

Appendix D

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Introduction

The Site

The site is located at approximate OS grid reference 252398, 665707 and is part of the overall existing Southern General Hospital. The area to be developed occupies half of the 29 hectares owned by the NHS at this facility.

scope

This document relates to reference 3.25 of the bid submission deliverable requirements and is prepared by WSP to support other design information that is also submitted in the form of drawings, schedules and specifications. It describes the design criteria and principles that have been applied to the below ground drainage design for this project.

2 FOUL DRAINAGE

2.1 Existing Foul Drainage System

The Foul drainage from the Southern General Hospital currently discharges to a number of private combined sewers which cross the site. This drainage is generally routed from south to north before finally exiting the site and connecting to the public sewer network. A copy of Scottish Water's sewer network record drawing is included as Appendix A.

The proposed development site is currently intersected 300mm diameter combined drain which collects foul water from a number of the buildings in the centre of the hospital site. It also collects some of the surface water run-off from impermeable areas within the site. This drain runs generally in a north easterly direction before connecting into the public combined sewer in Govan Road.

A portion of the private drainage runs under the existing Library building and is also under the south east corner of the proposed main building footprint. This drain will be diverted around the proposed building and into the hospital roadway as illustrated on CD-P1-00-PL-140-01.

2.2 Proposed foul drainage

It will be necessary to divert the existing 300mm diameter combined sewer which currently runs under the south east corner of the proposed building footprint. An extract from diversion drawing is included as figure 2.1, below.

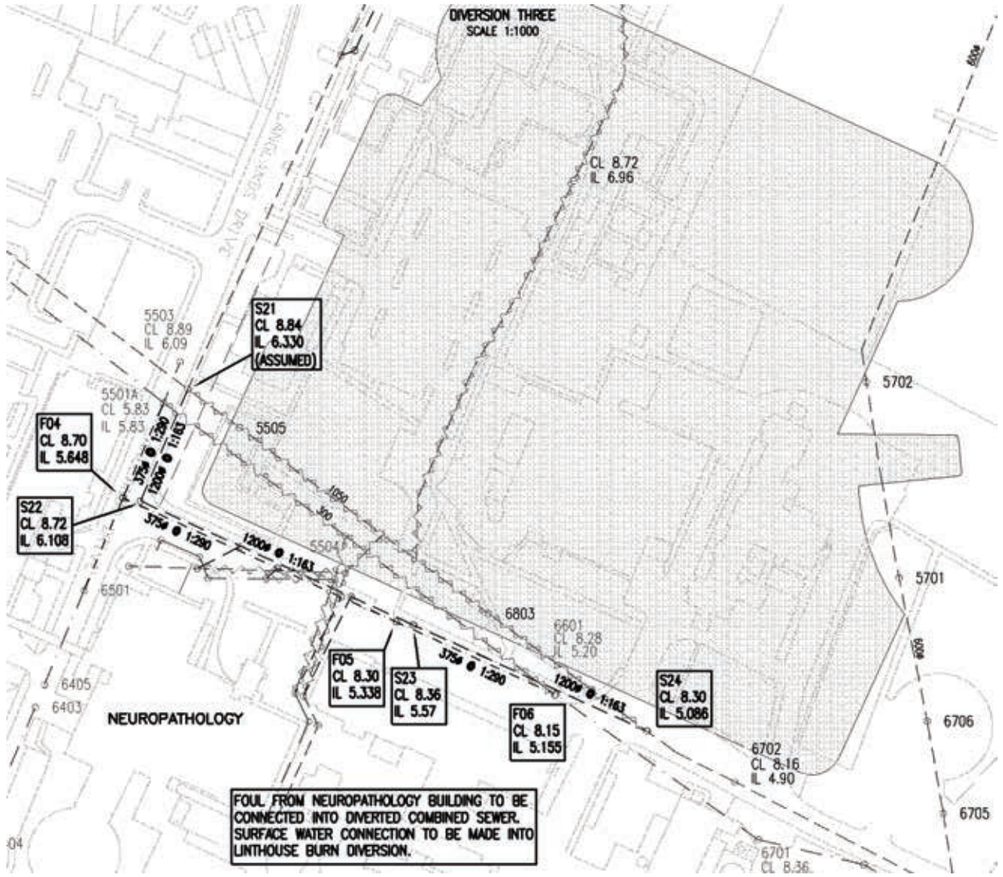

Figure 2.1: Extract from Drainage Diversion Drawing

Approximately two thirds of the foul flows from the new hospital will be connected at a number of locations to the 300mm diameter combined drain which runs under the access road immediately to the east of the building. These flows ultimately connect to the public sewer to the north of the site under Govan Road. The remainder of the foul flows taking the proposed Childrens Hospital, Laboratory and FM buildings will be directed to a new point of connection on the public combined sewer to the west of the site in Hardgate Road.

Flow rate allowances have been made for the maximum rates provided in section 4.3 of the URS Drainage Impact Assessment and Strategy Report 2009. These flow rates would be reviewed during the detailed design stage as the project progresses.

The foul water will be constructed using structured wall uPVC pipes for the majority of drain runs with the exception of those identified as carrying specialist waste. In these instances vitrified clay pipes shall be used incorporating EPDM Rubber seals at the joints.

External service areas that are covered, high pollution risk areas associated with on site processes and the helipad will drain to the foul sewer.

The foul water drainage strategy has been developed in consultation with Scottish Water. Foul drainage shall be designed in accordance with Sewers for Scotland and BS EN 752.

3.0 SURFACE WATER DRAINAGE

3.1 EXISTING SURFACE WATER DRAINAGE

The Hospital site is crossed by two culverted water courses. The principal water course (Linthouse Burn) runs from the south of the site and outfalls to an open section of ditch just to the north of Govan Road. This open section of the watercourse travels north before discharging in to the River Clyde. The River Clyde is tidal at this the point of discharge and therefore the levels in the Linthouse Burn are likely to be subject to change as a result of this influence.

The Jenny's Burn culvert enters the hospital site from the western boundary at Hardgate Road and heads in an easterly direction before connecting to the Linthouse Burn under the existing main access road near the helipad. Evidence from a recent CCTV inspection survey indicates that it is highly likely that the Jenny's Burn is capped off upstream of the hospital site and is probably redundant.

A section of Linthouse Burn is currently situated under the proposed building footprint and will be subject to diversion along a new route under the nearby access road.

The entire length of Jenny's Burn which passes under the site will need to be diverted to avoid building footprints. It is proposed that Jenny's Burn will be routed to the rear of the laboratory and waste compound buildings before heading east to a new point of connection on the Linthouse Burn. Refer to drawing number CD-WS-00-PL-140-07 included as Appendix B.

3.2 Proposed surface water Drainage

The URS DIA report indicates that approximately 3 hectares of the site currently discharges into the Linthouse Burn culvert. A copy of the URS plan showing the areas of combined separate systems is included as Appendix C. We have proposed a scheme which will discharge surface water from all roofs and hardstanding areas into this watercourse with no increase in flow rates to those that currently enter the Burn from the site. The new surface water system will also direct drainage from some areas that currently drain into the combined sewer and discharge these flows into the culvert. The removal of the connections for contributing surface water catchment areas to the on site combined sewers will result in a reduced surface water discharge to the nearby Shieldhall Sewage Treatment Works. The result of this will be a reduction in the dilution of the flows to the treatment works which Scottish Water have confirmed will be beneficial to the operation of the works.

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3.2.1 Discharge Rates and Capacity

With the use of source control techniques such as green roofs on some buildings and permeable surfaces on new large hardstandig areas we have been able to increase the time it takes for rain water to enter Linthouse Burn. This attenuation process together with the use of open swales in a soft landscaped area has been modelled using the design software suite WIN DES. The software has helped us to design a new surface water system which carries sufficient self cleansing velocities during a 1 in 2 year design storm and which will not flood at any point during a 1 in 1000 year storm.

3.3 sustainable drainage Considerations

Careful consideration has been given to minimise the impacts the development will have on the quantity and quality of surface water run off leaving the site. SUDS methods which are proposed include the following:-

Green-roof zones above the podium levels of the main hospital building.

Permeable paving areas for the surface level car parking areas and the service yard between the laboratory building and the waste compound.

Surface water swales located in the soft landscaped area to the north of the hospital.

These features perform two main roles in relation to water quality and surface water attenuation. A plan showing the areas that contribute to the SUDS treatment train is included as Appendix D.

3.3.1 Water Quality

All loading bays, service yards and car parks will be drained into lined granular storage areas beneath their surface. This will provide a form of primary treatment. Before discharging into Linthouse Burn all surface water drainage will pass through at least one swale feature to ensure that the levels of treatment are compliant with those described in table 5.2 of the URS drainage Impact Assessment and as directed by CIRIA Report C697.

3.3.1 Amenity

The swale features have been designed to provide the necessary storm water storage but also to add amenity value to the scheme. With regards to planning condition 36 and the fact that the hospital on the flight path of Glasgow Airport, the swales will not be permanent open water features, therefore they will not increase bird activity in the area. With due regard to safety in mind, the swales will be shallow and have gradually sloping sides.

We have developed the surface water strategy in consultation with SEPA, Glasgow City Council and Scottish Water.

4.0 SUMMARY

All foul drainage will be routed to the existing private combined sewers within the site. These flows ultimately drain to the Shieldhall Sewage Treatment Works immediately to the north of the site. Further consultation with Scottish Water will be required following the completion of an area network study before full approval can be granted.

All surface water will be routed to a new point of connection with the Linthouse Burn. The rate of flow will be limited through the use of storm water storage which will be provided to ensure that there is no increase in discharge beyond the current levels to the existing watercourse and the nearby River Clyde. There will be a further drainage area assessment required for the existing watercourses prior to detailed design to examine the effects of existing flows and tidal conditions.

The surface water drainage system has been designed to ensure that there will be no flooding of the system during storm events under a 1:1000 year return period criteria.

There will be a series of SUDS features such as green-roof areas, swales and permeable paving which will address the water treatment guidelines set out by SEPA.

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Structural Design Strategy

Section
3.26

Deliverable
Structural Design Strategy which should include:-

- Outline description demonstrating understanding of topography, geology, soil conditions, contamination, ground water, history, services
- Demonstrate outline principles or design including, general description, stability, joints, floors, vertical structure, foundations, stairs and ramps, retaining walls, earthworks, slope stability, drainage, external works etc.
- Design Standards and Sources of Reference (Codes of Practice and Standards)

The structural design strategy report has been prepared to demonstrate a thorough understanding of the situation and condition of the existing site and the complexities of addressing the limitations of constructing the new hospital facility there. The report also demonstrates that the design issues specific to complex hospital buildings are understood and have been addressed with reference to relevant design standards.

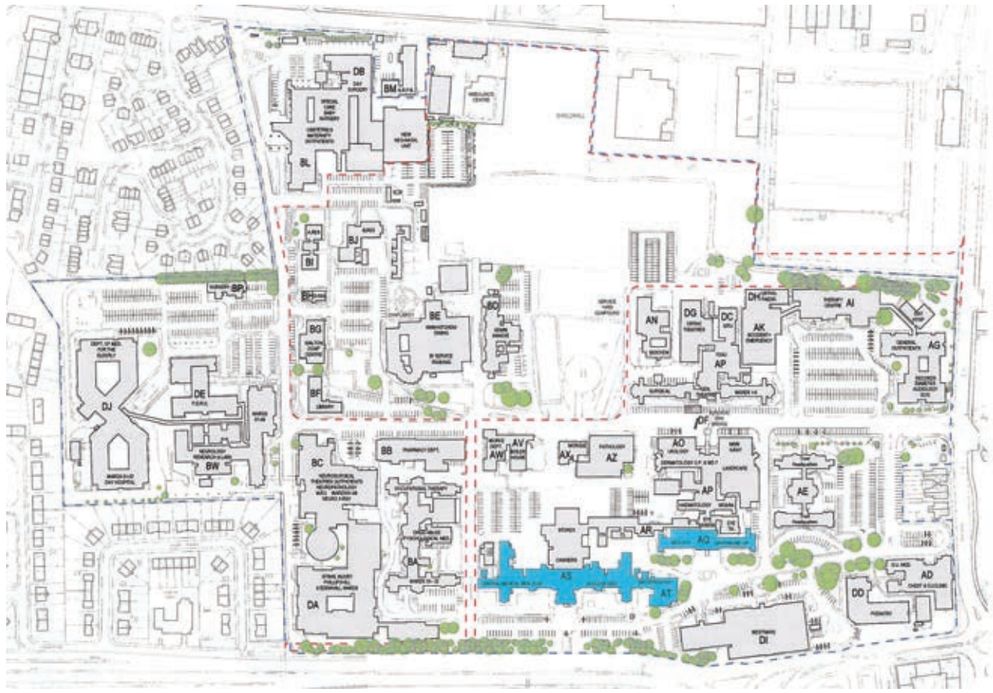

Figure 1.1: Existing Site Plan

1 Existing Information

1.1 THE SITE

1.1.1 Location
The site is located at approximate OS grid reference 253298,665707 and is part of the overall existing Southern General Hospital complex. The complex is bounded by Govan Road to the north, Hardgate Road to the west, the A739 to the east and Shieldhall Road to the south. Local landmarks in close proximity include junction 25 on the M8 motorway to the south, Scottish Water Shieldhall Waste Water Treatment Works to the west. Existing and proposed site plans are shown on figures 1.1 and 1.2 respectively, below.

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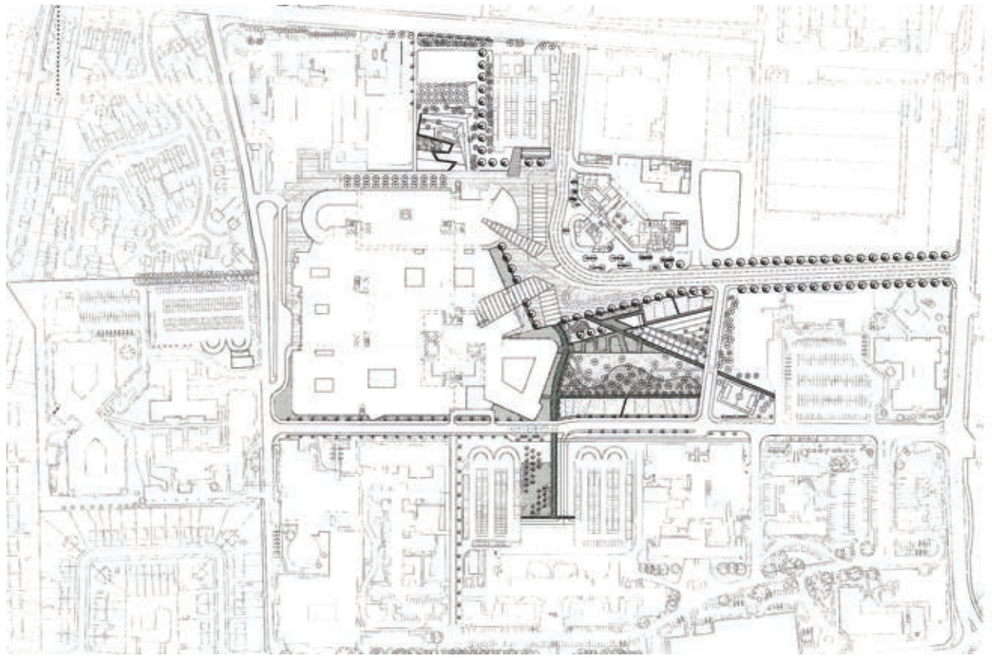

Figure 1.2: Proposed Site Plan

1.1.2 Building Footprint

The proposed building footprint area is currently occupied by existing buildings, roads, footpaths, car parks, vegetated areas etc and is underlain by existing drains, sewers, culverts, ducts and services. The buildings are to be demolished and all underground infrastructure is to be removed by the Board and a clean and clear site provided to the contractor ready for construction. This work will be carried out in phases with some parts of the overall site not being made available to the contractor until later in the programme due to being required to remain operational until after the new building has been constructed and operational.

1.1.3 Ground Conditions

Information on the site ground conditions has been derived from the preliminary Site Investigation Report information prepared by URS Corporation and provided by the Board. This report is provided at “Draft” status as results from contamination and geotechnical testing and monitoring are outstanding. The report further notes that it has been carried out to provide an indication of the conditions on site with further detailed investigation work being required to facilitate the final design and negotiations with the statutory regulators.

Therefore any assumptions with regard to contamination status and ground conditions are subject to review. Additional historical reports procured in support of various works that have been carried out at the site have also been provided and reviewed.

1.1.4 Contamination

A review of the available data from the reports notes that contamination testing in the historical reports is limited (except URS 2009) and the screening tools applied are no longer acceptable best practice. Made ground containing ash has been observed on site as a potential contaminant source beyond land use operations. The most recent reporting of URS 2009 including analytical results, gas and leachate testing are assumed to present the latest and most robust assessment of the site. This data remains outstanding, however a review of the raw analytical results by WSP suggests that the hazard at the site is low. This requires to be confimed however, following receipt of outstanding test data.

The full text of the contamination review is included in Appendix A.

1.1.5 Geotechnical

The solid geology plan for the site (Scotland Sheet 30 – Solid Edition) indicates the solid strata beneath the site to comprise the limestone coal group to the south and east of the site with the lower limestone group elsewhere. An igneous intrusion is shown to run from SE to NW across the middle of the site. A fault is recorded trending south east to north west towards the northern part of the site with the down throw to the south.

The exploratory hole records from the Norwest Holst factual report and bam Ritchies ground investigation report indicate the following sequence of strata:

Stratum	Depth to top of Stratum (mbegl)	Thickness (m)
Made Ground	0	0.4 – 3.0
Peat*	1.3 – 1.6	0 – 0.7
Alluvium	0.4 – 3.0	3.5 – 23.8
Glacial Till	4.1 – 24.8	0.3 – 19.5
Bedrock	17.4 – 26.3	-

*Only encountered within BH09 & BH17

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Made Ground
Made ground was generally encountered across the site. The made ground encountered generally comprised a very loose to loose sand occasionally containing fragments of brick, ceramics, shale, clinker, cinders or sandstone. The surface or near surface deposits include re-worked naturals soils, imported granular materials for road and hardstanding construction, imported topsoil and vegetated areas etc.

Alluvium
The alluvial deposits at the site generally comprise sand underlain by clay then silt. The sand is typically a very loose yellow brown slightly silty sand. The underlying clay generally comprises a very soft brown slightly sandy clay. The silt, where present normally comprises an un-compact grey very sandy silt with laminations.

Glacial Till Deposits
The glacial till encountered is typically a stiff and very stiff grey slightly sandy slightly gravelly clay with occasional cobbles.

Bedrock
Bedrock encountered comprises mostly moderately weak to moderately strong mudstones and sandstones with very closely to medium spaced sub vertical and sub horizontal discontinuities. Strong Siltstone is encountered in places. An intrusion of dolerite was encountered in the middle of area 1B.

Groundwater
Groundwater monitoring records for the main site area have not been made available. Once available, this section will require to be revised. Groundwater observations made during the drilling works indicate that groundwater in some areas may be encountered at shallow depths, i.e. within 3m of ground level. Although not specifically recorded in the reports supplied, given the nature of the superficial deposits and the proximity of the river, it would not be unreasonable to expect ground water levels to be up to 1.0m below existing ground level at times. This will vary due to seasonal and tidal effects.

The full text of the geotechnical review and recommendations is included in Appendix B.

2 Design Information

2.1 ARCHITECTURAL DESIGN PROPOSALS

2.1.1 Building Design
The main accommodation comprising outpatients, accident and emergency, theatres, imaging, support services etc is housed in the ground, first and second floor levels which covers the entire building footprint while the adult wards are housed in medium rise multi-storey section which extend over approximately one third of the overall footprint. Plans showing the relationship of the various departments are shown in figure 2.1 below.

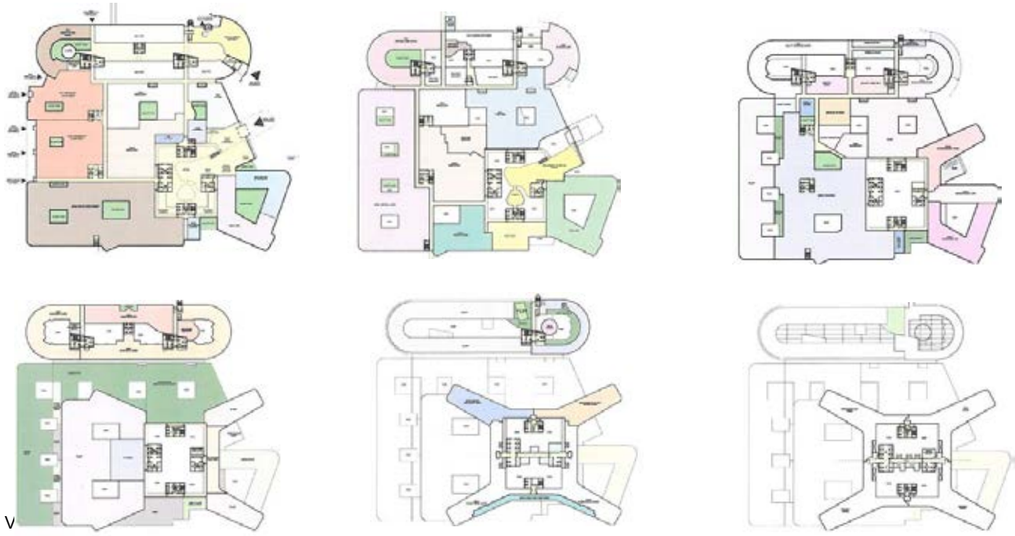

Figure 2.1: Architectural Departmental Plans

2.2 STRUCTURAL DESIGN PHILOSOPHY

2.2.1 Optioneering

The team reviewed a number of potential options for the building structure and assessed these based on compliance with the Employers Requirements (ER's), structural efficiency, buildability, flexibility, availability of materials and labour, economy, services integration, structural depth, sustainability, embodied energy, thermal mass, recyclability, fire resistance and vibration response.

In summary, the structural form for the main buildings with the highest ranking, and therefore adopted, was that consisting of cast in-situ reinforced concrete (RC) flat slab floors supported directly on columns without downstand beams or structural screeds.

This selection will be periodically reviewed and updated by the team to ensure that the principles on which it was made are still current.

Variations such as post tensioning and / or lightening dead loads using proprietary slab void formers may be included subject to the costs and potential risks in adopting these measures being satisfied. A schedule of possible variations and associated comments is included in Appendix C.

2.3 SUPERSTRUCTURE

2.3.1 Structure

The building is approximately 180x180m square on plan with most of the clinical functions being provided in the three to five storey "podium" area which is situated over most of the plan footprint. Departments and functions primarily serving the children's block are grouped to the west side of the podium while the adult wards are housed in a tower on levels five to twelve projecting above the podium. Plant is accommodated in various locations in the podium but primarily at the interstitial level five and on top of the adult ward tower roof. A helipad is incorporated on top of one wing of the ward block roof.

The building super structure is of in-situ RC flat slab construction with precast RC columns. The columns are arranged on a relatively regular grid with a maximum span of 7.5m. Internal columns are generally of square section with those situated on the building perimeter being rectangular blade columns to co-ordinate with the room arrangement and external wall construction.

Storey heights are generally 4.5m at ground, first and second floor levels, 5.4m at level four and 3.8m at the adult ward levels thereafter.

The slab thicknesses have generally been dictated by the vibration response requirements, particularly for theatres, imaging and wards and are shown on the structural drawings included in Bid Deliverable Reference 2.22. Refer also to section 3.5 of this report.

Plots from the structural analysis model are shown in figures 2.2 and 2.3, below.

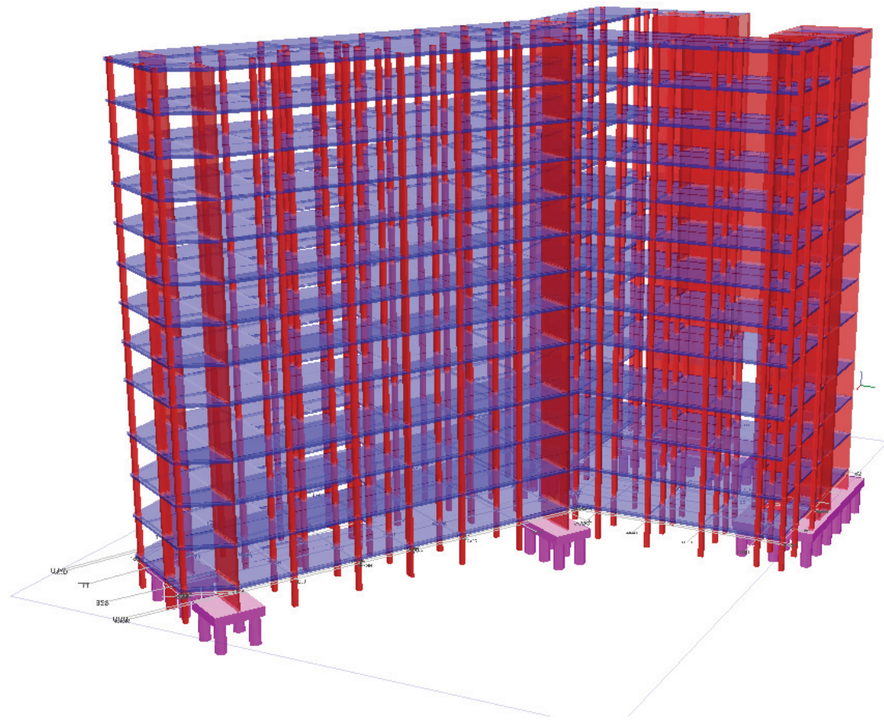

Figure 2.2: 3D View of Structural Analysis Model

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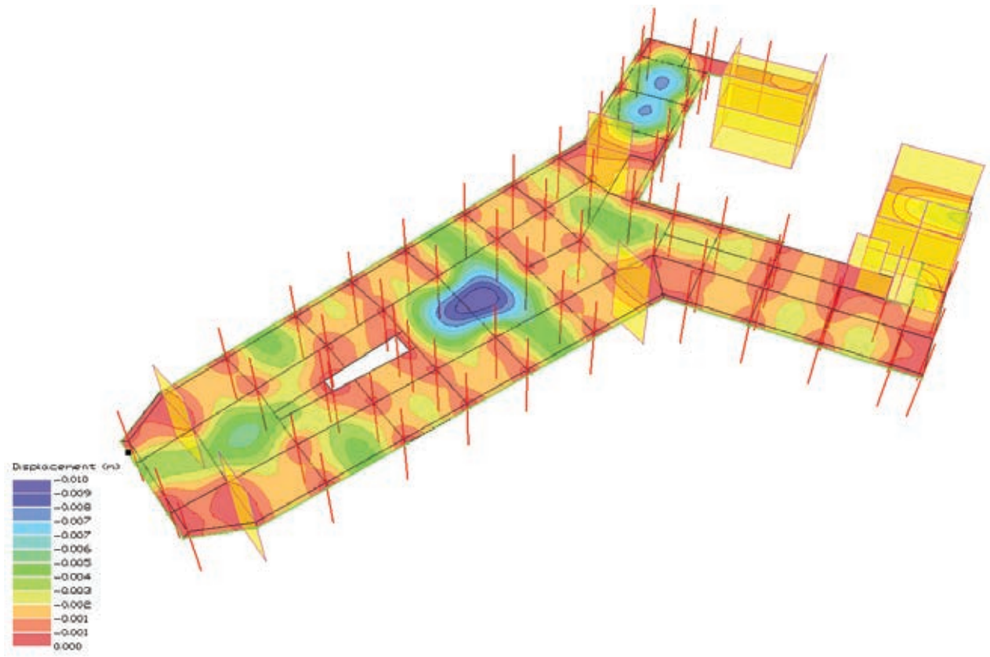

Figure 2.3: Contour Plot From Structural Analysis

2.3.2 External Walls

The external walls are understood to be of a proprietary panel glazed cladding system to the towers and a rainscreen cladding to the lower floors, all as specified by the architect. It is understood that these are designed to be fixed to, and span, between floor slabs, therefore no additional secondary support or restraint structure is required.

2.3.3 Internal Walls

Internal walls are generally non-loadbearing partitions for maximum flexibility and are to the architect's details.

2.3.4 Plant Rooms

Plant rooms serving the adult wards are situated on the tower roofs and are generally constructed of simple steel framing with sheet metal cladding roofs and walls on lightweight steel purlins and side rails.

Plant rooms serving the accommodation at the podium levels are situated between levels 2, 3 and 4. In these locations they can be housed within the concrete framed structure or in lighter weight steel framed enclosures as above, constructed on top of the main concrete superstructure.

2.3.5 Roofs

Roofs separate from the plant rooms generally comprise the upper level slab of the concrete framed structure and have a "green roof" finish to the landscape architect's details or a waterproof membrane finish as per the architect's details. Proprietary fabric ETFE roofs are proposed over the atrium spaces in the ward tower and children's block.

2.3.6 Stairs

The stairs generally will be constructed of precast concrete. These will be pre-fabricated off site and mechanically lifted into place as soon as the floor construction sequence allows to provide a safe means of access for construction operatives prior to being finished for their final use by the building occupants.

2.3.7 Atrium Upper Corridor Structure

A corridor at each level of the adult wards links the north and south stair and lift cores spanning 12m across the open atrium space below. There are also smaller rooms projecting from the sides of the corridor. This structure is a multiple storey height steel girder supported on and spanning between the concrete cores. The projecting rooms will be formed of braced lightweight framed boxes which will cantilever from the main girder structure.

2.3.8 External Link Bridges

Corridors are required to link the new main hospital building at first floor level to the existing maternity and neurosciences buildings adjacent. These corridors must span over existing roads and access areas and have been conceived as lightweight bridge structures separate from the main building. They are formed from a steel framed box structure with composite steel decking concrete slab floors.

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2.3.9 Builderswork in Connection with Services and Equipment

The services for each department are generally fed vertically through a dedicated service riser in each block passing through each floor and then distributed laterally through the block. The risers are typically located around lift and stair cores (although some are discrete) and effectively form holes in the slab that have to be taken into account in its structural design. Holes are also required to accommodate penetrations through the slabs for drainage pipes and other services. The main grouping of services distribution laterally is above the corridors and the design load adopted allows for the concentration of loading in these locations. The flat slab design adopted allows uninterrupted routing of the services along the ceiling without obstructions such as downstand beams etc. Cast-in channels have been allowed in the slab soffits to facilitate post fixing of bracketry to suspend services and equipment where known without the requirement for drilling.

The main plant items are housed in the dedicated plant rooms generally located on the roof of each block. Exceptionally heavy items such as MRI scanners, UPS batteries and water tanks have been identified and have been checked against the design load allowance for plant areas. Other items of plant are within the design load allowance for their location.

Other specific loads for medical equipment are being continually identified as and when possible and checked against the design load allowance and the actual structure design for their respective areas.

2.3.10 Energy Centre

The items of plant providing the main heat and power for the hospital complex are housed in the energy centre building separate from the main building and adjacent to the laboratories. This building is also conceived as an open plan concrete framed structure with masonry external walls to the ground floor level and metal faced cladding on cold rolled side rails above.

2.3.11 Laboratories and FM Buildings

The laboratories, mortuary, waste transfer and facilities management functions are housed in a combined building separate from the main hospital and adjacent to the energy centre. The building links to the main hospital by an underground tunnel to allow discrete and uninterrupted transfer between the areas by porters and remotely operated trolley vehicles (robots).

This building is also shown as a concrete framed structure similar to the main building.

The design of this building has been carried out up to scheme stage by the Board adviser team and as noted previously, WSP (and other team members) do not at present have a design remit for this area. The team has however reviewed the design and identified some possible amendments that could be made to incorporate some of the areas within the main hospital and / or energy centre building. Therefore drawings are included showing the revised building structure for consideration by the Board.

2.4 BUILDING STABILITY & MOVEMENT

The stability of the building will be considered for wind loads, seismic loads and code defined notional loads.

2.4.1 Wind Loading

Lateral wind loads acting on the building are transferred from the outer walls to the floor slabs at each level. The floor slabs act as stiff diaphragms to transfer these forces to full height RC shear walls or braced bays in the opposing direction and thus to the foundations. The walls comprise a mix of stair and lift shaft core walls and other independent concrete walls located throughout the structure, co-ordinated with the architectural layouts.

2.4.2 Seismic Loading

Seismic loading is not considered appropriate for a building at this location.

2.4.3 Disproportionate Collapse

The building will be designed in accordance with the current British Standards to avoid a situation where damage to a small area of structure or failure of a single element leads to a disproportionate collapse of a major part of the structure.

This system will provide an increased redundancy in the structure and alternative paths for the redistribution of loads should a destructive event occur.

2.4.4 Movement

The building structure will move throughout its life due to thermal effects, drying shrinkage, creep, wind loading etc. This movement is accommodated by splitting the building into blocks and incorporating movement joints at the interfaces. The joints are formed in the faces of the slab junctions and allow movement laterally in one or two directions but not vertically.

Joints are typically positioned to suit the grouping of various clinical functions and also to avoid joints passing through critical areas for cleanliness such as theatres and treatment rooms.

2.5 SUBSTRUCTURE

2.5.1 Foundation Strata

The existing ground is known to consist of approximately 20m of superficial deposits comprising made ground, alluvium and glacial till overlying sandstone and mudstone rockhead with the water table noted to be very high and possibly within 1m of ground level at times.

These deposits have been assessed as being unsuitable to accommodate foundations loads of the extent and magnitude of those required for the new buildings, therefore a non-standard solution will be required. This will involve a deep foundation solution, such as piling.

2.5.2 Foundation Design

A detailed review and assessment of all available information has been undertaken by WSP in-house Geotechnical Engineers in conjunction with discussions with specialist piling contractors. A variety piling options were considered as potentially suitable with varying cost and programme benefits and associated risks.

The review concluded that fluid supported rotary bored cast insitu reinforced concrete piling socketed into rock is the most suitable least risk option and the details have been prepared on this basis. Other options may give economy and programme benefits but carry associated greater risk. There is currently insufficient site investigation and geotechnical testing data to conclusively mitigate or address these risks. The risks and benefits of utilising any other method will continue to be reviewed and the most suitable system selected when all information has been received and incorporated. A schedule of possible variations and associated comments is included in Appendix C.

Working load capacities for various diameters of pile have been established and comparison of these with calculated column loads has allowed a number of piles per column foundation to be established and these are shown on the drawings submitted. Pile cap requirements per column location have also been established and are shown on the drawings.

The pile sizes have been selected such that the minimum load requirement has a three pile pilecap group which will be stable in the temporary condition without additional ground beams being required for lateral restraint. This will allow the superstructure frame to commence construction prior to the remainder of the substructure being in place. The installation of drainage and other services under the ground floor slab can also proceed unhindered by ground beam obstructions.

The piles will require to be temporarily cased through the made ground deposits and fluid support will be used while drilling through the alluvial deposits. All piles will also be drilled through the glacial till and socketed into the upper layers of the bedrock to transfer loads without differential settlement.

2.5.3 Shear Wall Foundations

Shear wall foundations will generally be of an extended pilecap linking multiple piles in a group to transfer the lateral stability loads rockhead.

2.5.4 Basement Structure

The excavation and construction of a basement on this site and the maintenance of its watertightness is potentially a significant undertaking and expensive option given the poor soils and groundwater regime on this site. Therefore, as part of the process discussed in 2.2.1, the design team has examined the design requirements to establish if the basement can be omitted and the planned accommodation re-located elsewhere while maintaining the required operations of those departments. The team has established that some, but not all, of the accommodation can be successfully relocated resulting in a less extensive, easier to construct and more economic basement being required. The basement area is linked by a tunnel to the facilities management and energy centre complex to facilitate the distribution of services and the transport of goods into and waste out of the hospital.

The basement and tunnel structure could be constructed of insitu concrete walls, interlocking secant piles, or sheet piles.

As in section 2.5.2 of this report, there are risks, limitations and benefits associated with each option and these are discussed in Appendix C. At present the rotary bored hard/firm secant piled wall with secondary concrete lining has been assessed as the most suitable least risk option although this will be continually reviewed as more relevant information is made available.

The piled wall will be designed as cantilevering in the temporary condition and propped by the basement and the ground floor slabs in the permanent case. The firm piles will require to be drilled at least into the glacial till to prevent water within the alluvial deposits transferring under the base of the piles and into the basement excavation. The wall can also be designed to align to the column positions from above and therefore the hard piles at these locations will require to be drilled to rock to transfer the loads as per section 2.5.2. The basement floor will be effectively suspended and will span between and be supported from the piled wall and resist uplift from water in the ground.

2.5.5 Basement Waterproofing

The basement walls will be designed to resist water penetration and provide accommodation to Grade 3 standard to BS 8102 ie a dry environment. This will be achieved primarily by the interlocking secant wall with a secondary cast-insitu internal waterproof concrete floor and wall lining incorporating sufficient reinforcement to limit crack widths and hydrophilic seals where appropriate.

2.5.6 Ground Floor Slab

As noted above, the founding strata is also unsuitable for supporting a ground bearing slab without improvement and therefore a suspended slab design has been adopted. This will be similar to the upper slabs and of cast insitu RC and will be two-way spanning between the column foundation pilecaps.

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2.6 EXTERNAL WORKS

2.6.1 Earthworks

The formation of the new building and associated infrastructure will require significant excavations, movement of materials and work in the ground. It is desirable from a cost, nuisance and sustainability perspective to minimise these works and also the export and import of materials. The proposed level for the buildings has been developed to allow as much as possible of the existing soils to remain insitu and for the new works to effectively be constructed on top. This is possible as the building foundations will be piled and the ground floor slab will be suspended.

Some suitable construction hardcore material could be gained from the demolition works and site strip subject to agreement with the Board. There will also be a significant quantity of arisings from basement, pile, pilecaps, drainage and services excavations but these will generally be of poor quality soils as noted in section 1.1.3. It may be possible to remediate these soils on site with cement or lime to enable them to be re-used as non- structural fill in landscaped areas or under suspended slabs and this will be the subject of further investigation works.

2.6.2 Drainage

New drainage will be provided to serve the new buildings and to incorporate the existing site drainage where affected by the removal of existing buildings and the positioning of the new building. The new system will incorporate separate foul and surface water networks and will be designed to ultimately connect to existing infrastructure within the hospital complex. The drainage design philosophy is the subject of a separate deliverable report reference 3.25 included in the overall submission.

2.6.3 Roads and Hardstandings

The layout of the road network and external hardstanding areas has been designed by the landscape architect with input from WSP on layout, traffic flows and junction geometry. Surface finishes are generally of traditional paving materials and details of the construction make-ups are shown on the drawings. These generally comprise granular sub-bases with bituminous macadam or small element paved concrete or stone paving upper layers.

As the near surface soils are in made ground, it is anticipated that in-situ CBR values will be low and that the roads and hardstandings will require the sub-base to be enhanced with a granular hardcore capping layer below.

3 Structural Design Criteria

3.1 DESIGN STANDARDS

3.1.1 General

British Standards will generally be adopted for the structural design. Some of the main relevant titles are noted below.

BS 5606: Guide to accuracy in building

3.1.2 Loading

BS 648: Guide to the weights of construction materials

BS 6399: Loading for Buildings.

- Part 1: Code of Practice for dead and imposed loads
- Part 2: Code of Practice for wind loads
- Part 3: Code of Practice for imposed roof loads

3.1.3 Concrete Works

BS 8500: Concrete - Method of specifying and guidance for specifier

BS 8002: Code of practice for earth retaining structures

BS 8004: Code of practice for foundations

BS 8007: Code of practice for the design of aqueous liquids

BS 8102: Code of practice for protection of structures against water from the ground

BS 8110: Structural use of concrete

- Part1: Code of practice for design and construction
- Part 2: Code of practice for special circumstances
- Part 3: Design charts for singly reinforced beams, doubly reinforced beams a rectangular columns

3.1.4 Steel / Composite Works
BS 5950: Structural use of steelwork in building

Part 1: Code of practice for design in simple and continuous construction: hot rolled sections.

Part 2: Specification for materials, fabrication and erection: hot rolled sections.

Part 3: Section 3.1: Code of practice for the design of simple and continuous composite beams.

Part 4: Code of practice for design of composite slabs with profiled steel sheeting.

3.1.5 Masonry
BS 5628: Code of Practice for use of masonry Part 1: Structural use of un-reinforced masonry.

3.1.6 Regulatory
UK Building Standards 2003.

3.1.7 Other
Current industry guidance and best practice will also be used and adopted where appropriate (eg Concrete Society, CIRIA, SCI, BCSA) as well as WSP Group Technical Centre internal published recommendations for design betterment.

3.2 UNITS
The structural calculations will be completed using the following units.

- Length: m and mm
- Mass: Kg and tonne
- Force: N and kN
- Stress: N/mm_, kN/mm_ and kN/m_
- Moment: kNm and Nmm
- Velocity: m/s and km/hr

Acceleration: m/s_ and proportion of g

3.3 DEFLECTIONS AND TOLERANCES
Deflections and tolerances will be the subject of a separate Movement and Tolerances Report that will be prepared following contract award, to describe these elements in more detail.

3.3.1 Deflection Generally
Details of deflection criteria for structural elements will be provided in the Movement and Tolerances Report.

Spandrel beam/slab edge live load deflection:

span / 360 or 12mm (beam / slab supported at each end)

span / 300 or 12mm (cantilever beam / slab)

Interior beams / slabs live load deflections:

span / 360 or 20mm (beam / slab supported at each end)

span / 180 or 20mm (cantilever beam / slab)

3.3.2 Horizontal Sway (Wind)
The movement criteria used for the design of the core walls are defined as follows:

Overall sway deflection of the building due to design wind load < H/500 where H = height of the building

Sway deflection of any one storey (to be accommodated by the perimeter cladding) < h/500 where h = storey height

The design wind load used in conjunction with these design criteria is the 1 in 50 year design wind speed.

3.3.3 Foundation Movement
Details of foundation movements will be provided in the Movement and Tolerances Specification that will be prepared following RIBA Stage D. All foundations are designed to be piled to rockhead thus limiting total and differential settlement to a minimum.

3.4 BASEMENT WATERPROOFING
Basement waterproofing will be designed to suit the following intended uses as defined by BS8102 table 1.

Mechanical plant rooms	Grade 2
Accommodation / circulation areas	Grade 3

3.5 VIBRATION LIMITS
The floor structures will be designed in accordance with the A Design Guide for Footfall Induced Vibration of Structures and Hospital Floor Vibration Study by The Concrete Centre.

The design guides recommend that the floors should be assessed on the basis of their response to an appropriate near-resonant component of a regular walking force. The criterion adopted for the design of floor beams on all occupied (non-plant) floors is as follows:

Theatre & Imaging Floors:	Response Factor R < 1
Wards Floors:	Response Factor R < 2
All other areas (non plant):	Undefined

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3.6 EXPOSURE CONDITIONS

In accordance with BS8110-1 table 3.2, the following exposure conditions are adopted for the design of the structure:

Substructure	
Piles generally	Moderate
Retaining Walls	Moderate
Basement Walls	Moderate
Basement Floors	Abrasive
Superstructure	
Internal floors, columns and walls	Mild

3.7 DURABILITY OF THE STRUCTURE

The structure is to have a design life of 70 years. Some structural elements, such as those with concrete wearing surfaces and corrosion protection will require periodic inspection and maintenance.

Steelwork members that are inaccessible and not easily maintained will be designed for the loss of steel section over the 100 year life of the building.

The substructure perimeter retaining walls will be designed in accordance with BS 8500-1: 2002, and satisfy this standard for the most onerous structural performance level, being a structure of long service life (more than 100 years).

3.8 FIRE RESISTANCE PERIODS

The following fire resistance periods have been assumed in the design of the structure:

Superstructure generally: 2 hours

Substructure generally: 2 hours

Medium duration compartmentation and short duration sub-compartmentation between / within departments and rooms for fire protection will be provided by the partition walls and ceilings specified by the architect. Isolated higher risk areas or fire hazard rooms exist within the building and these will also be separated by walls or partitioning specified by the architect.

Fire engineering is the subject of a separate deliverable report included in the overall submission.

3.9 MATERIAL PROPERTIES

3.9.1 Substructure concrete:

Piles, pile caps, ground beams, pad foundations, strip foundations, basement slabs, retaining walls and ground bearing slabs: Grade RC40 concrete.

Blinding or mass fill concrete (if required): Grade Gen 1 concrete.

3.9.2 Superstructure concrete:

Internal and external insitu RC columns, walls beams, upper slabs, roof slabs: Grade RC40 concrete

3.9.3 Reinforcement:

Reinforcement type ‘A’: grade 500, deformed type 2 conforming to BS 4449.

Fabric reinforcement conforming to BS 4483.

3.9.4 Structural Steelwork:

Grade S275 or S355 (in accordance with BS EN 10 025).

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4 Structural Design Loads

4.1 DEAD LOADS

4.1.1 Self Weight Dead Load

The self weight dead loads are calculated form the known density and geometry of the element under consideration.

4.1.2 Superimposed Dead Loads

Additional allowance is made for the fixed finishes and services as follows:

Typical Hospital / Office Floors	
(Floor finishes, ceiling, services and fixed equipment below)	2.5 kN/m_
Plant Rooms	
(ceiling, suspended services)	2.5 kN/m_
Green Roof	
(Finishes, insulation, tapered slab, ceiling and suspended services)	3.0 kN/m_
Other Roof	
(Finishes, insulation, tapered slab, ceiling and suspended services)	0.5 kN/m_
Perimeter Wall Cladding	10 kN/m

4.2 IMPOSED LOADS

4.2.1 Design Imposed Loads

Floor loadings have generally been standardised throughout the building floor plates to allow for future flexibility and to simplify design, detailing and construction. Specific exception loads for large items of plant or medical equipment will be included over and above these loads where necessary.

The following loads have been adopted in the design in kN/m_

Clinical / Admin Areas	4.0
Partitions	1.0
Staircases & Cores	5.0
Circulation Areas	5.0
Plant areas	7.5
Tower roof (with maintenance access)	7.5
Podium roof (access for maintenance only)	1.5
Plant roof (no access)	0.8

4.2.2 Environmental Loads

Wind and snow imposed loads acting on the main building frame and the various elements of cladding will be determined from BS 6399 Part 2.

4.2.3 Notional Loads

The building is designed to resist notional lateral loads applied at each floor simultaneously equal to 1.5% of the characteristic dead weight of the structure, as stipulated in BS 8110 Part1. This is an ultimate load and is applied in multiple directions.

4.2.4 Lift Loads

All lift shaft walls and lift motor room slabs will be designed to all dead and imposed loading information loadings provided by the lift consultant.

4.2.5 Temporary Hoist and Crane Loads

The permanent structure will be designed to support the loads from the temporary cranes and hoists required by the Contractor.

4.2.6 Construction Loads

To be determined by the Contractor and any enhancement to the structure required to account for such loads to be determined by the Contractor’s temporary works engineer and included in the construction requirements.

4.2.7 Piling Plant Loads

Loads from piling plant are to be accommodated by a temporary piling mat designed by the contractor’s temporary works engineer.

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Appendix A WSP SI Review - Contamination

New South Glasgow Hospital: Summary Land Quality Review.

The following reports have been provided for summary review in no particular chronological order. Note that salient points only have been extracted for consideration. It has not been WSP's objective to reiterate the findings of others, should further clarification be sought then reference to the original source materials is recommended:

- Aitken laboratories Ltd. Fax Message dated 5th Feb 2003;
- Ove Arup and Partners. Drawing No. 1481-2, date unknown;
- Nicholson Site Investigation, Site Investigation Report, Southern General Hospital, Dated September 1989;
- Fugro, 1985, Soils Investigation Report, Proposed Geriatric Units at Southern General Hospital, Glasgow, Reference 85/2580;
- Ove Arup and Partners 1998, Proposed Extension to Oral and Maxillofacial Unit, Southern General hospital, Glasgow Reference 53500\980129a.rep;
- URS, 2007. New Laboratory Facility at Southern General Hospital, Substructure Options Report. Reference 49339768;
- Rocksoil, 1998. Site Investigation at Southern General Hospital, Glasgow. Reference S97/1496;
- Thorburn and Partners, 1978. Southern General Hospital, Glasgow. Proposed Redevelopment, Geotechnical Study. No reference;
- Wimpey Environmental Ltd, 1994. Proposed Geriatric Unit Southern General Hospital, Glasgow. Reference SULY/7523; and
- URS, 2009. Preliminary Geo Environmental Report. New Southern General hospital. Draft. Reference 49339768/GL:RP0010.

Comments on these reports are provided below, followed by our overall conclusions and recommendations. It should be noted that WSP has not provided comment here on the geotechnical content (including mineral stability sections) of these reports. We have concentrated solely on the environmental aspects of the above reporting. Such review works are however to be delivered under separate cover by WSP.

Aitken Laboratories Ltd - Fax Message dated 5th Feb 2003.

- This document presents borehole logs denoted as BH1 and BH2 plus trial pit logs for 7 locations across an area of circa 480m2 in association with a proposed new theatre suite;
- No chemical test data is provided nor interpretation beyond factual logs;
- Maximum trial pit depth was 1.6m bgl and borehole depth was 6.0mbgl;
- Of note is made ground to a maximum observed depth of 0.75m bgl including ash, clay, gravel and bricks. The observed ash may be associated with PAH type contamination;
- Rockhead was not proven; and
- Below the observed made ground loose to medium dense sands and gravels were reported.

Ove Arup and Partners. Drawing No. 1481-2 date unknown.

- Inclusion of a site plan denoting borehole and trial pit locations in proximity to the sites Psychiatric Department;
- Two boreholes records are included neither without installation notes nor to British Standard nomenclature. These boreholes however support the observation of sands, gravels and boulder clay.

Nicholson Site Investigation, Site Investigation Report, Southern General Hospital, Dated September 1989.

- Delivered in support of the construction of a Spinal Unit at the request Beattie Watkinson Partners Consulting Engineers to the Greater Glasgow Health Board, works delivered included boreholes and laboratory testing;
- 3. No boreholes were advanced to a maximum depth of 18m bgl;
- No madeground was reported. Alluvium and glacial till dominated observations in this area of site;
- Groundwater's were observed 2-3m bgl;
- Factual reporting testing and interpretation were restricted to geotechnical issues only.

Fugro, 1985, Soils Investigation Report.

- Delivered in support of the construction of a 30 bed Geriatric Unit at the request Andrews, Kent and Stone Consulting Engineers to the Common Services Agency, works delivered consisted of four static cone penetration tests with two trial pits to inform foundation solutions;
- Chemical testing was limited to sulphate and pH;

- Madeground fill was again observed to a maximum of 1.3m including “slag waste” as a potential source of contamination. No testing of these materials were delivered compliant with an assessment of land quality;
- A near neutral pH was however observed and a total sulphate content of less that 0.5% was observed in the north of the target area while sulphate resisting cement was recommended elsewhere.

Ove Arup and Partners 1998, Proposed Extension to Oral and Maxillofacial Unit.

- Appointed as consulting civil and structural engineers for the scheme the reported intrusive works were delivered for the design of sub structures and land contamination;
- The ground investigation was performed by Wimtec Environmental 1997;
- Five boreholes were advanced by cable percussive drilling rig. All boreholes with the exception of BH5 were then advanced into rockhead by rotary drilling;
- Seven trial pits were advanced (5 by hand and 2 by excavator) to obtain soil samples for geotechnical and chemical testing;
- Selected samples of made ground (9 total) were assessed for a general suite of contaminants;
- No leachate, groundwater or gas testing was progressed;
- Groundwater levels were observed between 1.5 and 4.3m bgl;
- The use of ICRCL screening values is not considered in line with current UK best practice, however observation of the analytical results suggests limited concerns with the exception of
  - A maximum solvent extractable matter of 3162mg/kg;
  - High Copper concentrations
  - Absence of appropriate PAH and TPH testing that would be requisite in the presence of ash filled madeground limits the value of this investigation however under changes in best practice.

URS 2007, Laboratory Facility at Southern General Hospital, Substructure Options Report.

- Delivered by URS to assist in the building of a mixture of 4 and 5 storey structures with partial basements accommodating mortuary, facilities management and laboratory spaces;
- Ground conditions recorded were in summary – madeground consisting of silty gravelly sands or clayey ash fill ranging in thickness between 0.5 and 4.56m, underlain by granular alluvial deposits and then glacial till;
- Bedrock was encountered 16.8 to 27.7m bgl as generally moderately weak to moderately strong inter bedded sandstones, siltstones and mudstones;
- Groundwaters were monitored between 0.65 and 4.98m bgl;
- Artesian conditions were encountered in a single borehole;
- No borehole logs, chemical testing or gas monitoring results were reported for comment.

Rocksoil, 1998. Site Investigation at Southern General Hospital, Glasgow.

- Commissioned upon the instruction of Fleming Consultants of Glasgow to assess the engineering properties of the soils on site, fieldworks were performed in November and December 1997;
- Works were limited to 2 times 150mm boreholes (BH1 and BH2) to depths of 17.45 to 17.70m respectively;
- Testing was restricted towards geotechnical classification, strength and compressibility together with sulphate and pH;
- Chemical, gas, groundwater and leachate testing compliant with current best practice was again absent;
- Of note however was ash rich madeground in BH2.

Thorburn and Partners, 1978. Southern General Hospital, Glasgow. Proposed Redevelopment, Geotechnical Study.

- Committed by Greater Glasgow Health Board across an area of ~7.9ha this reporting pertains specifically to geotechnical observations;
- Works included the advancement of 10 boreholes and geotechnical testing;
- Madeground was noted to a maximum depth of 5.2 mbgl;
- No comments again made in regards to land contamination.

Wimpey Environmental Ltd, 1994. Proposed Geriatric Unit Southern General Hospital.

- Delivered as an “Environmental Audit” on the instructions of Wimpey Healthcare Limited” to provide information on ground conditions for foundation designs in support of a new geriatric unit build;
- 7 soils samples were retained for testing of madeground materials;
- Confirmation of the chemical test suite appears to be unavailable. However main body reporting denotes screening against ICRCL and Kelly values (no longer deemed as acceptable). Concentrations of analytes are not reported by WSP comment yet Wimpey observe that recorded levels were below thresholds assuming landscaped open areas;
- High levels of boron, copper, zinc and nickel were however noted as phytotoxic requiring the importation of clean fill.

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URS, 2009. Preliminary Geo Environmental Report. New Southern General hospital. Draft. Reference 49339768/GL:RP0010.

- Appointed by Currie and Brown in September 2008 the aim of this reporting has been to deliver compliant Phase 1 and Phase 2 reporting for 3 areas within the footprint of the Southern General Hospital;
- Reported in “Draft” awaiting final copy;
- 3 distinct areas have been defined
  - Area 1 at 9ha (subdivided into areas 1a and 1b);
  - Area 2 at 0.9ha; and
  - Area 1B at 0.95ha.

Site Investigation and Sampling Strategy

- URS did provide a summary of exploratory hole rationale stating that exploratory holes were placed to provide general coverage across the site post Phase 1 desk study reporting.
- A total of 41 trial pits have been mechanically excavated to a maximum depth of 4.4 metres below ground level (m bgl).
- 3 No light percussion boreholes were installed with groundwater/ground gas monitoring installations to a maximum depth of 5.0 m bgl in Area 1B.
- 45 No cable percussion boreholes advanced to a maximum depth of 15-29.4 m bgl.
- 23 No rotary boreholes were advanced to a maximum depth of 23.6 to 47.75 m bgl.
- Combined groundwater and gas monitoring installations were installed within 19 boreholes with response zones predominantly observed within the alluvial deposits.
- A total of 40 soil samples (24 madeground and 16 natural) and 19 groundwater samples were retained from site.
- Retained soil samples were submitted for an analytical suite including heavy and phytotoxic metals, _. Selected samples were analysed for polyaromatic hydrocarbons (PAHs), speciated total petroleum hydrocarbons with aromatic and aliphatic splits (TPH-CWG), Metals, phenols, asbestos screen, pH and total organic carbon.
- 14 soil samples were additionally analysed for a leachate suite comprising a similar test suite to the above soil analytical suite.
- Groundwater samples were analysed for a chemical suite comprising to the above soil analytical suite.
- Groundwater level and ground gas monitoring was carried out on 5 occasions between 12th March and 10th April 2009.

Investigation Results

- Ground conditions were generally consistent with the anticipated geology, with variable depths of Made Ground (up to 4.56 m bgl) comprising a silty gravelly sands or sandy clay fill with fragments of brick, tar, cinders, clinker, burnt shale, ash, and plastic bags. The underlying natural materials were found to comprise peat in three positions; granular cohesive alluvium (0.15 -15.36m bgl); glacial till (0.3 – 14.7m bgl) and bedrock comprising mudstone, sandstone, siltstone, limestone, dolerite and some coal.
- Bedrock was encountered in 23 exploratory holes at depths between 16.8 and 34.8m bgl
- Groundwater ingress was noted during advancement of exploratory holes at depths between 16.8 and 26.7m bgl. Subsequent standing waters were noted over 5 occasions ranging 0.65 – 4.98m bgl.
- No visual or olfactory evidence of contamination was noted by URS.
- Ground gas monitoring indicated carbon dioxide ranged between <0.1 and 4.1% v/v, methane between <0.1 and 80.1% v/v, and typical flows of <0.1l/hr. Oxygen varied between 3.5 and 20.9% v/v indicating mostly well-aerated conditions. Monitoring was carried out over a range of atmospheric pressures.

Chemical Results and Assessment

- The soil analytical results have not been compared against published Contaminated Land Exposure Assessment (CLEA) Soil Guideline Values (SGVs) protective of human health;
- Phytotoxic risks have not been assessed with reference to screening values.
- Risks to drinking water supply pipes have not been assessed with reference to the Water Regulatory Advisory Scheme (WRAS) document The Selection of Materials for Water Supply Pipes to be Laid in Contaminated Land (Reference 9-04-03, October 2002)
- Groundwater and leachate results have not been compared against published UK Drinking Water Standards (DWS) nor UK Environmental Quality Standards (EQS).

Site Investigation and Sampling Strategy

- The sampling density (77 exploratory hole locations on a 10.8 ha site) is considered to be appropriate and in accordance with guidance for a exploratory investigation given in 10175:2001, with an average grid spacing of exploratory holes of at least 30m.

Chemical Results and Assessment

- URS's chemical testing strategy is considered to be appropriate based on the site history and reported ground conditions observed.
- No assessment of the analytical soils results has been made. However, and by way of preliminary assessment only then when assuming a commercial land use and WSP Generic Assessment Criteria:
  - No Speciated TPH exceedences are noted in raw analytical results;
  - No PAH exceedences are noted in soils;
  - No Asbestos has been observed in soils;
  - No metals are noted in soils above screening criteria.
- No assessment of the analytical groundwater or leachate results has been made by URS. Again by way of preliminary assessment only:
  - No Speciated TPH exceedences are noted in raw analytical results;
  - No PAH exceedences are noted in groundwaters or leachates;
  - No Asbestos has been observed in groundwaters or leachates;
  - No metals are noted in groundwaters or leachates above screening criteria (minor exceedences noted in the vicinity of TP12 for copper and nickel.
- The presence of elevated carbon dioxide would indicate that the ground gas conditions are not representative of Characteristic Situation 1 despite the low flow rates. However it is observed that the gas exceedences are observed within an area out with our own red line boundary of concern.

Overall Conclusions

- Reporting to date has principally been of a geotechnical focus;
- Where available land contamination testing to date has been limited (except URS 2009) and screening tools applied are no longer acceptable best practice;
- Madeground containing ash has been observed on site as a potential contaminant source beyond land use operations;
- WSP's independent review of aerial mapping and geologic mapping is commensurate with the geologic sequence and land use operations denoted within the historic reporting listed;
- The most recent reporting of URS 2009 including analytical results, gas and leachate testing are assumed to present the latest and most robust assessment of the site. This data remains outstanding however a review of the raw analytical results by WSPsuggests that the hazard at the site is low.
- Detailed and compliant interpretation remains outstanding from URS (2009) beyond draft reporting.

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New South Glasgow Hospital							
Basis of Design Statement	Sheet No.	Ref 12141388/001/BDS01					
Section: General	33 of 1	Revision	-	A	B	C	
		Reviewed		21/08/09			
Status and Information Sources							

Status and Information Sources

This BDS is based on the information available in the following reports:

- Ove Arup and Partners. Drawing No. 1481-2, date unknown;
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- Wimpey Environmental Ltd, 1994. Proposed Geriatric Unit Southern General Hospital, Glasgow. Reference SULY/7523;
- Rocksoil, 1998. Site Investigation at Southern General Hospital, Glasgow. Reference S97/1496;
- Ove Arup and Partners 1998, Proposed Extension to Oral and Maxillofacial Unit, Southern General hospital, Glasgow Reference 53500\980129a.rep;
- Aitken laboratories Ltd. Fax Message dated 5th Feb 2003;
- URS, 2007. New Laboratory Facility at Southern General Hospital, Substructure Options Report. Reference 49339768; and
- URS, 2009. Preliminary Geo Environmental Report. New Southern General hospital. Draft. Reference 49339768/GL:RP0010.

Report Review

Ove Arup and Partners. Drawing No. 1481-2 date unknown.

This drawing comprised a site plan that showed the locations of 7 boreholes and 1 trial pit in the vicinity of the Psychiatric Department to the south of area 1B. Only two borehole records have been included indicating the sequence of strata as topsoil, alluvial sands, alluvial clay, alluvial silt, boulder clay, bedrock.

Thorburn and Partners, 1978. Southern General Hospital, Glasgow. Proposed Redevelopment, Geotechnical Study. No reference

These works comprised 10 cable percussion boreholes, CPTs and geotechnical testing. The plan that goes with this report is not available, and therefore the positions of the boreholes can not be ascertained. However, the report notes the possible existence of an exploratory shaft in the vicinity of the mortuary sunk in 1868 to a depth of about 70m to locate an ironstone seam. There is no evidence to suggest that mineral extraction took place beneath the site. The method of securing the shaft could not be established.

Ground water monitoring over a 4 month period recorded ground water levels from 2.75 to 7.55 mOD. Superficial deposits comprised alluvial sands, silts and clays.

Fugro, 1985, Soils Investigation Report, Proposed Geriatric Units at Southern General Hospital, Glasgow, Reference 85/2580

4 static cone penetration tests and 2 trial pits undertaken for the construction of a 30 bed Geriatric Unit south east of area 1B near Carleith Quadrant. The investigation indicated the sequence of strata to comprise Fill, loose to medium dense sand, soft to firm clay, soft to firm silt, loose to medium dense clay, stiff to very stiff sandy silty clay. The discussion on foundations in the report suggested that conventional shallow spread foundations founded at least 0.9m would suffice for a lightly loaded structure. Raft foundations could be used to reduce differential settlements. Piled foundations would be required for anything other than lightly loaded.

Nicholson Site Investigation, Site Investigation Report, Southern General Hospital, Dated September 1989

Works comprised 3 cable percussion boreholes sunk to maximum depth of 18 mbgl for the neurological building SE of area 1B. Ground conditions comprised 0.5m of sandy topsoil underlain by silty sand, very weak alluvium and glacial till. The glacial till was encountered at depths between 11 and 12 mbgl. Groundwater was encountered in 2 out of the 3 boreholes during drilling at depths of 3 – 4 mbgl. Nicholsons advised an allowable bearing pressure of 75 kPa for shallow foundations founded on the shallow sand layers. For heavier loads. Piles were recommended.

Wimpey Environmental Ltd, 1994. Proposed Geriatric Unit Southern General Hospital, Glasgow. Reference SULY/7523

Copy of the report provided does not include a plan showing the exploratory hole locations. Report notes that the investigation covered an area to the south of Langlands drive. This is

out with the development area currently being considered. 5 cable percussion boreholes, 3 of which were extended into bedrock were undertaken at the site. Ground conditions encountered comprised up to 1.75 of made ground underlain by loose sand; very soft, soft and firm clay; very soft and soft silt; clacial till; bedrock. An allowable bearing pressure of 50 kPa was advised for shallow foundations founded on natural soils. Vibro techniques and piling were discussed as alternatives.

Rocksoil, 1998. Site Investigation at Southern General Hospital, Glasgow. Reference S97/1496

Fieldworks comprised 2 cable percussion boreholes to 17.45 and 17.7m depth in the vicinity of the mortuary and wards 33 to 36. These structures were reported as settling at the time of the fieldworks. Ground conditions encountered comprised made ground (1.94 to 2m); intertidal marine deposits (marine silts and clays); and glacial till. Groundwater was encountered at depths of 6 and 8m during the fieldworks. The report recommended that underpinning in the form of either driven or CFA piles be used to mitigate the settlements. This report did not mention the possible exploratory shaft in the vicinity of the mortuary which was reported by Thorburns in their 1978 report.

Ove Arup and Partners 1998, Proposed Extension to Oral and Maxillofacial Unit, Southern General hospital, Glasgow Reference 53500\980129a.rep

Fieldworks comprised 7 trial pits and 5 cable percussion boreholes, 4 of which were advanced into rockhead by rotary drilling. The site is located to the SE of area 1B close to Carleith Quadrant. The fieldworks encountered topsoil (0.3 to 1.4 mbgl); Alluvium (3.7 to 17.5m bgl); Glacial Till (5.7 to 14.6 mbgl). Groundwater was encountered at levels of 4.7 to 7.2 mAOD. CFA piles were recommended as a foundation solution for the structures in this area.

Aitken laboratories Ltd. Fax Message dated 5th Feb 2003

Fieldworks undertaken in northern part of area 1B and comprised 2 cable percussion boreholes and 7 trial pits. Ground conditions encountered comprised made ground and alluvium.

URS, 2007. New Laboratory Facility at Southern General Hospital, Substructure Options Report. Reference 49339768

Report is dated 2007, but refers to 2009 ground investigation. Report discusses the options considered for the substructure elements for the proposed laborities facility. Driven, CFA and bored cast in place piles considered. Large diameter bored cast in place piles recommended as providing most appropriate solution. 900mm diameter piles socketed 3m into bedrock determined by URS as having SWL of 3500kN in compression and 1700kN in tension. Report also discusses retaining wall option.

URS, 2009. Preliminary Geo Environmental Report. New Southern General hospital. Draft. Reference 49339768/GL:RP0010.

This report was undertaken specifically for the development under consideration. The report currently available is a draft issue only. This investigation covered 4 separate areas:

Area 1A Covers the area adjacent to the NW of area 1A.

Area 1B covers the new ortho theateres to the north of the helipad all the way down to Langlands Drive.

Area 2 covers wards 30 – 32, the drug abuse and psychological Medicine building and the Pharmacy department.

Area 3 covers the podiatry department and the car parking area to the north of the trust headquarters.

This BDS adopts the same nomenclature throughout.

The fieldworks comprised 44 trial pits, 3 competitor boreholes, 33 cable percussion boreholes of which 23 were continued by rotary coring into rock, 7 CPTS, in-situ geotechnical testing, gas and groundwater monitoring, geotechnical and chemical laboratory testing. Ground conditions encountered generally comprised made ground, alluvium, glacial till and bedrock. The draft report does not include any groundwater monitoring records.

General

The proposed development is to comprise the construction of a new 15 storey hospital with laboratory building and energy centre in area 1; the construction of a research and development centre in area 2; and a residential cancer care unit in area 3.

This BDS discusses the ground conditions across the development areas and advises risks and recommendations for the following:

- Foundations
- Retaining Walls
- Earthworks
- Formations
- Designers Risk Assessment

This statements is intended to inform the tender design only. They should not be used for detailed design purposes for which an interpretative report will be required. These statements can be updated to incorporate new or revised information.

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Principal Material Types

The solid geology plan for the site (Scotland Sheet 30 – Solid Edition) indicates the solid strata beneath the site to comprise the limestone coal group to the south and east of the site with the lower limestone group elsewhere. An igneous intrusion is shown to run from SE to NW across the middle of the site. A fault is recorded trending south east to north west towards the northern part of the site with the down throw to the south.

The exploratory hole records from the Norwest Holst factual report and bam Ritchies ground investigation report indicate the following sequence of strata:

Area 1A

Stratum	Depth to top of Stratum (mbegl)	Thickness (m)
Made Ground	0	0.5 – 3.2
Alluvium	0.5 – 3.2	0.6 – 21.0
Glacial Till	0.6 – 21.4	0.3 – 19.4
Bedrock	16.8 – 25.2	-

Area 1B

Stratum	Depth to top of Stratum (mbegl)	Thickness (m)
Made Ground	0	0.4 – 3.0
Peat*	1.3 – 1.6	0 – 0.7
Alluvium	0.4 – 3.0	3.5 – 23.8
Glacial Till	4.1 – 24.8	0.3 – 19.5
Bedrock	17.4 – 26.3	-

*Only encountered within BH09 & BH17

Area 2

Stratum	Depth to top of Stratum (mbegl)	Thickness (m)
Made Ground	0	0.8 – 1.8
Alluvium	0.8 – 1.8	5.1 – 17.8
Glacial Till	6.6 – 18.3	5.6 – 18.8
Bedrock	17 – 18.8	-

Area 3

Stratum	Depth to top of Stratum (mbegl)	Thickness (m)
Made Ground	0	0.4 – 2.5
Alluvium	0.4 – 2.5	17.8 – 28.4
Glacial Till	18.7 – 28.8	0 – 6.0
Bedrock	25.5 – 34.8	-

Made Ground

Made ground was generally encountered across the site. The made ground encountered generally comprised a very loose to loose sand occasionally containing fragments of brick, ceramics, shale, clinker, cinders or sandstone.

Alluvium

The alluvial deposits at the site generally comprise sand underlain by clay then silt. The sand is typically a very loose yellow brown slightly silty sand. The underlying clay generally comprises a very soft brown slightly sandy clay. The silt, where present normally comprises an un-compact grey very sandy silt with laminations.

Glacial Till Deposits

The glacial till encountered is typically a stiff and very stiff grey slightly sandy slightly gravelly clay with occasional cobbles. Glacial till was absent to the south of the podiatry unit in area 3 (BH43).

Bedrock

Bedrock encountered comprises mostly moderately weak to moderately strong mudstones and sandstones with very closely to medium spaced sub vertical and sub horizontal discontinuities. Strong Siltstone is encountered in places. An intrusion of dolerite was encountered in the middle of area 1B.

Groundwater

Groundwater monitoring records for the main site area have not been made available. Once available, this section will require to be revised. Groundwater observations made during the drilling works indicate that groundwater in some areas may be encountered at shallow depths, i.e. within 3m of ground level.

Engineering Discussion & Recommendations

Foundations

In view of the nature and thickness of the compressible alluvial deposits traditional shallow spread footings will not be suitable as foundations for the proposed development. Suitable foundations can be provided by installing piled foundations

The construction of both bored and driven piles would be technically feasible at this site. The use of continuous flight auger (CFA) piles should not be considered due to the risk of over-flighting of parts of the alluvial deposits and the relatively low pile capacities compared to the high pile loads proposed. Overflighting is a significant risk where softer soils overlie very dense/stiff soils or rock. Overflighting causes large overbreaks and significant settlements in adjacent structures through extracting larger soil volumes than required. Reinforcement cage lengths greater than 15m are unsuitable for the CFA method.

Driven piled foundations, although technically feasible may be inappropriate due to likely noise restrictions at the site. Noise restrictions at the site need to be clarified. Silent hammers will reduce noise levels through the made ground and alluvial deposits but will be unable to drive piles through any boulder obstructions within the glacial till. Consideration should be given to the use of pre-boring at some pile locations to overcome obstructions.

Bored piles will require either temporary casing throughout their depth or the use of a polymer support fluid due to the presence of groundwater. There is the possibility that fine sands may ‘blow’ under semi-confined conditions within the alluvial sands.

The most appropriate form of piles for the proposed development are large diameter bored piles socketed into the bedrock.

A detailed pile design is outside the scope of this BDS. The design procedure for piles varies considerably, depending on the proposed type of pile. However, for illustrative purposes, the following table gives likely working pile loads for large diameter bored piles of various diameters with a 1m deep rock socket.

The bearing capacity of the bedrock is determined by the equation published by Kulhawy and Goodman and reproduced by Tomlinson (eq 7.16a) in Foundation Design and Construction 6th edition.

qub = cNc + _BNg/2 + _DNq

Rock socket skin friction = _ x Ø_x h x c

Parameters assumed:

UCS = 5000 kN/m2

_’ = 30o for RQD 0 – 70%

c’ = 0.1 UCS = 500 kN/m2

A factor of safety of 2.5 is applied to both end bearing and rock socket skin friction.

Preliminary Pile Capacities for Large Diameter Bored Piles

Typical Pile Working Loads (kN)					
Pile Diameter (m)					
0.6	0.8	1.0	1.2	1.5	1.8
1,000	1,700	2,600	3,600	5,400	7,600

It should be noted that pile group effects have not been taken into consideration in the above values.

Retaining Walls

Embedded retaining walls are required for the basement excavations. The ground investigation reports made available suggest that shallow ground water will be encountered. Lowering of the ground water out-with the excavations may result in settlements which adversely affect adjacent structures and services. In light of this, lowering of the groundwater outwith the excavation should not be considered.

Dewatering of the groundwater within the excavations also needs to ensure that hydraulic failure at the base of the excavation is avoided. This can be achieved by installing a water tight cut off wall with a penetration deep enough to prevent hydraulic failure. The penetration of the cut-off wall to prevent hydraulic failure should be designed in accordance with the method shown in the NAVFAC design manual.

Retaining walls types that will provide a water tight solution include diaphragm, sheet piles and secant pile walls. The cost of providing a diaphragm wall may prove prohibitive. A sheet pile wall will be cheaper, but noise restrictions at the site may preclude their use. Silent driving may be an option, but this will be dependant on the depth of penetration required and the materials through which the sheet piles are to be driven.

A secant pile wall may provide the most suitable solution. The installation process is relatively quiet when compared to a driven pile solution. The piles can also be used as permanent foundation piles, an advantage it has over steel sheet piles. The installation of a secant pile wall requires careful monitoring ensuring that the wall is water tight down to and beyond the dredge line. This can be done by tightening up the installation tolerances stipulated in the piling specification and/or increasing the diameter of the female (soft) piles to ensure that no gaps are formed between piles that allows the ingress of groundwater.

The provision of lateral support to the secant pile walls may reduce the cross sectional area of the piles and the embedment depth. The lateral support can be provided in the form of either tie back anchors or struts. The use of tie back anchors depends on the proximity of structures behind the excavation. In many areas of the site, this may preclude their use. The use of struts will be dictated by the sequence of operations within the excavation and access requirements.

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Mineral Stability

The CA report obtained by URS indicates that there may be shallow unrecorded workings at the site. The investigation undertaken by URS did not identify any workings. However, it would be prudent to undertake some mineral bores at the site to bottom this out. The Thorburn report from 1978 notes the possible existence of an exploratory shaft in the vicinity of the mortuary sunk in 1868 to a depth of about 70m to locate an ironstone seam. There was no evidence to suggest that mineral extraction took place beneath the site. The method of securing the shaft was not established. The URS report advises that this shaft is some 70m south of area 1B. However, a mortuary building is shown adjacent to the urology unit to the east of the helipad. An RFI was raised to query this matter and the Board have responded that the mortuary building referred to in the Thorburn's report is not the same as the current mortuary building.

Earthworks

There is insufficient earthworks testing to assess whether the material won from the site is likely to be acceptable for re-use as a general fill. However, it is likely that most of the material will be acceptable for re-use as a landscape fill subject to acceptable chemical testing.

Formations

The information made available does not include any CBR tests within the development area. However, it is anticipated that most of the formations to the road pavements will be formed in made ground deposits. Most local authority design guidelines for roads require full capping for formations in made ground. As such the tender should allow for full capping throughout with an allowance for removal of soft spots.

Risks

- Strength of rock may be weaker than assumed. Allow contingency for weaker rock in piling costs. Rock testing to be carried out to confirm strength of rock.
- Insufficient EW testing – Unable to assess proportion of site won material that may be re-used as general fill. Assume that all material will be unsuitable for re-use as general fill, but that most will be suitable for use as landscape fill subject to acceptable chemical testing.
- Insufficient Geotech testing – Again probably sufficient info for tender design but should allow contingency should ground conditions be worse than anticipated. This will impact on embedded retaining wall design for basement excavations. Assume worst case soil parameters.
- No permeability tests – Risk that should be addressed during tender design. Permeability of the soils may dictate depth of embedded retaining walls required for prevention of piping/ hydraulic failure.
- No CBR tests – Allow full depth capping everywhere to overcome this risk.
- Mineral stability – Issue that is yet to be bottomed out which will affect the consolidation works and piling depths.
- Shallow GWT – Dewatering should be allowed for within excavations only along with water tight embedded retaining walls.
- Running sands – All excavations through such material will require closed support.
- Piling system selected – Due to Clyde Alluvium, CFA piles must not be considered for use at this site due to risk of overflighting. EN 1536 recommends that where unstable ground conditions are encountered, the contractor should demonstrate the feasibility of CFAs by means of trial piles or local experience before the commencement of the works. Due to the scale and profile of the project, local experience alone should not be relied upon as it will probably be very selective and in a different context. If the project is keen to pursue the CFA option, despite the risk of overflighting, then the piling contractor should undertake trial piles before the piling type is finalised. If the trial piles indicate overflighting, then the piling contractor will need to resort to a different piling solution.
- Driven piles may be precluded due to nuisance factor and proximity of hospital buildings. Guidance and case studies for sound levels and peak particle velocity (ppv) associated with piling activities may be found in BS8233 pt 1 tables 4, C4 and C5. Acceptable noise levels and ppv limits have yet to be defined. Once these are available, the piling contractor should be consulted as to whether his piling operations will remain below these levels whilst still being able to install a pile that will achieve the required specified working load.
- Cased bored piles should be used. Piles will probably have to be founded on or into bedrock to achieve design loads likely to be required. If mineworkings close to bedrock are encountered (treated or otherwise), piles will need to be taken beyond.

Appendix C Building Structure and Foundation Options

Element	Presented Details	Options	Advantages	Disadvantages / Risks
Structural Frame	Traditional RC Frame			
		Traditional RC Frame with Bubbledeck or similar void formers	Same capacity, lighter slab dead loads, smaller columns, smaller foundations, less formwork	Reduced dead weight limits slabs' ability to resist vibration (limit's future flexibility)
		Post tensioned floors	Potential larger spans, potential thinner slabs, earlier striking times	More complex method, specialist design and installation required
Foundations	Small diameter cast insitu rotary bored			
		Large diameter cast insitu rotary bored	Can be placed in all conditions, fewer piles required	Ground beam lateral restraint required spoil produced.
		CFA	Quicker, quieter, less vibration,	Potential flighting, obstructions, spoil produced, insufficient GI to assess risks
		Driven	Quicker, no spoil,	Noise, vibration, obstructions, alignment, insufficient GI to assess risks
Basement	Cast in place rotary bored secant wall			
		Sheet piled wall	Quicker, no spoil	Noise, vibration, obstructions
		Open cut excavation and traditional tanked insitu RC retaining walls and tunnel box	Tried and tested method, visible structure integrity	Dewatering, large excavations, ground instability, space sterilisation

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Demolition Strategy

Submission Reference:

3.27 Demolition Strategy.

Submission Response.

Scope of Works.

The scope of demolition work by Brookfield at Stage 3A is Buildings AN, DG, DC, AP and the Surgical Link Bridge DF as shown on BMJ drawing PD- HLM-S(00)X-XX-005. (enclosed)

Programme

The Laboratory Facilities, Adult and Children's Hospitals and the Energy Centre will all be operational when demolition commences and the new access road off Govan Road will be in use.

Brookfield Logistic Drawing BE-DJ-LOG-104 (enclosed) shows our site arrangement at Stage 3A

Segregation

Our protection and safety measures for segregation between our demolition works and adjacent buildings will vary with the proximity to each one together with the structural heights of the buildings to be demolished.

The selection of barrier type is influenced by the duration required; if the demolition in an area is a 2 day operation after which the barrier needs to be adjusted for external landscaping works then a demountable system is more economical and convenient at the same time adequate for safety purposes.

Heras fencing also provides better sight lines for vehicles and pedestrians.

South Boundary.

The existing roadway to the south provides a substantial clearance zone between the single storey building AN and the public area. The erection of a Heras fence will suffice in this location.

West Boundary.

Buildings AN, DG and DC are all single storey and set back far enough from the new access road to allow Heras fencing to be used.

North Boundary

The close proximity of the Accident and Emergency building AK, to be retained, and buildings DC and AP to be demolished, does not allow for an effective hoarding to be erected. Our demolition contractor will provide hard barrier protection to windows and to the fabric of building AK for the short duration of demolition works to this location, removing on completion.

Building AK will provide segregation provided any doors are temporarily secured. If any doors on this elevation are fire exits then escape routes must be maintained or diverted. After demolition is complete Heras fencing will suffice.

Any connecting parts between demolition and retained structure will be made good.

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At the East of the North Boundary a full 2.4m high solid hoarding will be erected to give increased protection at the gable end of Wards 1-6 where public car parking and existing hospital facilities involve greater numbers of vehicles and pedestrians.

East Boundary

This boundary will also have full 2.4m high solid hoarding on the outside line of the footpath and if necessary, to the front of the car park bays. Although the existing footpath will be within our site and pedestrians using the footpath on the opposite side of the road, the Long Corridor Building is 3 storeys high and at a busy location, where enhanced dust and noise containment will be required.

It is also important that the image presented to the public is one of cleanliness, tidiness and control, and the solid hoarding will allow this to be effectively communicated whilst delivering robust physical protection.

Pedestrian Routes

Main routes pedestrians will be taking will be from Car Parks 1A and 1B to the newly constructed facilities, the existing facilities to the East side of the complex and along the access road off Govan Road.

From our enclosed phasing drawing it is evident that the demolition has the minimum effect on these routes.

Traffic Routes.

By the formation of the temporary link road, traffic routes to the Laboratory Building are maintained and the

New Site Entrance Road is unaffected.

Construction Works

Construction traffic will enter and exit from the demolition site directly onto the entrance road, leading to Govan Road. All demolition materials will be carted away via this route.

Our Site Accommodation and Welfare establishment will be located next to our site entrance but will be relatively small, providing for 6.Brookfield staff and the demolition subcontractor (external works subcontractor overlaps with demolition for a short period only).

Management

The Brookfield organisation chart for Stage 3A - Team for Demolition and Externals is enclosed.

Before any demolition work commences our HS&E manager will ensure that type 3 asbestos surveys are carried out that an initial survey for Aspergillus is completed and that a service decommission certificate is issued by the Board and verified on site by ourselves.

Temporary works designs for the Link Bridge demolition / removal will be produced by our subcontractor and checked by Brookfield.

Regular monitoring for Aspergillus will be carried out during demolition works and site inspections completed by managers.

Summary

On an initial visit we were accompanied by a potential demolition subcontractor to view the works to be carried out in stage 3A. We did not foresee any unusual features or complications on the demolition.

We did however recognise that the removal of the Link Bridge will require specific and detailed method statements after having ascertained how it has been constructed, The timing of removal of the bridge over the Blue Route must be agreed with the Board and demolition of the section over the east footpath carefully planned.

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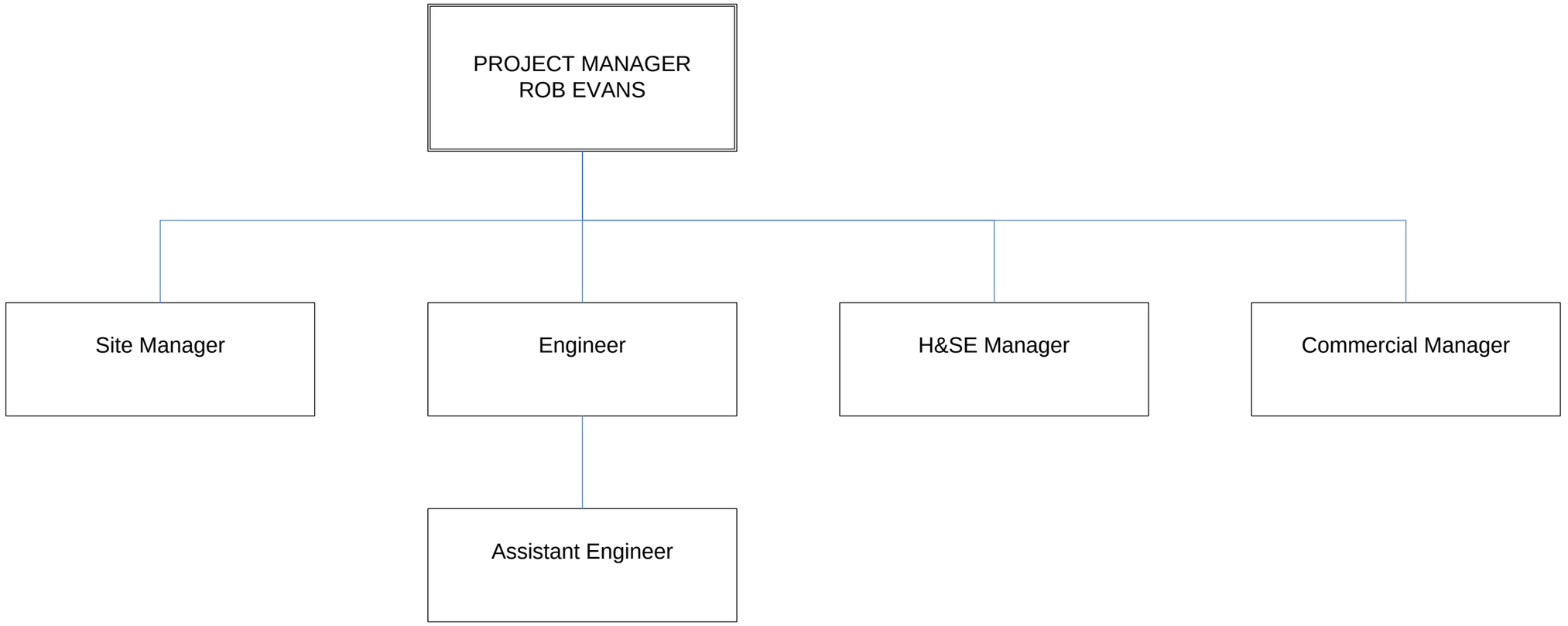
STAGE 3A TEAM – DEMOLITION AND EXTERNALS



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Diversion Strategy

Submission Reference

Volume 3 Section 3.28.1 Culvert Diversion

Submission Response

Existing Situation

Drawing WSP-WS-00-PL-140-03 identifies 3 drainage diversion location relating to the adult and Children's hospital works

The Maternity combined sewer diversion will be carried out within the confines of the site and will have no impact on the facility with a new manhole constructed over the existing sealed pipe before final connection is made out of normal working hours.

The Linthouse burn a 1050mm surface water culvert and a 300mm foul drain currently runs across the south east corner of the proposed Adult Hospital site. In order to facilitate the construction of the new hospital both these existing services require diverting away from the site. An existing underground HV electrical service runs around the perimeter of the south east corner of the site which must be maintained. The existing blue light ambulance route runs north / south into Langlands Drive adjacent to the south east corner of the site and 24 hour access MUST be maintained at all times. This set of constraints presents a particularly challenging activity to divert these culverts.

The foul drain diversions to the hospital main entrance area also presents a challenge an will require a detailed risk assessment and method statement to agree an acceptable traffic management strategy to install the new sewer connection.

The connection has been designed such that any traffic management requirements will not affect the Govan road blue route, but the less trafficked Renfrew road that is not generally used as an ambulance route with shieldhall and Hardgate road providing access from the west

In addition to this the Jenny Burn runs from the existing ambulance station site and will be diverted as part of the stage 1 operations. These works will also be contained within the site boundary with no impact on any hospital facilities.

Proposed culvert and foul drain Diversion

The proposed diversion routes for both services are shown on Diversion Strategy drawing No CD-WS-00-PL-140-14.

In order to maintain the blue light ambulance route along the main road we propose to utilize the tract of parking bays spaces shown orange hatch on the above drawing. The width of the track of road will be maintained at least 7.0m wide providing adequate separation for two way traffic and minimal impact on hospital service delivery.

A detailed risk assessment and method statement that will be agreed with the Board regarding method and timing prior to any activity commencing. This will enable suitable notifications to be issued to hospital staff on forthcoming activities so they are aware of the traffic management controls that will be instigated including signage and barriers to highlight the temporary road re-alignments.

The proposed hoarding line on the west side of the existing road will run approximately 3.0m away from the existing kerb line taking in the existing car parking bays on this side of the road and providing the opportunity to carry out the proposed drainage diversions inside the protective hoarding line, particularly to the south east corner of the site avoiding the need for any lane closure on to this busy corner of the blue route.

Live Services Protection and diversions

All works affecting the normal operation of the hospital campus will be planned and advised well in advance and raised at the weekly site liaison meetings with the Board's project administration team.

Brookfield propose to carry out a full subscan of the site area to confirm existing service routes. From this and in discussion with the Hospital board a diversion plan and methodology will follow that will identify areas where site works interface with functional services and proposals to protect or divert.

The existing HV service to the site perimeter will be traced along all boundaries through CAT scan and trial hole methods to validate the findings of the subscan survey. Any excavation work that is to be carried out in the vicinity of any section of the HV cable will be subjected to a detailed method statement and controlled through a strict permit to work system.

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Medical Gas Line Workplan.

Existing VIE Compound

The existing VIE compound will require relocation to the south and east during the construction phase of Stage 3.

To achieve the removal and relocation of this VIE compound with no disruption to the hospitals existing operations, we will in conjunction with Air products disconnect the existing pipework arrangement and move the stores approximately 35m to the south and 15m east of its current location.

To ensure that operations within the existing hospital campus does not suffer any down time or disruption we will with the approval of the hospital operational staff install J type cylinders and manifolds to temporally back feed the existing Oxygen systems during the relocation of the VIE store.

This temporary system will be linked to local Oxygen alarms that we will monitor during the relocation of the VIE compound.

In critical areas emergency back up oxygen bottles will be made available to give additional resilience in these areas should the need arise.

On completion of the relocation of the existing VIE compound all new lines will be tested and purged, the final installation will be checked and signed off by the Approved Person before the VIE compound is put back into service.

New Duplicated VIE Compounds.

It is proposed that two new VIE compounds will be form part of the installation within Phase 3 of the project, these stores will be sited within suitable locations to ensure compliance with the SHTM, Local Approved Person, suppliers requirements and will serve as operational and stand-by for the new the hospital.

Both these stores will be independent of each other and will come complete with alarms and telephone links as required within SHTM002.

The system shall be rated to accommodate the full site wide requirements and shall include interlinking the new plant with the retained estate systems via valved off interconnectors to improve overall site resilience.

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Introduction

Submission Reference:

Section 3.29: ‘Statement of Compliance with Lab design information contained in ITPD (Vol. 5 of BIW)’.

Submission Response:

Brookfield recognises the work carried out to date by Board’s designers for the Laboratory scheme and understands that certain areas are still being developed.

Nightingale Associates have considerable expertise in laboratory design and have an appreciation of the work carried out to date in defining the functional associations and adjacencies required.

We confirm having received the Laboratory design information contained in the ITPD (Volume 5 of BIW), as listed in the schedule 1. The Brookfield submission has taken cognisance of all the information contained therein and confirms the following:

- All design information in Volume 5 has been priced and is contained in Volume 12 of our bid submission
- Laboratory Construction Programme No BCL-NSGH-TN01-0017 has made allowance for the Laboratory Design Brief.

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Schedule of content – Labs BIW - Volume 5

File Name	Iss.	Rev.	Title	Status	Issue Date	Publishing Company	Publishing User
01 Employers Requirements Stage D	1	-	01 Employers Requirements Stage D	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A1 Master Plan	1	-	A1 Master Plan	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A10 BREEAM	1	-	A10 BREEAM	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A13 Risk	1	-	A13 Risk	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A2 Architectural Location	1		A2 Architectural Location	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A3 Stage D Plans 1	1	-	A3 Stage D Plans 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A3 Stage D Plans 1	2	A	A3 Stage D Plans 1	V5 Labs Stage D Tender Issue	09/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A3 Stage D Plans 2	1	-	A3 Stage D Plans 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A4 Elevations	1	-	A4 Elevations	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A4 Elevations	2	A	A4 Elevations	V5 Labs Stage D Tender Issue	08/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A5 Builderswork Plans 1	1	-	A5 Builderswork Plans 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A5 Builderswork Plans 2	1	-	A5 Builderswork Plans 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A6 Fitment Plans 1	1	-	A6 Fitment Plans 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A6 Fitment Plans 2	1	-	A6 Fitment Plans 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A6 Fitment Plans 3	1	-	A6 Fitment Plans 3	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib

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A6 Fitment Plans 4	1	-	A6 Fitment Plans 4	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A7 Fire Strategy	1	-	Fire Compartmentation Plans	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A7.2 Fire Strategy Report	1		Fire Strategy Report	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A8 Visuals 1	1	-	A8 Visuals 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A8 Visuals 2	1	-	A8 Visuals 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A8 Visuals 3	1	-	A8 Visuals 3	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 1	1	-	A9 Planning Application 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 1	2	A	A9 Planning Application 1	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 2	1	-	A9 Planning Application 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 2	2	A	A9 Planning Application 2	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 3	1	-	A9 Planning Application 3	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 3	2	A	A9 Planning Application 3	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 4	1	-	A9 Planning Application 4	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 5	1	-	A9 Planning Application 5	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 6	1	-	A9 Planning Application 6	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
A9 Planning Application 7	1	-	A9 Planning Application 7	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib

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AL(00)01	1	-	Level -1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)02	1	-	Level 0	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)03	1	-	Level 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)04	1	-	Level 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)05	1	-	Level 3	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)06	1	-	Level 4	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)07	1	-	Level 5	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)01	1	-	Elevation 1	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)02	1	-	Elevation 2	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)03	1	-	Elevation 3	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)04	1	-	Elevation 4	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)05	1	-	Elevation 5	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)06	1	-	Elevation 6	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(05)07	1	-	Elevation 7	V5 Labs Stage D Tender Issue	02/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(20)01	1	-	Section AA	V5 Labs Stage D Tender Issue	28/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(20)02	1	-	Section BB	V5 Labs Stage D Tender Issue	28/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(20)03	1	-	Section CC	V5 Labs Stage D Tender Issue	28/07/2009	Boswell Mitchell & Johnston	Deb, Rajib

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B2A Mortuary	1	-	Outline Brief Mortuary	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
B3A Blood Sciences	1	-	Outline Brief Blood Sciences	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
B4A Genetics	1	-	Outline Brief Genetics	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
B5A Pathology	1	-	Outline Brief Pathology	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
B6A Micro-Biology	1	-	Outline Brief Micro Biology	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
C Outline Specification rev A	1	-	Outline Specifications	V5 Labs Stage D Tender Issue	03/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
C Outline Specification rev A	2	B	Outline Specifications	V5 Labs Stage D Tender Issue	08/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
Site & Setting Out	1	-	A9 Site & Setting Out DWG	V5 Labs Stage D Tender Issue	21/07/2009	Boswell Mitchell & Johnston	Deb, Rajib
NSGACL B of approx Q	1	1	Labs BW B of Approx Quants	V5 Labs Stage D Tender Issue	22/07/2009	Currie & Brown	Gilmour, Ian
NSGACL Labs M&E Pricing Sch	1	1	M&E Pricing Sch for Labs	V5 Labs Stage D Tender Issue	22/07/2009	Currie & Brown	Gilmour, Ian
NSGACL 17-07m-16 mes stage d rev 01	1		Update - Appendix A11, Outline Description of Mechanical & Electrical Engineering Services & Outline	V5 Labs Stage D Tender Issue	22/07/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL 2475 Letter	1		Glasgow City Council Letter to BMJ re Labs Planning Submission 09/01676/ DC	V5 Labs Stage D Tender Issue	31/07/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL G1313_ M(54) SK01-A3	1		Natural Gas Schematic	V5 Labs Stage D Tender Issue	11/08/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL G1313_ U(96) SK01 Z (A1)	1		Site Utility Routes	V5 Labs Stage D Tender Issue	11/08/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL Laboratories BREEAM	1		Labs initial workshop template write up	V5 Labs Stage D Tender Issue	02/07/2009	NHS Greater Glasgow & Clyde	Craig, Carol

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File Name	Iss.	Rev.	Title	Status	Issue Date	Publishing Company	Publishing User
NSGACL Laboratory Block Con App Docs Final Draft	1		Laboratory block - Draft Consultants Appointment Document - 26 June 2009	V5 Labs Stage D Tender Issue	17/07/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL Labs M&E Spec	1		Laboratory Development, Stage D Appendix 2, Mechanical & Electrical Services Specification 12th July	V5 Labs Stage D Tender Issue	14/07/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL Lift Schedule Revision 3 07 08 09 Stage D	1		New Laboratory Facility, Lift Schedule Rev 03, 7 Aug '09 : Stage D	V5 Labs Stage D Tender Issue	10/08/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL Main M&E Plant Schedule - Labs	1		Labs Building - Main M&E Plant Schedule, 14/7/09	V5 Labs Stage D Tender Issue	16/07/2009	NHS Greater Glasgow & Clyde	Craig, Carol
NSGACL-G1313_ E(61) SK03	1		LEVEL 0 PLAN - MAIN ELECTRICAL CONTAINMENT ROUTES	V5 Labs Stage D Tender Issue	17/07/2009	NHS Greater Glasgow & Clyde	Controller, Tender
NSGACL-G1313_ E(61) (-)SK01	1		Power Connections Prior to Energy Centre	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ E(61) SK02	1		LEVEL -1 PLAN - MAIN ELECTRICAL CONTAINMENT ROUTES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ E(63) (-)SK01	1		Schematic Layout of Emergency Lighting Installation	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ E(64) (-)SK01	1		Schematic Layout of CCTV & Intruder Alarm Installation	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ E(65) (-)SK01	1		Schematic Layout of Data/Comms Installation	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ E(67) (-)SK01	1		Schematic Layout of Fire Detection and Alarm System	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ E(68) (-)SK01	1		Data/Comms Schematic Site Distribution	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ M(50) (-)SK01	1		Schematic Layout of Domestic Water Services	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ M(50) (-)SK02	1		Schematic Layout of Main Cooling Services	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ M(50) (-)SK03	1		Schematic Layout of Main Heating Services	V5 Labs Stage D Tender Issue	03/07/2009	Wallace Whittle	Administrator, Tender

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File Name	Iss.	Rev.	Title	Status	Issue Date	Publishing Company	Publishing User
NSGACL-G1313_E(62)(1)SK01	1		LEVEL 1 - INDICATIVE LAYOUT OF POWER SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_E(62)(1)SK01	2		LEVEL 1 - INDICATIVE LAYOUT OF POWER SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_E(63)(1)SK02	1		LEVEL 1 - INDICATIVE LAYOUT OF LIGHTING & EMERGENCY LIGHTING	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_E(63)(1)SK02	2		LEVEL 1 - INDICATIVE LAYOUT OF LIGHTING & EMERGENCY LIGHTING	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_E(67)(1)SK02	1		LEVEL 1 - INDICATIVE LAYOUT OF FIRE DETECTION & ALARM SYSTEM	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_E(67)(1)SK02	2		LEVEL 1 - INDICATIVE LAYOUT OF FIRE DETECTION & ALARM SYSTEM	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK04	1		LEVEL -1 PLAN - MORTUARY - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK04	2		LEVEL -1 PLAN - MORTUARY - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK05	1		LEVEL 0 PLAN - SHEET 1 of 3 - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK05	2		LEVEL 0 PLAN - SHEET 1 of 3 - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK06	1		LEVEL 0 PLAN - SHEET 2 of 3 - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK06	2		LEVEL 0 PLAN - SHEET 2 of 3 - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK07	1		LEVEL 0 PLAN - SHEET 3 of 3 - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(50)SK07	2		LEVEL 0 PLAN - SHEET 3 of 3 - TYPICAL MECHANICAL SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(56)(1)SK01	1		LEVEL 1 - INDICATIVE LAYOUT OF SPACE HEATING SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(56)(1)SK01	2		LEVEL 1 - INDICATIVE LAYOUT OF SPACE HEATING SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender

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NSGACL-G1313_M(57)(1)SK01	1		LEVEL 1 - INDICATIVE LAYOUT OF VENTILATION SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_M(57)(1)SK01	2		LEVEL 1 - INDICATIVE LAYOUT OF VENTILATION SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ME(50)SK01	1		FRONT OFFICE BLOCK - FIRST, SECOND, THIRD & ROOF PLANS - TYPICAL M&E SERVICES	V5 Labs Stage D Tender Issue	16/07/2009	Wallace Whittle	Administrator, Tender
NSGACL-G1313_ME(50)SK01	2		FRONT OFFICE BLOCK - FIRST, SECOND, THIRD & ROOF PLANS - TYPICAL M&E SERVICES	V5 Labs Stage D Tender Issue	17/07/2009	Wallace Whittle	Administrator, Tender
LABS FILES UPLOADED SINCE 14/08							
2475 Internal walls Spec	1	-	Internal Walls Specification	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 1	1	-	AA(70) BS Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 2	1	-	AA(70) BS Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 3	1	-	AA(70) BS Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 4	1	-	AA(70) BS Part 4	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 5	1	-	AA(70) BS Part 5	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 6	1	-	AA(70) BS Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) BS Part 7	1	-	AA(70) BS Part 7	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) FM Part 1	1	-	AA(70) FM Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) FM Part 2	1	-	AA(70) FM Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib

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AA(70) FM Part 3	1	-	AA(70) FM Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) FM Part 4	1	-	AA(70) FM Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 1 Genetics	1	-	AA(70) Level 1 Genetics	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 2 Gen Part 1	1	-	AA(70) Level 2 Gen Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 2 Gen Part 2	1	-	AA(70) Level 2 Gen Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 2 Gen Part 3	1	-	AA(70) Level 2 Gen Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 2 Gen Part 4	1	-	AA(70) Level 2 Gen Part 4	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 2 Gen Part 5	1	-	AA(70) Level 2 Gen Part 5	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 2 Gen Part 6	1	-	AA(70) Level 2 Gen Part 6	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 1	1	-	AA(70) Level 3 Path Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 2	1	-	AA(70) Level 3 Path Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 3	1	-	AA(70) Level 3 Path Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 4	1	-	AA(70) Level 3 Path Part 4	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 5	1	-	AA(70) Level 3 Path Part 5	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 6	1	-	AA(70) Level 3 Path Part 6	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 7	1	-	AA(70) Level 3 Path Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib

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AA(70) Level 3 Path Part 8	1	-	AA(70) Level 3 Path Part 8	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Level 3 Path Part 9	1	-	AA(70) Level 3 Path Part 9	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) MicroBiology Part 1	1	-	AA(70) MicroBiology Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) MicroBiology Part 2	1	-	AA(70) MicroBiology Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) MicroBiology Part 3	1	-	AA(70) MicroBiology Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) MicroBiology Part 4	1	-	AA(70) MicroBiology Part 4	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Mortuary Level 0	1	-	AA(70) Mortuary Level 0	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Path Part 1	1	-	AA(70) Level 2 Pathology Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Path Part 2	1	-	AA(70) Level 2 Pathology Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AA(70) Path Part 3	1	-	AA(70) Path Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)10 (S)	1	-	AL(00)10	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)11 (W)	1	-	AL(00)11	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)12 (N)	1	-	AL(00)12	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)13 (E)	1	-	AL(00)13	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)14 (S)	1	-	AL(00)14	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)15 (W)	1	-	AL(00)15	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib

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AL(00)16 (N)	1	-	AL(00)16	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)17 (E)	1	-	AL(00)17	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)18 (S)	1	-	AL(00)18	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)19 (W)	1	-	AL(00)19	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)20 (N)	1	-	AL(00)20	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)21 (E)	1	-	AL(00)21	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)22 (S)	1	-	AL(00)22	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)23 (W)	1	-	AL(00)23	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)24 (N)	1	-	AL(00)24	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)25 (E)	1	-	AL(00)25	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)26 (S)	1	-	AL(00)26	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)27 (W)	1	-	AL(00)27	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)28 (N)	1	-	AL(00)28	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)29 (E)	1	-	AL(00)29	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)30 (S)	1	-	AL(00)30	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)31 (W)	1	-	AL(00)31	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib

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AL(00)32 (N)	1	-	AL(00)32	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(00)33 (E)	1	-	AL(00)33	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(70) Level -1 Mortuary Part 1	1	-	AL(70) Level -1 Mortuary Part 1	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
AL(70) Level -1 Mortuary Part 2	1	-	AL(70) Level -1 Mortuary Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
Ceilings Level 0 Part 1	1	-	Ceilings Level 0 part 1	V5 Labs Stage D Tender Issue	20/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
Ceilings Level 0 Part 2	1	-	Ceilings Level 0 Part 2	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
Ceilings Level 0 Part 3	1	-	Ceilings Level 0 Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
Ceilings Level 1 part 1	1	-	Ceilings Level 1 part 1	V5 Labs Stage D Tender Issue	20/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
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Ceilings Level -1 Part 3	1	-	Ceilings Level -1 Part 3	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
Ceilings Level 2 part 1	1	-	Ceilings Level 2 part 1	V5 Labs Stage D Tender Issue	20/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
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Ceilings Level 3 part 2	1	-	Ceilings Level 3 part 2	V5 Labs Stage D Tender Issue	20/08/2009	Boswell Mitchell & Johnston	Deb, Rajib

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File Name	Iss.	Rev.	Title	Status	Issue Date	Publishing Company	Publishing User
Ceilings Level 4 part 1	1	-	Ceilings Level 4 part 1	V5 Labs Stage D Tender Issue	20/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
Ceilings Level 4 part 2	1	-	Ceilings Level 4 part 2	V5 Labs Stage D Tender Issue	20/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
SK(00)04	1	-	Mortuary Schematic Section	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
SK(22)01	1	-	Flue Tower schematic	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
SK(22)03	1	-	Roof Access	V5 Labs Stage D Tender Issue	21/08/2009	Boswell Mitchell & Johnston	Deb, Rajib
PD-HLM-S(00)X-XX-001 - Existing Site Boundary Plan	1	001	PD-HLM-S(00)X-XX-001 - Existing Site Boundary Plan.PDF	V5 Labs Stage D Tender Issue	21/08/2009	NHS Greater Glasgow & Clyde	Controller, Tender
Meeting Record - Drainage Stakeholders Meeting 10 July 2009	2		Meeting Record - Drainage Stakeholders 10 July 2009	V5 Labs Stage D Tender Issue	18/08/2009	URS Corporation Ltd	Denton, Chris
Meeting Record - Scottish Water 24 July 2009	2		Meeting Record - Scottish Water 24 July 2009	V5 Labs Stage D Tender Issue	18/08/2009	URS Corporation Ltd	Denton, Chris

Brookfield

Introduction

Submission Reference:

Section 3.29: ‘LABORATORY’.

Submission Response:

Brookfield recognises the thoroughness and completeness of the brief and scheme developed by the Board, Estates Office, Architects, service Engineers and Users. Our architects, Nightingale Associates have considerable expertise in Laboratory design and recognise the hard work the board and its team have put into defining the functional associations and adjacencies. We also understand that all buildings have to be future proofed and require inbuilt flexibility.

In proposing an alternative for the Laboratory building, Brookfield have reviewed the current design, taking Volume 2/2 Employers requirement and the above items into consideration. We have also reviewed how the laboratory building form, location, structure and function interfaces with the wider Masterplan context.

Our primary aim is to add value in terms of cost saving while delivering an exemplar Laboratory facility that meets the employer’s requirements. Our proposal therefore meets the employers requirements for planned area adjacencies and future proofing.

We have proposed minor changes to the laboratory building these are

- Repositioning of Post Mortem room to ground floor from basement.
- Rationalisation of M&E/ Plant services
- Extension of link from main laboratory building to blood science specialist accommodation building block.
- Realignment of gas storage compound at FM yard level.
- Repositioning of some hard FM facilities to a bespoke area within the energy centre.

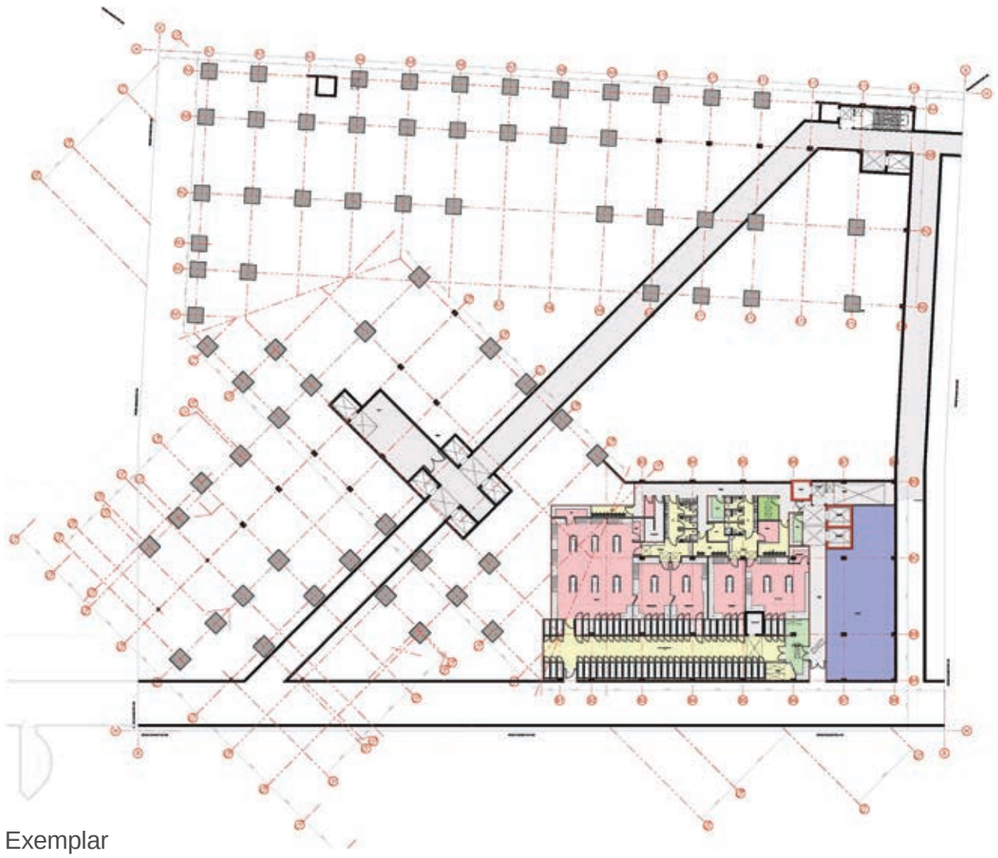
Brookfield

Repositioning Of Post Mortem Room To Ground Floor From Basement

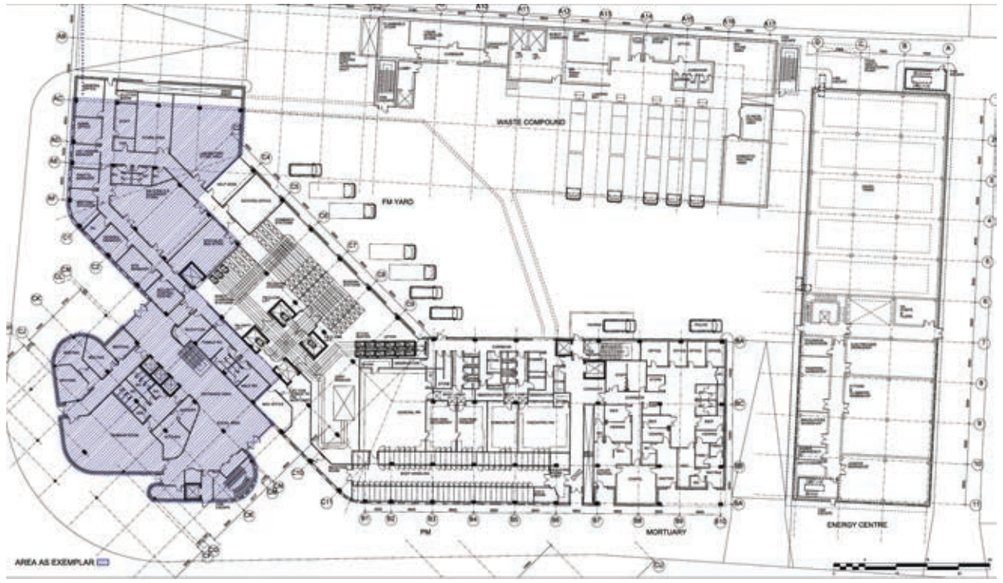
We believe we have added value to the exemplar scheme by co locating the PM/ Mortuary and Public Viewing facilities whilst allowing for natural light and ventilation where the function permits. Our scheme also has the added benefit of minimising travel distances, travel time and level changes should a body need to be moved between the body storage area and public viewing facility. Our use of the lift cores in the centre of the laboratory building also delivers resilience for body transfer from the underground tunnel should a lift be out of order or require maintenance.

Provision of double entry lift ensures no cross flow/ privacy issues when a body is in transfer.

The flows and adjacencies indicated in the exemplar design have been accommodated in our proposal.



Exemplar



Proposal

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Brookfield

Rationalisation Of Mechanical And Engineer/ Services Plants

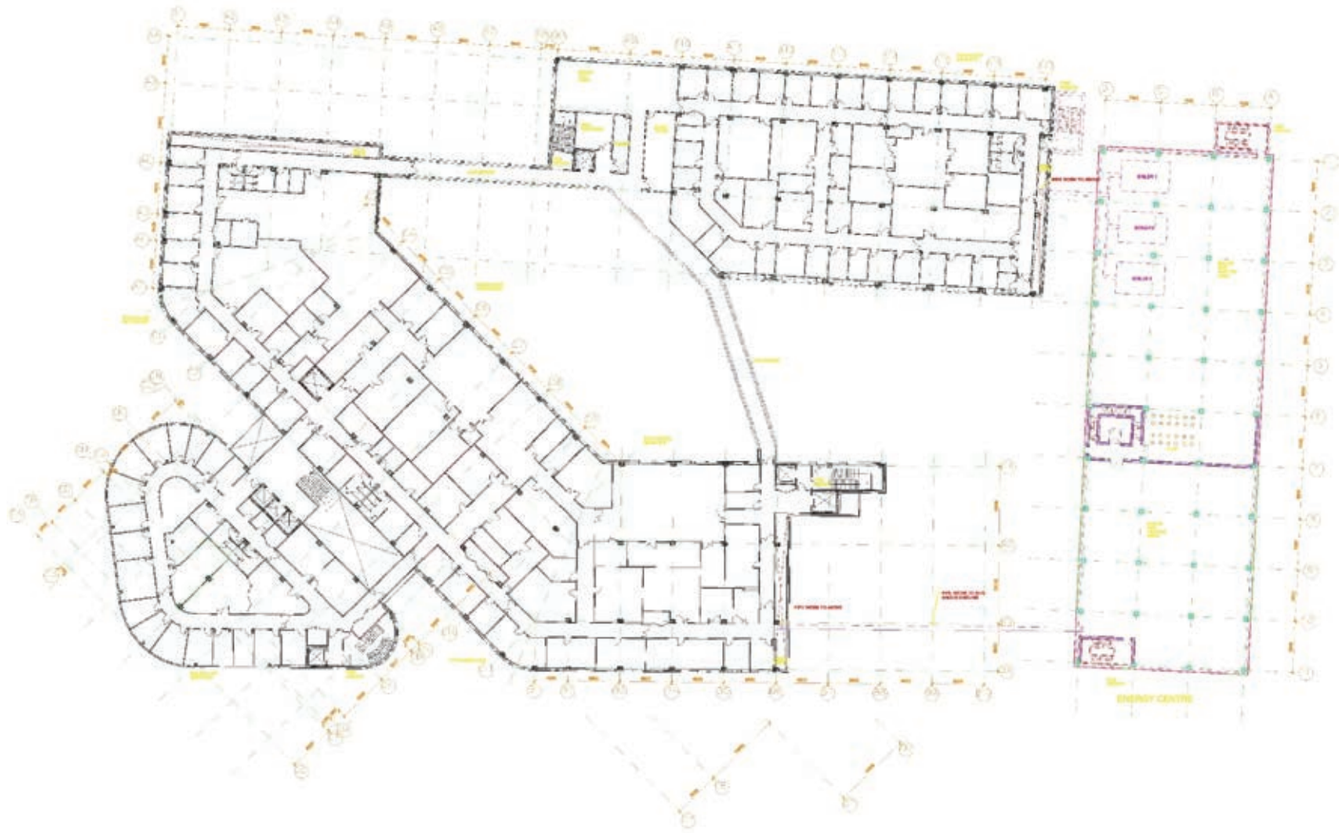
In response to RFI 144 and a review of the Stage D design proposals for the laboratories, it was evident that the buildings services design as detailed within the stage D would fall short in achieving the overall Carbon reduction requirement for the campus and the overall build budget for the Laboratories Building.

To achieve the overall carbon emission reduction target of 80KgCO_2m^2 for the hospital project which includes the laboratory building we would propose the following modifications to the current stage D design.

- Reduce the number of Boilers in the Labs from 54 located in the North/South/East and office plantrooms to a more manageable and efficient 3 boilers which will be rated to give the total connected load of heating elements within the design.

Option 1, we propose to use 3 boilers configured as 2 run and 1 standby. Each boiler will be selected to provide 66% of the connected load and this will provide a more efficient means of low load control throughout the life of the building.

There are 2 options within this proposal, firstly locate the boilers within the new energy centre and link at the front end of the project the energy centre to the Labs building. These boilers can be selected to act in the future as possible back up to the main hospital, and become a part of the final strategy for energy to the total campus.

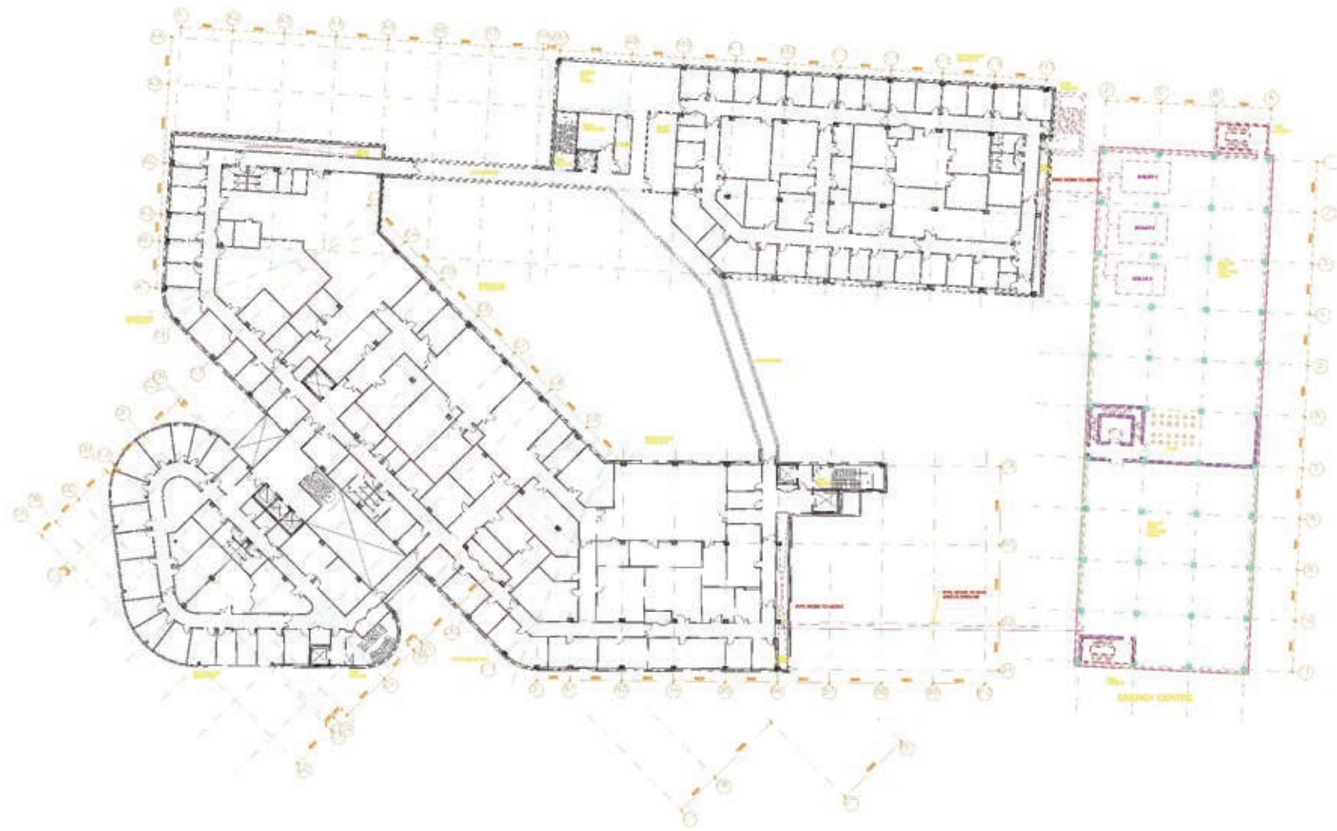


Brookfield

Option 2, locate these 3 boilers and HWS plant in a separate plantroom above the new Mortuary section. These boilers will distribute the heating water thought-out the building in a similar fashion to that already detailed in the stage D plans.

From an energy usage calculation, the use of 3 large boilers versus 54 smaller ones, will increase the overall efficiency of the required energy use within the building by increasing the COP of the boiler plant, by reducing the required electrical power connections , the number of flue and gas connections.

The cost reduction from 54 boilers to 3 boilers will add a substantial saving to the overall build cost of this building by reducing the, number of boilers, flues, pumps, BMS connections, gas connections, gas safety equipment etc.



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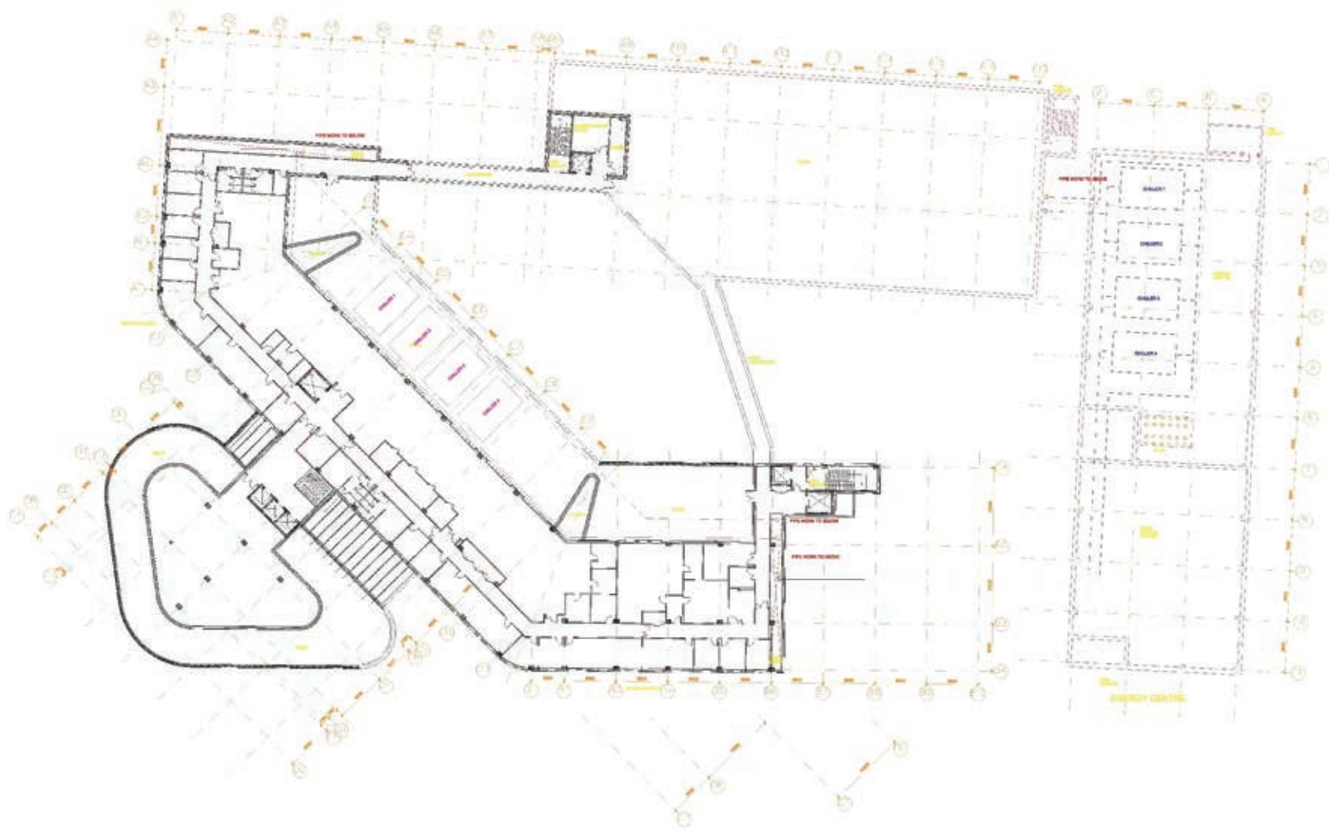
- Reduce the number of chillers currently selected in the stage D design.

Option 1, Again we would propose 2 options, install within the new Energy centre the required number of chillers for the connected load of the laboratories building plus one additional chiller for standby.

Connect the chilled water distribution lines from the new energy centre to the laboratories building during the construction of the Labs building and use these chillers to service the load of the labs during the build of the main hospital. The standby chiller will become the overall stand by chiller for the total complex and this will reduce the total number of large plant items within the complex.



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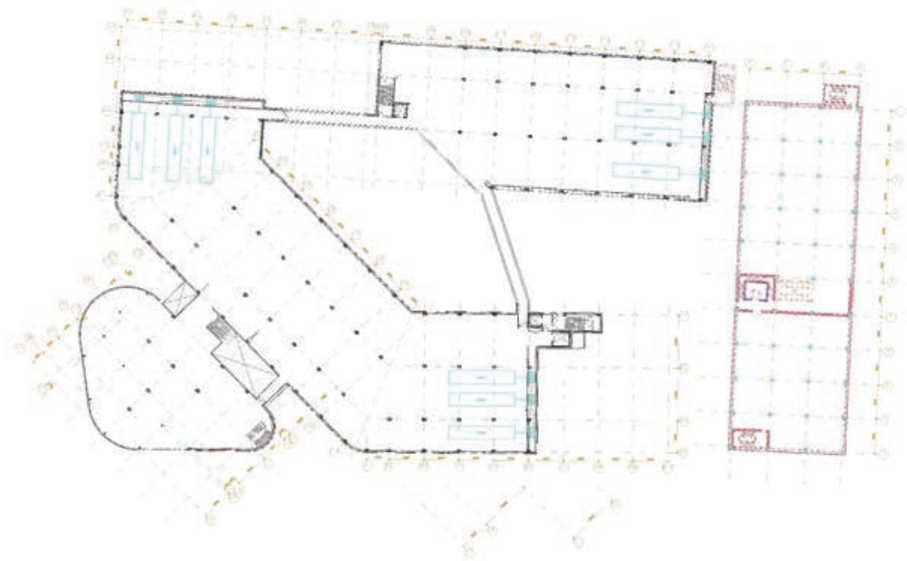
Option 2, If there is a requirement for the Labs building to maintain its own chilled water plant, we propose to locate 4 chillers centrally on the roof of the labs building and via a ring main distribute the chilled water to the 4 major plantrooms. This would remove the 4 standby chillers currently detailed in the stage D

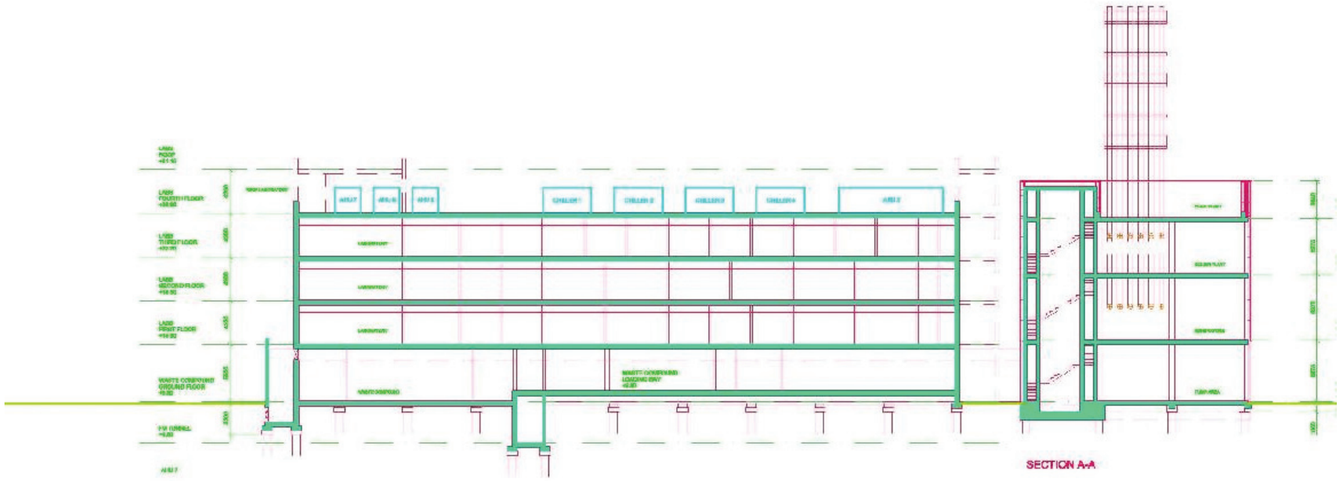
Similar to the cost savings associated with the boiler plant above, the reduction of chiller plant will initially reduce the capital expenditure of the total build of the labs in the short term, in the long term the running and operational costs will be reduce by improved efficiencies and reduced maintenance costs.

- Reduce the total number of large plant items within the complex.

To reduce the number of overall plantrooms detailed within the stage D design, we propose to reduce the number of Air Handing Units serving the Labs floors and locate 6 central units at roof level with vertical service risers at each corner of the building, these duct risers will connect to the horizontal ducts as detailed within the current stage D design.

The reduction in AHU's will initially reduce the capital expenditure of the total build but again the future reduction in energy cost and maintenance operational costs will add to the overall reduction of the carbon requirement of 80Kg for the campus.





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Brookfield

Extension of Link from Main Laboratory Building to Blood Science Specialist Accommodation Building

Our review of the exemplar scheme has identified that the access point to the FM yard for the vehicles required was a CDM risk issue. Our main concerns were

- Turning off main road on hospital campus into FM area.
- Location of gas storage facilities
- Access under laboratory building
- Maintenance issues within this narrow access zone.
- Delivery issues when/ if required to gas, storage facilities.
- Structural integrity of the building supports and layout due to FM traffic flow.

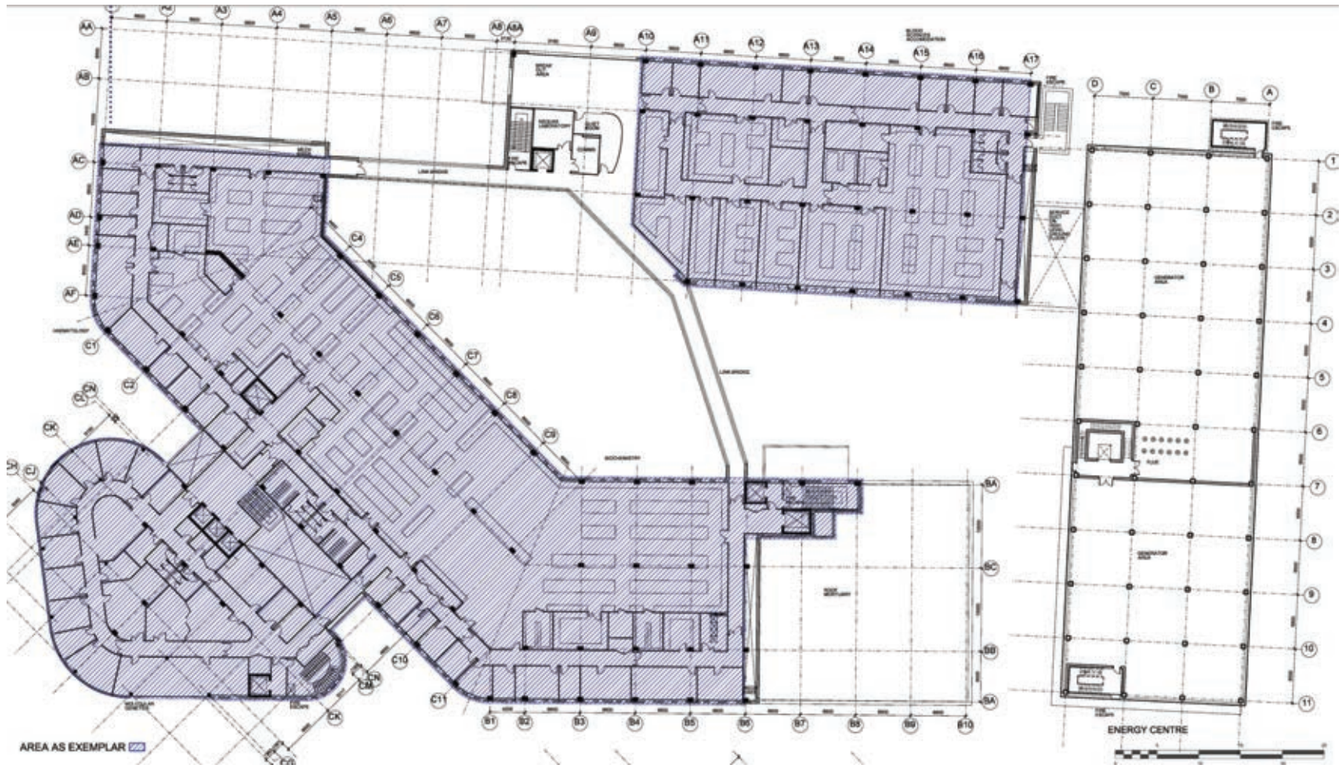
To address the above items our option

- Moves the gas storage facilities.
- Extends the link between the main laboratory building and the main blood sciences block.

Our proposal utilises the exemplar laboratory layouts and we therefore believe there is no impact on the exemplar adjacencies demonstrated in the Employers Requirements.

The proposal also provides the atrium, social facilities and seminar spaces that are required in the exemplar scheme.

Our reprovision of this space in its new location also allows for greater natural daylight, ventilation and views.



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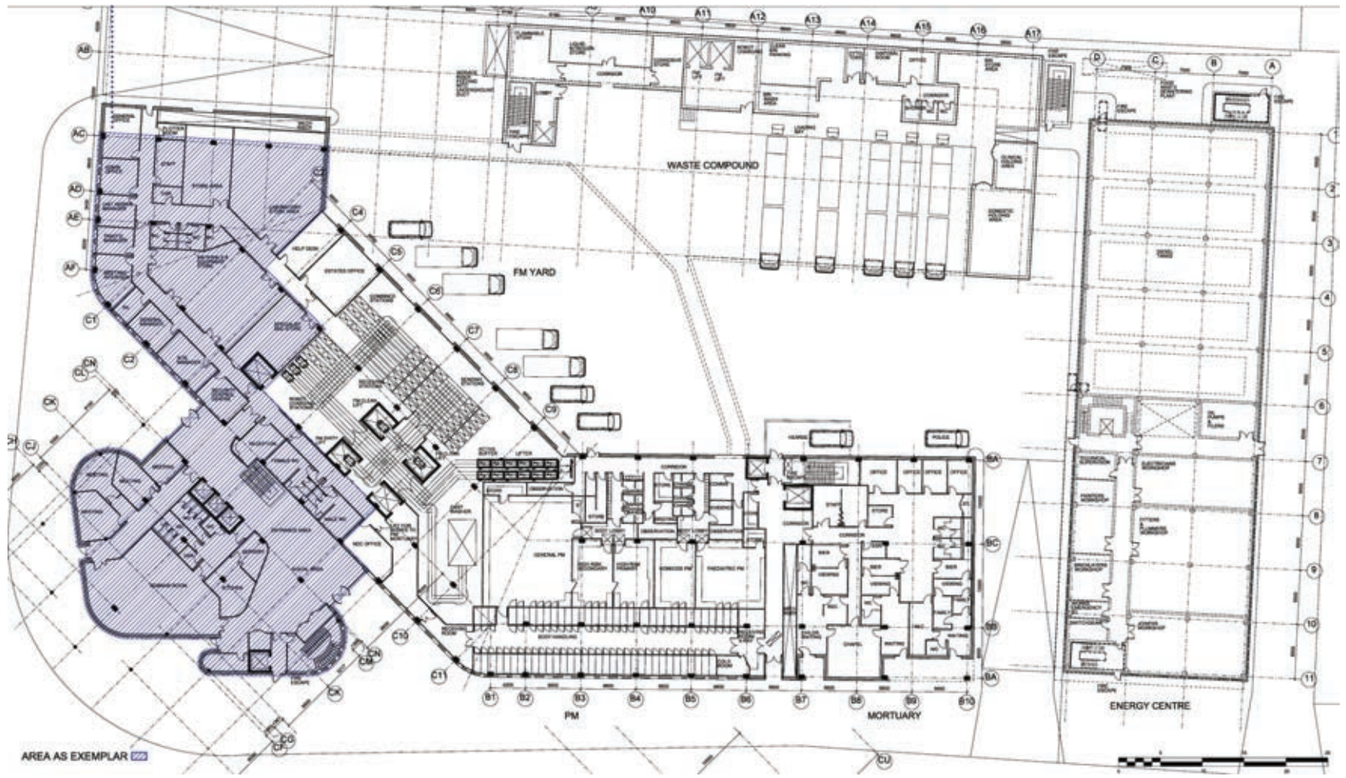
Realignment of Gas Storage Compound at Fm Yard Level

Our scheme provides a like for like alternative in a location that allows for ease of access and maintenance it also ensures that the compound is moved out of the narrow entry point to the FM yard.



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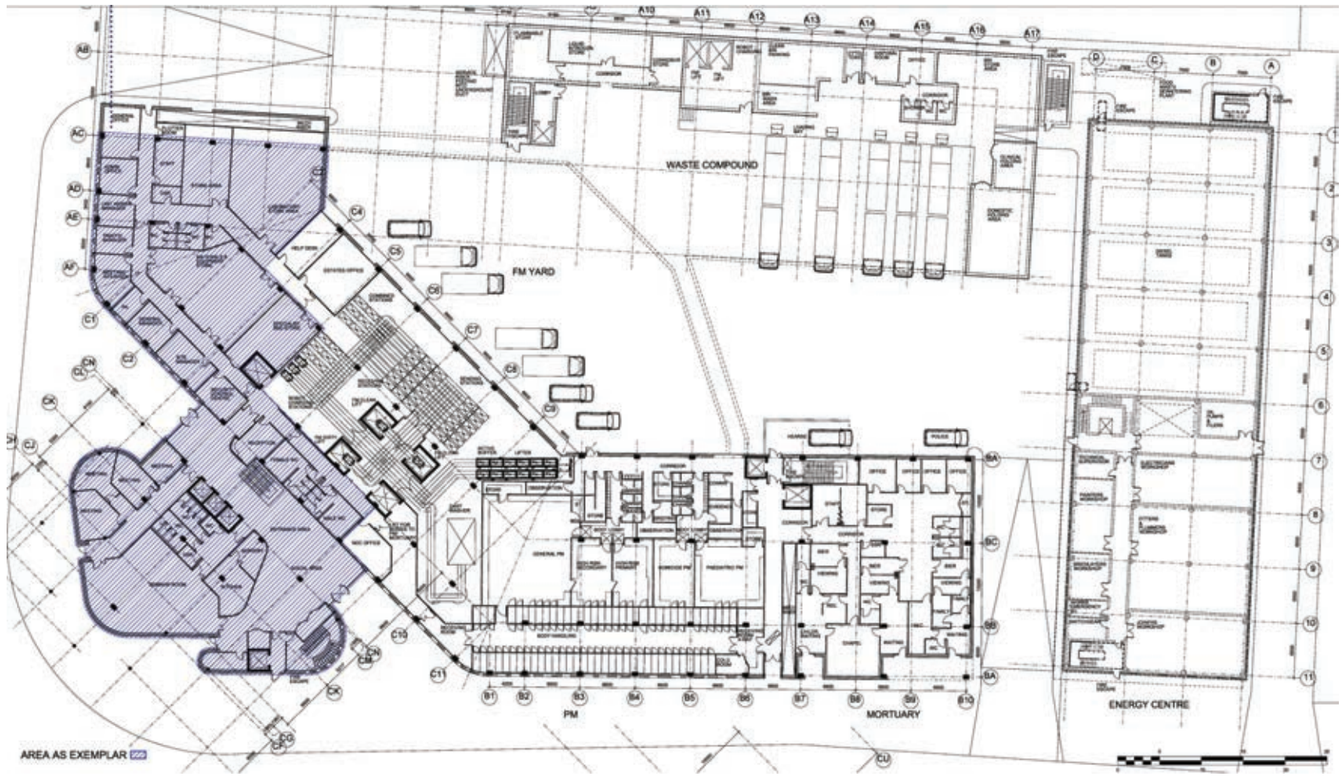
Brookfield

Repositioning of Some Hard Fm Facilities to a Bespoke Area within the Energy Centre

As agreed with the board we have repositioned some FM facilities into the Energy Centre. Our proposal clearly defined the service zone and activity, it also minimises activity cross flow issues.

Should we be successful we will review our current proposal with the board to ensure flows, links and service delivery are optimised



Introduction

Submission Reference:

Section 3.30: 'AEDET RESPONSE'.

Submission Response:

At the PQQ stage Nightingale Associates Organogram identified Brookfield proposal for ensuring that our scheme delivered a state of the art healthcare facility.

By including a peer review group who liaise with healthcare designers and operators on a worldwide basis, we have ensured that our scheme is mindful of and adheres to exemplar facilities worldwide.

Gillespie's, our Landscape and Masterplan Consultants, also have a representative on the Architecture and Design Scotland review panel, they have contributed to the review process.

Brookfield

As the scheme has progressed we have strengthened the peer review process by adding an external consultant John Jenner.

John Jenner is a founding partner of Greenhill and Jenner Architects, an award winning healthcare practice. Johns areas of expertise are architectural, interior and urban design, and masterplanning; especially for health buildings. His focus is on community and user group consultation and participation.

John is also a CABE Enabler and Chair of the Department of Health Design Review Panel which means he is a regular member of the review panels for major healthcare schemes in the UK.

John has facilitated and reviewed Brookfield's design proposal against the AEDET criteria.

Brookfield

Achieving Excellence Design Evaluation Toolkit (AEDET Evolution)

NHS

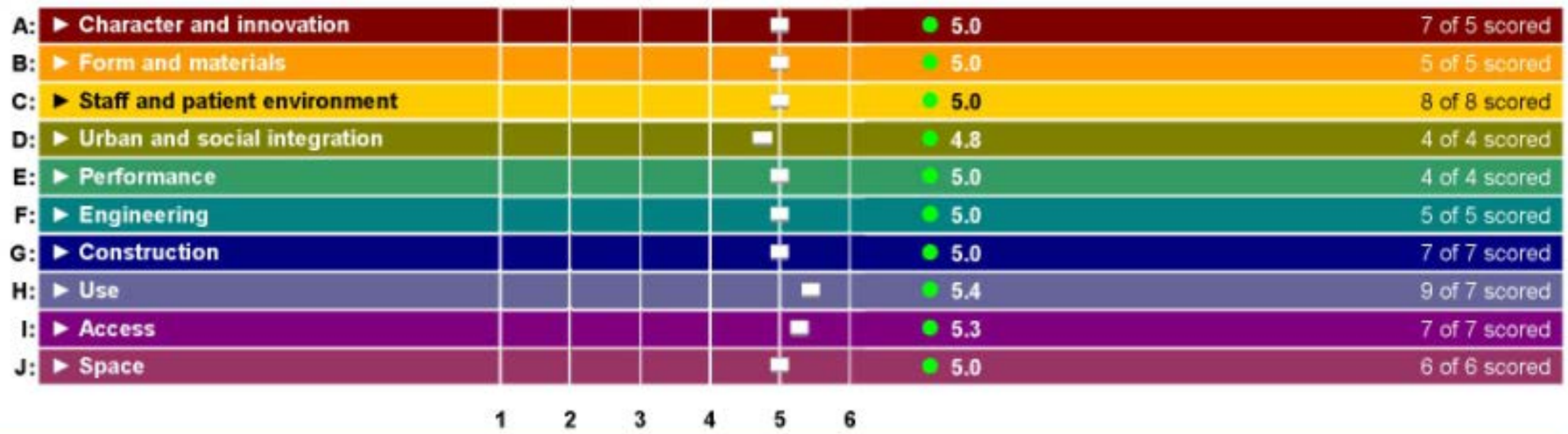
Project details: **Title**

New South Glasgow Hospitals

Workshop details: **Location** **Date**

Nightingale Associates, London Office 04.09.09

Results summary:



NOTE: A filled traffic light dot [●] in the table above indicates a valid average score, a hollow dot [○] indicates that one or more statements have been marked as 'unable to score'.

Brookfield

DH INFORMATION READER BOX	
Policy	**Estates**
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance		
ROCR Ref:		**Gateway Ref:**	9276
Title	Achieving Excellence Design Evaluation Toolkit documentation		
Author	DH Estates and Facilities		
Publication Date	10 Jan 2008		
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Estates and Facilities Directors		
Circulation List			
Description	AEDET Evolution toolkit is part of a benchmarking toolkit to assist trusts in measuring and managing the design quality of their healthcare facilities (new and existing).		
Cross Ref	AEDET Evolution documentation; AEDET/ ASPECT Evidence Layer		
Superseded Docs	AEDET Evolution toolkit (NHS Estates site)		
Action Required	N/A		
Timing	**N/A**		
Contact Details	Brian Coapes Design and Costing (GREFD) 3N10 Quarry House LEEDS LS2 7UE 0113 25 45696		
For Recipient's Use			

Brookfield

Achieving Excellence Design Evaluation Toolkit (AEDET Evolution)

NHS

Project details:	**Title**				
	New South Glasgow Hospitals				
Workshop details:	**Location**				**Date** *(dd.mm.yy)*
	Nightingale Associates, London Office				04.09.09
Completed by:	**First name**	**Last name**	**Organisation**	**Job title**	**Email address**
1:	john	jenner	Greenhill Jenner Architects	Director and Principal	
2:					
3:					
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Brookfield

IMPACT: Character and innovation

Average score: 5.0

The four IMPACT sections deal with the extent to which the building creates a sense of place and contributes positively to the lives of those who use it and are its neighbours.

Section A deals with the overall feeling of the building. It asks whether the building has clarity of design intention, and whether this is appropriate to its purpose. A building that scores well under this heading is likely to lift the spirits and to be seen as an exemplar of good architecture of its kind.

ID	Description	Weighting	Score	Notes
A.01	**There are clear ideas behind the design of the building**	High (2) ▼	Strong agreement (5) ▼	Clear and distinct buildings providing: Adult and Children and young peoples services
A.02	**The building is interesting to look at and move around in**	Normal (1) ▼	Strong agreement (5) ▼	Work in progress: further development of interior desin and arts strategy required
A.03	**The building projects a caring and reassuring atmosphere**	High (2) ▼	Strong agreement (5) ▼	Variety of environments for adults,children and young people have been provided
A.04	**The building appropriately expresses the values of the NHS**	Normal (1) ▼	Strong agreement (5) ▼	Design delivered will aid staff retention and will be a destination for the community and the people of Glasgow.
A.05	**The building is likely to influence future designs**	Normal (1) ▼	Strong agreement (5) ▼	Improvement on PSC to maximise clinical efficiences

◄ Project workshop setup ►► Results summary Form and materials ►

Brookfield

IMPACT: Form and materials

Average score: 5.0

Section B deals with the nature of the building in terms of its overall form and materials. It is primarily concerned with how the building presents itself to the outside world in terms of its appearance and organisation. Although it deals with the materials from which the building is constructed it is not concerned with these in a technical sense but rather the way they will appear and feel throughout the life of the building.

ID	Description	Weighting	Score	Notes
B.01	**The building has a human scale and feels welcoming**	Normal (1) ▼	Strong agreement (5) ▼	The building has a significant scale which fits within the existing urban context, the aspect of 'human scale' will rely upon the quality of detailing
B.02	**The design takes advantage of available sunlight and provides shelter from prevailing winds**	Normal (1) ▼	Strong agreement (5) ▼	Sunlight is maximised within the constraints of the site.
B.03	**Entrances are obvious and logically positioned in relation to likely points of arrival on site**	Normal (1) ▼	Strong agreement (5) ▼	Separation between pedestrians and vehicles, make the entrances more legible and achieve better connection to the external landscape.
B.04	**The external materials and detailing appear to be of high quality**	Normal (1) ▼	Strong agreement (5) ▼	Strong commitment to high quality external materials and detailing throughout project.
B.05	**The external colours and textures seem appropriate and attractive**	Normal (1) ▼	Strong agreement (5) ▼	

◄ Character and innovation ►► Results summary Staff and patient environment ►

Brookfield

IMPACT: Staff and patient environment		Average score: 5.0		
Section C deals with how well an environment complies with best practice as indicated by the research evidence.				
ID	Description	Weighting	Score	Notes
C.01	The building respects the dignity of patients and allows for appropriate levels of privacy and dignity	Normal (1) ▼	Strong agreement (5) ▼	100% single rooms in the acute building and 83% single rooms in childrens building.
C.02	There are good views inside and out of the building	Normal (1) ▼	Strong agreement (5) ▼	All wards planned to maximise views out of the building, good connections being proposed from inside to outside landscapes spaces.
C.03	Patients and staff have good access to outdoors	Normal (1) ▼	Strong agreement (5) ▼	The scheme providesa variety of outdoor spaces,well landscaped for patients, staff and visitors.
C.04	There are high levels of both comfort and control of comfort	Normal (1) ▼	Strong agreement (5) ▼	Good levels of comfort ventilation and lighting achieved.
C.05	The building is clearly understandable	Normal (1) ▼	Strong agreement (5) ▼	Clear distinction between acute and childrens services, the atriums provides a strong reference point for orientation and wayfinding.
C.06	The interior of the building is attractive in appearance	Normal (1) ▼	Strong agreement (5) ▼	
C.07	There are good bath/toilet and other facilities for patients	Normal (1) ▼	Strong agreement (5) ▼	Wards, visitors and staff have good access to generous bathroom/toilet facilities
C.08	There are good facilities for staff, including convenient places to work and relax without being on demand	Normal (1) ▼	Strong agreement (5) ▼	Good variety of staff rest and breakout spaces provided

◄ Form and materials ►► Results summary Urban and social integration ►

Brookfield

IMPACT: Urban and social integration

Average score: 4.8

Section D deals with the way the building relates to its surroundings. It asks whether the building plays a positive role in the neighbourhood whether that is urban, suburban or rural. A building that scores well is likely to improve its neighbourhood rather than detract from it.

ID	Description	Weighting	Score	Notes
D.01	**The height, volume and skyline of the building relate well to the surrounding environment**	Normal (1) ▼	Fair agreement (4) ▼	Work in progress: design tem are investigating long distance impact of building in the city
D.02	**The building contributes positively to its locality**	Normal (1) ▼	Strong agreement (5) ▼	
D.03	**The hard and soft landscape around the building contribute positively to the locality**	Normal (1) ▼	Strong agreement (5) ▼	Proviion of gardens, public spaces and childrens park all contribute to both public and private realms within the scheme.
D.04	**The building is sensitive to neighbours and passers-by**	Normal (1) ▼	Strong agreement (5) ▼	Building positioned sensitively to adjacent residential buildings.

◄ Staff and patient environment ►► Results summary Performance ►

Brookfield

BUILD QUALITY: Performance

Average score: 5.0

The three BUILD QUALITY sections deal with the physical components of the building rather than the spaces. This is therefore what might be thought of as the more technical and engineering aspects of the building. It asks whether the building is soundly built, will be reliable and easy to operate, last well and is sustainable. It is also concerned with the actual process of construction and the extent to which any disruption caused is minimised.

Section E is concerned with the technical performance of the building during its lifetime. It asks whether the components of the building are of high quality and fit for their purpose. However we are not concerned here with how well the building functions in relation to the human use of it which belongs in another section.

ID	Description	Weighting	Score	Notes
E.01	**The building is easy to operate**	Normal (1) ▼	Strong agreement (5) ▼	FM,AGV service yard and vertical cores ensure ease of operation
E.02	**The building is easy to clean**	Normal (1) ▼	Strong agreement (5) ▼	Durable and robust finishes,hard landscaping and cleaning cradles will ensure the building is easy to clean.
E.03	**The building has appropriately durable finishes**	Normal (1) ▼	Strong agreement (5) ▼	The consortia has a commitment to providing good quality durable materials throughout that meets lifecycle requirments
E.04	**The building will weather and age well**	Normal (1) ▼	Strong agreement (5) ▼	The consortia has a commitment to selecting external materials that will weather and age well.

◄ Urban and social integration ►► Results summary Engineering ►

Brookfield

BUILD QUALITY: Engineering

Average score: 5.0

Section F is concerned with those parts of the building that are engineering systems as opposed to the main architectural features. It asks whether the engineering systems are of high quality and fit for their purpose, will be easy to operate and if they are efficient and sustainable.

ID	Description	Weighting	Score	Notes
F.01	**The engineering systems are well designed, flexible and efficient in use**	Normal (1) ▼	Strong agreement (5) ▼	Well designed,integrated and efficient.
F.02	**The engineering systems exploit any benefits from standardisation and prefabrication where relevant**	Normal (1) ▼	Strong agreement (5) ▼	Very high percentage of service prefabrication throughout the design.
F.03	**The engineering systems are energy efficient**	Normal (1) ▼	Strong agreement (5) ▼	CHP units,absorbtion cooling and highly efficient plant will achieve TER objective.
F.04	**There are emergency backup systems that are designed to minimise disruption**	Normal (1) ▼	Strong agreement (5) ▼	High level of resiliance throughout design.
F.05	**During construction disruption to essential services is minimised**	Normal (1) ▼	Strong agreement (5) ▼	

◄ Performance ►► Results summary Construction ►

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Brookfield

BUILD QUALITY: Construction

● Average score: 5.0

Section G is concerned with the technical issues of actually constructing the building and with the performance of the main components. A building that scores well is likely to be constructed as quickly and easily as possible under the circumstances of the site and to offer a robust and easily maintained solution.

ID	Description	Weighting	Score	Notes
G.01	If phased planning and construction are necessary the various stages are well organised	Normal (1) ▼	Strong agreement (5) ▼	Phasing and construction well considered throughout building programme.
G.02	Temporary construction work is minimised	Normal (1) ▼	Strong agreement (5) ▼	
G.03	The impact of the building process on continuing healthcare provision is minimised	Normal (1) ▼	Strong agreement (5) ▼	Consortia are actively supporting and investing in maintaining healthcare provision on site.
G.04	The building can be readily maintained	Normal (1) ▼	Strong agreement (5) ▼	Plant replacement strategy and CDM compliance developed to provide ease of access and maintenance.
G.05	The construction is robust	Normal (1) ▼	Strong agreement (5) ▼	
G.06	The construction allows easy access to engineering systems for maintenance, replacement and expansion	Normal (1) ▼	Strong agreement (5) ▼	
G.07	The construction exploits any benefits from standardisation and prefabrication where relevant	Normal (1) ▼	Strong agreement (5) ▼	

◄ Engineering ►► Results summary Use ►

Brookfield

FUNCTIONALITY: Use

Average score: 5.4

The three FUNCTIONALITY sections deal with all those issues to do with the primary purpose or function of the building. It deals with how well the building serves these primary purposes and the extent to which it facilitates or inhibits the activities of the people who carry out the functions inside and around the building.

Section H is concerned with the way the building enables the users to perform their duties and operate the healthcare systems and facilities housed in the building. To get a good score the building will be highly functional and efficient, enabling people to have enough space for their activities and to move around economically and easily in a way that relates well to the policies and objective of the Trust. A high scoring building is also likely to have some flexibility in use.

ID	Description	Weighting	Score	Notes
H.01	**The prime functional requirements of the brief are satisfied**	High (2) ▼	Virtually total agreement (6) ▼	Adjacencies and health planning well considered and in line with Board requirements
H.02	**The design facilitates the care model of the Trust**	High (2) ▼	Strong agreement (5) ▼	Refinement of PSC scheme with exemplars demonstrated through bid dialogue and site visit
H.03	**Overall the building is capable of handling the projected throughput**	Normal (1) ▼	Virtually total agreement (6) ▼	
H.04	**Work flows and logistics are arranged optimally**	Normal (1) ▼	Virtually total agreement (6) ▼	Clearly demonstrated through workflow diagrms,FM strategy and AGV instillations Volume 2
H.05	**The building is sufficiently adaptable to respond to change and to enable expansion**	Normal (1) ▼	Strong agreement (5) ▼	Some provision has been made for increasing clinical rooms within departments and integrated service strategy will allow for adaptation and
H.06	**Where possible spaces are standardised and flexible in use patterns**	Normal (1) ▼	Strong agreement (5) ▼	Generic room sizes,modular construction and service strategy allows for flexible use patterns
H.07	**The layout facilitates both security and supervision**	Normal (1) ▼	Strong agreement (5) ▼	Layout facilitates passive surveillance

◄ Construction ►► Results summary Access ►

Brookfield

FUNCTIONALITY: Access

Average score: 5.3

Section I focuses on the way the users of the building can come and go. It asks whether people can easily and efficiently get onto and off the site using a variety of means of transport and whether they can logically, easily and safely get into and out of the building.

ID	Description	Weighting	Score	Notes
I.01	**There is good access from available public transport including any on-site roads**	Normal (1) ▼	Strong agreement (5) ▼	
I.02	**There is adequate parking for visitors and staff cars with appropriate provision for disabled people**	Normal (1) ▼	Strong agreement (5) ▼	
I.03	**The approach and access for ambulances is appropriately provided**	Normal (1) ▼	Virtually total agreement (6) ▼	
I.04	**Goods and waste disposal vehicle circulation is good and segregated from public and staff access where appropriate**	Normal (1) ▼	Virtually total agreement (6) ▼	
I.05	**Pedestrian access routes are obvious, pleasant and suitable for wheelchair users and people with other disabilities / impaired sight**	Normal (1) ▼	Strong agreement (5) ▼	Dedicated set down and pick up for OPD/Discharge lounge.
I.06	**Outdoor spaces are provided with appropriate and safe lighting indicating paths, ramps and steps**	Normal (1) ▼	Strong agreement (5) ▼	Good variety of public and private outdoor spaces.
I.07	**The fire planning strategy allows for ready access and egress**	Normal (1) ▼	Strong agreement (5) ▼	Independent peer review carried out by Waterman.

◄ Use ►► Results summary Space ►

Brookfield

FUNCTIONALITY: Space

Average score: 5.0

Section J concentrates on the amount of space in the building in relation to its purpose. It asks if this space is well located and efficient and whether people can move around in it efficiently and with dignity.

ID	Description	Weighting	Score	Notes
J.01	**The design achieves appropriate space standards**	Normal (1) ▼	Strong agreement (5) ▼	
J.02	**The ratio of usable space to the total area is good**	Normal (1) ▼	Strong agreement (5) ▼	
J.03	**The circulation distances travelled by staff, patients and visitors are minimised by the layout**	Normal (1) ▼	Strong agreement (5) ▼	Development of the PSC
J.04	**Any necessary isolation and segregation of spaces is achieved**	Normal (1) ▼	Strong agreement (5) ▼	
J.05	**The design makes appropriate provision for gender segregation**	Normal (1) ▼	Strong agreement (5) ▼	Including flexing of wards.
J.06	**There is adequate storage space**	Normal (1) ▼	Strong agreement (5) ▼	

◄ Access ►► Results summary

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The Sustainable Design Brief for the New South Glasgow Hospitals Project

"Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs."

Our Common Future, Brundtland Commission, 1987

"Our objective is to construct sustainable buildings which ensure that sustainable solutions and targets provide optimum performance using practical solutions."

Brookfield Construction Ltd

The entire design process for the New South Glasgow Hospital (NSGH) has been underpinned by Brookfield's corporate approach to sustainability, which acknowledges the principles of the Brundtland Commission and Brookfield's own role and responsibility in building new hospitals. The NHS, due to its large estate and workforce, has the potential to make a large impact in terms of reducing its environmental impact but also through educating its staff and patients by putting sustainability into practice. The design of the buildings plays a key role in this, as stated by the Sustainable Development Commission:

"Building sustainably provides healing environments and healthier workplaces that enhance public health. This helps reduce pressure on healthcare services, contributing to the long-term viability of the NHS."

Sustainability represents more than a design approach however, and this document illustrates how the sustainable design targets (for example BREEAM Excellent) have been met as well as ensuring that the social and economic impacts of the development have been addressed. Brookfield believe that the final proposal is sustainable through virtue of its comparatively low environmental impact and the social and economic benefits it would bring to the local community.

The Brookfield design and construction team has been working to put forward a design and construction proposal which fits with the Greater Glasgow and Clyde's (GG&C) NHS Board's requirements in terms of actual content and also meeting sustainability objectives. The sustainable design principles for the buildings are set out in the Board's Low Carbon Priorities and these have been addressed throughout the design and recorded in this document.

The following two extracts were fundamental reference points in developing the sustainable design approach for New South Glasgow Hospital:

GG&C NHS Board Environment and Sustainability policy:

- reduce the consumption of energy
- reduce, re-use and recycle waste
- sustainable procurement policy
- reduce the usage of transport
- reduce the use of water."

Key Principles for Healthcare Buildings, SHINE (Learning Network for Sustainable Healthcare Buildings):

1. Integrating with the local environment & promoting regeneration
2. Meeting the needs of & providing facilities for local communities
3. Providing accessible transport options for all members of the community
4. Delivering cleaner, greener and safer public spaces that are rich in biodiversity
5. Using resources (e.g. energy & water) efficiently
6. Providing flexibility and adaptability to meet changing service needs
7. Considering whole life performance, including long-term asset value
8. Providing a quality internal environment to support health and well-being for users
9. Using materials that reduce environmental and health impacts
10. Reducing pollution and waste to avoid health and other impacts."

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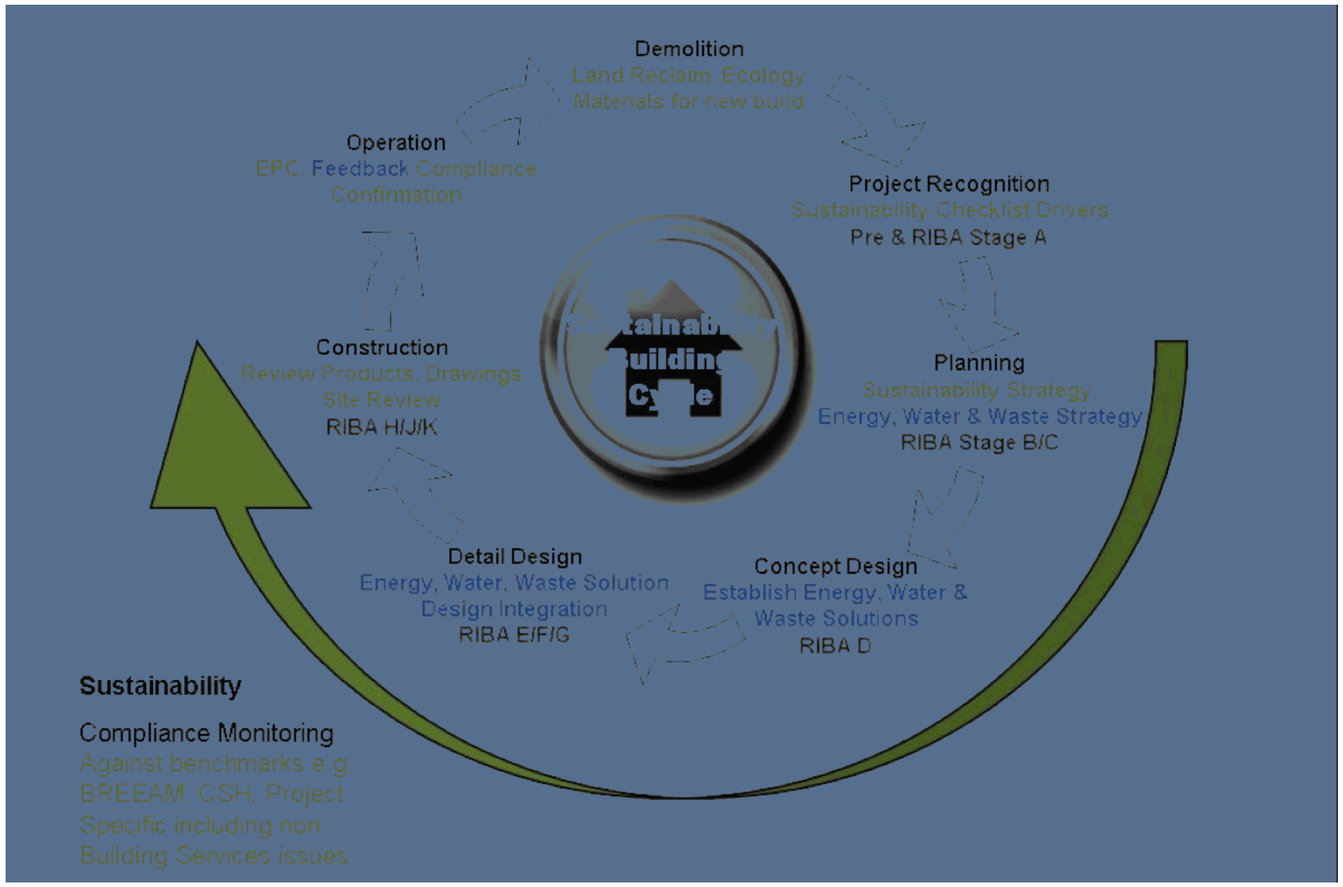
Contents



An outline of the sustainable design process followed so far and proposed for the remainder of the project.

Brookfield

1. Community Engagement

Design, Construction and Operation

An inclusive and comprehensive community engagement process underpins social sustainability. The community engagement strategy, which has been developed for the New South Glasgow Hospital, has been ongoing since the early design stages. Local residents, community groups, schools, colleges and businesses have been actively engaged wherever possible. Information has been made publicly available and distributed to stakeholders through a range of media including the NHS GG&C website. Stakeholders have been engaged in consultations on a wide range of topics including:

- Transport and Travel;
- Employment opportunities; and
- The design of the hospital.

The above process has influenced the outcome of the design, for example with the inclusion of a community garden and the levels and modes of transport provision (BREEAM Man 6 & 7).

The lengthy construction phase of New South Glasgow Hospital will offer significant employment opportunities in a variety of sectors. Brookfield and its contractors will combine meeting the 10% new entrant target set by the NHS Board by prioritising opportunities for local people and businesses. The new entrants will constitute a range of people and skills including the long-term unemployed, apprentices and students. Community engagement does not stop post-construction. The ethos of community engagement will be maintained throughout the life of the New South Glasgow Hospital. It will be a welcoming, user-friendly environment that will build upon the positive and strong community engagement that has been achieved during the design and construction stages. This will help maintain the 'sustainable community' that has been developed.

The full Community Engagement Strategy is included in this bid submission, under Volume.10.1.

2. Management

"Buildings constructed in line with environmentally conscious principles are good long-term investments, with lower operating costs and a greater ability to meet changing environmental controls and legislation." Building a Brighter Future: A Guide to Low Carbon Building Design – Carbon Trust.

Design

Sustainable Project Management is part of Brookfield's corporate Sustainable Strategy which provides clear guidelines for all their construction projects and ensures a minimum standard with regards to sustainability in their projects. During the design stage, early identification and then incorporation of the project's sustainability objectives in the design process along with the integration of the BREEAM pre-assessment into the design team meetings, established a sustainable project solution.

Decisions relating to the choice of building services and materials have been influenced by a lifecycle costing analysis, which has taken into account not only the costs of the different options, but also their environmental impact in terms of energy consumption or material source (Man 12). The results of this exercise were fed back into the design process and used to decide the final specifications for the building. To ensure that these sustainable objectives become reality, Brookfield will include a condition in all subcontracts to fulfil the predetermined targets. In addition to the lifecycle cost analysis, consideration has been taken of pending legislative changes relating to carbon emissions from large organisations in order to meet the overall goal of reducing Scotland's carbon emissions by 42% by 2020. The increasing importance of carbon emissions and the potential risk of not designing a low carbon building have been taken into account and influenced the final design, for example in relation to the choice of building service systems.

The approach to sustainable management of the design process can be summarised as follows:

- The BREEAM Assessment is integrated throughout the design process.
- Brookfield Sustainability Strategy underpins the project management structure.
- Life Cycle Costing to understand full financial and environmental cost of material and equipment choice.
- The design team has worked together with the facilities management team to choose engineering and design solutions that are practical and easy to maintain (Man 11).

Brookfield and their main civil construction contractor Dunne are confident of their performance and have a strong track record in the Considerate Constructors Scheme. This is therefore an area where an innovation credit has been targeted in the BREEAM Healthcare pre-assessment for New South Glasgow Hospital. The commissioning programme will extend to include post-occupancy monitoring to ensure that the commissioned systems perform in reality as they were designed. This will ensure that the sustainable design becomes reality (Man 1).

- Ongoing monitoring of the construction targets set by Brookfield during the design phase, relating to energy, water, pollution and waste.
- Brookfield has international ISO 14001 certification and will ensure that their operations at the NSGH construction site will meet the requisite Environmental Management System's standards.
- Sustainable management extends to the health and wellbeing of staff, for example the onsite canteen will also be offering healthy food choices in order to teach healthy food practice.

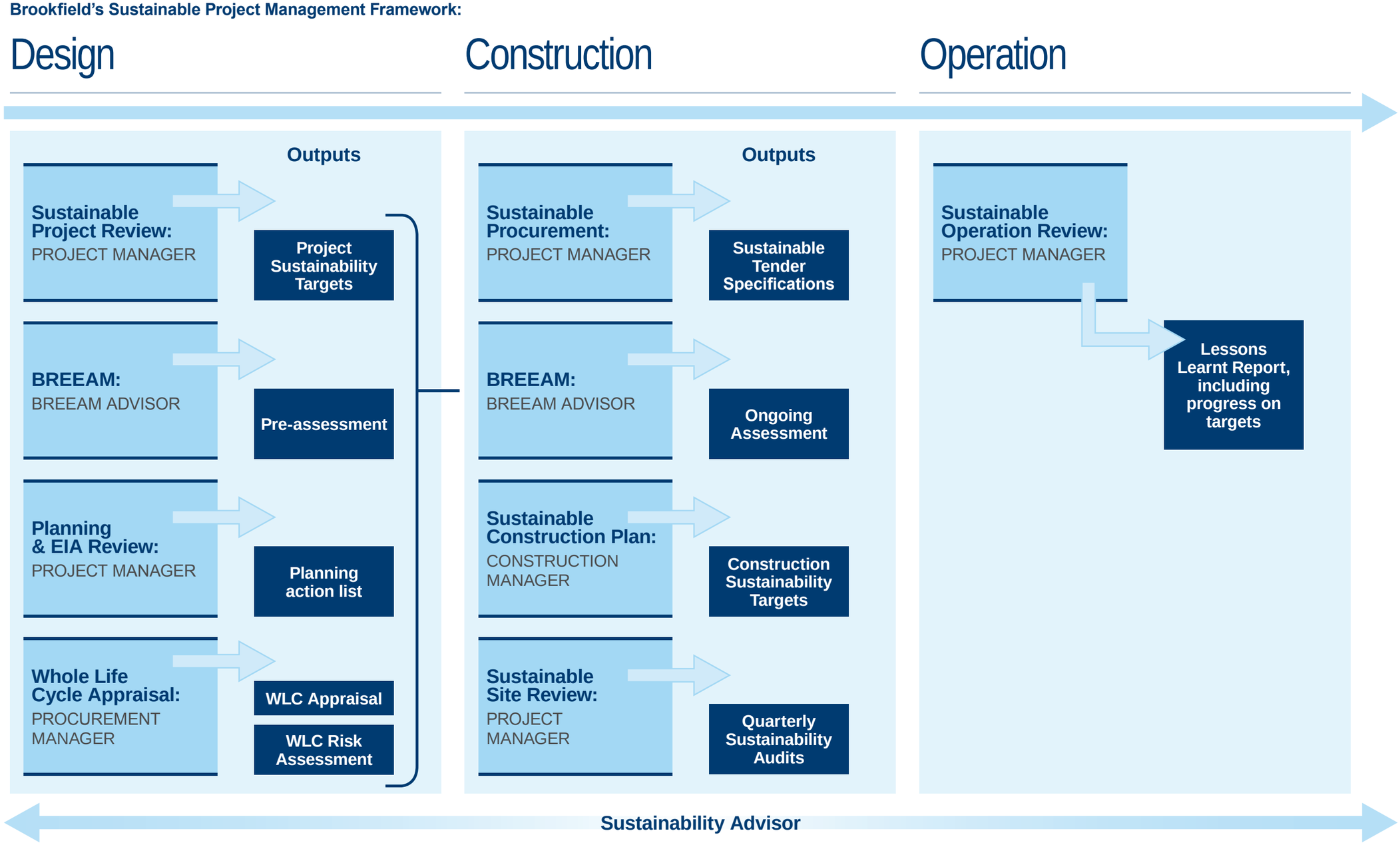
Brookfield

BREEAM Summary

Anticipated Credits:	Predicted Percentage Achieved:
Commissioning	100%
Considerate Constructors	
Construction Site Impacts	
Building User Guide	
Consultation	
Security	
Ease of Maintenance	
Life Cycle Costing	
Good Corporate Citizen	

Brookfield

Brookfield's Sustainable Project Management Framework:



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Brookfield

2. Health and Wellbeing

"The research team found rigorous studies that link the physical environment to patient and staff outcomes in four areas:

- Reduce staff stress and fatigue and increase effectiveness in delivering care
- Improve patient safety
- Reduce stress and improve outcomes
- Improve overall healthcare quality."

Ulrich, The Role of the Physical Environment in the Hospital of the 21st Century

Design

Health and Wellbeing encompasses not only the patients but staff and the local community as well. One way to ensure the health and wellbeing of users is to have a high level of stakeholder engagement. 99% of nurses believe it is important for them to be consulted about decisions relating to the design of hospitals, rising to 100% for nurses in a management position (CABE, Healthy Hospitals). Brookfield's consultation will expand upon the results of the Board's consultation to incorporate an extensive consultation process with all community stakeholders, from which Brookfield has developed a Community Engagement Strategy (Vol. 10.1).

A number of design decisions affect the health and wellbeing of building users and the following lists design considerations were made to make the hospital a pleasant place to work, recuperate and visit:

- The Ward Tower has been designed to ensure that each bedroom will be outward facing to take advantage of distant views and maximise natural daylight. The Children's Wards have a combination of inward and outward facing bedrooms, with the integration of both indoor and outdoor play spaces (BREEAM Hea 2). Building users will also be able to close blinds as required to reduce glare within the building (BREEAM Hea 3).
- All patient areas will have operable windows, allowing fresh air into the ward areas.
- Within internal areas, lighting will also be appropriately zoned, so that occupants can control it (BREEAM Hea 6).
- The main Ward Tower has been designed in conjunction with standard Health Guidance critical dimensions will reduce the risk of infection. The Children's Wards include a number of 4-Bedded Bays, which utilise Nightingales' Cruciform design, which ensures that each patient's bedhead is at the maximum possible distance from the other, thus reducing infection risks.
- The choice of internal fixtures and fittings has been made to reduce emissions of VOC[1]s as much as possible, in line with best practice recommended levels (BREEAM Hea 9).
- Noise levels, air quality and thermal comfort all significantly impact a person's health and wellbeing. In the New South Glasgow Hospital all elements impacting on air quality and thermal comfort will be specified to a high standard and noise levels will achieve the recommended performance benchmarks as outlined in HTM 08-01 Part A (BREEAM Hea 10 and 13).
- Wide corridors and access as well as clear signage will help to reduce stress and anxiety and improve a patient's experience when in the building.
- The provision of outdoor amenity space and green areas is a well recognised means to improve general wellbeing. Brookfield's proposal for the hospital has outdoor amenity space for patients and visitors to the acute and children's hospitals, a children's play area and plenty of seating provision (BREEAM Hea 15).
- An arts strategy is being prepared for New South Glasgow Hospital by Gingko Projects in conjunction with Gillespies and Nightingales, to address enhancing the healthcare environment and building relationships with the local community, patients and their families (BREEAM Hea 19).

Construction

During the construction phase of New South Glasgow Hospital there will be a number of issues affecting the health and wellbeing of the workforce, neighbouring residents and existing building users. The Glasgow South West Regeneration Agency (GSWRA) is working in partnership with Brookfield to liaise with the local community groups and agencies, thus ensuring their involvement is coordinated and effective.

- Dunne has an ongoing working relationship with the GSWRA to provide health and wellbeing open days for the local community.
- Health and safety on a construction site is paramount. All of the contractors involved for the Construction of the New South Glasgow Hospital and all employees, including new entrants, will abide by and follow the relevant Health and Safety regulations and codes and follow the Health and Safety Executive's best practices for health and safety in the construction sector.
- Personnel working on the construction of the hospital will need access to a range of amenities. During the lengthy construction phase, provision will be made on site for a permanent on site health advisor, who will undertake a series of awareness raising sessions to improve education and understanding around issues such as obesity and smoking.
- Brookfield will ensure that the onsite canteen for construction staff will promote healthy food and eating habits.

1 Volatile Organic Compounds, released from some man made materials.

Brookfield

Operation

The health and wellbeing of the local community is the ultimate goal of all operational hospitals. The New South Glasgow Hospital will be no exception and the design intends to support the delivery of a high standard of healthcare as well as providing a healthy working environment that promotes a work-life balance, a place that is safe and encourages speedy recuperation, and is a pleasant place for people to visit. The following points are the main issues that have been addressed to benefit health and wellbeing in the New South Glasgow Hospital:

- The proposed design will encourage people to walk or cycle to the hospital, improving health of the individual.
- The food retail outlets on site will promote healthy food options, using organic and locally sourced produce wherever possible to illustrate a balanced and varied diet.
- The landscaped areas are designed to allow staff, patients and visitors alike the opportunity to walk outside, take some fresh air and have some time to relax away from the inevitably busy hospital environment.

BREEAM Summary

Anticipated Credits	Predicted Percentage Score
View Out	77%
Glare Control	
High Frequency Lighting	
Internal and External Lighting Levels	
Lighting Zone & Controls	
Indoor Air Quality	
Volatile Organic Compounds	
Thermal Comfort	
Microbial Contamination	
Acoustic Performance	
Outdoor Space	
Arts in Health	

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Brookfield

3. Energy

"To provide an energy efficient building which provides better indoor conditions for patients and staff and reduces operational energy costs." HTM – 07-02:Encod – making energy work in healthcare..

Design

The most effective way to reduce energy consumption during operation is to create a design which eliminates and reduces energy use through the choice of materials, location, lay-out and design. This approach is clearly laid out in a range of guidance, including the HTM Encode, the Carbon Trust's guide to low carbon building design and reflected in GG&C NHS Board's requirements for this project, with the low carbon tracker. All of these documents have been referenced and integrated into the approach to developing the NSGH's final design, so that a structured approach, based on the energy hierarchy, was taken. This follows a simple hierarchy of measures to firstly eliminate energy demand where possible through building design, for example maximising daylight, thus reducing the need for lighting. Secondly, where energy is used, it is done so in an efficient manner, with items such as energy efficient lighting externally which is only illuminated when it's required (BREEAM Ene4). Finally, the feasibility of renewable energy sources to meet the remaining demand is assessed in line with the hospital's location and natural assets. The choice of natural gas CHP onsite means that when a stream of biogas from the Shieldhall STP becomes available, this can be directly used in the energy centre. Another alternative low carbon source of energy to be investigated is an off-site wind turbine, providing zero carbon electricity to the hospital.

For full details of how the energy demand of the building will be met, the energy strategy (Vol. 3.20) should be reviewed. The main features of the energy strategy are as follows:

- Energy demand has been eliminated through choosing external fabrics with good insulating properties and allowing natural ventilation to be used wherever possible.
- The design includes energy efficient lighting with intelligent lighting controls and heat recovery on all air handling units, which will ensure energy is used efficiently. High efficiency chillers are specified, which will result in high performance efficiencies, particularly at part load.
- The remaining energy demand for the hospital will be met through a natural gas CHP energy centre, which will have in total 3MWe of CHP plant and adsorption cooling, able to be respond to the changing demand. This will be supplemented by 12 on-site building mounted turbines to provide a visible commitment to renewable energy.
- The 15% reduction in CO_2 emissions as required under SPP 6 has been met by using the onsite natural gas CHP and 12 small wind turbines on site (BREEAM Ene 5). This will actually exceed the 15%.
- On the basis of the above design, the predicted EPC rating will be at least 31, which results in a score of 8 points under BREEAM Ene1.
- The design energy target of 80kgCO_2/m^2/annum will also be exceeded.

Construction

During construction the most important aspect will be to minimise the impact of the construction activities on carbon emissions. Targets will be set for the construction site as a whole to reduce energy consumption (BREEAM Man 3) through careful use of powered equipment, lighting and also through a construction site travel plan.

- Building (Scotland) Regulations, set by the Scottish Building Standards organisation, will be implemented and exceeded.
- Construction site targets will be set for site energy consumption and carbon emissions (BREEAM Man 3).
- The choice of recycled content and materials reduces embodied carbon in materials (reference the Materials section).
- Pre-fabrication will be specified for large parts of the hospital which is an energy and waste efficient means of production.

Operation

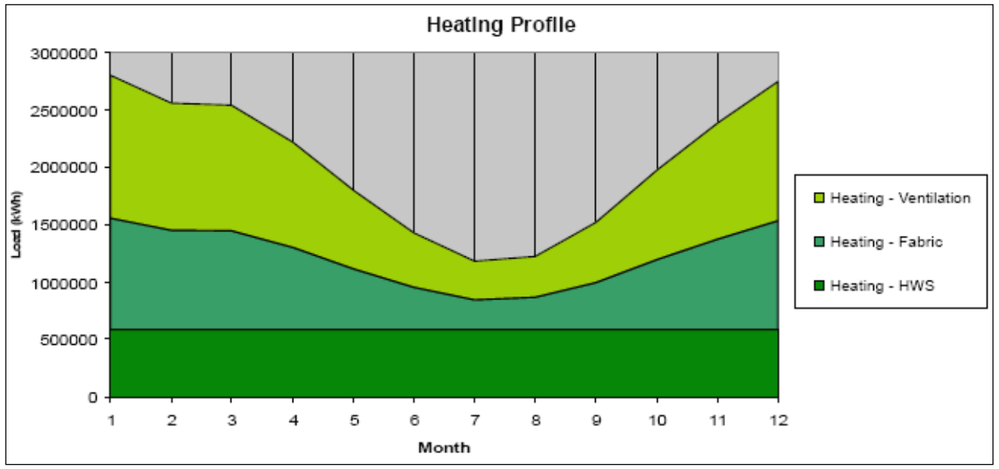
The GG&C Carbon Management plan includes a target to reduce its CO_2 by at least 25% over the period of 2006 – 2016. As the NSGH is a new hospital, replacing older building stock, it presents a real opportunity to contribute to this overall target. This will be achieved through meeting and exceeding the operational target of 55GJ/100m^3, as laid out in the Department of Health's guidance. Although hospitals are inevitably energy intensive to operate, with clear guidance as to how to operate the building to meet its designed level of performance, energy efficiency can be achieved. The proposed NSGH design includes features such as energy efficient lighting and lifts (BREEAM Ene 4 and Ene 8), HVAC systems with heat recovery and CHP units in the energy centre with an overall efficiency of 85% (approximately). Other aspects to reduce energy consumption include:

- Sub-metering of different areas of the building will facilitate monitoring of energy consumption within the hospital and, through the BMS, allow identification of areas of high energy usage and efficacy of energy saving measures (BREEAM Ene 2 and Ene 3).
- Regular audits of energy consumption and major energy using equipment to ensure operating efficiently.
- Post-occupancy audit to ensure building is meeting the expected performance standards.
- The operational energy demand is predicted to exceed the target set of 55 GJ/100m^3/yr.

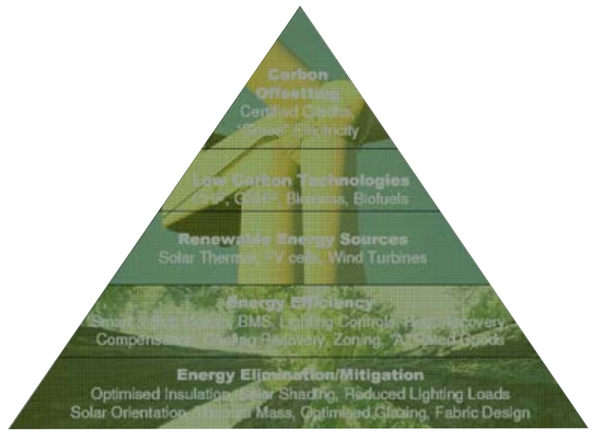
Brookfield

BREEAM Summary

Anticipated Credits:	Predicted Percentage Achieved:
Reduction in CO2 emissions	69%
Sub-metering of substantial energy Uses	
Sub-metering of high energy load areas and tenancy	
External lighting	
Low and zero carbon technologies	
Energy efficient lifts	
CHP Community Energy study	



Heating profile taken from the energy strategy (Vol.3.20), showing the demand could be met.



The Energy Hierarchy, used to structure the approach to designing NSGH.

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Brookfield

4. Transport

"Providing accessible transport options for all members of the community." SHINE

Design

The design and plan for transportation to and from the New South Glasgow Hospital will support Glasgow Council's Transport Strategy to provide a world class transport system that is safe, reliable, integrated and accessible to all citizens and visitors (Keeping Glasgow Moving: Glasgow's Local Transport Strategy, 2007-2009). In order to do this, transportation during the construction and operational phases of a building must be addressed during the design phase, if a sustainable transport plan is to be ensured. The following lists the design features of the proposed design which will reduce the reliance on private vehicles for travel:

- The new Clyde Fastlink is an integral part of the transport plan and so its route and stopping area within the hospital have been carefully incorporated to the landscape plans.
- A network of pedestrian and cyclist routes have been laid out across the site and designed in accordance with best practice such as the National Cycle Network 'Guidelines and Practical Details issue 2' (Sustrans, 1997) and LTN 2/04 'Adjacent and Shared Use Facilities for Pedestrians and Cyclists (DfT, 2005) to ensure safe and adequate pedestrian and cycle access (BREEAM Tra 4).
- Cycle storage racks for both staff and visitors have been placed close to the main entrances and staff entrances, with staff showering facilities available (BREEAM Tra 3).
- During the design phase there have been a large number of meetings, for which Brookfield has encouraged using teleconferences and webinars where possible or encouraging attendees to consider alternative options prior to opting for private vehicle use.

Construction

The potential for interruption to local services and facilities within the site during construction has been carefully analysed and will be managed to minimise the disruption to the hospital and nearby building users and residents (Southern General Hospital Travel Plan, 2007). It is envisaged that the hospital will continue to operate uninterrupted on a day-to-day basis during the construction and commissioning of the new facilities. The following actions will be undertaken to ensure impacts from transportation, whether noise, congestion or pollution, are minimised for both the local community and the staff and patients:

- A public website will give information about the construction activities in order to keep the local community informed about vehicle movements.
- Materials and construction traffic will be used as efficiently as possible for example, removal vehicles will be completely full before they leave site and delivery and removal vehicles will follow the most efficient routes.
- Contractors will be required to actively promote the transport hierarchy to all staff, encouraging walking, cycling, use of public transport and car sharing wherever possible.

Operation

The Sustainable Development Commission 'Healthy Futures #5: Sustainable Transport and Active Travel' suggests that the NHS can lead by example and encourage staff and visitors to get out of cars and onto bikes and public transport. The proposed design will facilitate a large number of travel options for the New South Glasgow Hospital to accommodate all building users, whether staff, patients or visitors. The design has referenced the 2007 Travel Plan (drawn up by JMP) to ensure a 'joined up' solution to transport. The following points illustrate the main measures that have been addressed to ensure New South Glasgow Hospital has a sustainable transport plan:

- GG&C NHS Board has a dedicated Travel Plan Coordinator to produce a comprehensive sustainable travel plan and travel options for users of the hospital, transport issues and options have been analysed as early as possible.
- The new hospital will have excellent public transport links. There is a large number of bus stops on and surrounding the site and these provide regular buses to and from the city centre and major towns. There is also a railway station less than 1000m from the new hospital site (BREEAM Tra 1).
- Real time public transportation information will be displayed in the hospital for building users to maximise the use of public transport (BREEAM Tra 7).
- The new hospital will have various amenities such as food outlets, cash machines, a post box and pharmacy either on-site or in close proximity. These amenities will all be reachable through safe pedestrian access and will help reduce the need for private vehicle use (BREEAM Tra 2).

For further information on all the above points and many other travel issues for the new hospital see: New South Glasgow Hospitals, Transport Assessment, April 2007.

Brookfield

BREEAM Summary

Anticipated Credits	Indicative Score
Provision of Public Transport	79%
Proximity to Amenities	
Cyclist Facilities	
Pedestrian and Cycle Safety	
Travel Plan	
Travel Information Point	
Deliveries and Manoeuvring	

Taken from the New South Glasgow Hospital Transport Assessment 2007

Brookfield

5. Land Use, Ecology and Pollution

"Delivering cleaner, greener and safer public spaces that are rich in biodiversity." SHINE

Design

Land-use and Ecology

The Brookfield design team has worked to incorporate requirements of the Glasgow Local Biodiversity Action Plan (LBAP) and the best practice recommendations from CIRIA's 'Working with Wildlife' in order to maximise the benefits to the local and wider natural environment, patients, staff, visitors and the community.

Although the existing green spaces have been identified as having 'low ecological value', there are in excess of 350 trees within the site boundary with a Glasgow City Council tree preservation order. Where possible, these trees have been protected and incorporated into the landscaping plans, preserving their ecological value. It is anticipated that there will be a positive change in the ecological value of the site as a result of the development and so it was concluded that there are likely be no negative ecological impacts (BREEAM Le 4/Le 5). This has been determined on the basis of the following features, recommended by the URS (appointed ecologists):

- The incorporation of bat bricks within the structure of the new buildings or bat boxes on the buildings.
- A wide variety of native plant species across the development as recommended in 'Scotland's Biodiversity (Scottish Executive). These include native trees (e.g. sycamore, birch), shrubs and grasses (e.g. hawthorn, dog-rose, oxeye daisy), aquatic plants and meadow flowers/ grasses for green roofs (including agrimony, St.John's Wort and meadow buttercup).
- Reed beds, which provide a diverse habitat for numerous species of plants, insects, birds and other wildlife.

Pollution

Localised pollution has been reduced or eliminated from the hospital's design through the following:

- Night time trespass of light from the site will be minimised by implementing an internal lighting design strategy which ensures all non-emergency lighting will be automatically switched off in rooms which are not occupied and exterior lighting will only be operational when required for safety and comfort.
- Water run off will be minimised to prevent overwhelming of existing stormwater drains and disruption of natural hydrology. Infiltration will be promoted on the site using permeable paving (Reference the Landscape Strategy by Gillespies for further information) and vegetated roofs and stream channels will be protected to prevent erosion.
- Although the hospital's site is located within a 'low flood risk' area (SEPA), measures such as infiltration of water onsite using permeable paving and diverse green roofs will be implemented to reduce the impact of potential future flooding with allowances made for climate change (BREEAM Pol 5) (Reference the Drainage Strategy).
- Leak detection systems are included in the building services systems to detect, capture and store refrigerant leaks when they occur (BREEAM Pol 2).
- Space and water heating systems with low levels of NOx (nitrogen oxides) will be specified by the Brookfield design team (BREEAM Pol 4).

Construction

Land Use and Ecology

Brookfield and Dunne will work together to ensure that the construction site management plan will include provision for protection of any existing ecological features (e.g. any trees to be retained) during site preparation and construction (BREEAM Le 3), These features will be protected using barriers and prohibition of entry by personnel as well as ensuring that all site personnel are aware of the need for protection. Habitats which will be lost as a result of the development will be compensated for through new landscaping, garden areas and diverse planting.

Habitat protection measures, which will be implemented, include the following:

- All scrub clearance will be undertaken outside of the bird breeding season, July to March. Any clearance which takes place during the nesting season (March to September) will only take place once a survey for active nests has been conducted and confirmation is provided that nests are no longer in use.
- Night surveys will be performed during the months of June and September to assess the use of buildings by bats. Construction workers shall be briefed as to the potential for bats to be discovered. An emergency procedure will be put in place in case bats are discovered during demolition/construction.
- Mature trees will be retained where possible as these provide a habitat type which is relatively uncommon within the development site and cannot be readily replaced.

Pollution

The following measures are recommended by the USA's Leadership in Energy Efficient Design (LEED) scheme to minimise the pollution of construction sites and will be implemented on the hospital development:

- Soil erosion will be prevented during construction by implementing temporary/permanent seeding and mulching, earth dikes and sedimentation traps/fences and basins where appropriate.
- Air pollution will be minimised by periodic water spraying of external areas during dry periods to discourage the generation of atmospheric particulates and minimising site traffic levels (see Transport section for further details).

Brookfield

Operation

Land Use and Ecology

When the buildings are occupied, Brookfield Facilities Management in collaboration with the GG&C NHS Board will maintain the onsite levels of biodiversity through the appointment of a Biodiversity Champion and following the Landscape and Habitat Management plan (BREEAM Le 6). This will be produced by the appointed ecologist and will cover at least the first five years after project completion and include:

- Management of any protected features on site
- Management of new, existing and enhanced habitats
- A reference to the Glasgow Local Biodiversity Action Plan[2]

Pollution

The main sources of pollution during operation will be from the hospital's use of energy, its waste streams and the means of transportation chosen by staff and visitors. These aspects have been covered in detail under the energy, waste and transport sections. Other aspects which will reduce pollution from operation include:

- Local noise-sensitive areas including residential areas, will be protected as much as possible from noise pollution through noise mitigation measures.
- In line with UK legislation, tobacco smoke will be confined to designated outdoor areas. Outdoor areas and shelters for staff and visitors who wish to smoke will be provided.

BREEAM Summary (Ecology and Land Use)

Anticipated Credits:	Predicted Percentage Achieved:
Ecological Value of Site and Protection of Ecological Features	70%
Mitigating Ecological Impact	
Enhancing Site Ecology	
Long Term Impact on Biodiversity	

BREEAM Summary (Pollution)

Anticipated Credits:	Predicted Percentage Achieved:
Preventing Refrigerant Leaks	62%
NOx emissions from heating source	
Flood Risk	
Minimising Watercourse Pollution	
Reduction of Night Time Light Pollution	
Noise Attenuation	

2 Glasgow Local Biodiversity Action Plan, 2008, www.glasgow.gov.uk/biodiversity

Brookfield

6. Materials

"Making changes to the materials, products and production processes used in the construction industry could significantly reduce their impact on the environment." Green Book Live

Design

When examining and selecting materials for use in New South Glasgow Hospital, both the environmental impacts and life cycle of materials have been assessed to ensure the most sustainable materials will be utilised. The BRE Green Guide to Specification and Green Book Live have been used to help specify and select the most sustainable materials for the construction of New South Glasgow hospital (BREEAM Mat 1), which will help to ensure that Brookfield's design is able to meet the 10% target for materials derived from recycled/reused content. From the onset of Brookfield's design, the efficient use of resources has been a priority and the design has aimed to reduce the use of materials and resources wherever possible.

- The dimensions of the proposed New South Glasgow Hospital have been designed to limit waste. Any masonry will be set-out to block dimensions to minimise cut-offs and the internal partitions will be set-out on a standard 300mm grid.
- Considerations have also been made during the design stages for the entire life cycle of the building. Materials designed for long life and low maintenance have been specified wherever possible, for example the solid masonry base for the external walls of the ground floor of the podium and the durable polymeric type paint finish (BREEAM Mat 7).
- Sandstone from the demolition of the surgical buildings is to be incorporated in the landscape design of the arrival space outside the main hospital entrance.
- ETFE roofs have been chosen over glass roofs for the atria due to their higher light transmission and improved thermal performance, helping to reduce energy demand as well as maintenance during the operation of the hospital.
- Materials with a low environmental impact have been prioritised for example, low VOC paints and vinyl floor coverings with an A rating in the Green Guide.
- The proposed materials with a recycled or reused content will include concrete, aggregates, steel, plasterboard as well as the re-use of demolition material in the landscaping.
- All timber to be used for New South Glasgow Hospital will be Forestry Stewardship Commission (FSC) certified and as many materials as possible used for most building elements will be responsibly sourced with proof of Chain of Custody (BREEAM Mat 5).

Construction

The following points illustrate a range of sustainability measures that will be undertaken during construction:

- Materials will be locally sourced wherever possible. Local sourcing of construction materials has a range of benefits including reduced carbon emissions through shorter vehicle journeys to the site and benefits for the local economy through utilising local suppliers and businesses.
- The nature of the cladding systems proposed dictates a large proportion of off-site fabrication utilising a modular system which provides greater production efficiency with less waste and energy expenditure.
- The concrete structure will incorporate a proportion of recycled material (for example, Ecocem which utilises GGBS to reduce cement content) within the concrete mix. Steel for reinforcement in the UK is 100% recycled.
- Brookfield's Sustainability Strategy outlines sustainable procurement as part of its construction project management, which will encompass choosing sustainable materials and minimising wastage allowances.

Operation

Brookfield FM operates a sustainable procurement policy for the operational phase of New South Glasgow Hospital. This will ensure the use of sustainable materials is continued throughout the life cycle of New South Glasgow Hospital.

- The internal wall build-up will be constructed to allow ease of adjustment to enable change of use in the future if required.
- The building has been designed so that when it reaches the end of its operational life, the structure can be recycled.

BREEAM Summary

Anticipated Credits:	Predicted Percentage Achieved:
Highly Rated Green Guide Materials	47%
Hard Landscaping and Boundary Protection	
Responsible sourcing of materials	
Highly Rated Green Guide Insulation	
Designing for Robustness	

7. Waste and meeting WRAP Best Practice

"Reducing pollution and waste to avoid health impacts and the depletion of natural resources." SHINE

Design

Best Practice Guidelines will be used to determine how waste will be managed on site and also to ensure that the waste hierarchy is put into practice, by minimising waste and reducing the amount which needs disposal[3] . One effective means to reduce the total amount of waste created by the project is to reduce the wastage allowances on each supply contract. This will be implemented by Brookfield ensuring that reduced levels are agreed as part of the tendering process, thus reducing the amount of materials which enter the site.

Modern Methods of Construction for some elements will also reduce the amount of waste generated. MEP Solutions will be used to supply ready made bathroom and ward components, which include multi-service modules of pipework, ductwork, medical gases and all electrical services. Pre-cast concrete beams and staircases are to be supplied from Dunne's own pre-casting site in Bathgate, reducing waste and carbon emissions through the avoidance of long journeys.

Given the fact some demolition on site will be undertaken, the demolition materials will be incorporated into the landscaping and construction. Sandstone from the demolished surgical buildings has already been allocated for parts of the landscaping elements. It is recommended, if Brookfield are not conducting the demolition, that it should follow the Institution of Civil Engineer's Demolition Protocol to maximise the amount of material available for re-use.

WRAP's Net Waste Tool

WRAP's guidance has been used to try and design out waste where possible, as detailed above, and for the remaining waste predicted to be generated on site, the Net Waste Tool will be utilised. Once the final design is complete and the materials have been specified, the Net Waste tool will be completed for the NSGH. The resulting waste targets, based on the analysis of waste segregation, recovery and recycling options, will be integrated into the Site Waste Management Plan (SWMP). Although this has not been completed as yet, it is anticipated that the tool will also assist in determining the targets for waste reduction in contractual conditions for sub-contractors and help Brookfield achieve a high level of resource efficiency across the construction site.

Details of the sustainable design for reducing waste:

- A Site Waste Management Plan will be developed before construction starts, which centres around the results from the WRAP Net Waste Tool, and will set targets and assign specific responsibilities to contractors and the Brookfield management team.
- The most significant waste streams will be identified through a pre-construction review and plans made for their segregation and most cost effective recovery solutions.
- The main hospitals and the ancillary buildings are designed to facilitate to segregation at source and accommodate the storage of different waste streams in a waste compound (Wst 3).

Construction

In Scotland, annual construction and demolition waste totals approximately 10.6 million tonnes (2005/2006). This is makes construction sites responsible for approximately 20% of all waste, with wasted materials worth millions disposed of in landfill each year. Avoidance of waste creation is the first step but waste that is generated on site will be segregated to allow ease of recovery or recycling. Brookfield has signed up to WRAP's commitment to halve waste to landfill, a target they have committed to exceeding by 30% in their Corporate Responsibility Statement. In order to achieve this, a Site Waste Management Plan is an integral part of Dunne's Site Environmental Management Plan. During construction, a dedicated waste compound will be established and to facilitate achievement of the waste targets on site; less than 12m^3 waste/100 m^2 of floor area and a landfill diversion rate of 80% (BREEAM Wst 1). Waste minimisation and management will be the direct responsibility of the construction site manager, with contract conditions to defer a mandatory requirement on all suppliers and contractors to reduce waste and packaging on site.

- Where possible, materials with a high level of recycled content will be chosen for use on site, to support the development of a recycled material supply chain. Examples at NSGH include cement replacement and recycled aggregates.
- Transportation of waste off site will be done as efficiently as possible in order to minimise the number of journeys.
- Through the use of the Net Waste Tool, recovery rates will be set for the different waste streams. These targets will be monitored as part of the overall construction site management, with financial penalties in place for contractors who do not meet these targets.
- Liaison with NISP Scotland will find as many alternative routes for waste generated on site as possible and thus reduce the amount of waste sent to landfill or reprocessing.

3 Using WRAP's Designing out Waste Guide for examples of best practice

Brookfield

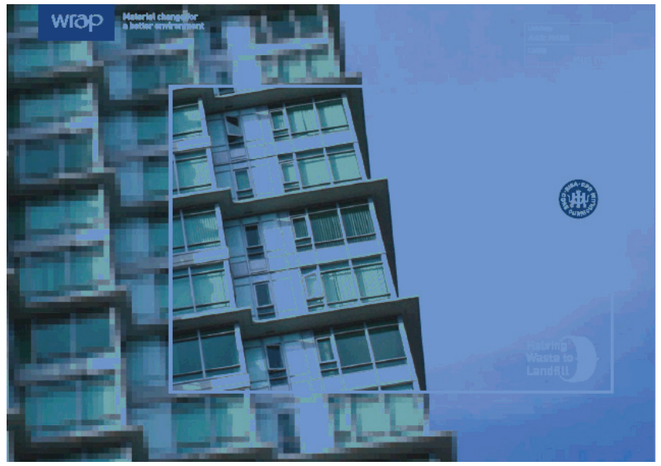
Operation

A review by the National Audit Office (2005) estimated that waste management costs the NHS around £8 million each year and that the cost of clinical waste disposal could be reduced by about £1.3 million if hospitals sorted waste properly. The way that the NSGH has been designed will ensure that for the foreseeable waste streams, this volume of waste can be minimised and properly segregated and managed. Public areas will be designed to accommodate separate waste streams and the food outlets will avoid supplying goods in packaging which cannot be recycled. Reducing the amount of waste sent to landfill is not only good for the environment as it reduces the depletion of natural resources but is also sound financial management as it avoids paying landfill tax, scheduled to keep rising. Brookfield's Waste Management Plan has been developed on the basis of WRAP guidance and Brookfield FM is committed to finding alternate waste recovery routes for the NSGH waste wherever possible.

- Once collected, sufficient space has been allocated to the waste compound so that waste on site can be stored in the necessary waste streams, compacted and baled on site where necessary (BREEAM Wst3/Wst4).
- Waste management will be the responsibility of a named individual on the Brookfield Facilities Management team.
- Retail outlets on site will be encouraged to reduce the amount waste for which they are responsible, by ensuring that they are fully aware of the waste management costs as part of their lease agreements.
- Food waste will be collected and stored separately on site so that it can be either composted and or transferred off site for use elsewhere (As stated in the Board's clarification to ITPCD Documents, Volume 2/1, Appendix M&E 7 Pneumatic and Automated Material Transfer Systems.).

BREEAM Summary

Anticipated Credits:	Predicted Percentage Achieved:
Construction Site Waste Management	63%
Recyclable Waste Storage	
Compactor/ Baler	
Composting	



Brookfield

8. Water

"Sustainable water management means minimising our impact on the healthy functioning of the water cycle, reducing carbon emissions and lowering environmental and economic costs." sustainablecities.org

Design

Although water is generally more than plentiful in Glasgow, water consumption is still an important issue to address in order to minimise the volumes consumed. Aside from the clear cost benefit from not consuming too much, the environmental costs need also to be considered. Waterwise produced figures, which show that the production of potable water requires chemicals and energy in large amounts and creates a carbon footprint for water of almost 300kgCO2/1000 m3. Therefore, the proposed NSGH design, which is designed to use low levels of water, will not only save money during the operation of the hospital but also reduce the total environmental impact of running a large acute and children's hospital.

As the Department of Health's HTM on Water Management and Water Efficiency states water minimisation is not just about sanitary fittings, as a large amount of water is also used in hospitals' energy centres, the catering areas and externally for irrigation. The landscaping has been designed so that no additional irrigation will be needed, other than during the settling in period on the green roof. Catering use of water will be reduced through improved preparation procedures and water efficient equipment. Other water saving features include:

- Low flow fixtures and fittings will be fitted in every ward, public area and staff accommodation (BREEAM Wat 1).
- Shut off valves are specified to the toilet blocks to reduce potable water consumption through leaks or faulty taps (BREEAM Wat 4).
- Proximity sensor taps will be installed in public areas, so that taps cannot be left on.
- The external landscaped areas have been designed so that no additional irrigation is needed (BREEAM Wat 6). The green roof has been designed so that it will retain approximately 60% of fallen rain, so it will only need additional manual irrigation in prolonged periods of dry weather.
- The target water consumption for NSGH has been based on the Environment Agency's Best Practice for Hospitals (May 2008), with anticipated consumption being in the order of 350-400 litres per bed /day.

Construction

Although in comparison to the operational period, less water will be used through the construction period, the same attention to water consumption will be observed by Brookfield and Dunne.

- Water consumption targets will be set for the construction site and usage will be monitored. Visible targets like these help to encourage behaviour change within staff members, so that hoses are not left running or excessive water usage for vehicle wash down is avoided.
- Any water from washing down of items on site or run off after storms will be captured and filtered to avoid contamination of local watercourses by sediment.

Operation

In addition to the outlined measures in the design to reduce the amount of water consumed through operation, water from the aquifer could be used for sanitary fittings. This is reliant on feedback from the study of the ground water levels and the aquifer and could still form part of the final design, dependent on when the results are available.

- Water meters will be installed on the mains supplies to each building so that consumption can be tracked through the BMS (BREEAM Wat 2). Sub-metering of water is provided to all major hospital zones and hot water will be separately metered for energy calculations.
- The BMS will include a water leak detection facility, which will monitor flows of water throughout the hospital buildings and make an alert when any anomalous consumption levels are identified, allowing leaks to be quickly investigated and dealt with (BREEAM Wat 3).

BREEAM Summary

Anticipated Credits:	Predicted Percentage Achieved:
Water Consumption	44%
Water Meter	
Major Leak Detection	
Sanitary Supply Shut-off	
Irrigation Systems	

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Strategy for Controls and Building Management System

General

The Building Management System will comply with the relevant clauses of the NHS Model Engineering Specification and provided local and site wide control of the building services systems associated with the hospital.

Building Management System

Overview

The key strategy objectives are:

- High Level of Distributed Control
- Modular Approach
- Full Open Protocol
- A Front End Graphical User Interface that works as a Systems Integration platform

Field Side Environment

The field side environment can be broken into three main areas:

- Primary plant control (AHU's, Chillers, Boilers, CHP, pumps, fans, etc.)
- Environmental Control (Chilled Beams, radiant panels, FCU's, underfloor heating, etc)
- Supervisory function Control (Systems requiring overview, leak detection, metering, etc.)

Primary Plant Control

The control solution for this type of application will be a fully contained controller with associated electrical requirements. Also the sensing and actuation required for the process will be controlled and connected directly to this unit. With regard to Air Handling Units, the control enclosure will be integrated. Pumps, Fans, etc. will be complete with an associated control and power cabinet located adjacent to the equipment.

Environmental Control

Within the building there are key environmental controls that control occupant comfort and also occupant driven energy usage. The two key areas of environmental control will be the operation of the HVAC systems and Lighting control.

Systems Integration and Graphical User Interface

The Open System Integration framework solution will have seamless transfer of information to and from certified field devices.

This system for the hospital will be a software solution of two parts:

- The Integration of field systems
- The Graphical User Interface (GUI)

Power Management System Overview

The hospital energy management needs will be viewed in two areas:

- Supply Side
- Demand Side

The demand side will be dealt with via the Building Management System (BMS) and the supply side, consisting of on site generating capacity and also connected capacity from the national grid, be dealt with by the Power Management System (PMS).

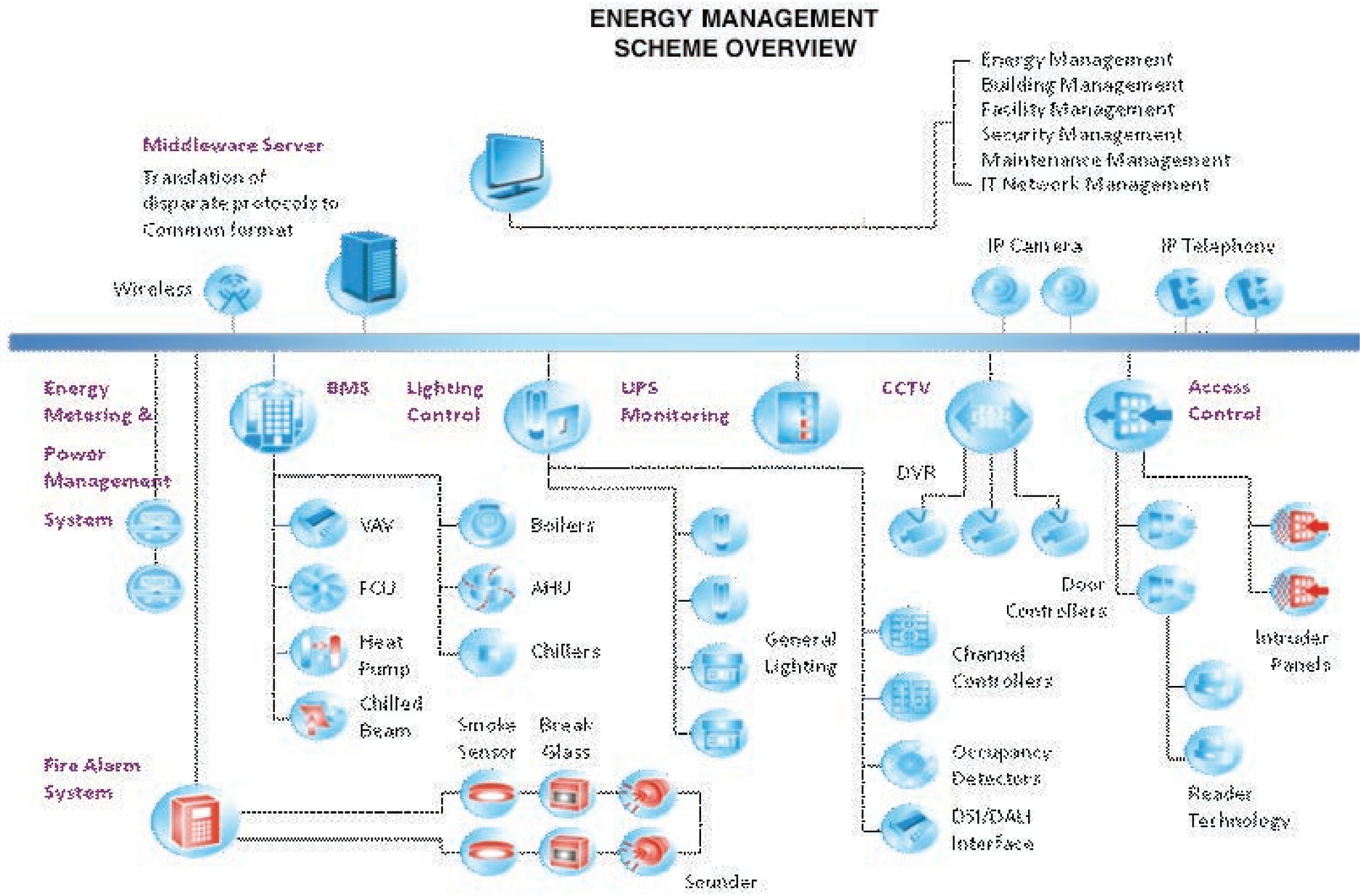
The overall energy supply, on site capacity, is a combination of different plant:

- Boilers
- Chillers
- Absorption Chillers
- CHP Engine Sets

It has been determined that these combined items give the best energy performance over the entire demand side operating range and ensure that the highest operating efficiencies overall are achieved.

For example; with the integration of the absorption chiller into the scheme and the gas fired CHP engines, it is desirable that the engines are loaded as much as is possible to ensure highest efficiency electricity is available to the demand side, while the heat is captured effectively and utilised for chilling (Via absorption chiller) and heating. The system will factor key plant characteristics and potentially present and forecast weather, to ensure effective sequencing of plant to take advantage of ambient conditions and also performance curves of equipment.

Brookfield


ENERGY MANAGEMENT
SCHEME OVERVIEW
Energy Management
Building Management
Facility Management
Security Management
Maintenance Management
IT Network Management
Middleware Server
Translation of
disparate protocols to
Common format
Wireless
IP Camera
IP Telephone
Energy
Metering &
Power
Management
System
BMS
Lighting
Control
UPS
Monitoring
CCTV
Access
Control
DVR
VAV
FCU
Heat
Pump
Chilled
Beam
Boilers
AHU
Chillers
General
Lighting
Door
Controllers
Channel
Controllers
Occupancy
Detectors
DSI/DALI
Interface
Intruder
Panels
Reader
Technology
Fire Alarm
System
Smoke
Sensor
Break
Glass
Sounder

Cooling Design Strategy

Selection of system

The choice of cooling medium has been considered and the use of Chilled Water

Location of Cooling Plant

The Exemplar scheme indentified a number of chiller plants located close to the load centres within the hospital. However, it is proposed to locate the main cooling plant at the main energy centre for the following reasons:-

- Chillers create noise and vibration which is easier to control remote from clinical use. The building can also be more economical to construct.
- Chillers are large and heavy. Locating chillers on the roof of the ward tower block would require very sizeable cranes to remove and replace them, and other large components, and would cause significant disruption adjacent to the hospital.
- Electrical power is derived from the energy centre. With the chiller being local transmission losses and major cable routes within the hospital are avoided.

The chillers will be air cooled and mounted on the energy centre roof with associated pumping equipment located on the first floor below.

The cooling plant will be divided into two in a similar way to the heating plant. The plant will be designated A and B and essentially work as independent systems to provide resilience.

Cooling Plant Sizing

The cooling load for the new hospital has been assessed using the ventilation plant volumetric flow rates calculated from the proposed scheme and are described in section 3.9. An allowance for heat recovery on ventilation plants has been assumed. In addition to this thermal modelling of sample parts of the building has been used to determine cooling requirements for terminal cooling devices

The total cooling load can be summarised in the following table:

Cooling (kW)								
Description	**Total AHU**	**Heat Recovery**	**Total AHUs**	**Chilled Beams**	**FCUs**	**Total Clg load**	**Pipe Gains 2%**	**Total HEX Duty**
Plantroom 21	610	-30	580	190	50	820	15	835
Plantroom 22	1085	-55	1030	0	20	1050	20	1070
Plantroom 31	2475	-120	2355	300	75	2730	55	2785
Plantroom 32	1620	-80	1540	750	50	2340	45	2385
Plantroom 41	515	-25	490	300	75	865	15	880

Total	5995	1540	270
Diversity	10%	25%	25%
Load diversity	-600	-385	-65
Corrected loads	5395	1155	205
Total Chiller Load (kW)	**6755**		

Therefore, the total cooling load for the new hospital will be in the order of 7,000kW, which equates to 42W/m^2. This compares favourably with similar projects as noted below;

Princess Royal University Hospital – 36 W/m^2 (Largely Naturally Ventilated)

Barnet Hospital Phases 1a/1b – 35 W/m^2 (Largely Naturally Ventilated)

Peterborough Hospital – 58 W/m^2 (High degree of Clinical Accommodation, inc atria with sealed windows, designed to 2006 Building Regulations)

Kings College Hospital – 50 W/m^2 (High degree of Clinical Accommodation, inc atria with sealed windows)

The laboratory/FM block is provided with its own cooling plant and therefore no capacity is included in the main hospital's cooling plant.

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Cooling Plant Arrangement

The total cooling load will be met by eight chillers at 1000kW providing standby capacity (N+1).

As described earlier, for resilience, the cooling plant will be divided into two. The total load to be supported by each part will therefore be some 3500kW, which will be met by four chillers at 1000kW. Therefore, each cooling plant will approach a capacity of 60% of the total building load, which should be sufficient to allow the hospital to continue to function in the event of a catastrophic failure on one system. This standby chiller can also be used for service capacity reserve.

It is proposed, in order to reduce carbon emissions, to provide CHP plant and use the waste heat in summer for cooling utilizing an absorption type chiller. Therefore, a 1000kW cooling capacity chiller will be installed on the 'A side' chilled water system and act as lead chiller whenever there is sufficient cooling load and waste heat available.

An ADsorption type chiller may be considered as an alternative to traditional absorption technology, since the chemicals employed in the cooling cycle are more environmentally friendly.

The heat driven chiller will still need to reject the cooling effect and driving heat to atmosphere very much as a vapour compression unit. This will be achieved by using dry air coolers mounted on the roof of the energy centre alongside the other chillers. Adiabatic spray coolers will be considered to improve efficiency.

The absorption chiller and dry air coolers will be linked by a closed loop condenser water circuit, with water temperature controlled by fan operation on each dry air cooler.

Free cooling from the dry air coolers, for the use with the chilled beams, has been considered but with the current location of the coolers and the additional pipework distribution required and the associated pumping energy currently it has been discounted.

Absorption type heat driven chiller

Dry air cooler

The balance of the cooling capacity (7000kW) will be met by seven high efficiency packaged air cooled chillers, each rated at 1000kW and located on the roof of the energy centre.

These high efficiency chillers will offer the following advantages:-

- low maintenance, oil-free compressor
- highly efficient performance, particularly at part load (COP approaching 9.0 at part load).
- high integrity refrigerant pipework giving low refrigerant losses
- Low starting current

High efficiency air cooled chiller

A48235836

Chilled Water Distribution

From the energy centre chilled water will be distributed to the main hospital to serve the various major plant zones.

It is proposed to employ buried underground pipe mains to avoid the need for a major tunnel system, with the associated complications of access, ventilation and fire protection, etc running in parallel with the heating mains (described in section 3.8).

The two cooling systems (A & B) will be replicated in the chilled water distribution between the energy centre and the main hospital building, thus providing resilience in the event of a pipework problem necessitating the shutdown of one circuit. At the main hospital the two circuits will be brought together for final distribution to the main load centres.

For resilience purposes the primary chilled water generated by the cooling plant will be separated from the final secondary circuits by heat exchange stations will be formed at load centres.

Whilst the Exemplar Design utilized a constant volume pumping distribution arrangement with 3-port bypass valves at the load centres this does mean that the pumps have to run at constant speed and offer no facility to reduce pump power across the site. It has been estimated that this could consume up to 1.4GWh across all pumping systems more than is necessary equating to 4kg/m^2 of CO_2, which with such a stringent carbon and energy target needs careful consideration.

It is therefore proposed to employ variable volume pumping arrangements and 2-port valve control to maximise pumping efficiency, with the pump speed being varied automatically as the heating load changes.

Plate heat exchanger used to separate primary and secondary cooling circuits

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IN STRICT CONFIDENCE

DIRECTORATE OF ACUTE SERVICES STRATEGY IMPLEMENTATION & PLANNING

PROJECT EXECUTIVE MEETING – 24th OCTOBER 2007

Re-Tender for Technical Advisers Role - ASR II

At the meeting of the PEG held on Wednesday 18th April a paper was tabled outlining the revised scope of the project. Following consideration of the aforementioned paper authority was granted to the Project Team to advertise and re-tender the Technical Team role for the new project at the Southern General Hospital; this course of action having been ratified by both the Board's legal advisers and auditors.

On 23 May 2007 the Board placed an advertisement within the Supplement of the Official Journal of the European Union (OJS), OJEU Ref 2007/S 97-119682, seeking the services of a technical advisory team to co-ordinate and manage the PFI/PPP procurement process for the re-development of the Southern General Hospital campus to provide a single in-patient site for South Glasgow, the project to comprise the creation of a new build Acute Hospital, Children's Hospital and Laboratory facility within the campus, linked to the more modern buildings within the site.

Following publication of the May advertisement the Board received some twenty six (26) expressions of interest. Of those twenty six expressions of interest, the Board received four tenders from the companies listed below;

Capita Symonds
Currie & Brown
Davis Langdon LLP
Mott Macdonald

Following receipt of tenders on Tuesday 3rd July and a clarification exercise, each of the four bidders were interviewed between 27th and 29th August. Following the interviews and tender evaluation process, one party is clearly lagging well behind the others and the Project Team would propose not to take them any further in the process. Of the three remaining, the Project Team has a preferred candidate, but with the continued uncertainty regarding the procurement route means that it is not possible to appoint Technical Advisers at present.

At the interviews the bidders were advised that the Board would update the teams towards the end of September. All of the teams have been back in touch on a number of occasions and to try and keep them on side until the Board can confirm the way ahead, Board Officers have met with the ASR legal advisers to discuss options, and the following course of action is proposed.

- The teams are advised of the current work to revise the OBC to consider various funding and procurement options.
- The Board cannot make an appointment until this work is complete; the legal view is that the scope of work for a PPP TA role as apposed to D&B role is substantive and not transferable.
- That the Board write to the top three bidders (Currie & Brown, Davis Langdon and Mott Macdonald) and explain the situation and ask that they hold their bids until late January 2008 until the situation becomes clearer. Advise the Capita team that they have been unsuccessful, rather than prolong the situation.

IN STRICT CONFIDENCE

In the meantime, the Davis Langdon team continue to provide advice to the Board in terms of the works associated with the completion of the OBC for the Acute and New Children's Hospitals. The cost of any works is agreed in advance and is based on their current hourly rates.

Recommendation

That the PEG note the current position and approve delegated authority to the Project Team to pursue the above course of action.

NHS Greater Glasgow and Clyde

New South Glasgow Hospitals

Full Business Case

OCTOBER 2010

Project Particulars	
Project ID	NHS Greater Glasgow and Clyde Health Board New South Glasgow Hospitals Project
Project Director	Alan Seabourne
Contact Details	[redacted] Address – New South Glasgow Hospitals Project NHS Greater Glasgow and Clyde Site Project Office Hardgate Road Glasgow G51 4SX
FBC Co-ordination	Heather Griffin, Project Manager
Contact Details	[redacted] Address – New South Glasgow Hospitals Project NHS Greater Glasgow and Clyde Site Project Office Hardgate Road Glasgow G51 4SX
Document Reference	Full Business Case for the New South Glasgow Hospitals. October 2010
Synopsis: .	This document is the Full Business Case for NHS Greater Glasgow and Clyde's New South Glasgow Hospitals. The document presents the proposals for a new children's hospital and new adult hospital on the site of the current Southern General Hospital and highlights how these form the pivotal phase of the Health Board's ASR strategy. The document details the Strategic Case, Economic Case, Commercial Case, Financial Case and Management Case for the building of the new hospitals.

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Appendix E	BENEFITS APPRAISAL
Appendix F	SAMPLE TRACKER FOR 1:200 DESIGN USER GROUP MEETINGS
Appendix G	RISK REGISTERS (Removed due to commercial sensitivity)
Appendix H	MASTER PROGRAMME (Indicative only – to be further detailed)
Appendix I	DRAFT COMMISSIONING PLAN
Appendix J	DESIGN STATEMENT PART 1: ARCHITECTURE
Appendix K	DESIGN STATEMENT PART 2: LANDSCAPE AND PUBLIC REALM
Appendix L	COMMUNITY ECONOMIC BENEFITS
Appendix M	GOVERNANCE ARRANGEMENTS: WORKGROUPS AND REMITS
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CHAPTER 1

EXECUTIVE SUMMARY

CHAPTER 1 - EXECUTIVE SUMMARY

INTRODUCTION

The purpose of this Full Business Case is twofold:

1) To present the proposals for a new children's hospital and new adults' hospital (The New South Glasgow Hospital) on the site of the current Southern General Hospital.

2) To confirm the proposals set out in this document are fully in line with the phased construction contract signed between NHS Greater Glasgow and Clyde[1] and Brookfield Construction UK Limited in December 2009.

The proposals represent the largest investment in health services undertaken in Scotland and will transform the experience of healthcare for patients and staff alike with Glasgow becoming the home to one of the largest, most advanced NHS developments in the UK.

This document confirms that the strategic drivers for the project have been reviewed and revalidated and that NHS GG&C's strategy (the Acute Services Review), to modernise the health services in Glasgow remains unchanged. This strategy has been implemented over the last 8 years with phase 1, two new state of the art ambulatory care hospitals, completed in 2009.

The option of a new build children's hospital and adult hospital on the Southern General Hospital campus (as described in the Outline Business Case) continues to be the preferred option. These new hospitals will achieve the gold standard triple co-location of adult, children's and maternity services and modernise services, facilitating the closure of the Western Infirmary, the Victoria Infirmary, Mansion House, Royal Hospital for Sick Children and some existing parts of the Southern General Hospital with the transfer of inpatient services to new, state of the art facilities.

The construction of the new hospitals will give the opportunity to redesign the way in which health services are delivered and to reappraise the skills and profile of the workforce to deliver modern health services for the 21st century. The development of this new hospital complex also has the potential to breathe new life into South West Glasgow and beyond, generating jobs and commercial opportunities for the local population both during construction and once in operation.

[1] For the remainder of this document NHS Greater Glasgow and Clyde is referred to as NHS GG&C or the Board, and Brookfield Construction Limited is referred to as BCL.

The Outline Business Case Approval

The proposals for a new adult and children's hospitals, new laboratory, facilities management (FM) and new 33KV electrical sub-station were previously presented to the Scottish Government in an Outline Business Case (OBC) which was approved in May 2008.

Procurement Process

Subsequent to OBC approval in May 2008 the Board commenced a procurement process to contract to design and build the new hospitals and laboratory facility which concluded in October 2009.

The outcome of the procurement was presented to the Board in November 2009. The Board approved the signing of a contract with Brookfield Construction UK Limited which was complete on 18th December 2009. The contract made provision for:-

- Stage 1- construct the new laboratory, the FM facility and the new 33kv electrical substation

- Stage 2 - design the new adult and children's hospitals which informed the work for this Full Business Case (FBC)

Upon Scottish Government approval of the new adult and children's hospitals FBC, BCL are contracted to complete stages 3 and 3a below

- Stage 3 - construct the new adult and children's hospitals

- Stage 3a - Demolition of the surgical block and associated buildings and completion of the soft landscaping

New Laboratory Build

A Full Business Case for the laboratory and FM component was approved by the Scottish Government on 4th December 2009. Building work commenced in February 2010 and is anticipated to complete on 10th March 2012. The construction work is on schedule and within the project budget with a governance structure, risk management and change control process fully established.

This document therefore addresses the remaining components of the current contract which are a new adult and new children's hospital. *(Please note details of the FM facility are given where relevant in explaining the functioning of the new hospitals.)*

It is planned to construct the adult and children's hospitals as a single building, (*albeit with distinctive and different external and internal identities reinforced by*

separate approach and entrance areas), in order to benefit from the clinical co-locations and support services synergies offered by an integrated build.

Business Need – Case for Change

In 2002 Greater Glasgow Health Board described the case for change for adult services. This identified that the status quo was not an option, due to significant challenges in the sustainability of services and improving patient pathways creating more efficient and effective care. All of the factors identified in 2002 remain relevant today with further challenges and pressures resulting in even greater need to reduce hospital sites and duplication of services. In brief the issues are:

- The need to achieve the objectives of government policy such as the 'Healthcare Quality Strategy for NHS Scotland' and 'Better Health, Better Care' and other key national policies. These policies drive clinical excellence, continuity of care and the modernisation of services. Implementation also drives efficiency and productivity through more streamlined service models and through investment in technology, leading to a reduction in waiting times and more rapid patient access to diagnosis and treatment. Implementation of the guidance puts patient needs at the centre and promotes the provision of a clean safe environment reducing rates of hospital acquired infection. To achieve these objectives a major programme of investment in buildings, information technology and redesign of services is required for Glasgow
- Fragmented services. At the moment there is a requirement for patients to move within and around sites and different buildings in Glasgow. This leads to a loss of continuity of patient care. Furthermore, important co-locations of services are not possible therefore making it challenging to achieve streamlined patient flows.
- An increasing need to move towards larger teams to ensure that all patients can access the appropriate Specialist on a 24-hours a day and 7-days a week basis
- Pressures on the workforce in sustaining the current number of multiple staff rotas across the different Glasgow hospital sites
- Outdated buildings which are unfit for modern healthcare offering a poor patient environment with unsuitable facilities for modernising services

THE SOLUTION - THE ACUTE SERVICES REVIEW (ASR)

In response to the above pressures the Board undertook a review of the acute services (The Acute Services Review) and proposed a strategy to address the Board's business needs by modernising services across Glasgow. The key components of the strategy are to reduce the number of adult inpatient sites from the current six hospital sites to three. Two sites, Glasgow Royal Infirmary and the new Southern Glasgow Hospitals, will have Accident & Emergency (A&E) and trauma facilities. The third inpatient hospital will be Gartnavel General Hospital. These acute sites will be supported by the two Ambulatory

Care Hospitals, one on the Stobhill Hospital site and one on a site adjacent to the Victoria Infirmary.

Implementation of the ASR strategy has been taking place over the last 8 years, and around two thirds of this strategy will be in place by the beginning of next year, 2011.

The two Ambulatory Care Hospitals (noted above) opened in 2009. These Ambulatory Care Hospitals represent a significant modernisation of Glasgow's healthcare facilities; however three of Glasgow's major adult hospital sites are now operating below physical capacity with inpatient services only remaining in some buildings in Stobhill Hospital, the Western Infirmary and the Victoria Infirmary.

NHS GG&C are currently carrying out an accelerated ASR in the North and East of the city with transfer of inpatient services from Stobhill Hospital to Glasgow Royal Infirmary planned for early 2011. This will allow the subsequent closure of the old Stobhill Hospital leaving the New Ambulatory Care Hospital on the Stobhill Hospital site.

The proposals for the new South Glasgow Hospitals on the Southern General Hospital campus form the pivotal phase of the ASR Strategy and therefore the key transitional aspect of the transformation of service delivery by the Board.

On completion in 2015, the Board will be able to enact the following:

- inpatient services in the Victoria Infirmary to transfer to the new South Glasgow Hospitals
- inpatient services at the Mansion House Unit (MHU) to transfer to the New Southern Campus allowing closure of the MHU
- inpatient services housed in outdated buildings on the Southern General Hospital and Western Infirmary sites to be relocated to the new South Glasgow Hospitals
- transfer of A&E services and associated beds from the Victoria Infirmary, the Western Infirmary and the Southern General Hospital to the new South Glasgow Hospitals
- these transfers will facilitate closure of the Western & Victoria Infirmary and Mansion House sites and the older parts of the Southern General Hospital

The above means that by 2015 the plans for the 3 site inpatient configuration of adult services in Glasgow will be achieved.

Children's hospital services are currently provided by the existing Royal Hospital for Sick Children (RHSC) which is sited at Yorkhill. In 2004 the Minister for Health and Community Care announced that the Scottish Government would provide funding to enable a new children's hospital to be built on a site which would support the "triple co-location of services".

Following an option appraisal in 2005 of potential locations for the new children's hospital, the Southern General site was identified as the only location to offer both co-location with maternity and adult services and appropriate vacant land for building. This process was undertaken in collaboration with a Ministerial Advisory Group chaired by Professor Andrew Calder. The report of that Group, published in March 2006, affirmed the selection of the Southern General site as the location for the new children's hospital. Following a period of consultation this recommendation was accepted by the Minister for Health and Community Care in 2006.

In 2009, some of the maternity services provided at the Queen Mother's (Maternity) Hospital (QMH) adjacent to the Children's Hospital transferred to the Southern General Hospital campus as part of the implementation of the ASR in preparation for the transfer of services from RHSC onto the Southern Site. (The remaining maternity services transferred to the Glasgow Royal Infirmary.)

As a result maternity and neonatal services are no longer co-located, and interim arrangements are in place in anticipation of the transfer and re-establishment of the co-location at the Southern campus.

PROPOSED FUTURE ADULT AND CHILDREN'S SERVICES

New Adult Hospital

A 1,109 bedded adult new build acute hospital is planned providing state of art A&E, critical care, theatre and diagnostics services. The facility will offer acute specialist in-patient care, medical day case services and will have out-patient clinics serving the local (South-West Glasgow) population. No day surgery will be undertaken as this will be provided at the new Victoria Hospital.

New Children's Hospital

The proposed new 256 bedded children's hospital will provide a comprehensive range of inpatient and day case specialist medical and surgical paediatric services on a local, regional and national basis. The new development will also have state of the art A&E, critical care, theatres, diagnostic and outpatient services. The Board's strategy is that all Glasgow's children's services (up to the age of 16 and up to 18 years where appropriate) will be provided at the new children's hospital.

EXPECTED BENEFITS OF THE PROJECT

It is anticipated that the project will deliver a range of benefits including:

- Provision of high quality services which are timely, accessible and consistently available by providing local access to core medical and surgical services and consolidation of specialist and tertiary services on fewer sites within the city

- Provision of gold standard services through the triple co-location of adult, children's and maternity services on a single site
- Provision of more efficient services with increased productivity and clinical capacity by:
    a) the concentration of clinical teams onto fewer sites
    b) optimising departmental and functional relationships
    c) protecting elective activity from disruption by emergencies
    d) improving patient flows
    e) improving access to diagnostic services such as laboratory and imaging services

This will allow the Board to continue to meet the Government HEAT targets and increase the ability to meet future waiting time guarantees for 2015.

- Implementation of the 'Healthcare Quality Strategy for NHS Scotland' guidance by providing a clean and safe environment with reduction in Hospital Acquired Infection. 100% single rooms in adult wards will afford patients greater privacy and dignity and improve private communication between staff and patients about diagnosis and treatment
- Fit for purpose hospitals providing a pleasant healing environment
- Enhanced staff skills and knowledge with improved recruitment and retention due to a radically better working environment
- Enhanced University links through co-location of University and NHS Staff within the new hospitals on the Southern General Campus. This will enhance teaching and research and will play a significant role in attracting and retaining high quality staff in all disciplines
- Reduction in carbon emissions and achievement of BREEAM ''Excellent Status'' for the new hospitals
- Contributing to the regeneration of the South West Glasgow community and beyond offering opportunities for local businesses and jobs

The Economic Case

To ensure that the project continues to provide the Board with optimum value for money the original options considered at the Outline Business Case were reconsidered and it was confirmed that the proposal for new Adult and Children's Hospitals at the Southern General site, with the retention of some existing buildings e.g. Neurosciences and Maternity, remains the preferred option.

The OBC also considered three potential procurement routes, i.e. traditional procurement, Private Finance Initiative (PFI) and Not for Profit Distribution Model (NPD). The NPD model provides for the redistribution to the Board of any excess profit which may arise in the form of a "charitable surplus".

In conjunction with the Board's Financial Advisors the three procurement routes were retested and it was confirmed that the traditional procurement route represents substantially better value for money than both the PFI and NPD options.

Commercial Case

As an outcome of the tender competition and procurement administered by the Board, all key commercial aspects of the project are clearly defined and have been agreed between the Board and the Contractor. These include scope and coverage of the specification requirement for the hospitals (from both a clinical and technical perspective), how risk is managed, the basis for payment for the design and construction services that have been purchased, the form of contract (including therefore the rights and obligations of the parties), and the timetable for the construction of the new facilities.

Financial Case

The capital and revenue requirements of the project have been fully reviewed in order to confirm that the preferred solution continues to be affordable in both capital and revenue terms.

This review concluded that the capital costs, including provision for Value Added Tax at the increased rate of 20% from January 2011, remains affordable. In addition, by proceeding with the project, the Board will achieve net overall recurring savings in excess of £18.2m through enhanced efficiencies.

Consequently the construction of the New Adult and Children's Hospitals is deemed to be affordable in both capital and revenue terms.

Management Case

The project has followed good management processes and has robust risk management and governance structures in place. The governance structure continues to be reviewed and reconfigured in response to the changing needs of the project through each different stage. There is a strict change control mechanism in place, the success of which is demonstrated by the cost of the project remaining stable since contract award in December 2009. The project is subject to regular external audit and there is close liaison with the Scottish Government regarding direction and progress of the project.

Stage 2 Design Work Undertaken

Pre-contract, over 70 user groups were involved in the development of the schedules of accommodation, clinical output specifications, identification of key critical co-locations and, for the podium specialties, development of exemplar drawings. Following award of the contract the user groups have been working closely with the Project Team and Contractor's architectural team to develop the detailed 1:200 layouts of their departments and 1:50 typical room drawings.

Full size mock-ups of an adult bedroom and en-suite, child's bedroom and en-suite with staff touchdown and a critical care space were built to assist users in developing the individual room layouts (1:50 drawings). This has proved to be extremely helpful in progressing the design.

The new hospitals incorporate state of the art design and equipment with a range of innovative features including the use of automated guided vehicles to provide transportation of catering and supplies around the hospital, advanced Information Technology supporting a paper-lite environment, a roof top helipad, a high tech Building Management System, in-built resilience and a range of low to zero carbon technologies.

The Board are taking cognisance of the Government's sustainability agenda and have been working in association with the Carbon Trust and Sustainability Glasgow to achieve substantial reductions in carbon output and obtain "Excellent" BREEAM Assessment rating for the new hospitals.

Planning Consent

In June 2010 planning consent was granted for the Masterplan Matters Specified in Conditions (MSC) application, based on the BCL scheme.

Planning approval for the design of the Adult and Children's Hospitals was given on 19th October 2010.

Community Economic Benefits

In order to realise potential regeneration opportunities to South West Glasgow and beyond targets were set in the contract to support local recruitment and Small /Medium Enterprises (SME's) and Social Enterprises (SE).

In brief 10% of recruits are to be new entrants and BCL are working in partnership with Glasgow South West Regeneration Agency and Glasgow City Council training and supporting local businesses to tender for work on the project.

Outcome of Gateway 3

A Gateway 3 Review was undertaken by the Scottish Government Gateway Review Team between 4th-6th October 2010. The project was awarded a green level of Delivery Confidence Assessment, defined as:- "successful delivery of the project/programme to time cost and quality appears highly likely and there are no major outstanding issues at this stage that appear to threaten delivery significantly."

The Gateway report is very positive and recommends that the project should develop a case study of the procurement approach (so this could be shared with other NHS and Government organisations). There are two actions highlighted to be completed before the next gateway review and these are to add some indirect risks (e.g. political risks) to the risk register and continue to develop the benefits management plan to define targets and gather baseline data.

Timetable

A summary timetable for the project is shown below.

Event	Milestone
Stage 2 completion, Full Business Case (FBC) approval by Health Board	26 October 2010
FBC considered by Scottish Government Capital Investment group	November 2010
Stage 3 (Construction of adult and children's hospitals) programmed to commence	November 2010
Stage 1 Completion (Construction) - laboratory facilities	March 2012
Stage 3 Completion (Construction) – adult and children's hospital	January 2015
Operational Date – adult and children's hospital complete service transfers.	Summer 2015
Stage 3a completion, demolition of surgical block and completion of landscaping	Summer 2016

LAYOUT OF THE DOCUMENT

The layout of this business case is summarised below:

Full Business Case – Structure & Content	
Chapter 1:	Executive Summary
Chapter 2:	The Strategic Case This chapter provides an overview of: • the organisation, NHS GG&C • the children's hospital - the current service and business needs and provides a description of the future requirements and redesign work • the adult hospital – business needs, future service requirements, the bed modelling, and redesign work undertaken • Investment Objectives and Benefits Criteria • the strategic risks facing the project and • constraints and dependencies
Chapter 3:	The Economic Case Revisits and revalidates the previous data in relation to options, calculations and selection of the preferred option.
Chapter 4:	The Commercial Case Details the agreed scope and services, allocation of risk, key contractual arrangements, timescales for delivery, and identifies accountancy treatment.
Chapter 5:	The Financial Case Examines the capital requirement, impact on the balance sheet and income & expenditure account, and any other costs or comments on the overall affordability.
Chapter 6:	The Management Case Demonstrates the approach to procurement, project management, risk management, benefits realisation, post project evaluation and the project timetable.

CHAPTER 2

THE STRATEGIC CASE

CHAPTER 2 - THE STRATEGIC CASE

2A. STRATEGIC CONTEXT

The main objective of NHS GG&C's strategy to modernise services, the Acute Services Review (ASR), is to address the mounting pressures to change the way in which services are delivered by reducing the number of acute sites across Glasgow and investing in fit for purpose facilities.

The new South Glasgow Hospitals comprise the major part of the plans to reconfigure services by reducing the adult inpatient sites from the current six hospital sites to three from 2015. Two sites, Glasgow Royal Infirmary and the new South Glasgow Hospitals, will have A&E and trauma facilities. The third inpatient hospital for Glasgow will be Gartnavel General Hospital. These acute sites will be supported by the two new build Ambulatory Care Hospitals which opened in 2009.

The construction of the new South Glasgow Hospitals provides the opportunity to redesign the way in which health services are delivered and reappraise the skills and profile of the workforce tailoring delivery of modern health services in keeping with the 21st century. The development also has the potential to regenerate and breathe new life into Govan and the wider area.

This chapter of the Full Business Case gives an overview of the organisation, its business aims and objectives and then identifies the strategic case for the new hospitals (adult and children's hospitals separately to allow their distinct and unique aspects to be clearly described). The investment objectives and benefits are highlighted as well as strategic risks and constraints to the scheme that exist.

2B. ORGANISATIONAL OVERVIEW

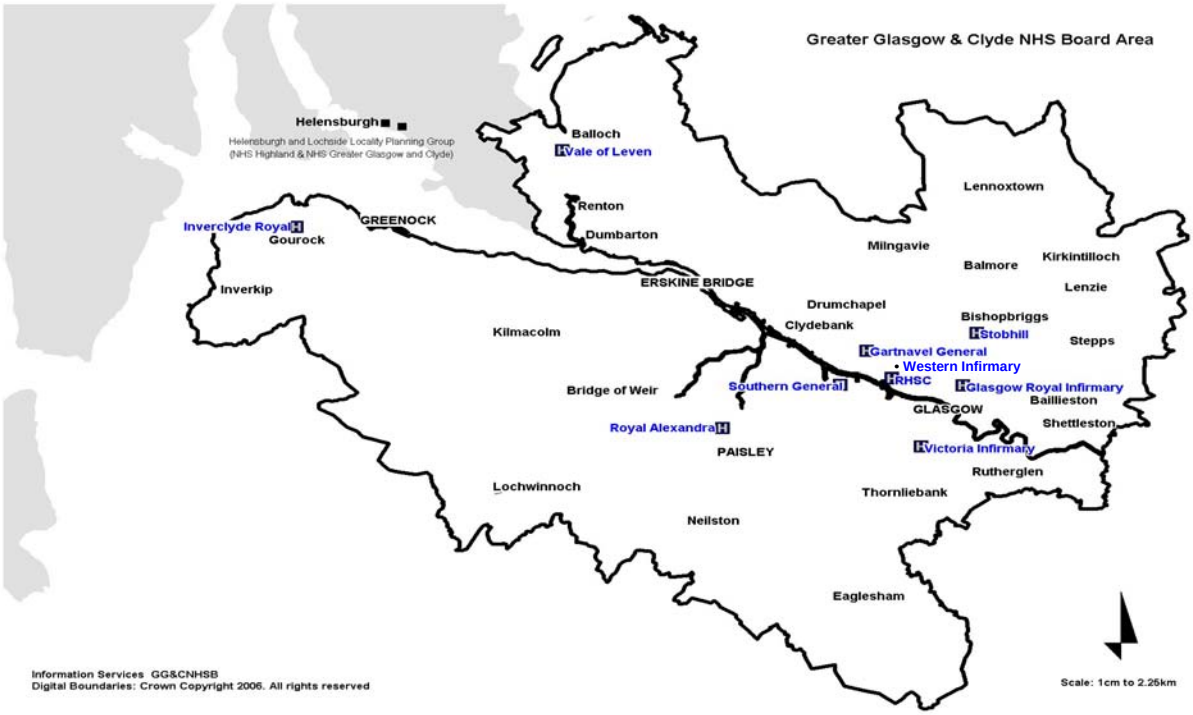
NHS GG&C, formed in April 2006, has 44,000 staff (with over 26,000 wte within the Acute Division) and serves a total population of 1.2million people, with an annual budget of £2.7 billion.

Acute services are delivered from 10 hospitals, 3 lie within the Clyde area and the remaining 7 are located within Glasgow City.

Within Glasgow, the Western Infirmary and Gartnavel General Hospitals operate in tandem delivering acute care in the west of the city. In the north and east of the city acute care is delivered from Stobhill Hospital and Glasgow Royal Infirmary. The Victoria Infirmary serves the south-east and the Southern General Hospital the south-west of the city. Services for children are provided centrally from the Royal Hospital for Sick Children, Yorkhill. Full adult Accident and Emergency (A&E) services are provided at the Western Infirmary, Glasgow Royal Infirmary, the Victoria Infirmary and the Southern General Hospital.

Stobhill Hospital has a casualty department which is covered by consultant staff from Glasgow Royal Infirmary and the Western Infirmary.

The location of these acute hospitals can be seen the in diagram below.



2B.1 Organisational Structure

NHS GG&C is comprised of an Acute Division, a Mental Health Partnership and 10 CHCPs/CHPs.

The Acute Division brings together all acute services across the City of Glasgow and Clyde under a single management structure led by the Chief Operating Officer (COO). The Division is made up of six directorates of clinical services each managed by a director and clinical management team supported by the Facilities Directorate. These are:

- Diagnostics
- Emergency Care and Medical Services (ECMS)
- Regional Services
- Rehabilitation
- Surgery and Anaesthetics
- Women's and Children's Services

2B.1.1 *Services and Activity*

The Acute Division of NHS GG&C provides a comprehensive range of services from community based care (midwives, dental services and various outreach services) in addition to the full range of general hospital services. The organisation also hosts some of the most specialised health services in the country, including: the new West of Scotland Cancer Care Centre on the Gartnavel General Hospital site, the Institute of Neurological Sciences at the Southern General Hospital campus, renal and bone marrow transplant services in addition to world-class specialist paediatrics and obstetric services.

In 2009/10 there were 269,987 inpatient, 146,972 day cases and 422,552 new outpatient attendances in Glasgow acute adult hospitals. Over 80% of this activity was attributable to residents of the NHS GG&C area.

In 2009/10 the following 0-15 year old patient activity was seen within NHS GG&C's hospitals; 19,550 inpatients, 10,370 day cases and 32,630 new outpatient attendances. Sixty four percent of this activity was attributable to NHS GG&C residents, with thirty six percent outwith the Health Board reflecting the specialist tertiary nature of Royal Hospital for Sick Children Services.

Further details of the breakdown of both adult and paediatric patient activity seen within Glasgow Acute Hospitals by Health Board of patient residence in 2009/10 is shown in Appendix A.

2.B.1.2 *Demography & Health Status*

The mid-year population estimate for NHS GG&C as of 30 June 2009 was 1,199,026. This makes NHS GG&C the largest health board in Scotland. The size and complexity of NHS GG&C pose unequalled management and service provision challenges. The social deprivation for which Glasgow is well known poses considerable further demands on health and social services. Further details of this are given in Appendix B.

2C. BUSINESS AIMS OF NHS GREATER GLASGOW AND CLYDE

NHS GG&C aims to ensure that the health needs of the local population are met, and national government targets and directives are implemented. In order to achieve safe, sustainable and equitable treatment for patients the Board's aims are:

- To achieve gold standard services through the triple co-location of Adult, Children's and maternity services onto a single site

- To provide facilities with capacity and capability to facilitate modern healthcare with flexibility to adapt to future requirements underpinned by effective use of technology

- To increase efficiency and productivity by –

    - reducing the number of acute adult hospital sites across Glasgow
    - centralising specialist services
    - investing in fit for purpose facilities with optimum co-locations and improved information technology.

These aims form the basis of the Investment Objectives and also reflect the benefits which are anticipated from the project.

2D. OTHER ORGANISATIONAL STRATEGIES

Health Information Systems and the underpinning Information Technologies will be key to successful clinical service delivery in the new hospitals.

NHS GG&C has developed a clear vision for HI&T (Health Information and Technology):

> ***"To enable a safe, high quality, equitable and efficient health system for the citizens of NHS GG&C - by transforming the way information is delivered, utilised and shared to plan, manage and provide patient care."***

This vision will be delivered through 6 core programmes, defined by the benefits they bring to patients, clinicians and other staff,

- Electronic Patient Record (EPR) – Clinical Portal / Paperlite
- Implementation of the Patient Management System (PMS)
- Acute Services Review (ASR) – including the new South Glasgow Hospitals and new laboratory facility
- Primary and Community Care – General Practice Systems
- Business Reporting
- Infrastructure Development

Whilst the drivers for these programmes are broader than the new hospitals, they will deliver in timescales that allow service change to be embedded into every day clinical practice before services move into the new buildings.

Further major change programmes will build on these core programmes and facilitate enhanced service provision across clinical specialties.

Key drivers for the core HI&T programme include:

- Requirement for information to be gathered and shared quickly and effectively to support complex modern care; the existing combination of paper and electronic systems that are not linked do not readily support this

- Availability of Information and Communication Technology (ICT) based tools; help clinicians to ensure that all patients receive appropriate, safe, secure health care and good-quality service

- Requirement to have single system working across organisational boundaries and multi-disciplinary areas

- Efficiency savings – NHS GG&C must maximise benefits from resources and investments

- Need to standardise the HI&T estate by reducing the number of applications and interfaces

The delivery of the planned programmes will therefore provide the information and tools to allow clinicians to work efficiently in a paperlite environment before they move into the new hospitals.

2D.1 Specific HI&T Requirements for New Hospitals

The NHS GG& C HI&T Strategy will deliver core programmes that will underpin the move to the new hospitals. The core programmes will identify and deliver both requirements that are specific to the new hospitals and act as a catalyst for health services across NHS GG&C. The new hospitals will also benefit from any new strategic HI&T priorities that are developed over the next 5 years.

The key areas of HI&T that are specific to the new hospitals are:

- the technical infrastructure
- equipment
- standardised systems
- transition

HI&T will also work with the service over the next 5 years to identify any further opportunities to improve patient care and deliver efficiencies through use of technology.

In terms of technical infrastructure the new hospitals will require a high speed resilient network with wireless capability available throughout to support new ways of accessing and sharing data.

The NHS GG&C current standard for new builds is I/P telephony and the network will be designed to enable this service. The network will also have the capability to support non-clinical services such as Building Management Systems and CCTV.

Description of the following sections 2E and 2F

For ease of understanding the following sections of this document describe separately the issues surrounding the children's hospital and then the adult hospital. The next section, 2E describes the children's hospital section 2F details the adult hospital.

2E. CHILDREN'S HOSPITAL (THE STRATEGIC CASE)

This section describes the following aspects of the new children's hospital scheme:

- The case for change and the future strategy for delivery of services
- A description of the current services
- A description of the future service requirements

The benefits that the scheme will deliver:

2E.1 Case For Change And Future Strategy

Children's hospital services are currently provided by the existing Royal Hospital for Sick Children (RHSC) which is sited at Yorkhill. In 2004 the Minister for Health and Community Care announced that the Scottish Government would provide funding to enable a new children's hospital to be built on a site which would support the "triple co-location of services". Following an option appraisal in 2005, of potential locations for the new children's hospital, the Southern General site was identified as the only location to offer both co-location with maternity and adult services and appropriate vacant land for building. This process was undertaken in collaboration with a Ministerial Advisory Group chaired by Professor Andrew Calder. The report of that Group, published in March 2006, affirmed the selection of the Southern General site as the location for the new children's hospital. This recommendation was accepted by the Minister for Health and Community Care in 2006 following a period of consultation.

In 2009, the maternity services provided at the Queen Mother's (Maternity) Hospital (QMH) adjacent to the Children's Hospital transferred to the Southern General Hospital campus as part of the implementation of the ASR in preparation for the subsequent transfer of services from RHSC onto the Southern Site.

As a result maternity and neonatal services are no longer co-located. The Regional Medical Genetics Service, which provides services to children, young people and adults remains on the Yorkhill site until it also transfers to the new laboratory build on the Southern General Campus.

2E.1.1 *Neonatal Transition Arrangements During Gap Period*

NHS GG&C has centralised all compromised neonates linked to Queen Mother's Hospital foetal medicine service to be born at the Southern General Maternity Hospital. To support the interface between this hospital and the RHSC Neonatal Intensive Care (NICU) a number of clinical pathways have been agreed. These include newborns with cardiac problems, complex airway anomalies, diaphragmatic hernia and abdominal wall defects, and these pathways are supported by the West of Scotland Neonatal Transport Service and the Scottish Ambulance Service.

Babies requiring surgery/complex tertiary medical care are managed in the RHSC NICU and then transferred back to their local neonatal unit across the West of Scotland Boards and indeed nationally in some instances. For Glasgow and Clyde surgical/ complex medical babies this could be the Southern General Maternity, Princess Royal Maternity and Royal Alexandria Hospital. RHSC paediatric teams continue to support foetal medicine counselling to mothers and families at the Southern General Maternity since closure of Queen Mother's Hospital.

NHS GG&C has set up a monthly transition group to review all clinical adjacencies between the Southern General Maternity neonatal and foetal medicine services, RHSC NICU and neonatal transport and Scottish Ambulance Service. This will include compliance and outcome measurement of babies and mothers using these established clinical pathways. From 1st April to 31st March each year there will be a 6 monthly and annual review of service. Individual cases can be referred by specialties for exceptional review through the monthly transition group. No cases have been referred to date by any specialty. This transition group is represented by a wide variety of senior medical staff from neonatology, neonatal surgery, ENT surgery, foetal medicine, radiology, cardiology and medical paediatric sub specialties including intensive care. It is also represented by senior nursing and the neonatal transport team.

The rationale for transferring Yorkhill services to the Southern General Hospital campus was explained at length in the Outline Business Case and agreed after consultation in 2004 and an 'options appraisal' to determine the optimal site in 2005. In essence, co-location of maternity and paediatric services provides 'gold standard' and seamless care for the foetus and the new born baby.

As described in the Outline Business Case, transfer of children's hospital services to the Southern General Hospital campus will also align some other key services to confer significant additional benefits:

- Provide enhanced and age-appropriate services for adolescents and young people, including easier 'shared care' arrangements between adult and paediatric staff

- Support collaboration between paediatric and adult specialties to support 'transition' from children's to adult services for those young people with long-term conditions for whom the transition from paediatric to adult services is often a very unsettling and clinically disruptive period

- Strengthen clinical links between paediatric and adult services. This is particularly important for specialties with only a small paediatric component (such as gynaecology) and for conditions in which training in adult practice is especially relevant (for example, some post-pubertal fractures)

- Co-location of childrens and adult neurosurgical services, will, for the first time in Glasgow, offer neurosurgical care in the context of a full complement of paediatric medical, surgical and intensive care expertise

2.E.2 Description Of The Current Services

The RHSC in Glasgow is Scotland's largest children's hospital and it provides a comprehensive range of secondary care locally and specialist services to the West of Scotland Region and the rest of Scotland.

Annual activity for 2009-2010 comprised:

- Out-patient attendances: 20,307 (New)
- Inpatient admissions 16,751
- Day Cases 9,822
- Emergency department attendances 40,000

In NHS GG&C, the RHSC essentially provides all inpatient care for children up to their 13th birthday (with the exception of most paediatric neurosurgery). The majority of young people aged 13 - 15 years receiving secondary care, however, are currently managed within adult hospital services. As discussed in the Outline Business Case, this is no longer considered appropriate and in the future, all young people aged up to the 16th birthday (and some aged 16 or 17) in Scotland will be cared for in children's hospitals with the emphasis on providing service and facilities that are appropriate for their age and maturity. This will result in an increase in overall activity in the new children's hospital of 5 – 10%. However, for some specialties (for example, orthopaedic trauma) the impact will be much greater.

In addition to the RHSC, Accident and Emergency (A&E) services for children aged 1 – 12 years continue to be provided at all the city's current A&E Departments (excluding the Western Infirmary) and the minor injuries Units at the Victoria and Stobhill Hospitals. Within the constraints of the current hospital at Yorkhill, centralisation of all emergency services for children and young people, whilst desirable, is not possible. However, all babies younger than 12 months are seen in the RHSC and there is an agreement with the Scottish Ambulance Service that, in the near future, all children younger than 13 years *'in extremis'* will be brought straight to the RHSC. It is also likely that, in the

future, the city's minor injuries units will continue to manage children, in line with the ethos of *'providing care as locally as possible'*.

The majority of paediatric outpatient activity takes place at the RHSC although there are close links with Community Health and Care Partnerships (CHCPs) and some work is carried out in Child Development Centres. A small number of children are seen in other hospitals (e.g. orthoptics, gait analysis). In considering local hospital services, it is important to remember that, as shown in the 2001 census, 25% of the children in the NHS GG&C area live in areas characterised by maximum deprivation ('Depcat 7'). This concentration of deprivation is not replicated elsewhere in the UK and impacts on both the pattern and the incidence of disease as well as aspects of service use.

The RHSC also supports the full range of specialist regional paediatric services comparable with those provided in an adult teaching hospital. These include cardiology, haemato-oncology, neurology, rheumatology, specialist surgical services, diabetes & endocrinology, burns, chronic pain and many others. Due to the specialist nature of these services and the long-term care required, patients frequently remain under the care of RHSC at least until they are 16 (or even older, if appropriate). These specialist services are accessed from across the West of Scotland and work in collaboration with, and in support of, the services provided by local paediatric units in district general hospitals. The Yorkhill campus also hosts the regional Medical Genetics Service. To maintain close links with paediatrics, this service will also relocate to the Southern General site as part of the new labs development.

In addition to these regional services, the RHSC hosts a number of specialties designated as national services and for which, in most cases, it is the sole provider in Scotland:

- Kidney transplantation
- Bone marrow transplantation
- Cardiac surgery
- Interventional cardiology
- Extra corporeal life support (for respiratory failure, this is delivered in collaboration with only three other UK centres)
- Paediatric intensive care transport (shared service with Edinburgh)
- Paediatric intensive care (from April 2007 – shared service with Edinburgh)
- Complex airways surgery
- Endoprosthetic bone replacement
- Vein of Galen aneurysm (a UK service shared with the Great Ormond Street Hospital for Children)
- In-patient child psychiatry
- Brachial plexus palsy
- Cleft lip and palate (shared service with Edinburgh / Aberdeen)

The role played by RHSC in the delivery and support of these regional and national services is reflected in the fact that more than half of the total inpatient activity is accounted for by patients beyond NHS GG&C.

2.E.3 Description Of Future Service Requirements

Relocation of the RHSC to the Southern General Hospital campus will not fundamentally change the role of the hospital to provide local, regional and national services. The future service will therefore closely mirror the current activity of all young people from Glasgow aged 13 up to 16 years, and some others aged 16 to 18 years, accessing secondary, specialist care and neurosurgical procedures. Psychiatric services for 13 - 15 years and obstetric patients will be treated elsewhere.

The increase in the upper age limit for admission equates to 2795 inpatient episodes, 545 day cases and 9992 new outpatient attendances each year (2009-10 activity). Neurosurgical activity equates to 297 admissions and 1,650 bed days annually for patients aged 0 - 15 years. The children's hospital will remain the main provider of specialist care for the West of Scotland, although there may be some scope for shared care with district general paediatric units so that at least some care can be delivered nearer home (i.e. *'as locally as possible'*). The growing Managed Clinical Networks (MCNs) are very important in supporting this. However, a number of drivers that affect the sustainability of district general paediatric services and arguments for increased specialist input into care, have tended in the past to increase inward referrals. There is no immediate evidence that this trend will not persist.

As explained in the Outline Business Case, children's neurosurgical services nationally are under review and there is still no decision on their future configuration. Clearly, this may lead to realignment of some of the services provided by the specialist children's hospital services (Glasgow, Edinburgh, Aberdeen, Dundee) with an impact on future activity in Glasgow.

The review of children's cancer services, linked to the National Delivery Plan, has now concluded. In the future, Scotland will function with two Level 4 services (of which one will be in Glasgow) supported by a MCN with no anticipated change in the requirement for beds at the new children's hospital.

In considering future service requirements, it is important to note that, for many hospital services, the RHSC in Glasgow is the sole provider either at a local or regional level (and for some cases nationally) and these are underpinned by range of specialties / disciplines It is vital therefore, to ensure that the accommodation and services provided in the new hospital are capable of maintaining activity levels commensurate with clinical demand and of coping with anticipated periods of peak activity.

2E.3.1 *Bed Model*

The proposed number of beds for the new children's hospital is 256. This number is based upon:

- Hospital activity data for patient flow into RHSC aged 0 – 15 years
- Comparison of average length of stay with comparable UK institutions
- Occupancy rates of 85% for elective work and 65% for non-elective work
- Transfer of all neurosurgical activity in patients aged up to 15 years from the Institute of Neurological Sciences
- Predictions for demographic changes

The model excludes young obstetric and adolescent psychiatric patients (who will be accommodated elsewhere) and secondary care activity in Clyde. The 256 beds comprise:

<u>207 in-patient beds</u>:

• Neonatal surgical cots in the Maternity Hospital	12
• Cardiology	14
• Haemato-oncology (including 4 Teenage Cancer Trust beds)	26
• Psychiatry	6
• Combined medical and surgical acute receiving unit	40
• Medical and surgical wards	72
• Intensive care / high dependency care	22
• 23 hour beds[1]	15

<u>49 day case / ambulatory care beds</u>:

• Observation ward	20
• Day surgery[1]	15
• Day case oncology	4
• Medical investigation unit	10

This number of beds is an increase on that submitted for the Outline Business Case, largely because of revised predictions for demographic change (see Appendix C) *'Bed complement for the New Children's Hospital. Review of planning assumptions'*). In order to provide a combined neonatal medical and surgical service serving both the maternity and children's hospitals, twelve of the 256 beds (the neonatal surgical cots) will be accommodated within the redeveloped maternity / neonatal building on the Southern General site to which the NCH will be immediately juxtaposed. These cots will be accessed by neonatal surgical patients currently cared for in RHSC.

[1] A total of 30 beds to be used flexibly for day surgery and 23-hour stay

The estimates for hospital activity also anticipate about 60,000 attendances at the A&E Department each year, depending upon the number of children and young people attending Minor Injuries Units.

2E.3.2 *Service Re-design*

The proposed overall reduction in beds and shift to day and short stay care needs to be accompanied by significant re-configuration of patient pathways and service delivery. Service re-design is already well embedded within the operational activities of the Women's and Children's Directorate. The aim is to ensure that optimal service models are implemented and tested before transfer to the new hospital.

A number of reviews are already complete, with the recommendations being implemented within the physical limitations of the current hospital:

- The *'Redesign of elective surgical and anaesthetic services'*. Surgical Short Stay Group (2008)

- A *'Rapid improvement event for theatres'* to review operating department processes and improve efficiency by adopting 'lean processes' (2009)

- *'Design of Front Door and Acute Receiving Services'*. Front Door Sub-group (2009)

Recent developments that will improve the quality of clinical care, reduce the length of stay, improve the utilization of resources and / or support more sustainable workforce models (including Hospital at Night) are:

- Day-case tonsillectomy
- Elective operating lists on Saturdays (ENT and general surgery)
- All day theatre lists and extended working (08:45 – 17:30 from 2010 compared with 09:00 – 16:30 in 2009)
- Day-case, rather than inpatient, diagnostic cardiac catheters as routine and pre-operative assessment for all patients undergoing cardiac surgery / catheterization
- Planned expansion of general pre-operative assessment services to all patients having elective surgery / anaesthesia (admission on the day of surgery to become the norm for all patients); development of an e-form for elective surgery / anaesthesia
- Integration of the Medical Assessment Unit and the A&E Department with a common workforce and shared rotas; common assessment framework for those attending the A&E Department with all patients managed according to their triage category rather than route of referral; transfer of initial management / observation of some surgical conditions to emergency care physicians (for example, minor head injuries)

- In anticipation of the model of care in the generic wards of the NCH, alignment of related medical and surgical specialties including co-location of gastro-intestinal medicine with general surgery (inpatient beds), complex airway surgery with respiratory medicine and cardiology / cardiac surgery (inpatient beds; pending) and renal medicine with urology (inpatient beds and outpatient clinics)
- Centralised height and weight facility in the Outpatient Department, releasing rooms for consultation / examination; revised clinic schedule so that the same specialty is accommodated in the same rooms throughout the day to avoid overruns impacting on other services
- Extended working day in diagnostic imaging and routine MR imaging at weekends; development of strategies to reduce the need for general anaesthesia in children (MR compatible video player as distraction) and infants (late evening scans after 'feed and sleep')
- Rationalisation of ward accommodation
- A new 'drop in' diabetes facility
- A joint base for paediatric and neonatal transport service has been established at the RHSC, with specialist ambulances interchangeable between the two services. The paediatric and adult Emergency Medicine Retrieval Services have undertaken joint missions in support of critically ill children in remote and rural locations.

Policies / practice under review to further reduce length of stay or follow up are:

- Minimum acceptable age and maximum acceptable distance to travel after day surgery
- Criteria for day case surgery / anaesthesia, including review of the management of diabetic patients
- Rationalisation of routine follow up after surgery
- Care pathway for patients with abdominal pain and the planned transfer of initial management from general paediatric surgeons to emergency department physicians

Planned future developments at the RHSC before move to the Southern General campus are:

- Establishment of a 23-hour surgical short stay ward (effectively extended day surgery)
- Pilot of extended working in the outpatient department (three sessions rather than the previous two)
- Establishing a joint medical and surgical Acute Receiving Unit across two wards on a single floor of the tower block, which would also free up space adjacent to the current A&E Department (see below)
- Expansion of the A&E Department with clear segregation of patients according to category of illness / injury (resuscitation, major, minor, 'see and treat') and provision of an observation ward

The Directorate is also collaborating with regional planners (for example, through the Regional Acute Paediatric Clinical Redesign Interface Group) and other West of Scotland Health Boards in order to identify and accommodate any anticipated changes in service that would impact on the future role and contribution of the Royal Hospital for Sick Children. Clearly, unidentified changes in provision elsewhere would impact on capacity in the new children's hospital.

2E.3.3 *Building The Capability To Deliver High Dependency Care Throughout The Hospital*

A high proportion of acute and specialist paediatric inpatient care can be defined as 'high dependency' (according to the national audit of paediatric high dependency care). In the RHSC currently, the greater part of this is provided across acute and specialist inpatient areas. In the new children's hospital, there will be clear separation of patient pathways according to illness severity and elective versus emergency care.

Most elective surgery will be managed, for example, through the combined day surgery / 23-hour unit and generally inpatients in ordinary wards elsewhere will be sicker than currently. This will mean 'high dependency care' being delivered more widely throughout the hospital. The critical care service is already committed to developing this capability before the move to the Southern General Hospital campus, building flexible and tiered high dependency care everywhere.

The current High Dependency Care Unit is integrated with the Paediatric Intensive Care Unit and is orientated towards intensive care 'step down' and post-operative care. It also supports intensive care capacity during peak periods of activity, especially during the winter. Care in other areas is supported by mobile and flexible support from the critical care service in conjunction with assessment and observation tools such as the Children's Early Warning Score system.

2E.4 The Benefits That The Scheme Will Deliver

The benefits of the scheme are categorised below under the four headings:

- Clinical effectiveness and patient safety
- Facilities that are 'fit for purpose'
- Positive impact for staff
- Maintaining and enhancing academic links

2.E.4.1 *Clinical Effectiveness And Patient Safety*

Fundamental to the rationale for locating the new children's hospital at the Southern General Hospital campus is the wish to achieve the clinical benefits of co-location with adult and, in particular, maternity services.

2E.4.1.1 Co-location of children's and maternity services and integration of medical and surgical neonatal care

Restoring the geographical links between maternity and paediatric facilities, such as existed previously at Yorkhill, will further facilitate the multi-disciplinary care of the high risk foetus and new-born baby. This care includes diagnosis, advice and intra-uterine management for the foetus with significant abnormalities, the appropriate management of labour and prompt intervention for newborns with serious abnormalities.

Co-location allows immediate access to all the relevant staff and clinical facilities whilst avoiding; transfer across the city, interventions by clinical teams working in an isolated site or inappropriate separation from the mother. This is particularly relevant to life-saving *'exit procedures'* that require immediate attendance by a multi-professional team of specialists such as paediatric surgeons, anaesthetists and neonatologists.

Co-location with other adult services, notably critical care, will additionally ensure that mothers with co-morbidity or pregnancy-related complications obtain the highest standard of appropriate clinical care in a timely manner.

Over recent years, the surgical neonatal critical care unit at Yorkhill has changed from a unit run entirely by paediatric general surgeons to one staffed jointly by them and neonatologists. Both bring their specialist skills and knowledge to this very vulnerable group of patients. In parallel, the nurse workforce has changed and now includes midwives trained in neonatal care as well as paediatric nurses.

The anticipated transfer of children's hospital services will fully integrate surgical and medical neonatal care within a purpose built facility on the Southern General campus to further strengthen these developing professional relationships to the benefit of patients and support a sustainable workforce model.

2E.4.1.2 Neurosurgery

Currently, the children's neurosurgical service in Glasgow, with the exception of neonatal surgery and some ventriculo-peritoneal shunts, is provided at the Institute of Neurological Sciences on the Southern General Hospital campus. Whilst this service is now supported by paediatric neurologists and anaesthetists, with input from paediatric intensive care staff, many important components of a comprehensive paediatric service are not immediately available on the Southern General Hospital site. This includes, for example, general paediatrics, neurology, paediatric rehabilitation medicine and oncology.

There would be significant clinical advantages to all these services being on the same site. Co-location of the children's hospital with the Institute of Neurological Sciences would also help sustain staff rotas and facilitate further professional collaboration between neurosurgical and other specialist paediatric staff.

2E.4.1.3 Young people

In the RHSC young people commonly share ward facilities with small children or babies and in adult hospitals, they share facilities with older adults/the elderly. Neither scenario is appropriate, and each fails to recognise either the vulnerabilities or the physical, emotional, social and behavioural needs of young people.

The new children's hospital provides an exciting opportunity for the first time in Glasgow to provide age-appropriate and needs-appropriate facilities and services for those aged up to the 16th birthday in line with the recommendations of the Age Appropriate Care Working Group (National Steering Group for Specialist Children's Services, 2008).

Whilst clinical staff have concluded that the safest model of care is for young people to be managed on specialist wards, rather than a multi-specialty adolescent unit, the configuration of beds, with a high proportion of single bedrooms, will ensure them privacy whilst providing opportunity to configure their personal space appropriately. As discussed in the Outline Business Case, co-location with adult services will more effectively support shared arrangements between adult and children's service with patients easily able to access the most appropriate clinical teams and facilitate smoother transition from children's to adult services for those with long term, chronic conditions.

In the proposed design for the new children's hospital, special consideration has been given to young people's social needs for example, through the facilities funded by the Teenage Cancer Trust on the haemato-oncology ward, dedicated social space on the third floor and separate waiting facilities within the same-day admission unit and outpatient department. The proposed information technology (IT) strategy, with personal entertainment consoles at each bed-space, will also help maintain important social and educational networks through the internet during episodes of inpatient care.

2E.4.1.4 Maximising resources

Hospital buildings and equipment are expensive. In order to maximise use of these resources, departments such as outpatients and theatres are already planning to extend their normal working hours with the aim of running from 08:30 – 18:00 (theatres) and 09:00 – 19:00 (outpatients).

The ergonomic design of the new children's hospital will further support efficiencies and flexibility through the internal co-location of key departments, separation of patient flows and the greater provision of single bedrooms (see below):

(a) Internal co-location of key departments

The new children's hospital project team and clinical staff have critically reviewed and realigned the adjacencies of key departments to improve safety, efficiency and the ergonomics of the patient journey. For example, in the new hospital:

- The general anaesthetic imaging facilities are integrated into the operating department. This enhances patient safety by minimising journey times for patients undergoing diagnostic imaging and surgery under one general anaesthetic, avoids the hazards of working in isolated sites and improves patient turn-over by the use of a well-staffed and centralised recovery ward
- In-patient beds for neurosurgery will be co-located with those for neurology to provide an integrated neuroscience service
- The A&E departments for adults and children are co-located to minimise the risk of ambulances and public attending the wrong site and support collaboration between clinical staff from both services in the event of a major incident

(b) Separation of emergency from planned care

Currently, many clinical areas in the RHSC manage both elective and emergency patients and a wide range of illness severity and lengths of stay. This mixing of patient types hinders the delivery of well-structured care and causes 'bottle-necks' and inefficiencies. Two of the key principles in designing the new children's hospital have been to review departmental layouts, critical adjacencies and the configuration of hospital services to separate and optimise different 'patient journeys and match staffing arrangements with clinical need. For example, in the new children's hospital:

- Most patients will be admitted on the day of surgery through a 'same day admission unit' co-located with the operating department and integrated day surgery/23-hour unit. This will effectively separate emergency from elective flows, reduce unnecessary admission to hospital and minimise journey times to theatre
- Post-operatively, most patients having elective procedures under general anaesthesia will be managed through the integrated day surgery/23-hour unit, clearly segregating them from those undergoing major procedures or with complex co-morbidity, who will be cared for in one of the generic wards
- Those wards with the greatest requirement for support from medical staff out-of-hours (haemato-oncology; acute medical and surgical receiving wards) will be co-located with the 'Hospital at Night' base on the same floor
- The design of the A&E Department will allow clear segregation of patients according to the severity of their illness / injury (in *'see and treat'*, minors, majors, resuscitation)

(c) Infection control and efficient use of beds

A significant constraint in the efficient use of beds in the RHSC currently, particularly during the winter with the seasonal rise of RSV bronchiolitis, is the need to isolate patients with infectious diseases in cubicles. The new children's hospital will provide more single bedrooms (> 80% for inpatient beds) than currently, thereby allowing greater flexibility to isolate patients and manage peaks of activity during the winter months. In addition, the new hospital has been designed in accordance with best practice for infection control to minimise hospital acquired infections and the associated risks.

2E.4.1.5 Information Technology

Information technology (IT) plays an increasingly vital role in healthcare by improving communication, supporting safer, more efficient care and providing better information for patients and families.

High quality IT can also support more equitable access to health services and maintain social and educational links for children and young people in hospital. As a tertiary centre, the RHSC has been at the forefront of developing *'telemedicine'*, particularly for remote and rural care, and already provides a telemedicine centre and links from the critical care unit. The new children's hospital offers opportunity to provide these links more widely to support, for example, shared care arrangements and pre-operative assessment of patients from other health boards and ensure that patient transfers are safe and timely. State-of-the-art patient management systems will facilitate good care, minimise risk and ensure efficient working practices.

2E.4.1.6 Centralisation of Children's A&E Department

An additional advantage of a new children's hospital will be the opportunity to centralise emergency care in Glasgow for children up to their 16th birthday and, for the first time, to provide an appropriate environment in which to meet the clinical, developmental, psychological and social needs of young people.

Centralisation will significantly increase overall activity and, although the policy has already been agreed in principle, physical constraints in the current RHSC that cannot be resolved even with significant capital investment, mean that centralisation can only be achieved with relocation. In the new children's hospital, the A&E department has been designed to cope with this additional work, manage peaks of clinical activity and take account of modern clinical practice and optimal patient pathways (including, for example, clear segregation of patients according to the severity of their illness / injury).

To reduce hospital admissions, the A&E department will be supported by a 20-bedded Observation Unit for assessment of minor head injuries, non-specific abdominal pain (both previously under the care of paediatric general surgeons), ingestion of poisons and medical patients.

2E.5 'Fit For Purpose' Facilities

The design of the new children's hospital will support optimal service delivery whilst retaining the flexibility to respond to changes in the technology and models of care in the future. The structure has been designed ergonomically *'around'* the patient pathway to reduce unnecessary journeys (both of staff and patients / families) and hospital admissions.

- Patient pathways have been clearly segregated in the A&E department according to the severity of illness or injury into the category of *'see and treat'*, minor and major injury/illness and resuscitation
- The theatre department is adjacent to both a same-day admissions unit and the integrated day/23-hour surgical unit. For most patients, this avoids admission on the day before surgery, which patients and their parents / carers dislike, and minimises journey times to improve efficiency and reduce *'bottlenecks'*
- The majority of patients having procedures under general anaesthesia will be transferred from theatre to the co-located integrated day / 23-hour surgical unit. Again this reduces journey times, which means safer transfers and fewer *'bottlenecks'*, and allows medical staff to easily review patients between cases
- Close proximity also improves communication between the staff involved in each stage of the patient's journey through admission, operating department, post-operative care and discharge

Relevant departments/services are co-located:

- The operating and general anaesthetic (GA) imaging departments are fully integrated. This enhances patient safety by minimising journey times for patients undergoing diagnostic imaging and surgery under one general anaesthetic, avoids the hazards of working in isolated sites and improves patient turnover by the use of a well-staffed and centralised recovery ward. There are a purpose-built interventional radiology facilities for complex multi-interventional procedures, including surgery
- The A&E department is co-located with diagnostic imaging and immediately beneath the critical care and operating theatres with easy access to both by a dedicated lift
- A&E departments for adults and children are co-located to minimise the risk of ambulances and public attending the wrong site and support collaboration between clinical staff from both services in the event of a major incident. The decontamination unit, which will be used only very rarely, is shared between both departments
- Co-location of interventional cardiology and neurosurgery with the critical care unit will also support improved working efficiencies
- The main block of the current children's hospital at Yorkhill was built in 1970 with amended and additional facilities added subsequently. The design therefore either reflects outdated models of care or the constraints of limited space and operational feasibility. The opportunity to develop a *'fit for purpose'* hospital built around current and anticipated patterns of

patient care and the flexibility to respond to change will offer significant advantages to staff, patients and their families:

- Integrated neonatal medical and surgical services
- Well-structured dedicated 23-hour, day and ambulatory care services
- Appropriate separation of emergency and elective activity and levels of acuity
- In-patient wards configured to support clinical synergies (for example co-location of neurology with neurosurgery and renal medicine with urology) but with the flexibility to manage peaks of activity especially during the winter
- Purpose-built discharge facilities associated with in-patient wards

The ease of movement for staff, patients and their families between related areas of the new children's hospital will have a number of benefits:

- Better, more efficient (and ultimately safer) pathways of care
- Enhanced communication between different teams and stronger professional links
- Improved sustainability of workforce models including staff rotas and the delivery of the *'Hospital at Night'* service
- Better infection control management
- More efficient use of resources

The new children's hospital will also give opportunity to centralise children's emergency care within Glasgow, with an anticipated increase from 40,000 to 60,000 attendances each year. The proposed scheme includes a purpose-built paediatric A&E department designed around best practice and ergonomic patient pathways supported by adjacent and adequately sized short-stay and assessment / observation facilities to minimise hospital admissions.

The planned arrangement of departments within the new hospital supports rapid access to diagnostic imaging and swift transfer to the critical care unit and operating department. As described above, co-location with the adult emergency department and shared emergency ambulance routes reduces confusion, supports joint working in the event of a major incident and provides the opportunity to share facilities that are only extremely rarely used, such as the decontamination unit.

Professionals providing therapy and rehabilitation services, who have traditionally worked in very separate parts of the hospital, will, for the first time, come together in a *'therapies and rehabilitation hub'*. These include physiotherapists, occupational therapists, psychologists, psychiatrists, orthotists, speech and language therapists, dieticians and nurses.

Providing a range of treatments in a single location will help reduce the burden of hospital visits for families by avoiding multiple appointments in different places on different dates and supports multi-disciplinary care through better coordinated treatment and improved communication. This is important for those children and young people with the most complex conditions. The hub

will also provide resources for patient education, such as a therapeutic kitchen. Learning about food, how to cook and how to manage their own diets is a powerful way of empowering young people to become increasingly independent in the face of ongoing illness. For those recovering from life-changing illness, the hub will be a real bridge from hospital into normal life.

Finally, there is evidence that the construction, layout and ambient environment of a hospital influences well-being, clinical outcomes and patient safety. Examples of good design include:

- Ergonomic wards that increase patient contact for nurses
- Single room accommodation with well-positioned and adequate hand-washing facilities to reduce hospital acquired infections
- Good lighting and well-designed facilities that reduce dispensing errors; facilities/pathways that limit patient transfers, improve continuity of care and minimise risk of clinical errors.
- Noise reduction, daylight and views of nature to reduce physiological and psychological stress

The ambient environment can impact positively on clinical outcomes, for example:

- Visual distraction reduces the experience of pain during procedures
- A view of nature (real or simulated) reduces analgesic requirements and length of stay after surgery
- Daylight reduces depression, improves pain control and reduces associated medication costs

Evidenced-based design principles in the new children's hospital, enhanced by other influences, such as the artwork and interior design, will have a very positive influence on everyone in it, patients, their families and the staff that care for them.

2E.5.1 *Child, Parent And Family-Friendly Facilities*

For many patients accessing regional or national services; admission to hospital will mean being a long way from home and for a long time. In some specialties, notably haemato-oncology, patients can remain in hospital for many months, with major disruption to family life, finances and social and educational links. The current arrangement of beds in the RHSC, with limited cubicle space, significantly compromises private family life. There is also no access for patients and families to modern means of communication, such as the internet, and restrictions on the use of mobile 'phones. In the new children's hospital:

- Patients' personal space will be more generous than it is currently, improving privacy and reducing stress. In inpatient general wards, more than 80% of beds will be in single rooms, thus providing more private family space, better sleep, reduced stress and minimising acquired infections

- Each bed space will have an entertainment console. In addition to entertainment, the console will be a source of distraction during treatments, give access to the internet to help maintain links with friends and family in the outside world and support continuing education during inpatient admission

The different psychological, developmental and clinical needs of babies, children and young people, their dependence on parents and carers and the complex dynamics of the wider family mean that hospital facilities need to be carefully designed with the whole family in mind. In contrast to the situation in adult hospitals, parents / carers not only provide emotional support and comfort to patients, but are joint partners with healthcare professionals in their care. Meeting the needs of parents / carers, especially their physical and psychological needs, is fundamental to improving the well-being of sick children.

Providing appropriate facilities for parents/carers and the wider family is a key principle in the design of new hospital, for example:

- The hospital will provide well-designed and dedicated facilities for parents/carers located particularly in areas of stress (for example, critical care) or the longer-stay wards including dignified and comfortable waiting areas, shower and wash facilities and convenient spaces near to the ward in which to relax, socialise and meet other parents
- Except for critical care, every inpatient bed space will have an adjacent bed for a parent
- There will be purpose-built facilities for a family resource centre and bereavement services

Play has developmental and therapeutic benefits for all children and young adolescents. It is fun, helps to keep them healthy, helps develop an awareness of risk and danger and is important for building social, emotional and life skills. All children and young adolescents have a right to play (UNCRC 1989) but for those with mobility, visual or auditory impairments or learning difficulties, special measures are required to provide access to play spaces. Due of their importance, access to play and socialisation spaces, for all patients and siblings, has been given a high priority:

- The master-plan for the new hospitals includes a children's play park, a roof garden and access to outdoor balcony space from the haemato-oncology and inpatient psychiatric wards

- Access to indoor recreation appropriate for all ages and needs is a theme that runs through the entire design of the new children's hospital

- Providing facilities and services appropriate to all age groups and abilities is challenging, and to date, the needs of adolescents and young people in hospital have been neglected. In the current RHSC, there are only limited facilities designed specifically for them (it is not uncommon, for example, to find a 15 year old adolescent nursed alongside babies and small

children). This situation will be even more challenging with the increase in the routine upper age for admission to the 16th birthday, with some patients aged 16 – 18 also accessing care. The plans for the new children's hospital incorporate both dedicated facilities and flexible accommodation that can be configured to meet their needs:

- The interior design and art strategy in generic spaces will be planned to appeal to all ages, from toddlers to adults
- The single bedroom accommodation provides privacy and the flexibility to personalise space
- Dedicated socialisation space has been provided for young people adjacent to the generic wards and separate waiting facilities are included in the designs for the outpatient department and operating department
- The entertainment console, described above, will allow young people access to social networking sites and e-mail as well as links for continuing education

In addition to NHS funding, the RHSC has relationships with a number of key partners. The project team is working very closely, for example, with the Yorkhill Children's Foundation, on proposals to further enhance the new children's hospital environment to ensure that these are flexibly age- and needs appropriate and improve facilities for patients and their families. The current RHSC benefits greatly from the additional parent/family accommodation provided adjacent to the hospital through the generosity of the charities Ronald McDonald House and CLIC / Sargent. These facilities have been designed specifically to meet the needs of the parents and families of those children who have to stay for long periods in hospital. The decisions to re-provide these facilities alongside the new children's hospital have been agreed with the charities involved and there is a clear intention to work closely with these respective charities to facilitate the continuation of the current, and much valued, arrangements.

2E.6 Positive Impact For Staff

Many of the potential advantages of the NCH discussed above are also of major benefit to staff. These include ergonomic physical design that will reduce stress, increased access to natural light that will improve general well-being, close proximity to other services that will support multi-disciplinary working and enhance professional relationships and development.

Evidence-based design, including architecture, interior finishes and the art strategy, will impact on the attitudes and behaviours of everyone using the hospital. The design team's close attention to detail in some of the more stressful areas (such as interview rooms and waiting spaces) will help defuse difficult emotional situations, making the new children's hospital a much more pleasant and rewarding place in which to work.

Co-location with adult and maternity services, an innovative building based on best practice and an understanding of the impact of environment on well-being and outcome, facilities appropriate for all age groups (including young people) and needs and access to first rate education and research facilities will further develop the reputation of the children's hospital as a world class institution.

2E.7 Research and Education

Yorkhill is a major academic institution, comprising Scotland's biggest children's hospital (the Royal Hospital for Sick Children), the medical genetics services for the West of Scotland (Duncan Guthrie Institute), the Scottish Centre for Autism, the Scottish Muscle Centre and, until 2009, one of Glasgow's principal maternity centres (the Queen Mother's Hospital).

Yorkhill is also the home of many internationally acclaimed research groups, and a major site for the teaching and training of doctors, nurses and other health professionals who care for children. Through the Children's Services Research Group, Yorkhill acts as a focal point for academic activity in community children's services. Glasgow is unique in Europe in having such a strong constellation of clinical, scientific and educational facilities dedicated to the care and study of mothers' and children's health and Yorkhill has contributed significantly to its national and international reputation, demonstrated by:

- the commitment of the Medical Research Council, Wellcome Trust, Scottish Office, Cancer Research Fund, European Commission, and many other external funders to support the large number of research projects underway
- the relevance and high quality of scientific research and publications by Yorkhill staff
- the excellence of teaching and training of doctors, nurses and students of all professions allied to medicine
- the affection and support shown by the public who respond willingly to appeals for new equipment and services
- Yorkhill has close links with the University of Glasgow and with the nursing and AHP departments of the University of the West of Scotland and Glasgow Caledonian University

2E.7.1 *Research*

A number of specific achievements over the years have had a major impact on the care and health of mothers and children. These include:

- the invention of ultrasound scanning to detect fetal abnormalities in the womb
- the development of extra-corporeal membrane oxygenation for critically sick babies
- new ways of correcting heart defects in babies without surgery
- molecular markers for the rapid detection of birth defects in the womb

- pioneering of minimal access fetal surgery to correct abnormalities in the womb
- understanding how brain development is influenced by diet in early life
- the development of non-invasive, safe methods to measure metabolism and body composition in children
- the use of viral vectors for gene transfer to treat childhood cancers

The pursuit of research, the provision of education, the delivery of medical care, and the promotion of child health are interdependent missions of Yorkhill. Research is inseparable from medical practice, and innovation and development are only possible through cooperative partnership between scientists and clinicians. The importance of supporting paediatric research has been increasingly highlighted by the Chief Scientist Office through initiative such as the Academic Health Sciences Collaboration and the Scottish Medicines for Children Network.

At Yorkhill, research occurs within the hospital and University departments, through partnership between NHS and academic staff. More than 60% of the hospitals' consultant staff are engaged in research and teaching, with around 30 senior university academic staff (professors and lecturers) collaborating with NHS research groups and over 100 postgraduate students undertaking PhD, MD and MSc projects.

Although research within children's nursing is still in development, there is a commitment for Paediatric Clinical Nurse Specialists and Paediatric Advanced Nurse Practitioners to be actively involved to further develop the nursing care of children, young people and their families.

Research grants held by Yorkhill staff exceed £6m. Publications total over 300 peer-reviewed papers per year. Yorkhill's position as a leading academic centre for child health is strengthened by its successful collaboration with others in Glasgow, Scotland, Europe and internationally, including with Dundee University (Wellcome Fetal Surgery Group, Paediatrics and Nutrition), Glasgow Caledonian (Faculty of Health Sciences - Nursing, Vision Sciences and Nutrition), Scottish Universities Research & Reactor Centre (stable isotope research), University of Newcastle-upon-Tyne (Fetal Medicine), University of Edinburgh (Nutrition & Surgery), University of Cambridge (MRC) and the Universities of New York and Cincinnati (Fetal Medicine & Genetics).

Many NHS staff are honorary professors, readers, senior lecturers, lecturers, research fellows and clinical teachers in the University of Glasgow, Strathclyde and Glasgow-Caledonian Universities, and play a vital role in teaching and training of medical and nursing staff, and those of professions allied to medicine.

A major strength is the multidisciplinary nature of its research teams, forming a critical mass of working partnerships of clinical and non-clinical scientists and staff supported by a well-organised NHS Research and Development department with dedicated staff for paediatric research.

The recently established Clinical Research Facility (CRF) at Yorkhill, developed with the support of the Children's Foundation and NHS GG&C Research and Development department, will further support and promote and high quality research in children. Co-location of adult, children and maternity services on the Southern General Hospital campus offers the opportunity for this children's CRF to be incorporated into a much larger generic facility with the benefits of efficient use of resources and close liaison between professionals and disciplines.

2E.7.2 *Teaching And Training*

Yorkhill is a major centre for higher and continuing education in medicine, nursing and allied health professions.

- Main provider of children's nursing experience for undergraduates from Glasgow Caledonian University and, as a centre of excellence, nursing students from other countries within the United Kingdom and the European Union frequently request practice placement experience
- Houses the only paediatric focussed research and practice development unit (RPDU) within NHS Scotland
- More than 250 medical students from Glasgow University undertake clinical attachments each year
- Students/trainees include over 190 occupational and physiotherapists, radiographers, dieticians, clinical psychologists, and child psychologists

Higher professional training and continuing education include courses for UK and overseas graduates as well as for local doctors, nurses and other professionals allied to medicine. Yorkhill offers four fulltime MSc courses (in human nutrition, medical genetics, paediatric sciences and clinical paediatrics), which attract more than 50 students each year, and an increasing number of children's nurses studying towards masters level qualification with a few children's nurses undertaking doctoral studies.

Significant investment has also been made in the nursing clinical educator role to support the development of the registered paediatric nurse and clinical nursing practice. The clinical nurse educators and RPDU work in close collaboration with the nursing schools in the University of the West of Scotland and Glasgow Caledonian University to develop clinically relevant undergraduate and post graduate education

2E.7.3 *Benefits Of The Southern General Hospital Campus Location*

A new children's hospital on the Southern General Hospital campus will re-establish the physical links between children's and maternal services and, for the first time in Glasgow, offers the opportunity for co-location with researchers and teachers from adult disciplines. Not only will this foster professional collaboration, it also offers the opportunities for efficient use of educational and research resources through economies of scale**.**

2F. ADULT HOSPITAL (THE STRATEGIC CASE)

This section describes the following aspects of the Acute adult hospital development: -

- The business needs (case for change)
- Overview of the Acute Services Review (ASR) Strategy
- Description of current service at the Southern General Hospital
- Proposed future adult services on the Southern General Hospital campus

2F.1 The Business Needs (Case For Change For Acute Services Within Glasgow)

NHS GG&C recognises the need to ensure that patients who require access to hospital care can be seen, fully investigated and treated as quickly as possible within appropriate facilities.

For patients presenting as an emergency there should be access to specialised care of the highest quality, with access to state of the art investigations and treatment facilities on a 24 hour/7days a week basis. For elective care, patients should be seen, investigated and leave the hospital with a diagnosis and treatment plan wherever possible on the first visit. Underpinning this should be effective information and computer systems which allow General Practitioners, Specialists and patients access to all relevant information needed to deliver high quality and effective joined up care.

In 2002 Greater Glasgow Health Board described the case for change, which identified that the status quo was not an option, as there were significant challenges to the sustainability of the configuration of services across Glasgow and to the ability to improve patient pathways and create more efficient and effective care pathways. All of the factors identified in 2002 remain relevant today with additional challenges and pressures resulting in even greater need to reduce hospital sites and duplication of services. These issues include:

- The need to achieve the objectives of the guidance in the 'Healthcare Quality Strategy for NHS Scotland' and 'Better Health, Better Care' and other key national policies. These policies drive clinical excellence, continuity of care, reductions in waiting times, fast track access to rapid diagnosis and treatment; provision of services designed around the needs of the patient; modernisation of healthcare through better use of technology, effective communication and collaboration with patients over their care and provision of a clean safe environment. To achieve these objectives a major programme of investment in buildings, information technology and redesign of services is required
- Fragmented services. There is a requirement for patients to move within and around sites and different buildings in Glasgow with an inevitable loss of continuity of patient care. Important co-locations of services are often not possible to achieve and difficulties arise in transferring information amongst services

- Increasing sub-specialisation in medicine and surgery and an increasing need to move towards larger teams to ensure all patients can access an appropriate specialist on a 24 hours a day and 7 days a week basis
- Pressures on staff in sustaining appropriate staffing levels, for example 'Reshaping the Workforce' (formally Modernising Medical Careers) and the European Working Time Directive impact upon the availability of medical staff and therefore on the sustainability of multiple (often duplicated) rotas
- Outdated buildings unsuitable and unfit for modern healthcare offering a poor patient environment with unsuitable facilities for modernising services. Many of the Victorian facilities do not meet statutory requirements around, for example, bed spacing leading to a poor healing environment and inadequate patient privacy. Poor departmental co-locations restrict capacity and create bottlenecks and delays in treatment. These older buildings are also difficult to heat and costly to maintain

In summary, the status quo is not an option, as it will result in the following:

- Potential failure to provide a clinical service in accordance with nationally recognised standards
- Failure to provide good clinical services with enhanced outcomes through sub-specialisation and redesign
- Failure to sustain services. For example, many of the existing clinical teams are too small to sustain rotas across multiple sites without significant cost, for example the use of external staff agencies with a corresponding knock on affect to quality and expenditure
- An increased incidence of elective cancellations to cope with the rising emergency workload. The consequence of this trend will be a reduced ability to deliver elective activity with a shift towards an 'emergency only' service
- Failure to attract and compete for staff, especially in areas of acute shortages
- Failure to provide a modern service with sub-specialisation and up to date technology

2F.2 The Acute Service Review (ASR) [to address business needs]

The Acute Services Review (ASR) identified a programme of change to address NHS GG&C's business needs and this has been implemented over the last 8 years following approval of the proposals by the then, Minister for Health and Community Care in 2002.

The ASR programme sees the reduction in the number of adult inpatient sites from the current six hospital sites to three. Two sites, Glasgow Royal Infirmary and the new South Glasgow hospitals, will have A&E and trauma facilities. The third inpatient hospital for Glasgow will be Gartnavel General Hospital. These acute sites will be supported by the two new build Ambulatory Care Hospitals.

The components of the Acute Services Review (ASR) Strategy are:

- Two Ambulatory Care Units, one on the Stobhill Hospital site and one on a site adjacent to the Victoria Infirmary. These were completed and opened in 2009.
- A reduction in Maternity services from three sites to two, those being the Princess Royal Maternity Hospital on the Glasgow Royal Infirmary site and the redeveloped maternity facility on the new Southern General Hospital campus. This was completed at the end of 2009.
- In North Glasgow, acute in-patient services will be provided from the Glasgow Royal Infirmary and Gartnavel General Hospital sites
- In South Glasgow, acute in-patient services will be provided from a major new development on the Southern General Hospital site (the new South Glasgow Hospitals).
- A new build laboratory on the Southern General Hospital campus to support the new adult and children's hospitals.
- Full A&E services will be provided from two sites, located at Glasgow Royal Infirmary and the new South Glasgow hospitals
- Trauma and orthopaedic in-patient services will be provided from the two full A&E sites. Orthopaedic out-patient and day-case services will be provided from all five adult sites (Gartnavel General Hospital, Stobhill Hospital, Glasgow Royal Infirmary, the new Victoria Hospital and the new South Glasgow hospitals)
- Minor injury units will be provided from all five adult sites

The Ambulatory Care Hospitals represent a significant modernisation of Glasgow's healthcare facilities. However three of Glasgow's major adult hospital sites are now operating below capacity with only inpatient services remaining in some buildings at Stobhill Hospital and the Victoria Infirmary.

NHS GG&C is currently carrying out an accelerated ASR with the redesign of services for the north and east of the city to transfer inpatient services from Stobhill Hospital to Glasgow Royal Infirmary in 2011; the recent rationalisation of urology services to 2 sites and the centralisation of vascular surgery and renal services to the Western Infirmary by the end of 2010 - in preparation for achieving a single site model within the New South Glasgow Hospitals.

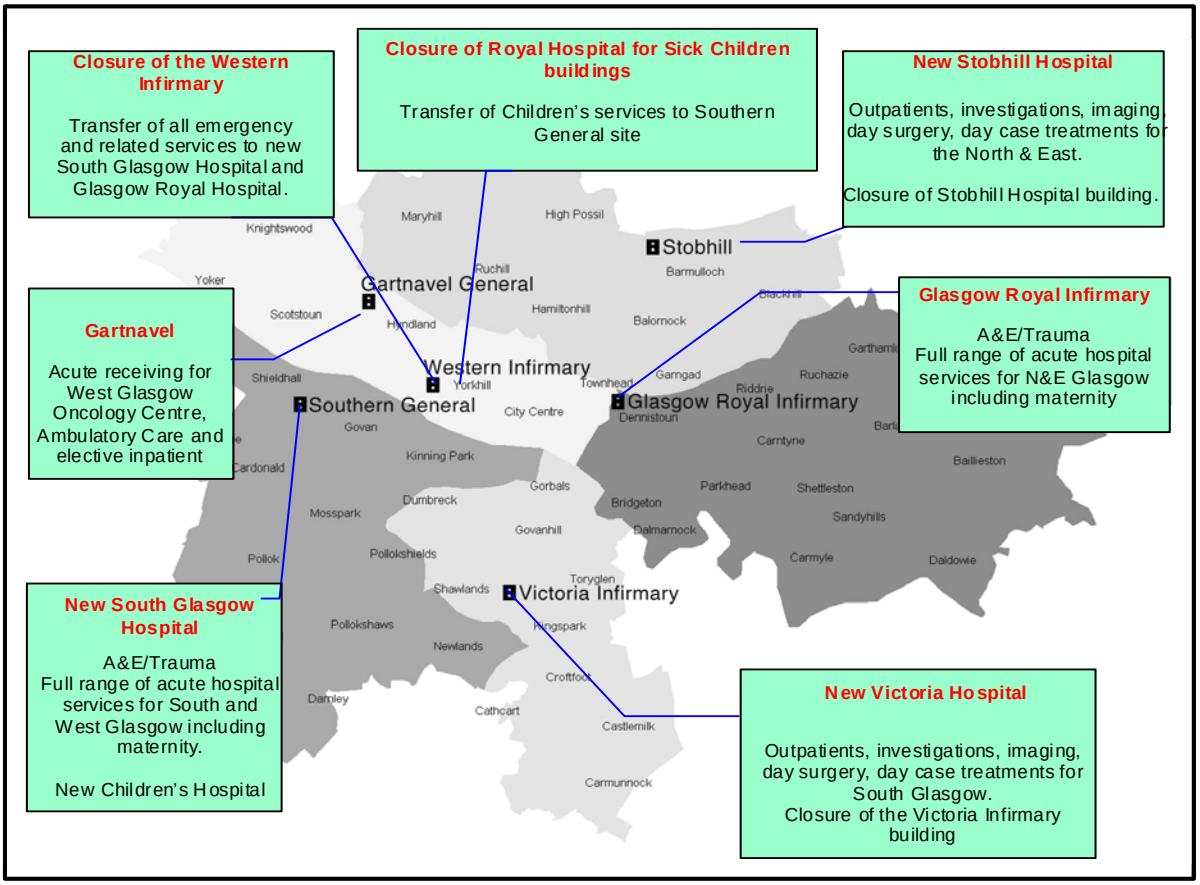
The proposals for the new South Glasgow Hospitals on the Southern General Hospital campus form the second phase of this Acute Strategy and are pivotal in achieving the transformation of services provided by NHS GG&C into a modern, fit for purpose 21st century healthcare system.

On completion in 2015, NHS GG&C will be able to enact the following:

- inpatient services in the Victoria Infirmary to transfer to the new South Glasgow Hospitals
- inpatient services at the Mansion House Unit (MHU) to transfer to the new South Glasgow Hospitals allowing closure of the MHU
- inpatient services housed in outdated buildings on the Southern General Hospital and Western Infirmary sites to be relocated to the new South Glasgow Hospitals .
- transfer of A&E services and associated beds from the Victoria Infirmary, the Western Infirmary and the Southern General Hospital to the new South Glasgow Hospitals

Following these transfers closure can take place of the Western & Victoria Infirmary sites and of older parts of the Southern General Hospital. This means that by 2015 the plans for the 3 site inpatient configuration of adult services in Glasgow will be achieved.

The planned future configuration of acute hospital services in Greater Glasgow is illustrated below.



2F.3 Description Of Current Services On The Southern General Hospital Site

The Southern General Hospital is a large teaching hospital with an acute operational bed complement of 900 beds. The hospital is situated in the South-West of Glasgow and provides a comprehensive range of acute and elective clinical services.

District General Hospital Services are provided for the South-West of Glasgow, with some services provided for the whole city. Services include Accident and Emergency, Dermatology, ENT, General Medicine (including sub-specialities), Assessment, Rehabilitation and Day Services, Gynaecology, Neonatal Paediatrics, Obstetrics, Ophthalmology, Orthopaedic Surgery, Urology, Physically Disabled Rehabilitation as well as in-patient Continuing Care. The Urology and Dermatology Departments provide the single in-patient location for South Glasgow and Glasgow respectively.

The Maxillofacial Surgery Service for NHS GG&C was centralised at the Southern General Hospital in the autumn of 2002 providing trauma and elective surgery and specialist provision for head and neck cancer. South and West Glasgow's In-patient Gynaecology Service was centralised at the Southern General Hospital in early 2004. The Assessment and Rehabilitation Service for the physically disabled is provided for the whole city from the Southern General Hospital campus. There is also a wide range of diagnostic and therapeutic services including audiology, clinical psychology, dietetics, occupational therapy, ECG, physiotherapy, radiology (including MRI and CT provision for the general hospital service) and speech therapy.

The Institute of Neurological Sciences is based at the Southern General Hospital and provides neurosurgical, neurological, clinical neurophysiology, neuroradiological and neuropathology facilities for the West of Scotland.

The Queen Elizabeth National Spinal Unit for Scotland provides a spinal injuries service to the whole of Scotland. This is housed in a purpose-built facility attached to the Institute of Neurological Sciences.

The Langlands building houses care of the elderly, young chronic sick and dermatology services. The WESTMARC (West of Scotland Mobility and Rehabilitation Centre) unit is a purpose built facility and houses the clinical services for prosthetics and orthotics including the artificial limb and appliance centre.

2F.3.1 *Buildings*

The Southern General site extends over 28.9 hectares and is located in Govan, South West of the city centre. The Southern General Hospital campus has evolved over 130 years. The site and the buildings within it are owned by NHS GG&C on behalf of the Scottish Ministers and incorporates the area of land earmarked for the development of the new adult and children's hospitals and laboratory build.

The facilities which make up the Southern General Hospital campus consist of a mix of buildings of varying ages, architectural style and quality spread across the site. The buildings date from 1872. In 1902-05 a facility accommodating a further 700 beds was built as the hospital continued to expand its services. A new maternity unit was opened in 1970 and the Institute of Neurological Sciences was completed in 1972. There have been a number of more recent additions to the campus over the last decade including the Langlands (PFI Project), and the WESTMARC buildings which house rehabilitation services.

As with all hospital sites of this vintage, piecemeal development throughout the lifespan of the site has resulted in the fragmentation of clinical facilities across the campus, resulting in a number of very poor clinical adjacencies and departmental relationships. Theatres are spread throughout a number of locations on site with each theatre suite dedicated to an individual specialty.

The A&E department is located next to the main rehabilitation facility with very poor adjacencies to other acute services on site. At present given the sprawling layout of the site there are two imaging departments - one co-located with the neurosciences/spinal complex and the other at the north of the site to service the main general medical and surgical inpatient facilities. The latter imaging facility, the main outpatient department and many of the in-patient wards are located some distance away from A&E.

2F.4 The New South Glasgow Hospital – Scope And Services

2F.4.1 *Proposed Future Demand - Bed Modelling*

Plans for the adult hospital include 1109 beds with an A&E Department with the capacity for 116,000 attendances per annum. The hospital will function as an acute site with an outpatient department and a medical day area serving the local population of South-West Glasgow. All surgical day case activity now takes place at the new Victoria Hospital. There will be no day surgery activity at the New South Glasgow Hospital.

The following section describes the bed modelling work which has informed the size and scope of the new hospital.

2F.4.1.1 Benchmarking with peer hospitals

NHS GG&C continues to progress a programme of benchmarking of acute services. Civil Eyes (an independent clinical activity analysis service), has been engaged to collaborate with NHS GG&C to build on the benchmarking exercises that the Board has undertaken for a number of years in order to review and determine the bed model for the acute adult services across Glasgow. The objectives of the programme are to:

- Provide an objective assessment as to the current performance of the acute adult hospitals across Glasgow relative to peers

- Identify the potential for improving efficiency in terms of use of beds and patient throughput
- Provide a projection of future demand in 2015
- Provide an indication as to the potential bed requirements

The planned bed model also takes cognisance of better clinical adjacencies, more efficient patient pathways, projected demographics and national policy adjustments.

Within the core specialties covered by the adult bed model there are currently inpatient beds across the 6 acute sites, against which the future bed provision is considered. The bed model for acute services was updated during 2009/10 using the 2008/9 activity, and performance information to identify the currently proposed bed model in support of this FBC.

In considering the Adult Bed Model 2008/9; data was used to consider the efficiencies to be delivered through improved performance of Glasgow's hospitals compared to a range of peer hospitals across the UK.

By incrementally applying the impact of,

a) operating at best peer performance rates across each specialty
b) achieving occupancy rates of 85% for elective work and 82% for non-elective activity
c) growth in medicine and the impact of demographic changes
d) performance targets on current and future activity such as waiting times

The number of beds required for the core specialties for implementation of the Acute Services Review (ASR) suggests a Pan Glasgow Bed Model of 2782. This number excludes beds associated with the following services; clinical haematology, oncology, homeopathy, spinal injuries and physical disabilities.

Modelling work has been undertaken to consider current patient activity flows and the extant strategy position, including the model for the single site specialties, in relation to the number of beds required in light of the future plan of 3 inpatient sites for the city (at Glasgow Royal Infirmary, Gartnavel General Hospital and at the new South Glasgow Hospitals site).

In addition, consideration has been given to potential developments to specialist services in Glasgow and changes to patient flows from Clyde in understanding the in-patient bed capacity required across the Glasgow acute hospitals.

At the time of undertaking the latest bed modelling exercise for the ASR it was recognised that there might be future changes to bed numbers as the result of changes to regional services provision such as neurosciences, oral-

maxillofacial services and renal services. With the exception of renal services, which has already been factored into the new South Glasgow adult hospital bed requirement other potential changes to requirements in relation to beds do not affect the new South Glasgow adult hospital current proposals and will be accommodated within existing services.

To ensure the focus on efficiency continues, the work in relation to the bed model will continue as an iterative process. Bed modelling with key performance indicators feeding into the ongoing service redesign will underpin the new service models that will be provided across Glasgow and in particular in the new South Glasgow hospitals.

2F.4.1.2 New South Glasgow Hospitals

The in-patient bed numbers used for planning purposes for the New South Hospital are as follows:

Table 1 – Planned New South Glasgow Hospital Bed Numbers

Specialty	Inpatient Beds
Acute Assessment Unit	118
Critical Care & Stroke	105
Medical Specialties & Care of Elderly	605
Surgical Specialties & Rehabilitation	281
Total Inpatient Beds	1,109

The total number of in-patient beds planned for the New South Glasgow Hospital is 1109. In addition, a medical day case unit (22 day beds) is proposed for the New South Hospital.

2F.4.1.3 Retained beds

There will be approximately 600 beds retained on the Southern Campus associated with care of the elderly, maternity, gynaecology, neurology & neurosurgery, and spinal services.

2F.5 Proposed Future New Adult Hospital Services (New South Glasgow Hospital)

Within the new hospital; emergency and elective work will be segregated as far as possible with inpatient and day attendances within one section of the hospital and A&E, critical care and the Acute Assessment Unit (the Emergency Complex), within another zone.

The adult wards will have 100% single rooms each with ensuite toilet/shower facilities. This will increase patient privacy and dignity and reduce risk around hospital acquired infection.

There will be separation of patient and staff routes through the building from visitor and Facilities Management (FM) flows. The schedules of accommodation reflect the opportunity for both (adult and children's) new hospitals to share facilities such as a pharmacy dispensing facility, aseptic suite, estates maintenance, waste compound, supplies delivery and distribution, kitchen, staff dining and other FM services.

A helipad is planned within the development with a rapid access route into the resuscitation area within A&E.

2F.5.1 *Service Profile*

The profile of specialties/services that will be provided at the new South Glasgow Hospital is set out in Table 2 below. All specialties will be providing inpatient care; some, but not necessarily all, will also provide outpatient clinics and medical day-care services on-site.

2F.5.2 *In-Patients*

The New South Glasgow hospital will be an acute in-patient site. The proposed in-patient services are shown in Table 2 below:

Table 2: Proposed Service Profile – Inpatient Services - New Adult Hospital (New South Glasgow Hospital)

Surgical Specialties	Medical Specialties	Other Specialties/Services
General Surgery	General Medicine	A & E
Urology	Cardiology	Acute Receiving
Vascular Surgery	Dermatology	Minor Injuries Unit
Trauma & Orthopaedics	Diabetes & Endocrinology	Critical Care
ENT	Gastroenterology	Rehabilitation Services
Renal Transplant Surgery	Haemato-Oncology	Complex Elderly, Care
		Radiology
		Endoscopy
	Medicine for the Elderly	Rehabilitation, Orthopaedic Rehabilitation & Surgery Rehabilitation)
	Nephrology	
	Respiratory Medicine	
	Rheumatology	
	Stroke Medicine & Rehabilitation	

2F.5.3 *Outpatients*

The New South Glasgow hospitals adult outpatients department will provide services for patients resident within the south west of Glasgow.

The anticipated profile of outpatient clinics is shown in Table 3 below:

Table 3: New South Glasgow Hospital - Proposed Outpatient Services

Surgical Specialties	Medical Specialties	Other Specialties/Services
ENT	Cardiology	Acute Assessment Unit outpatient service
General Surgery	Dermatology	Rehabilitation
Ophthalmology	Diabetes and Endocrinology	Radiology
Orthopaedics	General Medicine	
Urology	Medicine for the Elderly and Stroke Services	
Vascular Surgery	Haematology	
	Respiratory Medicine	
	Rheumatology	
	Gastroeneterology	

There will be a primary care out of hours service providing emergency GP access (which will utilise the children's outpatient area).

There will also be a 22 'bedded' Medical Day Unit providing day care relating to rheumatology, respiratory, diabetes and endocrinology and gastroenterology.

2F.5.4 *Principal Themes of the New Model of Care*

The key themes underpinning the new model of care are described below:

- Patient-focused services
- Systematic and managed services providing streamlined assessment of patients to facilitate early diagnosis and treatment avoiding bottlenecks and queuing
- Use of formally agreed pathways, guidelines and protocols
- Early involvement of Senior ''decision makers'' in the patient pathway
- Shared objectives of care by different teams, professionals and parts of the organisation
- Separation of emergency and elective pathways of care
- Single portal of entry for emergency admissions, through the Emergency Department and the Acute Assessment Unit
- Central emergency and elective operating theatres department.
- Rapid access to diagnostic services
- Patients requiring rehabilitation will move through a care pathway defined by their needs not by their age or disability. Early access to rehabilitation will be a feature of medical and surgical pathways
- Discharge planning will commence at the earliest opportunity including pre-assessment.

- Maximum use made of extended evening and weekend working to provide diagnostic services
- Modern career framework with both a multi-skilled and a specialist workforce
- Separation of staff and patient, public and facilities management routes

These key themes will be central to the design and operation of the new South Glasgow Hospital and will be at the core of the required service modernisation and new ways of working.

2F.5.5 *Elective Services*

The majority of elective services at the new South Glasgow Hospital will be undertaken on an inpatient basis. The development of elective services will be supported by the separation of elective and emergency care streams with the protection of capacity in relation to key facilities such as inpatient beds, operating theatres and post-operative recovery.

Elective admissions will be assessed pre-admission. The majority of elective patients will be asked to attend on the day of surgery and be admitted straight to theatre via a Day of Surgery Admission Unit which will work in close liaison with the pre-assessment clinic.

There will be no elective day surgery at the new hospital; therefore no day surgery facilities will be required.

A Medical Day Unit with 22 day care beds will provide day case investigation and treatment. This will be available to all medical specialties and provide care for patients resident in South-West Glasgow.

Outpatient facilities will be provide services for the local South-West Glasgow population.

The majority of day-case endoscopies and therapeutic endoscopy, will be provided at the Victoria Ambulatory Care Hospital and Gartnavel Hospital, with the exception of ERCPs, which will be carried out at the new South Glasgow Hospital.

2F.5.6 *Emergency Care*

Emergency Care Services will be provided in an Emergency Complex, which comprises the Emergency Department, the Acute Assessment Unit and Critical Care.

As part of the Emergency Complex there will be an ‘Acute Assessment Unit’, consisting of 118 beds organised into the following components:

- An Immediate Assessment Area
- An Acute Admissions Area
- A Clinical Decisions Unit
- An emergency outpatient area

These units will all be co-located, alongside the Emergency Department (ED), and will be the focal point of emergency service provision for the majority of patients (some patients may be admitted directly to specialist wards including stroke maxillo-facial surgery, gynaecology and ENT).

It is essential for patients with a high risk of being a source of infection to others to be managed "separately" to avoid the risk of infecting other patients. This will include; Influenza, Norovirus, Gastroenteritis, SARS, MRSA etc. This will require isolation facilities. The Infection Control Team have been fully involved in the planning of hospital to address and reduce the risk of spread infection through the design of the facilities. For example departments, especially those at the 'front door' emergency receiving will be capable of sectioning off areas to allow infected patients to be co-horted into one area and the single bed rooms and choice of easily cleaned floor and wall finishes will reduce the spread of infection.

2F.5.7 *Diagnostics*

It is anticipated that the majority of routine diagnostic tests for patients from South and West Glasgow will be undertaken at the Victoria Ambulatory Care Hospital and Gartnavel Hospital respectively. Investigations carried out at the new South Glasgow Hospital will therefore be of a specialist nature, with the exception of support provided for out-patient attendances.

Rapid Access imaging is particularly important for ED, Critical Care and theatres. Redesign of the diagnostic and imaging services, the physical layout of imaging in the new hospital and linkage with the new labs build will help to achieve this. The following describes this in more detail.

Strategic Reviews of Imaging and Laboratory Medicine Services resulted in a range of service redesign initiatives. NHS GG&C are putting in place high-volume, no-wait services which support rapid diagnosis and treatment for all patients. The separation of emergency and elective flows will support the work towards the new targets. The modernisation strategies have resulted in automation of haematology and biochemistry laboratory services. Major redesign of the workforce for Diagnostic services will include a transition to full shift working, moving away from the traditional on-call arrangements currently in place. To support the delivery of the bed model for Glasgow, Imaging Services will be provided in A&E and Acute Receiving 24/7. This redesign strategy will achieve radical increases in capacity allowing NHS to achieve a high volume no-wait service. Much of this work has been undertaken through the Diagnostics Collaborative, providing a good foundation on which to take forward further redesign.

The effective functioning of the Emergency Complex is underpinned by the support provided by Radiology and laboratory services. The redesign described above allows for extended day working and rapid patient access to diagnostics. This affords the opportunity to further develop ambulatory care within the fields of acute medicine and surgery (and admission avoidance) and to be associated with significant reductions in lengths of stay.

The design of the New Adult Hospital arranges imaging over 2 floors. On the ground floor the diagnostic facilities can easily be accessed by both outpatients and patients attending the emergency complex while the diagnostic services located on the first floor are adjacent to Critical Care, Stroke and Theatres but can also be easily accessed by the in-patient wards in the tower block.

Haematology, biochemistry, microbiology, pathology, genetics and mortuary services will be provided in the new laboratory building at the Southern site. This will be linked to the New South Hospital via an underground passage and pneumatic tube system which will facilitate rapid transport, and rapid turnaround of test results.

2F.5.8 *Critical Care*

The Critical Care Unit will be located on the first floor and will have rapid access to ED and theatres. It is composed of 4 discrete co-located areas as follows:

- Intensive Care Unit (ICU)
- Medical High Dependency Unit
- Surgical High Dependency Unit
- Coronary Care Unit (CCU)

The proposed design allows flexibility of bed use between the units, for example the High Dependency Unit (HDU) beds which can be used flexibility for either surgical or medical patients, and in cases of pandemic can be upgraded to an ICU bed. There will also be flexibility between the HDU area and co-located CCU.

In addition to the above there is a renal HDU which will be located within the renal unit with close access to both the critical care zone and the theatres department.

2F.5.9 *Theatres*

The theatre department will consist of 20 theatres with appropriate designation and separation of elective and emergency theatres. These theatres will have state of the art facilities, 10 theatres will have ultraclean facilities. The theatres will be supported by a dedicated recovery room.

2F.5.10 *Therapy Services*

Therapy areas will be located alongside the Care of Elderly beds, surgery beds and General Medicine beds in order to enhance service integration.

The design of the hospitals has been developed in liaison with a wide range of staff user groups and the Community Engagement Team has undertaken a comprehensive programme of consultation with patients and carers, groups such as 'Better Access To Health', and local community organisations. Further detail is available in Section 6.

2F.6 Service Re-Design

The new hospitals will facilitate service redesign which in turn will maximise the full potential of the new hospitals allowing new ways of working to be developed ensuring services are patient focussed and quality driven.

Key national guidance and good practice will be incorporated in the models of care, including:

- Patient centred care
- Investing in the latest Information Technology (IT)
- Extending the roles of nurses, Allied Health Professionals and other non-medical personnel
- Extending the availability of senior (trained) medical staff within elective and emergency care so patients see the most appropriate clinician in the most appropriate setting in a timely fashion
- Fully utilising the most modern healthcare equipment and technology in patient care
- Delivery of services associated with low rates of healthcare acquired infection
- Provision of facilities which promote high levels of staff morale and job satisfaction

The New Victoria and Stobhill Ambulatory Care Hospitals (ACH's) have set the scene for the new post ASR reconfiguration of services. The separation of planned and emergency care and the anticipated increase in day surgery rates will require major redesign in relation to how care is delivered. Some of the redesign work required at the new hospitals is already in place at the ACH's and in other hospital sites and is supported by the development of new roles. Examples of this include Emergency Nurse Practitioners who support new service models, such as the Minor Injury Units in the new Ambulatory Care Hospitals and Acute Care Medicine Consultants who in the future can provide leadership around the working of the new Emergency Medicine Complex.

The service redesign strategy work that was carried out by the Ambulatory Care Hospitals Team was closely linked to the planned changes in regional planning. This process will be continued in the redesign work for the new hospitals build. The redesign process will also be closely linked to the development and implementation of the Health Information and Technology (HIT) strategy and its phased rollout across the acute division.

The Accelerated ASR will mean that services such as renal, and vascular will be centralised in the West and therefore have an established single site service model before transfer in to the New South Glasgow Hospital.

The methodology and templates that have been put into place within the ASR work to date will also be applied to the New South Glasgow Hospital ensuring consistency in care models and a streamlined, joined up flow of service provision within Glasgow.

The sections below highlight the mechanisms for taking forward redesign in relation to scheduled care, unscheduled care and diagnostics.

2F.6.1 *Elective Care*

In implementing 'Better Health Better Care' Boards are tasked with achieving a shift in the balance of care and ensuring improvements are made in productivity and capacity, whilst sustaining improvements in waiting times and reducing the need for hospital admissions.

Key areas around the redesign of services required for elective care relate to improved day surgery rates and the development of integrated care pathways, which promote pre-assessment, pre-admission planning and improved discharge and follow-up procedures

Integral to delivering these improvements will be:

- improved referral and diagnostic pathways;
- treating day surgery (rather than inpatient surgery) as the norm;
- actively managing admissions to hospital;
- actively managing discharge and length of stay;
- actively managing follow up.

Clearly the acute services will be subject to a range of government targets and the HEAT targets are already embedded into the plans for the new hospitals, however the new service models and systems facilitated by the New South Glasgow Hospital will allow the targets to be fully sustained and provide the flexibility to meet future targets.

Managing change across the whole patient management pathway is key to achieving success in this area. Patient care pathways are being mapped and developed often requiring existing staff to work differently. Changes in working patterns however need to be underpinned by access to appropriate training through a competency based approach. This approach allows working roles to be adapted and expanded and helps avoid restrictions around the way services are delivered within previously traditional ways of working.

The new South Glasgow Hospitals Build supports these developments within elective care. Examples of this include:

- Development of an Admission on Day of Surgery (AODOS) area. AODOS requires robust pre-admission assessment but results in better admissions planning and shorter lengths of stay
- More care is being delivered now, and will be delivered in the future, through multi-disciplinary teams (MDTs). MDTs require access to good information (good IT) and good communication across all team members. Areas for MDTs to meet are of importance. Meeting areas suitable for this purpose have been developed across all in-patient areas in the new hospital
- Telemedicine is becoming of ever increasing importance. Space for this and IT support will be provided within the new hospitals build. Telemedicine has an increasing role to play in both elective and emergency care. Examples of this might include dermatology reviews to remote/rural areas and assessments that can be provided by the emergency retrieval team
- In many healthcare set-ups elective care can be threatened by peaks in emergency activity. This risk can be minimised by effective separation of these two functions. This thinking is integral to the design for the new South Glasgow Hospitals where emergency and elective work is clearly separated. Examples of this separation include having a dedicated radiology area to support the Emergency Complex with a separate area on the floor providing services for in-patients (and some out-patient work) as well as taking care to provide physical separation between “emergency” and “elective” areas
- A Medical Day Unit will be developed. This area will link with outpatients and with emergency care to provide high quality investigation/treatment facilities. This area will also provide a function in supporting early hospital discharge where some ongoing treatments might still be required

2F.6.2 *Emergency Services*

There are plans for the redesign of acute receiving within Glasgow hospitals, some of which is already in place. This has modernised and transformed the front-end of the acute hospitals allowing improved triage for patients, the introduction of streaming, separating patient flows and minor injuries to be assessed and treated by Emergency Nurse Practitioners separate to the main A&E/Acute Receiving areas within Glasgow's hospitals.

The current old, often Victorian, real estate of the Victoria Infirmary, the Southern General Hospital and the Western Infirmary have limited opportunity for redesign. A new build hospital will allow significant opportunity for redesign one of the key areas being the new adult hospital Emergency Complex which will embrace the changes described above but also promote:

- Streaming of GP referred medical patients into a dedicated Immediate Assessment Area (within the Acute Admissions Area) bypassing the Emergency Department
- Development of a design that allows very close proximity of the Emergency Department, the Acute Admissions Unit (AAU), emergency imaging (Radiology) , critical care facilities and theatres.

- Development of a Medical High Dependency Unit
- Design of facilities that allow complex use – such as interventional theatres and dedicated interventional labs within radiology
- Development of a dedicated acute stroke unit

Optimal operation of these facilities will require changes to current working practice. These changes include primary assessment of "999" presentations being completed within the Emergency Department, the further development of the role of the consultant acute care physician to staff the Immediate Assessment Area and provide clinical leadership within Medical High Dependency. These changes have the support of key members of medical staff involved in the redesign process.

The bringing together of three acute hospitals onto one site allows significant opportunities for economies of scale especially around the clinical and non-clinical workforce. Out of hours rotas can be significantly redesigned allowing opportunity to reduce the number of people who need to be on call and develop extended day working for more senior medical staff.

The large number of emergency admissions that will be seen daily (110-150/day) makes it practical to develop on call teams by speciality rather than have emergency cover provided solely by generalists. This has a number of advantages including: quicker patient access to the relevant "specialist", quicker "front door" decision making, better use of diagnostics and a likely shorter patient length of stay.

Although extended day working will be developed across a number of key areas; out of hours service provision will remain a challenge. The design of the New Adult and Children's Hospitals with their proximity (and physical linkage) to the maternity departments and Institute for Neurological Sciences allows the extension of the current Hospital at Night service to be developed into a Hospital Out-of Hours Service. A focus for this service has been planned within AAU.

2F.6.3 *Whole Service Issues*

There are a number of important services/developments as part of the new South Glasgow Hospitals build which have clear benefits across the whole hospital. These include:

Development of high quality, state of the art IM&T. The aim is for this hospital to be paper light/less as far a possible. This aim will be supported by the effective use of IT with easy access for staff to appropriate clinical information both through networked IT links and a whole hospital wireless facility. Facilities for telemedicine are of importance (as described above) and will be supported by the IT strategy. Other areas critically dependent on IM & T include bed management with bed availability information required in real time.

The separation of elective and emergency work has been alluded to above however in addition to this there is clear separation of staff and public routes as

far as possible. This is important from both a general security perspective and also from a staff safety perspective (especially out of hours).

2G. INVESTMENT OBJECTIVES

The Investment Objectives stem from the Board's business aims. Core Investment Objectives are: the need to modernise patient care, speed up the patient journey, reduce the number of inpatient sites, invest in fit for purpose facilities and information technology, reduce hospital acquired Infection rates, make more effective use of clinical time to ensure patients are seen by the specialist team much earlier in their care pathway and the achievement of gold standard services through the triple co-location of Adult, Children's and Maternity Services onto a single site.

The fundamental aim of this project is to provide modern, state of the art facilities that will deliver redesigned patient pathways which streamline patient care, deliver improved efficiency and productivity and more effective service models. This will ensure that the Health Board are providing the best level of patient care to the highest standard, as good as any to be found throughout Europe.

The Investment Objectives reflect the benefits which are anticipated from the project, and these are given in more detail below along with a description of how they will be measured.

2H. BENEFITS CRITERIA AND REALISATION

The benefits expected from this project fall into the following 9 categories:

1. Clinical Quality
2. Sustainability of Services – (consolidation of services)
3. Physical Environment (quality environment)
4. Performance Improvement
5. Staffing and Workforce
6. Environmental considerations
7. University
8. Accessibility to hospital
9. Economic and Community

These are unchanged from the Outline Business Case with the exception of the additional benefit category of Economic and Community.

The following table outlines the benefits along with how and when success will be measured. Further detailed description of each benefit, and the process for reviewing and monitoring is given in Appendix D.

Table 4: Anticipated Project Benefits and Benefits Realisation – Adult and Children's New Hospitals

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
1	Clinical Quality	The 'gold service' triple location of adult, paediatric and maternity services.	Development of integrated services. These include integration of neonatal and maternal ICU, integration of adult medicine and maternity services and development of streamlined transitional care.	Adult, paediatric and maternity services located on a single site. Reduction in number of inter-hospital transfers for adult, maternity & paediatric patients and babies. Improved transitional care for young people as measured by patient satisfaction survey.	Yes. 12 months post transfer of services.	Project Director Medical Director, Director of Nursing
2	Clinical Quality	24/7 patient access to specialist services.	Implementation of the Acute Assessment model means that patients will be seen by senior medical staff at an earlier stage than currently, and, as a result will have quicker diagnosis and implementation of treatment plans.	Senior decision makers available at the beginning of the patient journey. Implementation of viable sub-specialty rotas. Sustained delivery of Government targets, e.g. 4-hour trolley waits; 18 –	Yes. 6 months post transfer to new hospitals.	Medical Director, Director of Nursing

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			Enhanced critical care with state of the art facilities including Development of a Medical High Dependency Unit. Improved access to electronic patient information supports diagnosis and commencement of treatments & continuity of care.	week waiting time target. A&E. Shorter lengths of stay & reduction in unnecessary admissions. Access to electronic records at point of care.		
3	Clinical Quality	Achievement of the guidance in 'Healthcare Quality strategy for NHS Scotland ' for providing :a clean and safe environment, clinical excellence and continuity of care with clear communication and effective collaboration between staff and patients about their condition and treatment.	Single room provision will reduce patient transfers due to gender, infection etc. Provision of single room with en-suite shower & toilet facilities aids infection prevention and control as there is greater flexibility in isolating patients. Patients who are	Reduction in HAI rate attaining the Scottish Government Health Departments HAI targets for 2015 onwards. Fewer patient moves once admitted Reduced boarding of patients. Compliant with CEL27 (2010) and SHFN 30	Yes. 12 months post transfer to new build adult and childrens hospitals.	Medical Director Nursing Director

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			subsequently diagnosed as having an infection will already be in a single room and therefore risk to other patients reduced.	Patient satisfaction survey, monitoring communication and collaboration in diagnosis and treatment.		
		Provision of a modern environment	Provision of single rooms will facilitate private conversations between clinicians and patients supporting shared decision making regarding treatment.	Improve compliance with hand hygiene. Address CEL 05 (2005), improved audit scores and reduced HAI rate. Achievement of the SGHD HAI targets for 2015 onwards.		
			Improved hand hygiene through easily accessible wash hand basins.	Adherence to CEL 53 (2008) NHS Scotland Dress Code.		
			Hand hygiene training facilitated through provision of training and seminar rooms within the new hospitals. In addition to monthly	Compliant with SHFN Note 30 V3 Infection Control in the Built Environment.		

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			teaching sessions and the online Training Tracker, sessions of supported learning are being run for the Cleanliness Champions programme. Careful selection of materials/finishes which are easy to clean and maintain. Segregation of clean and dirty routes through the hospitals.			
4	Sustainability of Services (consolidation of services)	Continued sustainability of clinical services and compliance with Workforce Directives. Development of new service models through service redesign.	Centralisation of clinical staff, services and resources onto a single site.	Reduction in the number of medical rotas following reduction of sites. Sustained achievement of European Working Time Directive and 'Reshaping the Workforce' (formally Modernising Medical Careers).	Yes. Immediate effect post transfer of services to new hospitals.	Medical Director, Director of Nursing Directors for Surgery & Anaesthetics, Diagnostics and Emergency Care

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
				Reduction in the number of sites requiring overnight staffing e.g. emergency theatres, emergency imaging and Emergency Departments.		
5	Sustainability of Services (consolidation of services)	Enhanced quality and sustainability of children's neurosurgical services.	Delivery through state of the art/fit for purpose design with physical links between children's hospital and neurosciences.	Physical links to facilitate an integrated paediatric neurosurgical service.	Yes. Immediate effect post transfer of services to new hospitals.	Director of Women and Childrens services and Regional Services Director
6	Physical Environment (Compliance, Adjacencies and Links)	Modern 21st century fit for purpose facilities. More patient and staff amenities for example, cafeteria, shops, changing facilities. Good levels of natural light and ventilation Aesthetic environment Improved maintenance Improved wayfinding	Through delivery of the Employer's Requirements with interlinked equipment strategy and healing arts strategy. Compliance with NHS guidance and statutory regulation. Improved Health and Safety regimes. Improved logistics support.	Optimum co-location of departments as specified in Employers Requirements resulting in improved communication. Achievement of physical links between adult and children's, neurology and maternity services. Evidence of 100% single rooms. Patient satisfaction survey	Yes. Measure 6 months post transfer.	Project Director (Delivery of ER's) Medical Director, Director of Nursing

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			Easily cleaned and maintained finishes.	Achievement of physical link between new hospitals and new labs build via tunnel and pneumatic tube hence faster turnaround of lab results. Reduced number of reported accidents. Evidence of energy efficiencies and reduced maintenance costs.		
7	Physical Environment (Operational Benefits)	Operational benefits through efficient working practices and design e.g. Efficient delivery of goods and removal of waste through distribution by AGV and Pneumatic systems. Increased security with controlled access to	Through delivery of ERs and subsequent implementation and appropriate use of systems and controls. Separation of FM routes from patient/staff and visitor routes, i.e. dedicated AGV lifts and routes.	Staff efficiencies through distribution by AGV and Pneumatic systems. Specimen response times improved. High levels of control of access and egress to relevant areas. Full BMS system with monitoring, recording and management ability of building systems. Improved scores from	Yes. 6 months post transfer.	Project Director (Delivery of ER's) Director of Facilities (Implementation)

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
		wards and departments, extensive CCTV and ability to lockdown areas.		national monitoring system re cleaning specifications. Reduction in reported security incidents.		
8	Performance Improvement	Increased efficiency and throughput to sustain current HEAT Targets, and increased ability to meet future waiting time guarantees for 2015 (and beyond).	By consolidation onto 1 site, achieving better co-locations, new more efficient models of care such as the Acute Assessment Unit and Day of Admission area in theatres leading to more streamlined patient flows.	Achieving Gov waiting time targets. Increased throughput of beds. Reduced length of stay for emergency admissions (by improved clinical adjacencies, diagnostic resources availability and efficient and appropriate utilisation of diagnostics). Reductions in re-admission rates (through the Acute Assessment model using early ambulatory care supported by appropriate specialist input). Reduced new to return outpatient appointments. Evidence of more senior	Yes. 6 months post transfer.	All Acute Directors

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
				clinicians involved in the front end emergency care ensuring appropriate referrals to diagnostics and good use of resources.		
9	Performance Improvement	Increased efficiency in support services such as Facilities (materials) Management and pharmacy, communications and maintenance supporting a higher throughput of patient care. High speed material and specimen transport 24/7to the new lab building facilitating a faster turnaround of test results in conjunction with the new IT system allowing automatic down load of lab results.	Through use of installation of Automated Guided Vehicles and automated pharmacy dispensary. Through installation of pneumatic tube system.	Increased delivery of goods to scheduled times –'just in time' scheduling. Pharmacy - increase in number of discharges before noon (i.e. reduced delay through getting discharge prescriptions), efficient and effective delivery of services, improved tracking of specimens.	Yes. 6 months post transfer.	Director of Facilities Head of Pharmacy
10	Staffing and workforce	Improved quality of recruitment and retention.	New state-of-the-art facilities and equipment, together with co-location of university attracting	Increase in the number of applications for posts and a reduction in leavers to other NHS boards.	Yes. 12 months post commissioning.	Director of Human Resources

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			potential employees and improving ability to retain staff.			
11	Staffing and workforce	Improved staff access and work towards a greener environment.	Dedicated transport hub designed in conjunction with local public transport providers. Reduction in the need for inter-site travel by staff due to consolidation of services.	Measuring change in staff's method of travel to work through staff survey. Reduce number of miles claimed.	Yes. 6 months post commissioning.	Director of Human Resources
12	Staffing and workforce	Reduction in staff absence and increase in staff morale.	New fit for purpose facilities and good working environment. Good access to natural daylight.	Improved absence levels in 12 months post move compared to 12 months prior to move. Staff questionnaire.	12 months	Director of Human Resources
13	Environmental Considerations (Carbon Reduction)	New hospitals to contribute to reduction in CO2 emissions in line with Board's Carbon Reduction and Management Plans in compliance with Climate Change Act (Scotland).	Through consultation with stakeholders including Carbon Trust during design stage to set targets prior to procurement. Employer's requirement's to	Achieve operational 80kg/CO_2/per sq meter per annum target or lower.	Yes. Immediate and ongoing with follow on benefit delivered when retained estate connected to new Energy Centre.	Project Director (delivery of ER's) Director of Facilities

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			prioritise low carbon and ensure that future reductions in retained estate CO_2 emissions can be realised from investment in advanced Energy Centre. Achievable with use of modern technologies such as CHP & Heat Recovery. Also through Green Travel Plan, cycle routes in the campus, promotion of car share, access for public transport.			
14	Environmental Considerations	New Hospitals will deliver sustainable high quality User product and User environment.	Appoint BREEAM advisor to advise on Design Development and Track Status.	Targeting of BREEAM "Excellent Status"	Yes. Immediate and ongoing, design assessment to be approved by BRE at design completion and certification to be applied for and measured on	Project Director

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
					completion of project.	
15	University	Consolidation of 3 sites onto 1 will enhance opportunities for teaching, and research and play a significant role in attracting and retaining high quality staff in all disciplines.	Through implementation of engagement plans with the teaching organisations.	Teacher and student satisfaction surveys. Increased high quality research output as measured by publications and award of research funding.	Yes. 12 months post transfer of services.	Chief Operating Officer
16	Accessibility to Hospital Campus	Easy transport links to support patient and visitors attending the hospital, improved cycling and walking routes + provision of appropriate car parking.	Through construction of physical roadways, paths and access routes followed by implementation of the Board's Travel Plan.	Travel survey monitoring mode of travel to hospital and ease of travel experienced.	Yes. 6 months after completion and then every 2 years.	Project Director (Infrastructure) Director of Facilities (Implementation)
17	Economic and Community Benefits	Recruitment protocol to support route to employment	Through establishment of a recruitment protocol with the Contractor and Regeneration Agency.	Identifiable protocol enabled for use individuals employed on the construction project recruited through the recruitment protocol.	Yes. Annually to the end of the construction period.	Community Engagement Manager
18	Economic and Community Benefits	Regeneration of the South West Glasgow Community.	By developing, assessing and supporting SMEs and Social Enterprises in	Number of local businesses and Social Enterprises securing contracts in the	Yes. Annually to the end of the construction period.	Community Engagement Manager

No	Criterion	Benefit	Action to achieve	Measurement of success	Realistic/ Timescale	Responsibility
			conjunction with the Contractor.	construction of the building.		
19	Economic and Community Benefits	Learning pathway in South West Glasgow for individuals to pursue a career in healthcare.	Through local and pan-Glasgow awareness and support to potential employees and individuals with a healthcare interest.	Level of NHS Greater Glasgow & Clyde employees who work on the NSGH site resident in South West Glasgow.	2020	Director of HR Community Engagement Manager

2I. STRATEGIC RISKS

In developing all aspects of planning the new facilities the Project Team and advisors have pro-actively managed potential risks by identifying them early and taking early action to ensure maximum reduction and mitigation of risk. Therefore, this approach has been enacted at all key stages of the project such as:

Pre-procurement:	Tender and process development
During procurement:	Competitive dialogue, evaluation and due diligence
Post procurement:	Construction and design stages.

Headline examples of this essential activity to mitigate and manage strategic risks includes:

- Acknowledgement of the wider economic background – in order to assess viable market uptake and bidder interest in the scheme a thorough market sounding exercise was under taken to support and test the proposed procurement route and approach to the competitive dialogue process;

- Consultation with key organisations – extensive consultation took place with the Scottish Government Health Directorates, Partnerships UK and A+DS in order that the procurement and market engagement proposals were thoroughly transparent and agreed prior to implementation;

- Community engagement – thorough and wide ranging consultation and interaction with local neighbours, communities and businesses has resulted in the project being accepted. The potential benefits to the local economy and landscape have been clearly identified and the impacts discussed locally with information pertaining to the project readily available and provided to interested parties;

- Consent and approvals – as an extension of the community engagement the Health Board has actively engaged with Glasgow City Council, Strathclyde Partnership for Transport (SPT), the Fastlink Team and other organisations throughout the planning process. This has been a two-way process that has demonstrated joint working and allowed issues, concerns and relevant considerations to be raised, discussed and resolved as the project has moved through the regulatory system. This included, for example, undertaking various environmental impact studies and associated activity in order to thoroughly assess and consider the impacts of the scheme;

- Service planning – the hospitals have been scoped to ensure the sustainable delivery of present and future healthcare targets and clinical aims. Clear output requirements have been established through extensive consultation with clinical users and benchmarking with other large hospital new builds for example in Birmingham, Forth Valley Health

Board, Peterborough, and Oslo. Finally the Board commissioned consultants to provide bed modelling analysis.

- Control of change - There is a robust change management control mechanism in place. Requests for change need to be supported by the respective Director, and a case presented to the Acute Services Strategy Board Executive Sub Group for consideration and approval. Due to the extensive user consultation undertaken prior to tender there have been very few requests for change from users during the development of the 1:200 and 1:50 design.

- Programme and resources – effective project management and leadership is displayed by the Board which supports a robust delivery team that is well resourced and supported to work in partnership with the contractor and with other agencies and parties engaged in delivery of the project.

- Financial Planning – Financial planning and financial risk management have been at the heart of the project and controlled through each of the project's stages. Making allowance for known and unforeseen risks has been integral in planning as can be seen from the contract risk registers.

2J. CONSTRAINTS & DEPENDENCIES

Constraints that affect the project are the physical site for the construction works, due to this being located within the boundary of the existing Southern General Hospital, and the financial envelope as there are dependencies with regard to the provision of capital and revenue funding for the project.

2J.1 The Physical Site

The Southern General campus is bordered and accessed from the north by Govan Road and on its west side off Hardgate Road.

The eastern boundary is formed by the Clyde Tunnel approach and Moss Road. The southern boundary is bordered by residential property. Road access is not currently available along either of these edges.

The north-western corner of campus site between Govan Road and Hardgate Road is bordered by existing industrial land and Sheildhall Water Treatment Works. At present Hardgate Road does not extend beyond the Treatment Works and therefore does not link with Govan Road.

The existing hospital buildings are spread out over a large area of the campus and in a number of cases require elevated bridge links across the spine road. Surface car parking is distributed sporadically adjacent to the numerous entrances arising from the existing fragmented site layout.

A number of bus services pass close to, or through, the site.

Emergency blue light traffic use the same spine road network to access A+E, Maternity and Neuro/Spinal Injuries.

The site area within the campus, which is 15.5 acres or 6.3 hectares, will be passed to the contractor in a phased sequence (firstly for the construction of the laboratories, secondly to allow demolitions to proceed and thirdly to allow the main hospitals build to commence) while the existing SGH services continue to operate.

The potential for interruption to day-to-day services and facilities within the site during construction has been carefully analysed, and will be managed by a series of enabling works. The construction site will be isolated from the remainder of the hospital with materials and construction traffic accessing the site from a discrete entrance off Hardgate Road and a link road to Govan Road that presently exists within the site. Details of the various enabling and de-risking activities and planning for the site are included in the project risk section in Chapter 4B.

The hospital will continue to operate uninterrupted during construction and commissioning of the new facilities. Control of all activities is managed in conjunction with the Southern General Hospital FM Department through a series of regular formal meetings.

2J.2 The Financial Envelope

Specific detail around the funding and affordability of the project is included in both Chapter 3 (The Economic Case) and Chapter 5 (The Financial Case). In headline terms however, the proposals within this Business Case are that the Scottish Government will provide the capital funding for the project and the Board will be responsible for providing the revenue funding for the project.

CHAPTER 3

THE ECONOMIC CASE

CHAPTER 3 – THE ECONOMIC CASE

3A. CRITICAL SUCCESS FACTORS

As stated the purpose of this Full Business Case is to reaffirm the case laid out in the Outline Business Case, in other words that the Board's Strategic direction remains the same and that the preferred option is still valid and supports the Board's overall service change strategy and subsequent capital programme.

Key CSFs	Broad Description
Strategic fit and business needs	The preferred option remains the key phase in the overall Board's strategy for service change, the Acute Services Review. This is further detailed in chapter 2. The benefits and efficiencies arising from the implementation of the project are integral to the sustainability of Glasgow's acute health service.
Potential VFM	The project continues to demonstrate Value for Money; this is further detailed in Chapter's 3 and 5.
Potential achievability	Extensive pre-planning has taken place to establish the Board's clinical and technical requirements and a construction partner capable of delivering the scheme is appointed. Specific logistics pre-planning and engagement is taking place to minimise any impact on the delivery of clinical services on the exiting site. The design and construction plans are developing as are outline plans for commissioning and transfer of services.
Supply-side capacity and capability	The new hospitals will create capacity to enable the sustained delivery of current government targets e.g. HEAT targets and create flexibility in meeting new future targets.
Potential affordability	The project continues to demonstrate an affordable solution in both capital and revenue terms, this is detailed in Chapter 5. The capital and revenue remain within the funding envelope identified in the OBC.

3B. ECONOMIC CASE – VALUE FOR MONEY

3B.1 Introduction

This section covers the economic appraisal of the value for money implications of the project. The appraisal has been conducted with reference to the relevant guidance from HM Treasury, Scottish Futures Trust and the Scottish Capital Investment Manual published by the Scottish Government in August 2009. The economic case is structured as follows:

- A summary of the position at OBC stage is presented
- Developments that have occurred since completion of the OBC are described and their impact on the preferred way forward assessed;
- Details of the costs to be included in the appraisal are provided;
- Results of the appraisal are presented.

The following paragraphs consider each point in turn.

3B.1 Summary of Economic Case at Outline Business Case

The OBC considered three options for implementing the project

1. Greenfield Option – A new build whole site solution for all facilities currently provided at the Southern General site, together with new Adult Acute and Children's Hospitals, plus related facilities. Land for a Greenfield site would be required under this option.

2. "Option 1" – This option represents an entire new build solution on the current Southern General site for the Adult Acute and Children's Hospitals, plus new build Laboratories, and other related services.

3. "Option 1A" – A new build provision on the Southern General site for the Adult Acute and Children's Hospitals, plus the refurbishment of some existing facilities on the Southern General site to provide Laboratories and other related services. This option allows for the retention of Neurosciences, Maternity, the Spinal Unit and the Langlands buildings currently on site.

   For options 1 and 1(A) two scenarios were also considered. These were:
   - Base case, which modelled a scenario with 57% single room provision for the Adult Hospital; and
   - Alternative case with 100% single room provision within the Adult Hospital.

In addition the Board considered three potential procurement routes:

1. Traditional Procurement – also referred to as the Conventionally Procured Asset Model ("CPAM");

2. Private Finance Initiative ("PFI");

3. Not for Profit Distribution Model ("NPD"). This model provides for the redistribution to the Board of any excess profit which may arise, in the form of "charitable surplus".

   The risk adjusted net present values from this exercise are set out in the following table:

Table 5 - OBC Position: Summary of risk adjusted net present values by option

OBC Position: Summary of risk adjusted net present values by option							
	Greenfield CPAM £'000	**Option 1 CPAM £'000**	**Option 1A CPAM £'000**	**Option 1A PFI £'000**	**Option 1A NPD £'000**	**Option 1A PFI Bond £'000**	**Option 1A NPD Bond £'000**
Base Case	2,031,093	1,099,535	1,012,725	1,020,915	1,009,694	997,749	984141
100% Single Rooms	2,068,056	1,129,425	1,042,615	1,051,924	1,040,160	1,028,700	1,014,531
Ranking (excluding bond)			*2*	*3*	*1*		

For both the "base case" and "100% single rooms" scenarios, Option 1A represented the preferred option, when compared to the Greenfield site and Option 1, in terms of risk adjusted net present value. On this basis, a full value for money appraisal was carried out on Option 1A, examining the relative costs of each alternative procurement route.

When assessed in risk adjusted net present value terms the three procurement routes produced very similar results, the variation between the options being only 1.1%. In terms of ranking, excluding Bond, the NPD model ranked first, followed by CPAM then PFI. At the time of the OBC, it was noted that a Bond had not been used to finance any NPD project which had closed in Scotland.

The Board reviewed the options, particularly in light of the results of the affordability assessment, and the OBC proposed the adoption of a Traditional procurement route for Option 1A with 100% single room provision. This position was ratified by the Scottish Government in its approval of the OBC.

3B.3 Main Business Options

In the period following the approval of the OBC there have been a number of developments in both a policy context and market positions that have an impact on the economic case. These developments include:

- For the Greenfield site option a suitable site had not been available to the Board at the time the OBC was prepared. During the intervening period an appropriate site has still not become available;

- The Board has commenced the investment of over £100m in major capital works on the Southern General site including the recently completed extension of the Maternity Hospital (£28m) together with construction of a major new Laboratory and combined Facilities Management complex at a total cost of £90m. Both of these developments form part of the programme of building works associated with the Acute Services Review;

- The Scottish Government, through the work of the Scottish Futures Trust, has developed the Non Profit Distributing Model as its preferred form of Public Private Partnership. The model has been successfully used on education projects and also in the health market for NHS Tayside's Mental Health Developments Project. It is currently being applied in the transport sector for the procurement of the Borders railway project;

- In common with the wider economy the global financial crisis had a significant impact on the infrastructure market. The availability of credit has severely contracted and the price of credit has increased substantially. This has resulted in a significant reduction in both the number of lenders in the market and the number of transactions reaching completion. Furthermore there has been no use of bond funding of PFI transactions, in part due to the exit from the market of monoline insurance providers.

Each of these factors has influenced the Board's preferred way of taking the project forward.

3B.4 Preferred Way Forward

In considering the way forward the Board re-examined the Greenfield option. The conclusion was reached that due to the lack of a suitable site this option was not viable. Accordingly this option was not taken forward.

With respect to Option 1, the new build option, the significant demolition of existing buildings and the development of new facilities on the current site precludes further analysis of the new build option.

Consequently, Option 1A, with 100% single room provision for the Adult Hospital per CEL 27 (2010), remains the preferred option against which the various procurement routes should be retested.

The traditional, PFI and NPD procurement routes all remain potential options for delivery. However, as the use of bond funding is no longer deliverable, this funding option was not taken forward.

On this basis the options for assessment in the economic case within this FBC are:

1. Option 1A – Traditional Procurement;

2. Option 1A – PFI Procurement (Bank funding);

3. Option 1A – NPD Procurement (Bank Funding);

The three options have been appraised using the same methodology as in the OBC, with the risk adjusted net present cost of the CPAM compared to that of the PFI and NPD options.

3B.5 Assessment of Procurement Routes

This section provides details of the main inputs and assumptions used in the economic case. It covers the capital, lifecycle and facilities management costs, plus details on adjustments in respect of tax and risk quantification.

3B.5.1*Capital costs*

The capital costs are summarised in the following table

Table 6 – Capital Costs

	£'000
Base Costs	585,394
Equipment	51,700
VAT	114,856
Total Capital Costs	**751,950**

The capital costs represent the cost to the Board for construction of the new Adult Acute and Children's Hospitals, plus the provision of equipment. The Board's approach to equipment remains unchanged from the OBC position, with equipment being the subject of a separate procurement exercise. Accordingly for the purposes of the economic case equipment costs are excluded from the analysis.

3B.5.2*Movements from OBC*

The table above demonstrates that the total capital cost amounts to £751.950m. At the OBC stage the figure of capital costs was £841.700m. The difference between the amounts is a result of the removal of laboratories costs, as demonstrated below:

	£'000
Total Capital Costs including Optimism Bias at FBC	751,950
Laboratory project Costs	89,750
Capital costs at OBC Stage	**841,700**

The procurement of the new multi-disciplinary laboratory and facilities management building was considered in a separate Full Business Case approved in December 2009. As this project was the subject to a separate appraisal and approval process the costs have been excluded from this economic case in order to avoid double counting.

3B.5.3 *Lifecycle and facilities management costs*

The appraisal includes costs in relation to the provision of lifecycle and facilities management for the new facilities. The following table summarises the lifecycle and hard facilities management costs, discounted to present values, which will be incurred over a 30 year operating period.

Table 7 – Lifecycle and facilities management costs

	£'000
Lifecycle costs	157,684
Facilities management costs	153,878

3B.5.4 *Tax Adjustment*

It is necessary to take account of the relative impact of taxation applicable to each procurement route in carrying out VFM assessments. This has been provided for as required by existing Green Book Guidance at 6%.

3B.5.5 *Short list of procurement routes*

As described above the PFI and NPD procurement routes are based on a senior bank debt funding solution. Funding terms have been estimated by Finance Advisors on the basis of current market conditions. A LIBOR rate of 4.1% has been used, representing the market rate in June 2010 when it is envisaged that financial close would have occurred under these procurement routes. A fully indexed unitary charge has been applied.

3B.5.6 *Discount rates*

In order to demonstrate transparency and to allow comparability the discount rate assumptions remain unchanged from the OBC.

The net present value calculations have been performed to a base date of 1 May 2010.The Treasury discount rate of 3.5% real (6.0875% nominal) has been used for all cash flows except for any charitable surpluses (NPD model only) Charitable surpluses are discounted at 6.0% real (8.65% nominal) reflecting the fact that the surplus cash flows are at risk.

3B.5.7 *Risk Adjustment*

As different procurement methods bring different risks which require to be managed, it is necessary to identify and quantify relative risk impact in carrying out VFM assessments.

Incorporated into the value for money analysis are risk adjustments based on the outcomes of risk workshops carried out by the Board. These take account of the relative impact which a wide range of different risks might be expected to have on every cost element within each of the alternative procurement routes. For the CPAM procurement model, the risk adjustment for the base case scenario equates to 8.3% of the value of the CPAM, of this 5.4% could be transferred under the NPD or PFI procurement models with 2.9% retained under all procurements.

Further details on the Board's approach to risk management are set out within Chapter 4 of this FBC.

3B.6 *Results of appraisal*

The results of the appraisal, in terms of the net present cost on a risk adjusted basis, are set out in the following table:

Table 8 - FBC Position: Risk Adjusted Net Present Values by Option

	Option 1A CPAM £'000	Option 1A PFI £'000	Option 1A NPD £'000
NPV of CPAM / Unitary Charge Payments	695,928	893,946	895,882
Risk adjustment	57,840	20,440	20,477
	753,768	**914,386**	**916,359**
Tax adjustment	41,756	-	-
Charitable distributions	-	-	(15,358)
Risk Adjusted NPV	**795,524**	**914,386**	**901,001**
Ranking	*1*	*3*	*2*

The results demonstrate that the traditional procurement represents better value for money than the PFI and NPD options by £118,862,000 and £105,477,000 respectively. This supports the Board decision to procure the facilities through the traditional procurement route.

3C. BENEFITS APPRAISAL

The Project Team reviewed and re-affirmed the benefits appraisal undertaken at Outline Business Case Stage. In other words the weightings and scores of the options remain as per Outline Business Case with the scores in a very tight band, those options involving an increased percentage in new build producing slightly higher scoring. For details of scoring please see Appendix E.

3D. WORKFORCE

3D.1 Introduction

The new South hospitals project will have a significant impact on the overall workforce of the Acute Services Division. As the anticipated economies of scale are realised from consolidating the acute sites we have the opportunity to review existing practices and redesign the way patient services are currently delivered. With over 26,000 WTE staff within the Acute Services Division of NHS Greater Glasgow and Clyde (NHSGG&C), accounting for three quarters of the Board's workforce, this project will, ultimately, impact either directly or indirectly on all employees.

NHSGGC recognises that in order to deliver new models of care within the new hospital significant workforce development and engagement will be required. Over the last few years, NHSGGC has been responding to workforce modernisation and technological advances, in particular with the new Beatson Oncology Centre, the 2 new Ambulatory Care Hospitals and the new Laboratory on the South Campus and will continue with this approach in the wider Board area. The new hospital buildings will provide further opportunities to develop and modernise the way in which the workforce deliver services in response to the developing models of clinical care.

3D.1.1 *Workforce Engagement*

In developing new roles and redesigning service provision, NHSGGC has put in place arrangements for regular strategic engagement with staff representatives. In addition to regular updates through the Acute Partnership Forum, there are formal and regular engagement with employees and their representatives at Directorate level and at Division level through an overarching Acute Workforce Engagement Group.

This model of engagement provides staff and their representatives with meaningful opportunities to participate in the change programme from inception to implementation.

3D.2 Current Workforce Profile

3D.2.1 *Whole Time Equivalents*

During the summer of 2010, the Acute Services Division of NHS Greater Glasgow & Clyde employed 26003.9 WTE members of staff (see Table 9).

Table 9 - Current Workforce

Administrative Services	4046.4
Allied Health Profession	1754.6
Senior Management	169.1
Healthcare Sciences	1783.4
Medical and Dental	2599.0
Medical and Dental Support	307.5
Nursing and Midwifery	10812.2
Other Therapeutic	657.8
Personal and Social Care	52.9
Support Services	3820.8
Total	26003.9

3D.2.2 *Workforce Demographics*

The workforce within the Division is predominantly female (76.3%) with 34.7% of those between the ages of 41 and 55. A more detailed breakdown of the Division's workforce demographics is contained in Tables 20-22 at the end of this section.

Based on a default retirement age of 65 for both men and women, approximately 1,409 WTE staff will retire over the next five years. See Table 10 below.

Table 10 - Retirement Projections

	WTE
2011/12	298.3
2012/13	179.8
2013/14	311.3
2014/15	293.5
2015/16	326.2
Total	1409.1

3D.3 Workforce Redesign

The process of workforce design is already underway within our Directorates and Partnerships. By evaluating the ways in which our workforce skills and practices can be modified we can ensure we are developing the best practice pathways and at the same time ensuring best practice is applied consistently across the Division and wider Board.

In the Rehabilitation and Assessment Directorate there were two pilot schemes funded by the Scottish Government Health Directorate. The first considered the practicability of establishing more skilled support workers to assist Allied Health Professionals, thereby shifting our skill mix by increasing the number of Band 4 posts in order to free registered Nursing and AHP time to perform tasks more appropriate to their skills and experience. The second pilot explored the development of an advanced practitioner role to assist with assessment of patients within medical receiving, thus freeing the time of medical staff.

Within the Diagnostics Directorate work has commenced to consider the competencies required in laboratories and the educational pathways required providing greater flexibility in accessing careers in laboratory medicine. This work is being undertaken in partnership with our local higher education establishments.

A significant piece of the redesigned workforce will be in the greater use of trained workers on levels three and four of the NHS Careers Framework which should allow a shift in skill mix of 10% from Band 5 to Bands 3/4. These posts will operate in a support worker role across a range of disciplines. To this end, we are working in partnership with a number of further and higher education establishments to develop a curriculum to facilitate recruitment to these new roles. The first students from the new courses are expected to qualify in 2012. The curriculum has been developed in conjunction with the colleges using nationally agreed core competencies to ensure the qualifications are both nationally and officially recognised.

The creation of this new pathway into a career in the NHS will assist the Board in not only enhancing the skills of some of our existing staff but also in promoting opportunities in the local communities of which our hospitals are often the main employer in the area. This is particularly important as it is predicted that over the next five years (see Table 23), within the Board's area the proportion of the population at working age will decrease whilst the number of over 65 will increase. Through our partnership arrangements with local regeneration agencies and local education services we aim to make the NHS an employer of choice for pupils and students of all disciplines which will help deliver the aims of *a Force for Improvement.*

A considerable amount of work has been on-going over the previous three years in shaping the medical workforce for the new hospitals in 2014/15 taking account of Modernising Medical Careers and the announced Scottish Government intention to move towards a trained medical workforce. This work coincided with CEL 28 (2009) which asked Health Boards to review the shape of their medical workforce for 2014 and to use a number of key assumptions which were taken into account in our medical workforce modelling.

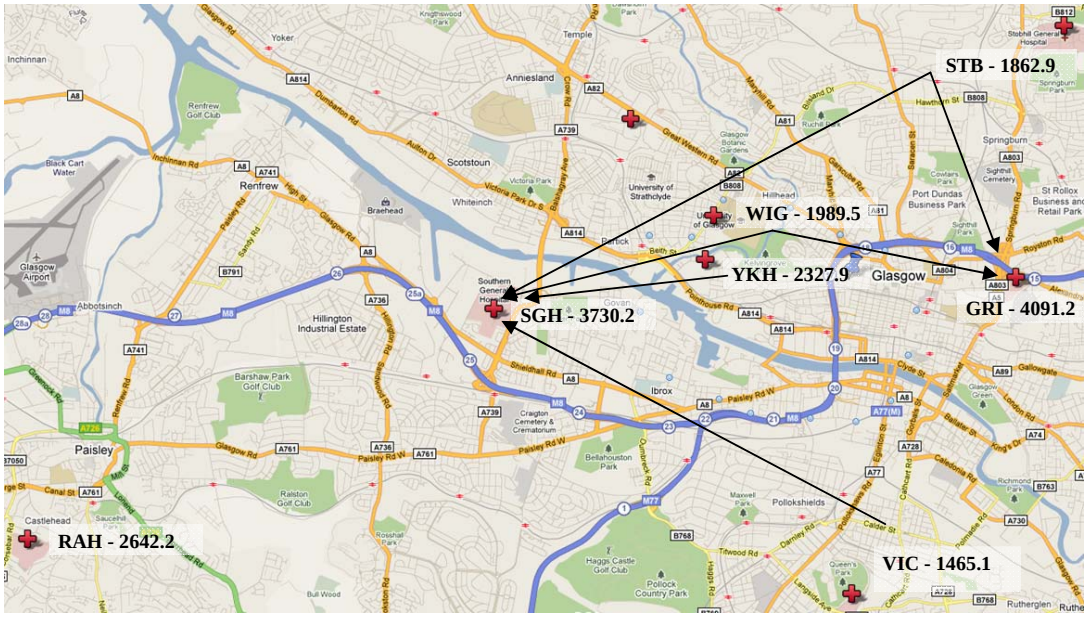
Some significant rota remodelling was undertaken for senior and trainee medical staff creating new rotas which help determine the numbers of new staff required, i.e. Acute Care Physicians in Medicine and in Emergency Medicine to determine the numbers of specialty doctors and consultants needed. These rotas have been designed on a real life basis, with the assumption (also in anaesthesia) that consultant staff will be expected to undertake shift work on a 24/7 basis shared amongst substantial numbers of consultants.

3D.4 Site Consolidation

As part of the consolidation of the acute sites approximately 6250 staff will be affected by moving site. The majority are on four existing hospital sites; Yorkhill Hospital, the Western Infirmary, Stobhill Hospital and the Victoria Infirmary. A proportion of staff on the Western Infirmary and Stobhill Hospital sites will move to the existing Glasgow Royal Infirmary as part of the wider Acute Services Strategy.

The complexity and scope of the relocation of such significant numbers of staff from the four major sites in the north, north-west and south-east of the city to north-east and south-west localities is well understood and it is recognised that good communications will be key to the successful delivery of workforce re-location. Extensive and in-depth consultation at all levels will take place with staff and staff representatives, together with regular meetings and newsletters. Consultation has already commenced with those affected by the relocation of laboratory services within the city to the new laboratory building on the Southern General Hospital site, which is due to open in 2012.

The map below shows the locations of the Glasgow city hospitals affected by the relocation of services to the new South Glasgow Hospital site.



3D.5 Workforce Change

As previously indicated, the development of the new South Hospital provides an opportunity to redesign the way current services are delivered and for a thorough review of potential new roles to support service delivery issues. The Organisational Development and Learning and Education Teams of Human Resources are working with Directorates to provide appropriate levels of change management and leadership development support to underpin the change programme. The detailed work, thus far, on the implications for the workforce due to the new hospitals has been underpinned by working completely in partnership with our trade union and professional association colleagues from the outset. The use of standard workforce planning and workforce tools together with comprehensive staff involvement has been instrumental in ensuring patient care is at the forefront of the proposed workforce change.

3D.5.1 *Allied Health Professions*

The Allied Health Professions (AHP) workforce within adult is split into a number of professions, as shown in Table 11 below.

Table 11 – Allied Health Professions WTE as at Summer 2010

	WTE (all grades excl admin)
Dietetics	89.6
Speech and Language Therapy	66.41
Physiotherapy	394
Occupational Therapy	201.6
Podiatry	22.96
Orthotics	10.48
Prosthetics	21.5
TOTAL	806.55

An AHP redesign group has been working in Acute and across the Board's Community Health Partnerships over recent months and this will result in the transfer of the physiotherapy musculoskeletal outpatient service of 59.69 WTE to a Community Health Partnership, the podiatry service will also transfer to a Community Health Partnership. 87.81 AHP and support workers working in supported discharge and community disability services are also transferring to community management later this year. This will reduce AHP staffing in the Acute Division by 170.46 WTE during 2010 -11 resulting in a total workforce of 636.09 WTE.

The AHP workforce will experience significant changes over the coming years which include the introduction of 7 day working, alteration of skill mix and new service models

AHPs traditionally have provided services within fixed hours on a Monday – Friday basis. Physiotherapy services have additionally provided a respiratory on call service to ensure 24hour cover on a 7 day basis. To assist reducing the time that patients spend in hospital some AHPs will be moving towards working longer days and at weekends.

It is anticipated that this will result in a reduction in the requirement for on-call services with a rationalisation from 5 separate on call services to 2 overnight services commencing at 9pm rather than from 5pm as at present. Initial work has indicated that the majority of calls are prior to 9pm.

Workforce redesign is ongoing to alter the existing skill mix. This redesign will increase the use of support workers at levels 2, 3 and 4. The rationalisation of sites will also offer the opportunity to reduce management overheads. It is anticipated that there will be a reduction of 20 Band 6 WTE which will be replaced with support worker posts with a resultant saving

AHP services are currently managed across sites by profession, where appropriate a move to AHP team leads will be introduced rather than Profession specific Team Leads. This will result in a minimum reduction of three Band 7 WTE with the potential of further reductions over the next five years

Acute medicine is concerned with the immediate and early specialist management of adult patients. It is fundamental that specialist AHP management also occurs at this early stage. strong multi-professional working is pivotal to providing an integrated and coherent standard of service with rapid assessments and discharge planning.

Occupational Therapists and Physiotherapists play a central role in the preliminary assessments required for prevention of admission, early intervention and timely discharge and have a positive effect on efficiency and patient flow. It is proposed to introduce Band 7 AHP clinical decision makers from within existing resources to provide a service to the new Emergency Receiving Centres.

The overall reduction of 404 beds will not reduce the numbers of AHP staff required as inpatients will require speedier interventions by AHPs to ensure rapid discharge from hospital and surgical patients being treated as daycases will continue to require AHP input at pre-assessment and on treatment.

Within radiography, the implementation of a 4 tier structure continues. The Board has positively embraced the 4 tier structure, demonstrated by the recruitment and training of 8 assistant practitioners and 2 consultant sonographers. Overall the Board anticipate no significant changes to the diagnostic imaging workforce.

The overall changes within AHP staffing are shown in Table 12 (below).

Table 12 – Changes within AHP Staffing by 2015/16

AfC Band	Change (WTE)
Band 7	- 3
Band 6	-20
Band 4	+20
Band 3	- 8
Band 2	+ 8
Total	-3

3D.5.2 *Nursing & Midwifery*

The Nursing and Midwifery workforce will see some significant changes to workforce numbers due to the overall reduction in beds and the efficiency gains of working in the new hospitals, whilst retaining the current average nurse to bed ratio of 1.19. This will see a reduction of some 480 WTE nursing posts over the next five years.

The changes in bed numbers will see a reduction of 278 beds during 2011/12 with a further reduction of 126 being phased out over the following four years. The overall reduction of 404 beds includes an increase of 54 beds in General Medicine. The overall savings accruable are shown below at Table 13.

Table 13 – Nursing changes due to bed reductions

	Bed Reduction	WTE Change
By 2011/12	-278	-330.8
By 2015/16	-404	-480.8

At the same time, nursing is undertaking workforce redesign to alter the existing skill mix. This redesign will increase the number of support workers at levels 3 and 4 of the NHS Career Framework to allow the professionally qualified workforce to focus their time to direct patient care. Overall the number of level 3 and level 4 support workers is anticipated to increase by approximately 440 WTE across the Acute Services Division over the next five years. The national workload tools are being used to assist in predicting our future workforce numbers, with the Nursing and Midwifery Workload Tool being used to test the professional judgement used to predict the nursing numbers for the new South Glasgow Hospitals. The review of skill mix is being delivered in partnership with key staff side organisations through a structured Programme Board and Implementation Group.

Whilst the overall affect of the change in skill mix on nurse staffing numbers will be neutral, the associated savings of these changes are set out below at Table 14.

Table 14 - Nursing Workforce Skill mix change by 2015/16

NHS Careers Framework	Current WTE	New WTE
Level 3	876.4	1183.9
Level 4	39.4	171.1
Level 5	4393.0	3953.7
Total:	5308.8	5308.8

In addition to these savings there will be an additional 6.25 WTE of efficiencies from reduced nurse management overheads due to the reduction in beds.

3D.5.3 *Medical Workforce*

The Medical workforce will experience three significant changes over the next five years. First, the number of core trainees is expected to decrease by 44 WTE, secondly the number of specialty trainees is expected to reduce by 82 WTE and lastly the number of consultant doctors is expected to increase by 16 WTE. This will assist NHSGGC in working towards an increasingly consultant-led service.

The following describes some of the specific changes under scope.

Anaesthesia

Anaesthesia is an on-call, on-site specialty, it is expected that rationalisation of the number of sites will produce a dramatic reduction in the number of staff required to be on-call. Virtually all elective work is now performed by consultants, and while a reduction in junior staff may reduce the capacity to flexibly cover annual leave, the capacity released by the reduction in acute sites, particularly consultants committed to day time on-call will assist in covering this. A detailed analysis of existing rotas revealed that only about 60% of a core trainee's and around 66% of ST3+ trainees work is for service. On-call arrangements for consultants will include on-site working till 10 o'clock in the evening in both our major receiving sites, and within intensive care there will be two consultants present until 10 pm and thereafter there will be a consultant presence on the floor on-site overnight.

General Surgery

General Surgery also benefits from substantial reduction in the on-site, on-call commitment by trainee staff. It is not proposed to increase the numbers of consultant staff, as in most sub-specialties the elective workload is such that the critical balance between the number of cases and retained practical skills has been reached already.

Acute Medicine

Within Acute Medicine, in both GRI and the new Southern General there will be a substantial redesign of the receiving arrangements for medicine. The current medical receiving model proposed for the new SGH (with some variation at GRI) is based on receiving driven by specialty teams supported by a general physician and an acute care physician. Bringing our acute units together will give us critical mass in two acute sites to give us the capacity to provide senior staff for these receiving teams. This model will see an increase of 14 acute care physicians (seven on each site).

In addition, on-call work already allocated in job plans will be redirected to the new model. The increase in consultant numbers of 14 posts will all be Acute Care Physicians. There will be two rotas of Acute Care Physicians, one on each site receiving and they will play a significant role in handling seriously ill medical receiving cases and running the medical HDU. This represents a substantial investment and will enable us to reduce the role of trainee medical staff in these areas. There is also an increase in specialty doctor numbers, but this is mainly to allow replacement in certain specialties of the elective component performed by ST trainees.

Emergency Medicine

Emergency Medicine will be re-aligned from four sites to two, and take cognisance of the previous decision to close the casualty at Stobhill Hospital and realign to Glasgow Royal Infirmary. It is also proposed to have a 24/7 presence of consultant staff in both of the remaining A&E departments, these departments will be amongst the busiest units in the UK and this 24/7 consultant model is already present in A&E departments in London where similar numbers of patients are seen.

The overall changes within medical staffing are shown below at Table 15.

Table 15 – Changes within Medical Staffing by 2015/16

Grade	Change (WTE)
Consultant	+16 *
Specialty Registrars	-82
Core Trainees	-44
Specialty Doctors	+38
Totals	-72

* Includes a reduction of 5 Consultant posts within Anaesthetics

3D.5.4 *Senior Management / Admin Support Staff*

As the Board continues to improve productivity and adopt new technologies to support administrative functions, the relocation of a significant volume of the Acute Division's activity on a single site and the associated rationalisation of services, together with the adoption of a paper-lite strategy, will allow deliver further economies of scale within both senior management and admin/clerical support staff.

Further information is set out below at Table 16.

Table 16 – Senior Management and Administration Staff Changes by 2015/16

Staff	Reduction (WTE)
Senior Management	7.0
Admin Support	30.75

3D.5.5 *Facilities – Support Services*

A rationalisation of hotel services is underway and will result in significant changes, particularly within catering which will see a reduction in production units across the Board to two sites. The closure of major parts of the Board's existing estate with the associated relocation of patient activity will further allow rationalisation within the portering and estates/maintenance functions. The move to 100% single rooms within the new hospital will, however, see an increase in domestic staff on the site.

The overall effect on Facilities staffing will see a reduction of some 170 WTE however work is continuing to identify further possible efficiencies.

3D.6 Consolidated Changes

The overall effect on current staffing due to changes to the current bed model, skill mix changes and associated rationalisation of services for each of the staff groups is shown below at tables 17 and 18.

Table 17 – Overall Effect of Skill Mix change on the workforce implemented by 2015/16

NHS Career Framework Level	AHPs (WTE)	Nursing (WTE)
Level 2	8	0
Level 3	-8	307.5
Level 4	20	131.8
Level 5	0	-439.3
Level 6	-20	0

Table 18 –Summary of Changes to Workforce by Job Family

Workforce	Current	By 2015/16	Difference
Administrative Services	4046.6	4016.4	-30.2
Allied Health Profession	1754.6	1751.6	-3.0
Senior Management	169.1	162.1	-7.0
Healthcare Sciences	1783.4	1783.4	0.0
Medical and Dental	2569.0	2527.0	-72.0
Medical and Dental Support	307.5	307.5	0.0
Nursing and Midwifery	10812.2	10325.2	-487.0
Other Therapeutic	657.8	657.8	0.0
Personal and Social Care	52.9	52.9	0.0
Support Services	3820.8	3648.8	-172.0
Job Family To be Assigned	194.3	194.3	0.0
Total	26003.9	25232.2	-771.8

3D.7 Linkage With Community Care Services

Within NHS Greater Glasgow and Clyde, the Acute Services Division together with CHCPs/CHPs and Mental Health Services are working together to look at different ways in which the balance of care can be shifted with more people receiving care within their own home supported through GP and community nursing input.

There are a number of areas of work focussing on how we can better improve care through Acute Services and community colleagues working more closely. The Collaboratives for Planned Care, Unscheduled Care and for Diagnostics established a programme of joint working where Acute and CHCP/CHP colleagues have been working together to improve the interface between primary and secondary care, streamline the patient journey and deliver the access targets. The Board will continue to build on this approach as progress is made in the programme to deliver the 18 week referral to treatment standard. With the new Long Term Condition Programme both Acute and CHCP/CHPs are working together to consider new ways of delivering patient care and further development of existing schemes, which look to maintain patients at home, through anticipatory care models that seek to avoid admission and readmission as well as to support getting patients home earlier.

The planning process for the opening of the new Stobhill and Victoria Hospitals in 2009 saw a number of clinical specialty planning groups established involving representatives from the Acute Division and from CHCPs/ CHPs. The role of planning groups will be built upon and they will consider new patient pathways between primary and secondary care allowing a shift in care. This redesign work was integral to the implementation of the Acute Services Review both in preparation for the recently opened Ambulatory Care Hospitals at the Victoria and Stobhill sites but also sets the framework for the redesign of inpatient healthcare in Glasgow's acute sector in particular for the New South Glasgow Hospitals.

The shape of the workforce will need to support this transition. Work is already underway to redesign the workforce in Children's Services to develop integrated children's teams bringing health and social care professionals together. Specialist paediatric staff, many of whom are already managed within CHCP/CHPs, will be further augmented from the acute sector as services develop further. The Board are at an advanced stage in looking at the role of Health Visitors in this model.

The Long Term Conditions Programme will require a community based workforce which has the skills to maintain patients at home. This will require existing community nursing staff to acquire more specialist skills or for more specialist staff to be more readily accessible. The Board will continue to develop this based on the range of competencies necessary in line with the NHS Careers Framework.

Table 19 – Gender Breakdown by Age Range (At Summer 2010)

Age Range	F	M	Total	F	M	Total
<21	101.8	38.6	140.4	0.4%	0.1%	0.5%
21 - 25	1,433.5	319.3	1,752.8	5.5%	1.2%	6.7%
26 - 30	2,459.1	618.0	3,077.1	9.5%	2.4%	11.8%
31 - 35	2,124.2	745.0	2,869.2	8.2%	2.9%	11.0%
36 - 40	2,265.9	812.3	3,078.2	8.7%	3.1%	11.8%
41 - 45	2,894.2	892.9	3,787.1	11.1%	3.4%	14.6%
46 - 50	3,378.9	950.5	4,329.4	13.0%	3.7%	16.6%
51 - 55	2,750.3	782.2	3,532.5	10.6%	3.0%	13.6%
56 - 60	1,710.3	615.6	2,325.9	6.6%	2.4%	8.9%
61 - 65	613.6	330.5	944.1	2.4%	1.3%	3.6%
66>	115.1	52.1	167.1	0.4%	0.2%	0.6%
Totals	19,846.9	6,157.0	26,003.9	76.3%	23.7%	100.0%
	76.3%	23.7%	100.0%			

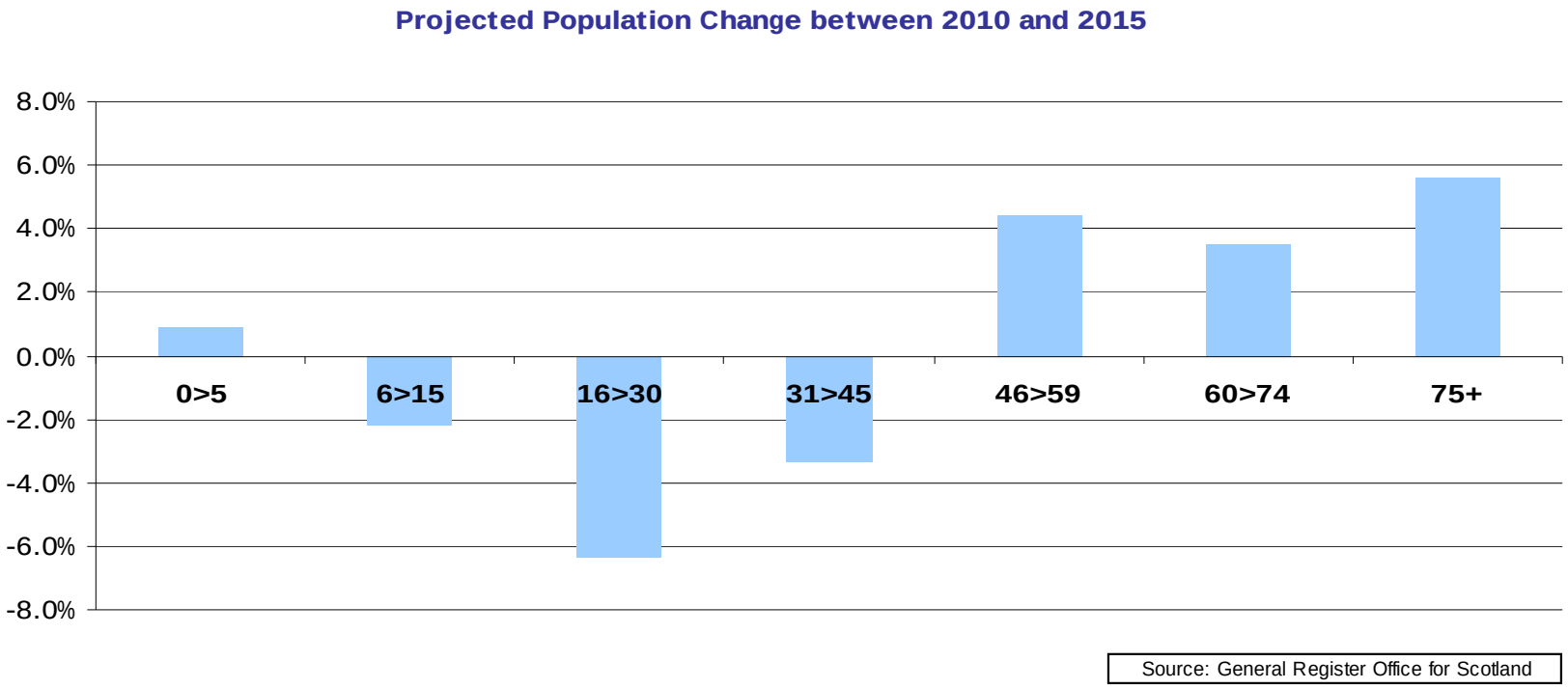
Table 20 – Gender Breakdown by Job Family (At Summer 2010)

Job Family	F	M	Totals	F	M	Totals
Administrative Services	3,397.0	619.4	4,016.4	13.1%	2.4%	15.4%
Allied Health Profession	1,520.8	220.7	1,741.5	5.8%	0.8%	6.7%
Senior Management	104.0	63.8	167.8	0.4%	0.2%	0.6%
Healthcare Sciences	1,083.9	686.1	1,770.0	4.2%	2.6%	6.8%
Medical and Dental	1,174.3	1,405.3	2,579.6	4.5%	5.4%	9.9%
Medical and Dental Support	277.2	28.1	305.3	1.1%	0.1%	1.2%
Nursing and Midwifery	9,711.0	1,020.3	10,731.4	37.3%	3.9%	41.3%
Other Therapeutic	508.6	1,44.3	652.9	2.0%	0.6%	2.5%
Personal and Social Care	41.0	11.5	52.5	0.2%	0.0%	0.2%
Support Services	1,883.6	1,908.6	3,792.2	7.2%	7.3%	14.6%
Job Family To be Assigned	145.4	49.0	1,94.3	0.6%	0.2%	0.7%
Totals	19,846.9	6,157.0	26,003.9	76.3%	23.7%	100.0%

Table 21 – Age Distribution by Job Family (At Summer 2010)

Job Family	<21	21 - 25	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 - 55	56 - 60	61 - 65	66>	Totals	
Administrative Services	52.1	199.7	348.3	352.0	433.9	580.0	676.7	662.0	516.9	175.0	19.8	4016.4	15.4%
Allied Health Profession	1.4	194.1	381.9	270.7	197.3	197.6	203.2	167.4	105.1	19.6	3.2	1741.5	6.7%
Senior Management			0.7	3.0	13.8	35.5	48.9	41.0	22.0	3.0		167.8	0.6%
Healthcare Sciences	8.4	100.9	236.7	203.1	185.9	215.2	276.3	276.9	188.2	65.9	12.6	1770.0	6.8%
Medical and Dental		221.0	434.5	499.9	428.5	312.7	295.1	198.4	138.9	43.3	7.3	2579.6	9.9%
Medical and Dental Support	14.4	60.2	54.4	43.9	29.5	27.6	29.0	27.1	14.6	4.2	0.5	305.3	1.2%
Nursing and Midwifery	27.8	748.0	1273.4	1132.7	1351.7	1752.9	1965.9	1400.6	747.1	294.6	36.7	10731.4	41.3%
Other Therapeutic	5.0	72.6	111.9	103.7	89.7	75.9	78.0	70.0	35.9	9.9	0.4	652.9	2.5%
Personal and Social Care		1.0	2.0	10.3	6.0	7.5	9.0	7.0	6.5	2.0	1.3	52.5	0.2%
Support Services	31.4	140.9	206.0	229.0	311.7	553.2	715.1	660.1	541.8	318.2	85.0	3792.2	14.6%
Grand Total	140.4	1752.8	3077.1	2869.2	3078.2	3787.0	4329.4	3532.5	2325.9	944.1	167.1	26003.9	100.0%
	0.5%	6.7%	11.8%	11.0%	11.8%	14.6%	16.6%	13.6%	8.9%	3.6%	0.6%	100.0%	

Table 22 – Projection of Population Change in NHSGGC Board Area



CHAPTER 4

THE COMMERCIAL CASE

CHAPTER 4 – THE COMMERCIAL CASE

4A. AGREED SCOPE & SERVICES

The following section describes:

> the requirements for the new adult and children's hospitals
> concept and vision of the overall design
> the agreed output specifications
> design development
> timetable for the project

Project Requirements

The Project includes the provision of 1,109 adult and 256 children's beds. Key elements of the project include:

a) Development of an integrated adult acute and children's hospital proving the full range of acute health services;

b) Provision of a rooftop helipad; and

c) The supply and installation of Group 1 equipment, location and/or fitting of Group 2 equipment supplied by the Board and provision of structural, space and services requirements to support Group 3 and 4 equipment.

The project requires advanced IT networks. Hardwired and wireless infrastructure are included throughout the hospitals providing the backbone for developing systems. This will support the implementation of a paper-lite environment, the efficient input and re-call of patient records and other telemedicine initiatives and practices.

4A.1 Accommodation Overview

4A.1.1 *New Adult Hospital*

This will provide A&E services and acute specialist in-patient care as well as medical day services and out-patient clinics serving the local population.

Key components of the facility include:

a) In Patient Accommodation - Surgical beds (general surgery, orthopaedics, urology, vascular, ENT and renal); Medical beds; Acute Assessment Unit – 118 beds, ICU/HDU/CCU – 79 beds, Acute Stroke – 26 Beds and Care of the Elderly beds;

b) Out Patient Accommodation - Full range of general outpatient clinics including, among others, diabetic unit, respiratory, orthopaedics and urology;

c) Day Services - 22 medical day bed area; 30 station dialysis unit;

d) Treatment & Diagnostic Services - Emergency Department, 20 operating theatres, imaging, and endoscopy;

e) Clinical Support Services - Pharmacy dispensary, medical physics, medical illustration. Laboratory services linked to the hospital by underground route and pneumatic tube system, aseptic unit within the children's hospital. Capability of the pneumatic system to extend across the abutment with maternity and the link to neurosciences to provide for expansion of the system to these areas has been planned; and;

f) Non Clinical Support Services - Main entrance, medical records, administration, sanctuary, staff changing, switchboard, estates, facilities, security, catering, portering, domestic, management and energy centre.

Main Entrance - Adult Hospital

4.A.1.2 *New Children's Hospital*

This will provide A&E services and a comprehensive range of inpatient and day case specialist medical and surgical paediatric services on a local, regional and national basis. The new development will also have outpatient facilities. The care strategy is that all of Glasgow's Children's Services (up to the age of 16 and up to 18 years where appropriate) will be provided at the New Children's Hospital. Of the 256 beds planned, around 20% of the beds will be for day patients and the balance for in-patient requirements.

Key components of the facility include:

a) Outpatient Accommodation - Full range of Children's outpatient clinics including audiology, general paediatrics, orthopaedics, ENT etc

b) Day Services - Circa 10 medical day beds; 4 dialysis stations and circa 15 day surgery beds

c) Treatment & Diagnostic - Emergency Department, Imaging, 9 theatres, rehabilitation

d) Clinical Support Services - Aseptic unit, pharmacy, medical physics, medical illustration (laboratory services linked to hospital by underground route and pneumatic tube system and

e) Non Clinical Support Services - Facilities, ancillary services, administration, spiritual services, medical records, staff change, main entrance,

Main Entrance - Children's Hospital

4.A.1.3 *Other Relevant Accommodation*

- **Facilities Management Building and Energy Centre**

This is located to the north-west of the site and provides accommodation for all the power and heat generation requirements for the new hospitals and capacity to also support the retained estate. The facilities management accommodation is integrated into the laboratories facility, with access provided to the new hospitals by an underground tunnel link. The Energy Centre is a stand alone structure adjacent to the laboratories build and constructed as an aspect of the new hospitals programme.

- **Retained Estate**

The Southern General Hospital site will retain approximately 600 beds within the Institute of Neurological Sciences, Maternity and Neo-natal, Spinal Injuries and Langlands buildings. The Langlands facility provides older people's services and services for the young physically disabled. This retained accommodation does not form part of the scope of the Project, although energy generation to support the retained estate is included in the scope of the Project.

- **Laboratory Facilities**

The new laboratory facilities were a feature of the overall procurement process, although approvals in relation to that aspect of the facilities were considered under a separate FBC (approved in December 2009). The laboratory facility is currently on site (forming Stage 1 of the implementation phase) and therefore not a feature of the development considered by this FBC.

For information, it can be noted that the new laboratory facilities will be one of two major Laboratory sites in Glasgow. The services planned to be delivered from the new laboratories at the New South Glasgow Hospitals include Biochemistry, Microbiology, Haematology, Medical Genetics, Mortuary and Post Mortem. The mortuary and post mortem facilities include the re-provision of the Glasgow City mortuary which also provides forensic services for the City of Glasgow.

- **Car Parking**

Car Parking is a key feature of the overall development and sustainability of the Southern General campus. Additional car parking is being procured separately by the Board (Carparks 1A and 1B to the east of the site, Carpark 2 to the west of the site and Carpark 3 to the south of the site) and therefore do not form part of the FBC.

4A.2 Agreed Output Specifications

The accommodation requirements noted above are included in the Employers Requirements (ERs) documentation. The ERs are the output based specification documentation agreed between the Board and the contractor that identify the specific requirements and standards to be achieved in the construction of the new facilities.

The ERs include specific outputs to be met for all aspects of the construction and design, including reference to and application of NHS (e.g. Scottish Health Technical Memorandum) and other standards, commissioning and handover requirements, sustainability targets, treatment of arts, community engagement and benefits, plus other technical requirements, together forming a comprehensive set of requirements to be met by the contractor.

The ERs comprise the under noted sections (plus associated appendices):

Employer's Requirement Contents
Section 1 – Development Context
Section 2 – Responsibilities of the Parties
Section 3 – The Site
Section 4 – General Design Requirements
Section 5 – General Construction Requirements
Section 6 – Construction Phase Requirements
Section 7 – Architectural Requirements
Section 8 – Building Services Requirements
Section 9 – Civil and Structural Engineering Requirements
Section 10 – Sustainability
Section 11 – Community Engagement

As is noted below and further described and discussed at Section 6A, the ERs were developed following extensive consultation with User Groups in order to develop and agree the required clinical output specifications.

The clinical output specifications, as well as forming an essential element of the ERs in themselves, therefore informed development of the wider brief, the establishment of a Board exemplar design and schedule of accommodation and associated ADB room data sheets and room layouts. This overall package of output requirements and statements forms the 'backbone' of the project brief and therefore the output requirements, establishing particular 'must have' aspects of the Project including, for example, a physical link to the existing Institute of Neurosciences building and an abutment to the existing maternity facility to the west.

4A.3 Design Development

The requirement to develop the design post-contract and pre-FBC (Stage 2 of the contract) is an integral element of the procurement strategy and a managed process involving the Board and the contractor that is tracked and reported to the Project Management Group. A collaborative approach involves interaction with Users in specific workstreams/areas of design development, including, for example the review and sign-off of the departmental plans.

Additionally, the established technical workgroups have been reviewing the wider design development, with inputs from the Project Team (including, for example, the infection control representative), Board technical advisers and other specialists where necessary. This activity is in order to ensure that the level of detail provided is commensurate with the stage of the process and the that requirements of the Board are being demonstrated and developed as well as allowing cost checks and procurement plans to be progressed by the contractor. As with any design process, the evolving design is 'moving' as it is influenced by internal and external factors and requirements – including, for example, planning and roads department inputs, fire strategy consultations and the like.

The requirement for information submissions during the pre-FBC (Stage 2) design development, and tracking of due dates and status is controlled and captured through the "Appendix K" tracker. The tracker is a 'live' document that is discussed between all parties, controlled and updated by the contractor in order that progress in design development can be monitored.

The design process will continue to develop into the next stage (Stage 3) of the process (post-FBC), with both further development of design and construction activity taking place. At FBC the extensive interaction with the User groups and technical review and activity has resulted in 1:500 and 1:200 floor plans for all levels and all departments signed off by the Board, with the 1:50 review process well developed such that each individual room type has been reviewed and agreed as representative of the Boards requirements in terms of size, equipment content and generic layout. Additionally, an extensive programme of workshops and reviews of technical data is in place and being progressed – this considering and addressing, for example, mechanical and electrical systems, access controls, acoustics, fire strategy,

finishes, equipment, wayfinding, arts and other technical and related project data.

This level of sign-off has been facilitated by the engagement with over 70 separate User groups, each consulted on rounds of 1:200 and 1:50 reviews to provide the current position. The process was managed by the Board Project Team who co-ordinated and supported the User input and interface with the designers and contractor. A sample tracker for the 1:200 'Design User Group Meetings' (DUGM), is attached at Appendix F for information.

4A.3.1 *Other Relevant Aspects of Scope, Content and Context*

The following identify additional relevant and important aspects of scope, content and context of the Project:

- **Sustainability**

The Board have consulted and worked in association with both the Carbon Trust and Sustainability Glasgow in scoping the project, during the bidding stage and evaluation of bid returns as well as into the design development phase. The requirement is to target an "Excellent" rating under the BREEAM Healthcare Assessment in order to achieve a high quality user environment and amenity for patients, visitor's and staff as well as reduced carbon outputs and reduced energy costs.

The design development includes input and support from the Carbon Trust in order that the sustainability agenda is maintained through the process and all partners are challenged to continue to actively contribute and support the aims of the project in this regard. The under noted low to zero carbon technologies are included in the project scope:

a) 3 no. 1MW Combined Heat and Power Plant: will reduce carbon and energy costs by using a modular approach to track loads and target operating efficiencies

b) Thermal Wheel Ventilation Equipment: to ensure high performance of heat recovery in the ventilation systems

c) The installation of 12 no. Vertical Axis wind Turbines prominently on the energy centre roof

d) An "Absorption Chiller" unit to facilitate waste heat from the CHP to be used to provide cooling during the high summer demand periods

e) High efficiency (normal) chiller units with magnetic bearings within the compressors;

f) High efficiency motors in equipment to reduce consumption

g) High standards of air tightness and insulation materials to reduce the building demand for energy

h) Modern efficient metering, monitoring and control systems to allow the performance of equipment and building facilities to be monitored and controlled

i) Electric Vehicle Charging points provided in the Facilities yard

j) Low energy lighting systems to reduce consumption; and

k) Variable Volume Circulation systems incorporated in heating and cooling pumps which allow the pumps to slow down during low demand periods reducing consumption

4A.3.2 *FM Requirements*

The new hospitals will include a range of leading edge equipment and operational systems in order that clinical services are supported by high quality, efficient and technologically advanced facilities management services. In this regard the following are included:

- **Automated Guided Vehicles (AGVs)** – these will be utilised to provide on-time transportation of catering, linen/laundry, sterile supplies and general supplies around the facilities by the use of technologically advanced, fully programmable laser-guided vehicles. Goods will be transported from the dedicated FM Centre through the underground link to the hospitals and on to departments and wards via dedicated FM lifts. Efficiency gains in portering models will be achieved through the extensive use of AGVs, with a consequential reduction in injuries to staff associated with movement of materials. Additionally, the system will allow the exchange of waste bins on a 'full for empty' basis and therefore eliminate double handling of waste by FM personnel.

- **Pneumatic Tube System (PTS)** – the placing of ninety-two strategic 'send and receive' stations throughout the facilities will provide extensive coverage to all wards and departments allowing high speed and efficient movement of supplies (including specimens and medication) around the buildings via a fully sealed and secure distribution network. This will ensure a direct link between Emergency Department and Pathology facilitating a 'high priority' service to support the ED function on a 24/7 basis.

- **Automated Pharmacy** – Outpatient dispensing will be provided from an automated dispenser in the new hospitals supporting the efficient distribution of medication.

- **Dedicated FM Service Centre** – a dedicated and strategically placed FM Service Centre will function as the operational hub for the FM services and logistics: serving both the new facilities and the existing estate. Critically, separate vehicle access is incorporated in order to minimise impact on

hospital operations, with all deliveries being received at the FM Centre for checking, storage and distribution via the tunnel network to the hospitals.

- **Bedhead Services** – all bedheads will include highest level of patient services including data points, appropriate voice and data comms in accordance with current SGHD guidance.

- **Information Technology (IT)** - technologically advanced IT networks providing hardwired and wireless infrastructure are included throughout the hospitals providing the backbone for developing systems. This will support the implementation of a paper-lite environment, the efficient input and re-call of patient records and other telemedicine initiatives and practices.

- **Building Management System** – a comprehensive and extensive building management system is incorporated that allows control and reporting of all major building functions and systems. This will allow an extensive volume of building performance and fault situations to be monitored and managed, including adjustment of controls and systems where necessary.

- **In-Built Resilience** – a key design feature is the introduction of specific resilient systems to minimise the occurrence or impact of failures on service delivery. This includes compartmentalised plant rooms, bunded plant areas with drainage, contingent access routes to theatres and other key areas, dedicated AHUs per theatre and specific access detailing for maintenance to avoid disruption. Additionally, routes for the removal of expired and delivery of new specialist equipment (e.g. MRI) have been established. This includes specific loading to floors and access along corridors to minimise interruption and provide safe routes for transportation. Power supplies are provided on a [100%] back-up basis, with heating able to be run stand alone for 200 hours should supplies be affected, with resilience in water supply created by supply split between two mains (one to the west and one to the north of the site) in addition to on site storage.

- **Energy Efficiencies** – as noted previously, a range of low to zero carbon technologies are incorporated in the design – including high efficiency CHP plant, thermal wheels, efficient metering and monitoring systems, low energy lighting and the provision of electric vehicle charging points.

- **Security Systems** – extensive coverage and controls to ensure a safe environment for patients, staff and visitors are incorporated. A mixture of active and passive systems will be provided, including extensive CCTV coverage to internal and external areas, dedicated controls to departments and staff areas and specific ‘hospital at night’ provisions.

- **Specialist systems** – a range of specialist systems and accommodation are included in order to support the clinical services and capability in the hospitals, including RO water and a dedicated decontamination suite.

- **Rooftop Helipad** – the hospital is served by a roof-top helipad, located on the south-west limb of the tower and providing a key direct vertical link to the Emergency Department (Resuscitation) or Theatres. This significant support element will allow both Scottish Ambulance Service and Air/Sea aircraft to service the hospitals on a local and national basis.

- **Medicinema and Retail** – the facilities are supported by integral education and entertainment facilities, including spiritual centres and a cinema located in the children's hospital as well as retail outlets adjacent to the main entrances.

4A.3.3 *Improving Health & Health Inequalities*

In order to continue the promotion of health improvement as well as reducing health inequalities appropriate aspects have been incorporated into the ERs and service planning activity (flowing from consultations and activity arising from the *Design Action Plan* as well as the *Health Promoting ASR Action Plan*) as follows:

- Development of a Patient Information Centre (PiC) within the central Atrium of both the Adult's and Children's hospitals. The PiC's are based on the successful developments in the New Ambulatory Care Hospitals within Glasgow and will provide the following:

  > A 'shop front' for the voluntary sector, encouraging patients to utilise the range of specialist support and counselling services in cases of disease diagnosis and bereavement

  > a programme of onsite health promotion services for both staff and patients to address health behaviours in relation to smoking, physical activity, alcohol and weight management; and

  > a personalised information service, providing advocacy and patient information tailored to the needs of individuals and families and extending the 'information prescription' service currently being piloted with clinicians and library services

  > The integration of the existing family support centre at Yorkhill with the PiC programme to maximise support for the current service and secure continuation of good practice into the new children's hospital

  > Within the defined retail space, retailers will be required to comply with Board policies to ensure support for health living through initiatives such as a Healthy Living Award, Fruit and Vegetable retail, healthy vending options etc. A current pilot with community enterprise initiatives at the GRI hospital site will inform the potential to support a similar initiative; and

- the inclusion of an external environment that provides significant areas of accessible green space which can be used by patients, visitors and staff including well lit and clearly marked walk ways across the campus, bike parking facilities, therapeutic gardens and play areas and a range of seating and defined outdoor relaxation spaces.

Additionally, accessibility has been promoted across the campus with a number of engagement and consultation exercises having informed current proposals including: work to identify options for the designation of disabled parking spaces; consideration of patient journeys across the campus and within buildings has informed both the location of services and wayfinding strategies; drop-off points are closely located to key departments/buildings and on-site transport options to help less able patients move across the campus are being considered

In order to monitor and ensure incorporation of relevant and appropriate physical measures a number of Equality Impact Assessments have been identified and will be undertaken at different stages of the development.

Further, as an aspect of the procurement process, social economy policies have been developed to promote local regeneration and afford community benefit through employment and procurement. These are further described in Section 6A (Procurement Strategy).

4A.3.4 *Integration of Healing Arts Strategy*

The Board recognises that good design in healthcare buildings makes a measurable difference to the experience of patients, visitors and staff. A wide cross section of individuals and groups have and are engaged in influencing the design development with regard to environment and ambience, with a specific Workgroup established by the Board to actively agree and manage the Arts Strategy and advise the design process on opportunities for art.

The ER plan for the development and delivery of an arts strategy is illustrated below, with the Stage 2 (Design Development) phase presently seeing the development of the strategy between the Board and contractor for implementation in the Stage 3 construction phase.

STAGE	TASKS	RESOURCES
Stage 0: Competitive Dialogue	Develop Art Strategy as part of bid proposals. The strategy developed by your team will form part of the evaluation process.	Identify bidder resources that will be provided during Stage 2 design and anticipated costs over the time period for stage, along with assumptions on frequency of meetings etc. The proposals should therefore ring fence money and time for Stage 2.
Stage 2: Design Development	The successful bid team will develop their strategy along with Board managers and other associated groups as noted earlier. As a key member of the Board's Arts Development Group you will meet monthly to develop plans and incorporate a full arts strategy into the detailed designs for the new builds. Prepare detailed costs and budgets for these works for Board consideration. Working to the Arts Development Group will be the artists and designers who will meet weekly through design development forum to discuss concepts, plans, detailed and help prepare detailed costs.	The successful bid team will be required to take forward the strategy subject to Board involvement and work with teams to develop a workable proposal that is both achievable, realistic and affordable in the run up to FBC and approval to proceed with construction of the adult and children's hospitals. Note: costs for the arts strategy may be included within the contractor's price, or funded by external Board source, or from a combination of these.
Stage 3: Construction of Adult and Children's Hospitals	Incorporate the agreed art strategy design into the new builds.	Manage the construction and full integration of the approved strategy on site by the successful bid team. Attend periodic meetings (quarterly) to review progress.
Stage 4: Commissioning	Fully commission any loose art works requiring service connections.	This would occur during post handover Board equipping stage, detail and input from bidders would be developed during Stage 2.

The Stage 2 (design and development phase) updated Arts Strategy includes input from desk based research and a number of Design Workshops, Clinician led 'Walk and Talks', review of other new build hospitals, consultation with Spiritual Care and Better Access to Health groups, a review of existing archive and engagement with the Glasgow arts and cultural sector.

This initial consultation process identified a universal ambition to ensure the Arts Strategy added value to the patient journey and was integrated into the hospitals in a way which energises the hospital environment and makes the most difference to patients, families, carers and staff. In addition the Arts strategy draws on the existing evidence base for therapeutic design focusing on; reducing recovery time, de-institutionalisation and orientation and way finding.

The analysis driving the strategy includes;

- New South Glasgow Hospitals landscape is well developed and provides key opportunities
- The Atrium in both Hospitals expresses ambitions and provides opportunities to link to wider way-finding language
- There are Sanctuaries, but there are many other spaces used for bereavement, families, relatives, etc that could be enhanced
- The Beacon provides an opportunity to link to the catchment area directly
- The Podium is a large area and will benefit from landmarking
- Bringing the detail of the landscape into the building will add points of interest
- The strength of patient and staff impact on the environment at Yorkhill emphasises the need for participatory strategies
- With a modest art budget the strategy is to focus on places where significant impact can be made, building on existing design infrastructure

The strategy therefore incorporates 4 central themes:

- To create a sense of place
- To meet stress with dignity
- To support treatment through distraction
- To promote participation and personalisation

The strategy comprises a comprehensive programme of art and design with 3 stages:

- Integrated projects delivered during construction
- Stand alone artworks delivered during the commissioning phase
- A post construction arts programme

Further detail of the 3 stages is given in Chapter 6.

4A.4 Timelines for Delivery for the Project

The project timelines from publication of the OJEU notice in early 2009 to operational handover in 2015 are detailed below. Further specific detail around the contract work stages and timelines are included in Section 6, as are details with regard to Post Project Evaluation (PPE) Proposals and Commissioning Plans.

Table 23 – Overall Project Timetable

Event	Milestone
Publication of OJEU (incl MoI and PQQ)	06 February 2009
Issue of Invitation to Participate in Competitive Dialogue (ITPD) to bidders	May 2009
Stage 1 Final Tender Return	11 September 2009
Evaluation of Bids and Contract Award	18 December 2009
FBC For New Children's and Adult Hospital and approval by Health Board	November 2010
Stage 3 (Construction of Adult and Children's Hospitals) programmed to commence	November 2010
Completion (Construction) – Adult Hospital and Children's Hospitals	January 2015
Operational Date – Adult and Children's Hospitals	Summer 2015
Stage 3a completion, demolition of surgical block and completion of landscaping	Summer 2016
Post Project Evaluation	Summer 2017

4B. AGREED RISK ALLOCATION

Risk Management has been, and remains, a primary focus in the management of the Project.

From the outset of the procurement process the Board have completed a Risk Register and this has been continually maintained throughout the life of the Project to date, and will continue to be managed until completion of the project.

As part of the contract agreement with BCL the Board and the Contractor each have an agreed risk allocation. As noted in Chapter 6A (Procurement Strategy) risk transfer was a key discussions topic during Competitive Dialogue (as an agenda item in the Commercial Group as well as inherent in the Design and, specifically the Logistics, workstreams).

The following describes the risk management undertaken pre procurement, the risk allocation in the contract and risk management in the stages 1 and 2.

4B.1 Managing Risk Pre-Procurement

Active identification and management of risks in the procurement planning stage led to adopting risk strategies to mitigate potential adverse impacts on the project. These included developing and implementing a market engagement/sounding exercise to determine the capability of the players in the market to deliver the project. This activity was carried out in order to improve the chances of strong market engagement, avoid delays and 'challenges' to process where possible and to ensure appropriate review and approvals of project planning were adhered to and incorporated into the process. Activities in this regarded included:

- consultation with potential private sector partners (contractors) to establish appetite to bid for the project
- workshops to option test procurement routes with adviser/consultancy firms
- detailed workshops with three main contractors to further test approach to procurement
- validation of chosen procurement route/approach through tiered approvals and subject to external scrutiny and comment (audit and Gateway)
- establishment of key workgroups and design-development sessions to support the drafting of the Employer's Requirements
- clear direction, leadership and management of the timetable and requirements to take the project to market, combined with a close collaborative working between the core NHS team and the advisers in the project team
- determination of robust output requirements (captured in the ERs) as a result of User stakeholder consultation as well as engagement with Facilities Management and other specialist (technical) groups and individuals
- visits to other UK hospital sites to review relevant technical and clinical aspects of operational hospitals to inform the ER requirement
- continued engagement and communication with the public locally (neighbours) as well as updates to the wider population and staff with regard to progress and details of the proposals
- continued engagement and communication with the Scottish Government Health Directorates with regard to process, progress and programme
- strict adherence to internal governance and reporting lines within NHS GG&C
- continued engagement with external partners and stakeholders (including, for example, Glasgow City Council, A+DS, and local businesses)
- review and refinement process to ensure coverage and completeness of documentation prior to tender issue
- clear bid programme and engagement plan for competitive dialogue as well as expectation (requirement) for bid returns
- setting of distinct competitive dialogue workstreams, populated by appropriate Board and adviser personnel to engage with the bidders

4B.2 Risk Allocation in the Contract Agreement

As part of the NEC3 contract conditions a risk allocation matrix was agreed. The mechanism to agree maximum and target price relies on the agreed risk sharing between the Board and the Contractor and this was agreed during the Competitive Dialogue Process.

The under noted matrix identifies some of the key risk allocation between the Board and the Contractor:-

Risk	Board	Contractor
Secure Detailed Planning Consent – design information and submission by required programme dates		X
Planning Authority do not comply with Statutory timescales for review and approval of Planning Submissions	X	
Building scale, layout and form to meet NHS Schedule of accommodation and Clinical Adjacencies		X
Design Development / Co-ordination / Programme		X
Detailed Design		X
Ground conditions below existing buildings vary significantly from that interpreted from Site Investigations	X	
Ground conditions across site vary significantly from that interpreted from Site Investigations	X	
Ground conditions across site generally in accordance with Site Investigation information		X
Schedule of Accommodation – Rooms & Net Area requirements	X	
Group 1 & 2 Equipment arising from User Group 1:50 room layout development identifies additional equipment out with standard ADB Data Sheets	X	
Inflation – below 2.5% p.a.		X
Inflation – above 2.5% p.a.	X	
Failure to achieve Key Approval Dates – FBC Approval	X	
Unknown existing services discovered within site boundary	X	
Drawing approval process – Reviewable Design Data – not	X	

undertaken to agreed timescales		
Scottish Ambulance Service land acquisition not achieved to programme	X	
Construction Programme		X
Sub-contractor procurement		X
Construction design information		X
Construction interfaces		X

Since appointment of the Contractor the risk management process of ongoing reviews / mitigation meetings is undertaken at regular intervals through the commercial group meetings (please see Section 6B for Governance Arrangements).

In addition to formal reviews of the Contract Risk Register, as part of the Contract Management processes, a weekly Early Warning Notice[2] review meeting is held. This meeting is the Risk Reduction Meeting to review progress and close out of any Early Warning notices issued by either the Board or the Contractor in accordance with the Contract, recognising that in a project of this scale the arrangement of individual meetings for each Early Warning Notice would be inefficient.

The current Risk Registers are included in Appendix G.

4B.3 Risk Management – Project Measures in Stage 1 & 2

As is noted in the earlier sections of this chapter, risk management is inherent in the structure of the project governance as well as in the NEC form of contract that is being utilised.

This manifests itself in a governance structure which has direct and frequent reporting lines both within the core project structure as well as to the groups established by the Board to monitor and oversee the programme (e.g. the Acute Services Strategy Board Executive Sub-Group).

The contract utilises the raising of Early Warnings by either party and these are reviewed weekly by a combined Board/contractor team in order that potential impacts are understood and acted upon.

[2] Early Warning Notice is a defined term in NEC3 contract conditions and is the first identification of potential risk or change to the project.

This active risk management of the project supports partnership working as well as providing clarity with regard to status and impacts of potential risks to the project. The project risk registers, which are owned by the Project Director, are updated and reviewed jointly by the Board and contractor at frequent intervals in order that the impact of events and passage of time on the project is reflected in the detailed registers of individual classifications of risk.

Continuing to think ahead regarding adverse impacts on the project, the project team have endeavoured to reduce future project risks (post FBC) by planning associate works in advance such as:

- **Demolitions/site clearance** – this enablement work is being procured in readiness for providing a clear site to the contractor as well as to allow key diversion works to be carried out and maintain programme. The lead time for demolitions included the decanting of staff and equipment to allow services isolations to take place and provide access for intrusive surveys (in the buildings as well as in associated service ducts) and the carrying out of further site investigations to support the ongoing design development of the hospitals. These key tasks could not take place while the buildings (non-clinical support accommodation) were occupied and in use. The accommodation in question includes the main hospital kitchen which has been relocated to another area of the campus in a modular arrangement until the new hospital is operational. The (temporary) kitchen relocation, which is an aspect of a Board-wide catering review and service implementation, has been discussed and co-ordinated with the relevant managers of the existing hospital campus in order that the service is kept live and operational and the moves dovetail with the timelines and requirements of the project in a collaborative and safe manner.

- **Detailed site investigations** (SI) – as is noted above, detailed SI works have been carried out in the areas decanted for demolitions. This has allowed access to gain information to support and verify the initial SI exercise and inform the design development process as well as the treatment of ground conditions risk under the contract.

- **Culvert diversion consents** – the relevant agreements and pre-planning matters are being arranged for the necessary diversion of the culvert to the south of the site. The demolition of non-retained estate in that locale will support the construction of a temporary roadway to ensure that the culvert works can be carried out whilst maintaining blue-light access through the hospital campus and day to day vehicular traffic (public transport, private transport and hospital traffic) movement around the site.

- **Off-site parking agreement** – the contractor has an agreement in place to utilise an adjacent commercially owned site for the purposes of car parking into the Stage 3 construction phase. This pre-planning will allow the construction site to grow in a managed and capacity led manner and supports the overall logistics management of the site and access for the workforce.

- **Helipad relocation** – as the Stage 3 works necessitate the handover to the contractor of the area where the helipad is presently located, the Board have been in consultation with several partners and associated organisations with regard to the relocation of the helipad. The Board has successfully reached agreement with its partner organisations and an off-site (near site) relocation of the helipad has been agreed.

- **Relocation of Scottish Ambulance Service Facilities** – the existing SAS facility is located in an area to the west edge of the site that is part of the project masterplan. The Board have been working with SAS to reach agreement for the relocation of their facilities and ownership of the (SAS) land reverting to the NHS. Agreement is in place and alternative accommodation is being provided for the SAS services to allow on-time handover of the land to avoid impact on the construction process and programme of the contractor.

- **Agreement to Purchase Scottish Water Land** – in order to facilitate construction of the new hospitals and create the associated infrastructure the logistics dialogue identified the requirement for the Board to acquire a portion of land from its Scottish Water neighbour. The necessary negotiations have been carried out and agreement reached with Scottish Water in respect of the land. The legal work was progressed (with the agreement execution dependant upon FBC approval) in order to avoid delay and provide clarity of this essential requirement and timeline to the Board and contractor.

- **Staged Building Warrant Application** – the contractor has proposed and agreed with Glasgow City Council that the Building Warrant will be submitted in stages including sub-structure, super-structure and fit out. This allows forward planning and activity in specific segments of design and detail to be captured and submitted into the necessary regulatory process promptly which will allow warrants to be secured in cognisance of the stage of design and construction and mitigate work at risk by the contractor. An addition benefit is the associated clarity around cashflow of application related fees.

- **Early Stage Application (Fire Strategy)** – the relevant fire strategy information was submitted (by agreement) at an early stage in the overall process in order to engage GCC Building Control and other essential parties in key discussions and communications. This was carried out in order to de-risk this specialised aspect of design development and progress by engaging with the relevant parties.

- **Sub-Structure Warrant Application** – the building warrant application for the Energy Centre and Hospitals sub-structure is to be submitted immediately post-approval of FBC to mitigate design risk and support on-programme commencement of works on site. Stage 2 design related activity has therefore been carried out to develop this aspect of design and related warrant information and paperwork to the requisite level of detail. This management of information, requirement and detail is a pre-planned activity to seek to maintain programme whilst gaining the necessary approvals through liaison and joint-working with GCC.

4B.4 Risk Management – Strategic Risks

The approach to and treatment of strategic risks is identified and discussed at Section 2i of the FBC, above.

4C. AGREED CHARGING MECHANISMS

The Contract Payment Mechanism is generally in accordance with the NEC3 Conditions of Contract Option C Target Price.

In recognition that the Contractor has formally committed to contract for the Design & Build of the Hospitals at a relatively early stage in the design life cycle, the Contract has been varied to introduce the principal of shared risk within a Target and Maximum Price threshold.

Essentially, if outturn costs are less than the Target the Board and Contractor share in any savings at pre agreed ratios. Where outturn costs are above Target then there is a share of the overrun costs at pre agreed ratios and should outturn costs exceed the Maximum Price then any liability for the Board to make further payments stop, and the Contractor absorbs 100% of the overrun.

4C.1 Target & Maximum Price

Based on the Employers Requirements (Works Information) and the agreed risk allocation, the Contractor has provided a Target and Maximum Price for the Design and Build of the New Hospitals and associated landscaping works.

The Contract Price is structured into three discrete areas that require approval Gateways prior to any expenditure within each Stage being incurred:

- Design Stage – commenced Jan 2010
- Hospitals Construction – approval to commence to be given following FBC Approval
- Demolition and Landscaping Completion – approval to commence to be given on handover of Hospitals

Any changes to the agreed Target and Maximum Price arising from changes to the Works Information or the Board Accepted Risks will be administered in accordance with the Conditions of Contract.

The pricing / payment mechanisms are on basis of risk and reward structure. By accepting risk transfer, the contractor is participating in a pain / gain share contract structure. He is incentivised to manage costs within his Target through good supply chain procurement, value engineering, and general efficiencies etc and share in any savings below the Target with the NHS. A further incentive to control costs is that should costs exceed the Target he will only recover a percentage of his costs through a pain share mechanism with the NHS. This sharing mechanism applies only up to the agreed Maximum

Price. The Maximum Price is the maximum liability of the Board and all costs incurred above the Maximum Price are borne by the Contractor.

Detail regarding the agreed pain / gain share split has been removed due to commercial sensitivity.

4C.2 Payments

Payment Assessments are based on standard Conditions of Contract Cashflow derived from an Activity Schedule, with a Contract Amendment confirming Board liability only to pay each month the lesser of actual cost incurred or the Cash flow forecast.

Retention is held on Design Stage Payments at 10% of amount due, and progressively released as one of five under noted Design Milestones are achieved:-

- Achieve 85% User Group sign off to 1:200 Drawings for Adult Hospital
- Achieve 85% User Group sign off to 1:200 Drawings for Children's Hospital
- Achieve 95% sign off to Standard Room Type ADB sheets and 1:50 Drawings
- Conclusion of Planning Submission - Final Reserved Matters Approvals
- Achieve Formal Planning Consent from Glasgow City Council

Due to the value of the project, a standard retention approach was not favoured by any of the bidding contractors. In order to address concerns and avoid any premium being added to bids the under noted approach has been included in the contract:-

- No retention held during construction years 1 to 3
- Retention fund built up during Year 4 payments to arrive at fund on handover equivalent to 2½ % of overall Hospitals Construction Value
- Retention held for 24 months and released on completion of defects period

Standard 5% retention is held on final stage of works - Demolition and Landscaping Completion – with half retention released on handover, 24 months defects period and final retention release on completion of defects period.

4C.3 Damages for Late Completion

Delay Damages are included as follows:-

Hospitals Construction: £250,000 - provided that In the first 4 weeks after the *completion date* delay damages will be levied at 25% of £250,000 per week; in weeks 5 - 8 inclusive after the *completion date* delay damages will be

levied at 50% of £250,000 per week; in weeks 9 - 12 inclusive after the *completion date* delay damages will be levied at 75% of £250,000 per week; and from week 13 after the *completion date* delay damages will be levied at 100% of £250,000 per week

Demolition and Landscaping Completion: £20,000 per week

4D. AGREED KEY CONTRACT ARRANGEMENTS

The Contract Conditions are generally in accordance with NEC3 Conditions of Contract Option C Target Price.

Amendments were made to accommodate bidders' requirements (only insofar as did not amend NHS protection under contract) and the discussions agreed during Competitive Dialogue.

4D.1 Key Amendments to Standard Form

The under noted is a summary of key amendments to the Contract and X Clauses included:-

- Appendix to Contract introduction Overriding Principle of Partnership / Collaborative working
- Amendment to incorporate Target & Maximum Price mechanism
- Amendment to Stage works and have approvals before commencement of each Stage, ability to terminate contract at end of each stage without penalty, and transfer of ownership of design to NHS on termination
- 24 months defect period, and timescales for priority based defect correction
- Incorporation of Board Retained Risk Register, and confirmation all other risks to deliver Works Information are transferred to Contractor
- Damages for Late Completions as noted in Section 4C above
- Performance Bond for 5% on works value
- Collateral Warranty requirements from Designers and Sub-contractors
- Programme based deliverables for Design Stage retention payments
- Payment Assessment periods amended to 4 week overall - 2 weeks for review of actual costs incurred in month, and 2 weeks for NHS to process payments

4E. AGREED IMPLEMENTATION TIMESCALES

The overall timetable from publication of OJEU is noted in Table 24. The more specific implementation timescales, in relation to the staged activity schedules recognised under the contract, are as under noted. The Stage 1 activity (Design & Construction of the New Laboratory Building) FBC was approved in Q4 2009 and as such that activity is not a feature of this FBC, the inclusion in the table below is for information and context purposes only with regard to identification of overall timescales and concurrent activity.

Stage	Activity	Start	Finish
Stage 1	Design & Construction of the New Laboratory Building	Q1 2010	Q1 2012
Stage 2	Design Development of New Hospitals	Q4 2009	Q4 2010
Stage 3	Finalise Design + Construct New Hospitals	Q4 2010	Q1 2015
Stage 3A	Demolition of Surgical Block and completion of Landscaping	Q3 2015	Q3 2016

4E.1 The Construction Stage Programme

The contract (NEC3 Option C, Target and Maximum price with Activity Schedule) provides for the inclusion of a detailed construction stage programme which identifies the key dates for deliverables. In this instance, the overall project is to be delivered in four stages:

- ***Stage 1: New Laboratories and Mortuary***

Previously approved under a separate Business Case in December 2009, the construction of the facility, which includes not only the mortuary facilities but also the Facilities Management Centre for the new hospitals, began in March 2010 and is currently on programme to be completed and handed over to the Board in March 2012.

- ***Stage 2: Detailed Design of the Adult Acute and Children's Hospital***

Commenced in January 2010, following execution of the contract in December 2009, the detailed designs for both hospitals have advanced as programmed, to the point where 1:500 scale adjacency layouts, 1:200 departmental layouts and the vast majority of 1:50 room layouts have been agreed and signed off with user groups.

Concurrent with this clinical design, the architectural design has been further developed, with external agencies including Glasgow City Council and Architecture & Design Scotland being consulted with at length. Full Planning Consent for the Masterplan was granted in June 2010 and a subsequent application for approval of Matters Specified in Conditions (MSC) relating to the architecture of the two hospitals and the associated Energy Centre was due for consideration at Glasgow City Council Planning Committee on 19th October 2010. However, due to there being only one formal objection from the local neighbourhood the project can now be dealt with under delegated powers by officers without reference to their planning committee. The collaborative work carried out by the Board, and the design team provides a high level of confidence that approval will be granted.

Further MSC applications will be submitted in the coming months to satisfy the conditions contained within the original outline consent, but these are not pre-start requirements and are therefore do not impact upon programme at this stage. Furthermore the detailed matters affected by these conditions do not represent any un-assessed risk to the Board.

An initial application for Building Warrant has been submitted to Glasgow City Council in order to allow consideration of key elements including the Fire Strategy and this has been successful in resolving a potentially complex issue at an early stage, thus allowing design development to conclude without impact upon programme. These negotiations also provide greater cost certainty in the design.

- ***Stage 3: Construction***

Enabling works, including demolition, to deliver a clean site for development are currently underway and are planned to complete by the end of October 2010 and the purchase of two additional land parcels from Scottish Water and Scottish Ambulance Service are subject only to the approval of the Full Business Case.

A November approval will permit instruction to be issued to BCL in line with the current programme and will ensure that the impacts upon the Laboratories Development will be minimised as the structure of the Energy Centre, for the full facility, will be completed in advance of service delivery from the new Laboratories.

Site works including expansion of the existing Contractors/Board Accommodation and diversion of water courses will commence in January 2011, with the works to the Hospitals commencing in March 2011.

The construction and technical commissioning of the Hospitals will complete in January 2015 with service transfer commencing late Spring 2015 and concluding in Summer 2015.

- ***Stage 3a: Demolition and Completion of Landscaping***

The demolition of existing Surgical Block and completion of external landscaping cannot commence until after decommissioning of the affected buildings and require service delivery to be transferred to the new facility before they can commence. These works will be completed without significant impact upon the operation of the new facility and will complete in the summer of 2016.

A feature of the contract is the treatment and management of the programme, whereby the programme is submitted by the contractor on a monthly basis for acceptance by the Project Manager. There are only set, specific reasons for the programme to be rejected by the Project Manager and the 'live' nature of the programme supports awareness of all aspects of the process and activities as well as management of issues (Early Warnings/Risk Reduction) as they occur during the contract. This scrutiny, awareness and real time management of the programme is beneficial in reporting status internally and to stakeholders as well as in providing clarity to concurrent activity (such as planning and implementation of transition of services to the new facilities) to the workgroups engaged in those activities.

A copy of the master programme as at September 2010 is attached at Appendix H for information.

4E.2 Commissioning Plan

The construction process dove-tails with commissioning and handover requirements and activities.

An outline operational commissioning plan for the transfer of services from Yorkhill Hospital, Western Infirmary, Victoria Infirmary and part of the Southern General to the New South Glasgow Hospitals is given in Appendix I.

This document describes the new structure to take forward the commissioning plan which is based upon the good work undertaken in commissioning the two new ACHs. The paper also gives a 'first pass' at the operational commissioning plan which will be further developed through the new structure.

CHAPTER 5

THE FINANCIAL CASE

CHAPTER 5 – THE FINANCIAL CASE

5A. INTRODUCTION

This chapter explains the methodology used to calculate the capital and revenue consequences of the New South Glasgow Adult and Children's Hospitals.

It utilises the output from a number of key elements of the project, including workforce planning, capacity planning and design to establish the capital and revenue implications and confirm the preferred solution is affordable in both capital and revenue terms.

All relevant current guidance has been followed in constructing the financial appraisal, principally the Scottish Government Capital Investment Manual – Business Case Guide (2010).

The Outline Business Case approved in May 2008, presented a proposal for new Adult and Children's Hospitals and a new Laboratory and Facilities Management complex with a combined capital cost of £841.7m. A Full Business Case for the Laboratory and FM complex was approved by the Scottish Government on 4th December 2009. The capital value of this aspect of the overall project amounted to £89.750m and building work commenced at the beginning of 2010 and is on target to be completed by March 2012.

The purpose of this FBC is therefore to address the remaining elements of the development, namely the New Adult and Children's Hospitals with a capital value of £751.950m.

For completeness and to improve users' understanding of the full financial position of the development, the tables within this section include details of the Laboratory and FM aspects for information only.

The table below states the key assumptions used in the Financial Case:

Table 24 - Key Assumptions used in the Financial Case

Key Assumption	
Price Base for Revenue	2010/11 – no inflationary uplifts applied
Contract Type	NEC3 Option C Target contract with activity schedule
Main Construction Contract Costs	Brookfield Construction Ltd. Maximum Price
Optimism Bias	All Risks are now quantified and included within the Risk Registers.
VAT Rate	17.5% to 3rd Jan 2011 and 20% from 4th Jan 2011
Depreciation Rate for New Build	60 years
Depreciation Rate for Equipment	10 - 15 years
Interest on Capital	Nil

5B. CAPITAL REQUIREMENTS

A summary of the capital costs of the development are shown in the table below:

Table 25 – Summary of Capital Costs

Capital Cost	Adult & Children's £'000	Laboratory & FM FBC £'000	TOTAL £'000
Total Capital Costs	**751,950**	**89,750**	**841,700**

* Detail of costs removed due to commercial sensitivity

Key drivers that underpin the capital costs for the Adult & Children's Hospitals are:

- The capital costs reflect the construction programme with a Stage 3 commencement date of November 2010;
- In accordance with NHS Scotland Sustainability Objectives, costs include the requirement to target a BREEAM "Excellent" rating;
- Construction costs include group 1 equipment and fitting of group 2 equipment;
- An Allowance for quantified risk is also included within the capital costs;
- All capital costs are inclusive of VAT at 17.5% up to 3rd January 2011 and 20% thereafter.

5B.1 Risk

Full details of the identification and mitigation of risk within the project are contained within Chapter 4 – The Commercial Case. This describes the robust procedures in place to both identify and manage potential risks, including regular and formal reviews of the Risk Registers and Early Warnings, and notes that risk management is inherent in the structure of the project governance as well as in the NEC form of contract that is being utilised.

This approach, together with the advanced stage of design undertaken to date, has enabled, through detailed modelling of risk probability, a fully costed risk provision which is included in the capital expenditure requirements.

5B.2 Capital Spend Profiles

The capital expenditure profiles of the project are forecast as follows:

Table 26 – Capital Expenditure Profiles

Financial Year	Adult & Children's £'000	Laboratory & FM FBC £'000	TOTAL £'000
2008/09	2,652	-	2,652
2009/10	7,717	3,455	11,172
2010/11	16,556	44,669	61,225
2011/12	120,374	41,626	162,000
2012/13	270,213	-	270,213
2013/14	234,607	-	234,607
2014/15	94,204	-	94,204
2015/16	3,824	-	3,824
2016/17	1,803	-	1,803
Total capital spend	**751,950**	**89,750**	**841,700**

5B.3 Capital Funding

The Scottish Government has confirmed that, subject to approval, it has assigned overall capital funding for this project, as highlighted below:

- New South Glasgow Hospitals Project (This FBC) £751.950m
- New South Glasgow Hospitals Laboratory Project (Approved) £ 89.750m

£841.700m

5C. IMPACT ON BALANCE SHEET

The project will be funded via Public Capital through a specific capital allocation to be received from Scottish Government Health Department (SGHD). This will form part of NHSGG&C's overall Capital Resource Limit (CRL). The expenditure will be capitalised in the Board's Balance Sheet and will be recorded as a fixed asset on NHSGG&C's Fixed Asset Register in accordance with International Financial Reporting Standards (IFRS) and the requirements of the NHS Capital Accounting Manual.

5C.1 Impairment

Construction of the new Hospitals is scheduled to be completed in the first Quarter 2015. As current valuation guidance is only available up to the second quarter of 2011, it is not presently feasible to accurately assess the final valuation of the completed building.

However, on completion, the new build will be subject to initial valuation by the District Valuer. In the likely event that the assessed value of the asset is less than the capital spend, an impairment value will be calculated. This impairment value will be communicated to the Scottish Government Health Directorate and a request for funding made. This business case makes the assumption that funding will be granted by the Scottish Government for the full

amount of the impairment. The asset will subsequently be capitalised at the assessed value and depreciated over the useful life of the asset.

The level of any potential impairment will be kept under continual review as construction progresses towards completion and appropriate updates on the potential level of any impairment will be provided to SGHD as required.

5C.2 Disposals

The Outline Business Case noted that the Board would target generating £135m, over a 10 year period, from the disposal of sites declared surplus. This was based on a series of projections carried out by the Board's Property Advisors, based on the potential disposal of a wide range of sites within the Board's portfolio.

Subsequent to Outline Business Case, and per recent guidance CEL 32 (2010), it is now assumed that any capital receipts which accrue will go directly to SGHD.

5D. REVENUE COSTS AND SAVINGS

5D.1 Methodology & Approach

The revenue cost and savings analyses focus on the additional costs and savings that will accrue under the proposed project and revisits the work previously undertaken at OBC stage.

Key Revenue Assumptions:

- All costs and savings are based on full year impact at 2010/11 price base – no inflationary uplifts have been applied;
- The useful economic life of the new builds is assumed to be 60 years. The useful economic life of equipment is assumed to be between 10 & 15 years;
- 3.5% interest has been excluded for capital charges.

5D.2 Summary of Revenue Costs

The table below summarises the gross revenue impact for the Preferred Option:

Table 27 – Gross Revenue Impact for the Preferred Option

Gross Revenue Costs	**Adult & Children's £'000**	**Laboratory &FM FBC £'000**	**TOTAL £'000**
Building & Non Works Cost Depreciation	11,490	1,496	12,986
Equipment depreciation	5,737	-	5,737
Life Cycle Costs	4,600	-	4,600
Total Gross Revenue Costs	**21,827**	**1,496**	**23,323**

5D.3 Summary Revenue Savings

The table below presents a summary of service and site savings associated with the total project:

Table 28 - Summary Revenue Savings

	£'000
Service Savings	30,689
Site Savings (Depreciation & Maintenance)	12,985
Total Recurring Revenue Savings	**43,674**

5D.4 Overall Revenue Impact

As can be seen from the table below, the project presents a recurring net saving of £18.2m and confirms the overall affordability of the project.

This net saving also recognises depreciation of £2.1m arising from capital costs connected to enabling work required at the Southern General site. The capital costs of this work are already included in the Board's capital plan and do not form part of the capital requirements noted in this full business case.

Table 29 - Overall Affordability of the Project

	£'000
Gross Revenue Costs (per above)	(23,323)
Total Revenue savings (per above)	43,674
Gross Savings before Depreciation on Enabling Costs	**20,351**
Less Depreciation charge associated with Enabling Costs	(2,100)
Recurring Net Cost Savings after Depreciation on Enabling Costs	**18,251**

5D.5 Description of Service Savings

The New South Glasgow Hospitals will have a significant impact on the workforce. This results from economies of scale generated from site consolidations and enhanced efficiencies arising from the redesign of Patient Service delivery models.

This is described in further detail under the Workforce section of the Full Business Case, however, the savings can be summarised as follows:

1. Site Consolidations - This is anticipated to deliver savings in the following areas:

- Medical - due to improved efficiencies in rotas and on-call arrangements;
- Facilities including Rates, Heat, Light & Power and Hotel services;
- Depreciation and Maintenance;
- Site Management and Administration.

2. Redesign of Patient Service Delivery Models – This is anticipated to deliver savings in the following areas:

- Nursing
- Nursing Skill Mix
- Allied Health Professionals Skill Mix

5E. TRANSITIONAL/NON RECURRING COSTS

A high level assessment of Transitional /Non recurring costs has been undertaken and will be continually developed and refined in the years leading up to the handover of the buildings. It is anticipated that such costs will be funded through the non recurrent use of service savings capable of early release.

5F. NET EFFECT ON PRICES

As the project is forecast to produce recurring revenue savings, there will have no adverse impact upon the Board's prices.

5G. IMPACT ON INCOME AND EXPENDITURE ACCOUNT

The revenue assumptions noted within this FBC will be incorporated within NHS Greater Glasgow & Clyde's future revenue plans.

5H. OVERALL AFFORDABILITY

Both the Target and Maximum Prices for the construction of the Adult and Children's Hospitals are within the capital affordability limits for the project. Other areas of capital expenditure, including equipment, other non-works costs and fees are also within the capital provisions available. Extensive risk reviews have also enabled a risk provision to be established which is supported by robust risk registers which remain under continual review. The capital costs, including provision for Value Added Tax at the increased rate from January 2011, all remain with the capital funding levels noted within this FBC.

By proceeding with the project the Board will achieve net overall recurring savings of £18.2m through enhanced efficiencies and the project is therefore self-funding.

Achievement of this level of savings is not dependent upon increased future revenue funding which is deemed to be a prudent assumption in the current economic climate. Indeed, proceeding with the project and enabling these savings to be achieved will directly support the Board in its efforts to address any future negative funding growth and the financial impact this may have.

Consequently the construction of the New Adult and Children's Hospitals is deemed to be affordable in both capital and revenue terms.

CHAPTER 6

THE MANAGEMENT CASE

CHAPTER 6 – THE MANAGEMENT CASE

6A. PROCUREMENT STRATEGY

6A.1 Process To Contract Signature

The Procurement exercise for the New South Glasgow Hospital project concluded with the appointment of BCL to design and construct the works within the following contractual stages:

- Stage 1 – Design & Construction of the New Laboratory Building
- Stage 2 – Design Development of New Hospitals
- Stage 3 – Finalise Design and construction of New Hospitals
- Stage 3A – Demolition of Surgical Block and completion of Hard Landscaping

The contract has approval Gateways prior to the Contractor commencing any Stage. Stage 1 & 2 were given approval to start at NHS GG&C Main Board meeting 3rd November 2009 which endorsed the Project Team recommendation to appoint BCL. In the event of subsequent Stages not progressing the Contract protects the Board from any damages etc and ensures ownership of design completed at end of Stage 2 transfers to the Board.

6A.1.1 *Governance / Approval Of Procurement Strategy*

At all Stages in the process NHS GG&C Procurement & Finance Group (as in existence during Pre Contract Stages) were fully engaged in the development and implementation of the Procurement Strategy. In addition to Senior NHS Staff, key non NHS GG&C members of this Group were representatives from Partnerships UK and Scottish Government.

Other external Peer Review Groups endorsing the Procurement Strategy were:-

- Gateway Review Team
- PWC Board Auditors
- Atkins Consulting – third Party review engaged by Project Team

6A.1.2 *Market Engagement*

Due to the scale and complexity of the Project a major consultation exercise was undertaken to engage with the Contracting market to test thoughts on the procurement process to arrive at a solution that would both engage the market to bid by limiting cost to bid, and protect the Boards commercial position.

Initial market engagement commenced early 2008 with a number of major contractors contacted to establish their appetite to bid for the project. This initial exercise resulted in a small number of contractors actually indicating they would be interested in bidding for the Project.

Shortly after this initial market engagement, a workshop was arranged with NHS Staff, and 4 Construction Consultancy companies, with whom the Board had previous experience, to test thoughts and ideas over potential ways to procure the project. This workshop presented a range of options to be further tested with the Contractors who expressed an interest in bidding for the Contract.

After appointment of the Board's Technical Advisors, Currie & Brown, detailed workshops were organised with 3 Main Contractors to test further thoughts and opportunities for procurement of the Project. Key outcomes from these workshops were:-

- Contractors concern over use of Competitive Dialogue and potential for protracted bidding period
- Protracted bid period leading to abortive bid costs for unsuccessful contractors
- Cross contamination of bids during competitive dialogue
- Fair competition and evaluation process – quality / price ratio selection
- Form of 2 stage design & build was acceptable
- No issues with use of Incentivised NEC3 Target Price type contracts

Based on market engagement and consideration of Board requirements in terms of Guaranteed Maximum Price type framework, the Procurement Strategy outlined as follows was recommended and implemented:-

- Prequalification of Contractors based on key criteria including:
  - Financial Standing
  - Technical Capability
  - Experience of Hospitals in excess of £200M
  - Personnel
- Shorlisting minimum of 3 contractors
- Single stage bid – quick selection of Preferred Bidder
- Single overall contract Price for delivery of the total project requirements. Approval Gateways included to provide control mechanism
- Competitive Dialogue structured to maximise benefit of dialogue within short period
- Robust procurement programme – set deadlines and achieve them
- Pricing Structure set to provide incentivised delivery framework – Target & Maximum Price
- Contractor Selection based on Most Economically Advantageous Tender – best ratio of quality & price
- Affordability threshold test – deselecting if bid exceeded threshold

6A.1.3 *Development Of The Tender Documentation*

Between September 2008 and April 2009, the Project Team and Technical Advisers worked with users, legal and financial advisers and others, preparing the clinical, technical and other information required to take the Project to market. This information formed the tender documentation which informed bidders of the NHS Board's requirements.

The tender documentation constituted 3 volumes as follows:-

Volume 1 Project Scope and Commercial Document

This provided an overview and outlined the scope and commercial parameters of the Project. It set out the background to the Project, outlined the detailed procurement process and timetable, identified the competitive dialogue process and incorporated the draft construction contract.

Volume 2 Employer's Requirements

This set out the technical and clinical requirements of the Board. These included Clinical Output Specifications for all departments, master plan and exemplar design information, output specifications regarding the construction works, building and engineering services to be provided plus Activity database (ADB) Room Data Sheets and Equipment Lists (by Group).

Volume 3 Bid Return and Evaluation

This detailed the range of deliverables required from bidders and the evaluation strategy and scoring approach to be applied by the Board.

6A.1.4 *Exemplar*

Key aspects of the Employer's Requirements (ER) were an Exemplar of the Hospitals to Royal Institute of British Architects (RIBA) Stage C, Schedule of Accommodation and Clinical Output Specifications. The Exemplar was developed with input from User representatives from over 70 User Groups from Specialties/Departments which will be housed within the New Adult and Children's hospitals.

The Exemplar involved development of 1:500 block plans for the Adult and Children's Hospitals, a number of 1:200 detailed design plans and 1:50 room information. The following describes this in more detail.

The 1:500 block plans demonstrate:

(i) the clinical adjacencies required for the key specialties;
(ii) flows of visitors, patients, staff and Facilities Management through the building;
(iii) the clinical links required between the new hospitals and the Neurosciences Institute and Maternity Buildings.

User Groups worked with the Board's Project Team and Technical Advisers to develop detailed 1:200 departmental layouts for 8 major clinical Department/areas, these being: A&E, Theatres, Critical Care, Imaging, Wards, Acute Assessment Unit in the Adult Hospital and Imaging and Emergency Department for the Children's Hospital. The detailed design plans illustrate how the department might be laid out and the flows for patients, staff and Facilities Management (FM) within it.

1:50 room information was developed using the ADB activity database which is a standard database for all UK hospitals showing general arrangements of standard rooms and suggested positions and location of equipment.

6A.1.5 *Tender Process*

In compliance with European Procurement Directive the Project was advertised utilising the OJEU process on 6th February 2009 and invited Expressions of Interest/Prequalification Questionnaire Completion from suitably qualified/competent Contractors. The PQQ required responses from Contractors to the following key criteria:

> Financial Standing
> Technical Capability
> Experience of Hospitals in excess of £200M
> Personnel

Completed documents were received from five Contractors and following a detailed evaluation process only three Contactors were deemed to have satisfied fully the required criteria to be selected to be invited to tender for the project. A full debrief was provided to the contractors not selected.

On 1st May 2009 the tender documents were issued to the three selected Contactors. The documents clearly set out the bidding timeframe and Competitive Dialogue structure.

Dialogue meetings were held to cover the following topics:

- **Design** – as bids were invited based on Exemplar Design and Output based specification, design dialogue sessions were required to allow bidders to test their design solution against the Employers Requirements, refine bid solution and allow the Board to clarify any areas of the brief

- **Logistics** – due to scale of development and impact on existing hospital site and surrounding neighbourhood, a Logistics group was formed to allow bidders to discuss solutions around construction methodology, temporary access arrangements, temporary car parking, temporary offices etc

- **Commercial** – this Group had three key remits, namely to continually test the affordability threshold with bidders to ensure affordable bids were received, fine tune any contract terms drafting and agree pre bid submission, and to test some key contract conditions with the bidders. Key contract items

discussed were Inflation risk, general risk management, who was best placed to hold risks, damages for late completion, retention and payment process; and

- **Laboratories** – as this element of the Project involved detailed design work continuing direct with the Board and novation of the Design Team post contract, this Dialogue presented design updates to the Bidders to provide an overview of design development and identify any construction / logistics issues

Four corresponding Groups were formed to represent the key areas with members from a range of stakeholders and advisers including Board Representatives, Medical, Nursing, FM and infection control representatives and Technical, Legal & Financial Advisers.

The bidders were represented from their own internal teams and their associated partners.

As part of the dialogue process the bidders formulated the agenda items based on their need to clarify any aspects regarding the tender documentation/project. The agenda items were discussed and subsequently action/query lists were drawn up and responded to within agreed timescales. A Request for Information (RfI) process was also operated whereby bidders sent questions for clarification to the Board.

Through the process described above bidders were given clear and detailed direction on the Board's requirements.

The Competitive Dialogue Period closed 14th August 2009 with the Invitation to Submit Final Bids issued which provided clarity on any changes to the Employers Requirements and the basis of bids to be submitted.

After dialogue and before submitting their tenders offers, bidders were asked to present their proposals to date as a final pre-submission exercise to determine that, through competitive dialogue, they were in line with the Employer's Requirements.

Contractor's bids were submitted on programme on 11th September 2009 and before a detailed evaluation process commenced bidders were requested to present their bids to the evaluation team to enable the evaluation team to gain a full and clear understanding of their bid content.

The evaluation process was rigorous and measured the bids received against the set criteria stated in the Invitation To Participate In Dialogue (ITPD). The ITPD clearly set out the Evaluation Methodology and provided scoring information on the items being evaluated, method of scoring and items individual and group weighting. The following describes this in more detail.

To ensure that the Evaluation Team complied fully with the process as outlined, training workshops for the evaluators were held in advance of the tender return date.

An Evaluation Centre was established at Gartnavel Royal Hospital, providing a secure base from which to manage and undertake the process. All members of the Design and Logistics groups co-located to this Centre for the full 5 week duration, thus ensuring interaction between individuals and Groups was possible at all times

A detailed evaluation programme was produced for the Team in advance, setting out the key actions and dates for the Groups, areas covered by the evaluation, were:

- Design
- Logistic
- Commercial

The evaluation of the Design and Logistics sub-groups were then reviewed, for consistency of approach, scoring and reasoning, by Senior Managers in the first instance and then finally by the Commercial Group who were tasked with making a recommendation to the Board.

The tender prices submitted were assessed for errors, inconsistencies, exclusions and caveats, then equalised to adjust for bid allowances and missing items. The out turn adjusted bid prices reflecting the estimated target were then calculated

The Most Economically Advantageous Tender (MEAT) scores , calculated as a ratio of quality and price were then generated using the full quality score and the adjusted bid prices, with a higher score representing better Value for Money.

The conclusions of the Evaluation Group were presented to the Project Executive Board on 22nd October 2009, which included the attendance and involvement of the Chair, Vice Chair and Non Executive Member of the NHS Board. Consequently on 26th October 2009 the Project Executive Board considered the comments from the meeting on 22nd October and formally endorsed the outcome.

Recommendations for appointment of the Preferred Bidder were presented to the NHS GG&C Board on 3rd November 2009. The Health Board endorsed the recommendations of the Project Team.

A comprehensive debrief was offered to, and accepted by, the two unsuccessful bidders. The de-brief comprised of a written feedback report, a presentation on Evaluation Team findings and a Question & Answer Session.

The formal Contract to award BCL to Design & Build the New South Glasgow Hospitals & Laboratory Project was signed on 18th December 2009.

6A.2 The Planning Process

6A.2.1 *Outline Planning Permission*

In April 2007 the Board lodged an outline planning application with Glasgow City Council which was accompanied by an Environmental Statement (ES). The planning application and ES were the subject of consultation with an extensive range of statutory and non statutory bodies, agencies and the general public. The application was reported to the Council's Development and Regeneration (Development Applications) Sub Committee in January 2008, with a recommendation for approval. The Sub Committee voted to grant outline planning permission subject to 43 planning conditions and the signing of a Section 75 Agreement. The outline planning consent for the New South Glasgow Hospitals project was issued by Glasgow City Council on 30th July 2009.

The consent stated that subsequent planning approvals would be dealt with as 'Reserved Matters'. This two-stage approach meant that there would be a requirement for reserved matters applications to be scrutinised by the planning authority to determine whether further environmental information and assessment is required to allow the detailed consideration and determination of reserved matters.

With the implementation of the Development Management component of the Planning Etc. (Scotland) Act 2006 on the 3rd August 2009, the submission of 'reserved matters' applications was replaced by the submission of 'Matters Specified in Conditions' applications.

6A.2.2 *Approval of Masterplan*

In April 2010, a Matters Specified in Conditions (MCS) application (Ref: 10/00945/DC) was submitted to Glasgow City Council to audit the changes between the indicative campus masterplan and the finalised masterplan, and assess the extent to which the finalised masterplan accords with the ES, as required by Condition No.1 of the Outline Planning Permission. The application outlined the following information.

- Setting the scene
    - Strategic Context
    - 2007 Campus Development Plan
    - 2009 Campus Masterplan
- 2010 Masterplan
    - Site Context
    - Design Vision
    - Masterplan Layout
    - Landscape Framework
    - Elements of the Masterplan

- 2010 Masterplan Strategies

    - Transportation
    - Site Circulation
    - Landscape
    - Drainage
    - Arts and Healthy Environment
    - Sustainability

The MSC application was approved by Glasgow City Council on 24 June 2010, subject to six conditions addressing issues including waste management, surface water, residential amenity, and wind turbines.

A further MSC Application was submitted to Glasgow City Council on 14th July 2010, covering the architecture of the buildings and the external areas. Planning approval was given on the 19th October 2010.

Architecture and Design Scotland (A+DS) have been a key partner and provided support and input review and commentary to the evolving design from the exemplar through to the submitted planning documents.

6A.2.3 *Building Warrant Status*

- The Building Warrant application will be submitted in stages including sub-structure, super-structure and fit out;
- Early stage application submitted to engage GCC Building Control in discussions regarding the Fire Strategy (close to conclusion);
- Negotiated fee levels agreed by the contractor with GCC;
- Energy Centre and Hospitals sub-structure application to be submitted on approval of FBC to allow early commencement of works on-site; and
- Further staged applications to be submitted to meet project programme and cash flow requirements.

6A.3 Architectural Design Statement & Design Development

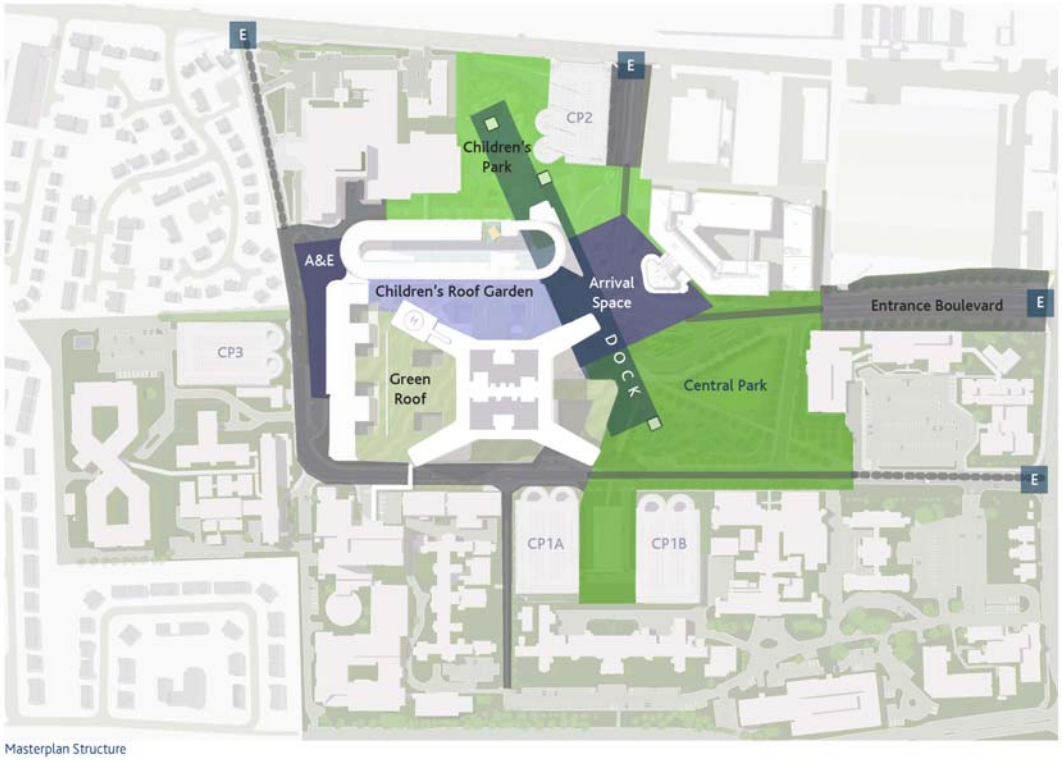
The Architectural Design Statement which accompanied the 'Matters specified in Conditions' application follows the principles set out in the Scottish Government's *Planning Advice Note No. 68 Design Statement* published in August 2003. It sets out to explain the scheme in terms of the brief, analysis of context, design development (following consultations) and the final proposals. The Design Statement, part 1 and 2, is attached at Appendices J and K for information, and highlights are summarised below.

The following describes the concept and vision of the overall design:

6A.3.1 *Design Vision*

The vision is based upon the creation of a landmark healthcare campus environment with emphasis upon a green character as an influential setting for state of the art hospital facilities.

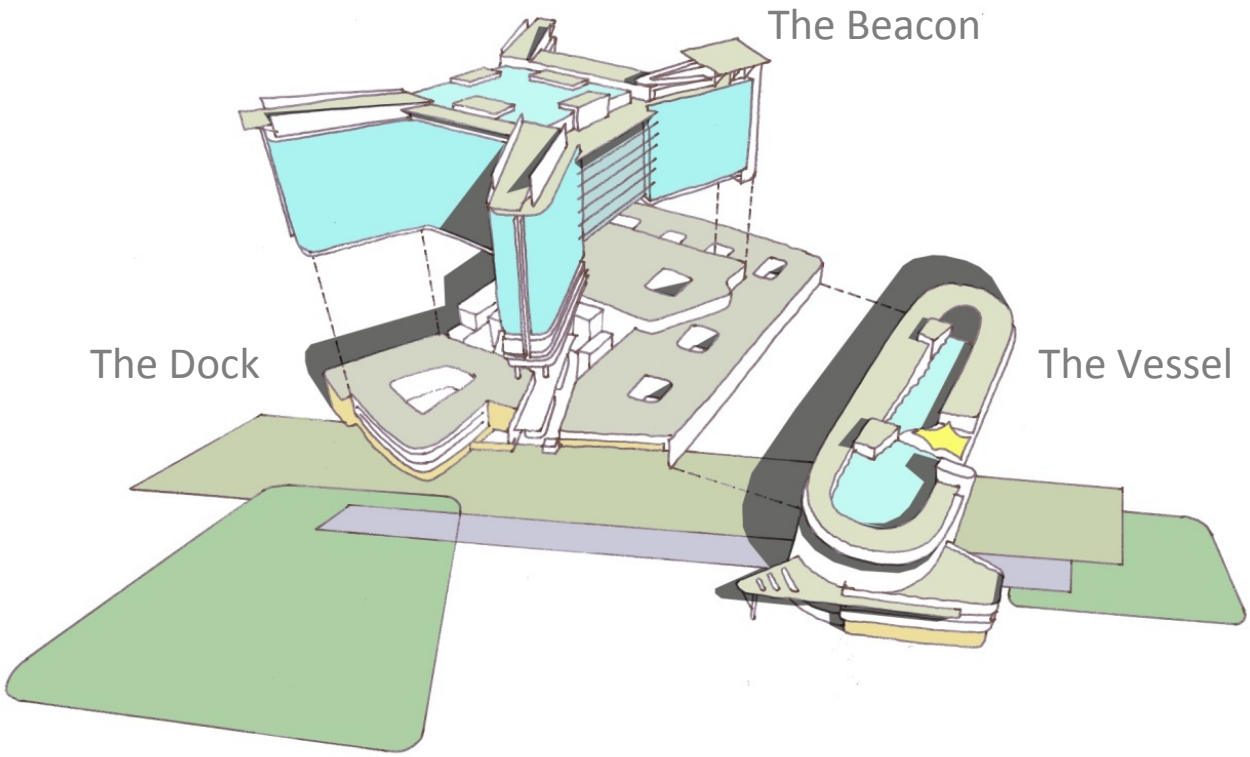
The setting of the new buildings within a designed sequence of public spaces is intended to de-institutionalise the hospital environment as far as possible and to create an engaging environment with a variety of designed external spaces. The masterplan design includes an arrival space which functions as a transport hub, an enhanced central park, a further Children's park dedicated to the new Children's hospital and a new entrance boulevard.



Masterplan Structure

6A.3.2 *Design Concept*

The project is large and complex and a simplified conceptual approach to exploring the forms and their relationships can assist in explaining the design. A ship-building concept applies to the form and character of the new buildings, which have been defined as a Dock (the broad podium), a Landmark Beacon (the ward tower located on the podium) and a vessel anchored alongside the dock (the Children's hospital). This captures the coming together of the primary components of the new hospital buildings and links to maternity and neurosciences are referred to as anchor points for the new hospital buildings to connect appropriately with the existing site.



6A.3.3 *Masterplan Structure*

The layout of the new campus heart has been structured in response to the functional requirements of the hospital site. The hospitals have three main public entrances. The new entrance boulevard from Govan/Renfrew Road is aligned with the main entrance to the acute hospital. The layout has been arranged to aid way-finding through the placement of key destinations in visible locations.

A public transport hub is located in front of the hospital entrances to provide a high quality experience for bus users. The extent of the arrival space also encapsulates the entrance to the new laboratories building.

A blue light route for ambulances provides a second main route through the campus and this gives direct access to accident and emergency to the south of the building. This route is also used by buses within the campus and for access to the two eastern car parks which frame the listed tower clock and surgical block.

An illustrative plan of the Masterplan is shown below.

Illustrative Plan-Landscape Masterplan

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6A.3.4 *Adult Inpatient Block – 'The Beacon'*

The inpatient block consists of 8 floors with four 28 bed wards provided per floor (typically). In order to allow a degree of flexibility of use, and in particular to allow notional departmental boundaries to adjust to meet varying service demands, the plan form of this block is arranged to ensure a continuous 'ribbon' of bedroom accommodation around the perimeter. [This approach ensures the optimum response to this requirement and, coupled with the 'internalisation' of fire escape and vertical circulation cores, allows every inpatient bedroom an uninterrupted view with zero overlooking other bedrooms]. This innovative approach to ward planning also provides the opportunity for each ward to be arranged around a central, covered day-lit atrium. The adult atrium provides a naturally lit, temperate space for provision of day-light to 'internal' spaces and at its base, for orientation, waiting and amenity. The connection of the two proposed 'FM' circulation cores by bridge links at levels 4 to 11 within the adult ward tower provides an opportunity for drama through the expression of support services as coloured pods linked to the bridge. Although conceived as a continuous ribbon of bedroom accommodation the plan form opens up at the end of each wing through the introduction of a shared 'social space'. This space allows a direct visual link to the outside, exploits elevated panoramic views and provides an appropriate termination to the internal ward corridor axis. The beacon is conceived as essentially glazed with alternate pairs of floors grouped and separated with a horizontal recessed channel. This device mitigates the effects of scale and introduces a strong horizontal emphasis.

6A.3.5 *Adult Podium – 'The Dock'*

Having located all adult inpatient facilities in the beacon the remaining (OPD, diagnostic, day, emergency, interventional) adult facilities are all contained in the podium (dock).

The dock consists of three storeys of clinical accommodation (with plant on a fourth floor where necessary). Courtyards and light-wells are inserted into strategic locations to mitigate any 'deep-plan' effects and to ensure adequate access to day light and view.

The dock is treated as a simple architectural element. Horizontal emphasis, through the use of recessed channels aligning with the building floor levels, with full-height vertical panels/windows set within the bands, provides an appropriate back-drop for the more expressive 'Beacon' and 'Vessel'.

6A.3.6 *Children's Hospital – 'The Vessel'*

The children's hospital, whilst sharing some of the podium is a hospital in its own right. In response to a requirement to invest the children's hospital with an identity all of its own, the building is conceived as a more transitory form, 'moored' alongside the 'dock' (adult podium). It is in the 'vessel' (the children's hospital) that maritime references are most evident. The 'apsed'

North and South treatments are also intended to provide a clear sense of identity and a link to maritime forms. The building is arranged as a simple linear block on the West side of the site, to connect to the existing Neo-Natal facilities. There is a 15m wide atrium separating the East and West sides, providing a large, internal, day-lit, temperate space. The atrium provides a large, covered amenity/waiting space as well as an intuitive internal way-finding device providing easy access to key vertical circulation cores.

Externally, an emphasis is placed upon the North and North Western facades (facing the arrival space and children's park). The main entrance and adjoining facilities at levels 1 and 2 have been developed to ensure response to the diagonal geometry and link between parks, as well as appropriate level of transparency and openness at the entrance.

A 'DNA' theme is employed in the compositional treatment of the vessels' facades, ensuring a consistent campus approach to the suite of buildings. In order to express the identity of the children's hospital, and to encourage a degree of 'playfullness', vertical coloured fins are applied radially around the entrance façade and along the West façade, where oblique views when moving North and South along the façade can be exploited. As a further gesture to integration with the children's park the consult/examination suites on the Western façade have been expressed as coloured 'play-boxes'.

View of children's hospital from the children's park

6A.3.7 *Development of the Arts Strategy*

The key strategic elements incorporated in the ERs have been developed and incorporate core, and enhanced elements that reflect consideration of building scale and funding aspects. A number of criteria such as improved care, function of space, level of impact, sustainability, inclusion and value for money were considered in prioritisation of the final programme and the relevant enabling works have been identified within the build programme. In collaboration with the core landscaping, architectural design and interior design programmes the Arts Strategy will specifically undertake the following programme of work:

Table 30 – Art Strategy Programme of Works

1. Building Design and Healing Environment	
The Beacon Project - therapeutic environment of socialisation spaces in Adult ward block The Beacon Project - Ward identity location and orientation marking in Adult ward block	Core - Adult
Dignified Spaces - Therapy rooms, imaging departments and long stay wards e.g. Distraction therapy	Fundraising - NCH
Dignified Spaces – Interior upgrading of quiet and respite spaces including installation of arts (Bereavement rooms/ Family rooms / Discharge Lounge / Waiting Rooms)	Core - NCH / Adult
2. Interior design and landscaping	
Atrium Colours and finishes - staff participation in colour palette development	Core – Adult
Stencils and Graphics - Way-finding in Wards and Podium	Core & enhanced - Children
Dignified Spaces -100 flowers for multiple location installations (themed works in waiting areas, staff areas and quiet rooms)	Core & enhanced - Adult
Orchard and therapeutic gardens/ landscape	Fundraised Adult / Children
Landscaped Courtyards	Core & enhanced - Adult
3. Integrated art, specimen art	
Podium Landmarking – Feature wall wayfinding at key junctures in podium	Core - Adult / Children

4. Architectural elements	
Focal points and human spaces - External shelters within Adult landscape and Children's play park, internal atrium Play Pods in NCH	Core - Adult / Children
Roof garden shelter structure NCH	Core- Children
5. The provision of programmable spaces	
Flexible exhibition space, framing devices and corridor artwork	Core - Adult / Children
Personalised spaces - Flexible white walls	Fundraised - Adult / Children
Atrium public performance space for ongoing commissioning e.g. Music	Core - Adult / Children
Artist Residencies: performing and visual arts	Fundraised - Adult / Children

6A.4 Design Development

To inform the development of service models and departmental designs members of the User Groups and project team undertook benchmarking visits to a number of UK hospitals, to gain ideas and identify service models/design which work well or, just as importantly, don't work well and to learn from other NHS hospital staff experiences.

The hospitals visited were chosen for their innovative models, single room provision and comparable size of departments. Of particular interest were Acute Assessment models for management of emergency activity, the layout of Theatres and models of Day of Admission, issues of other comparably large Critical Care and the optimum organisation and design layout of wards. The models of nursing within a single room environment was of interest along with differing ward bedroom arrangements comparing inboard, outboard and interlocking ensuites and different arrangements of support facilities.

The focus of benchmarking in relation to the new children's hospital was the design of the Emergency and Outpatient Departments, innovations in distraction therapy and the type and location of parental overnight beds.

The work described above helped confirm the service models and 1:200 design as users were able to see the options proposals tried and tested at other sites. It was also invaluable in highlighting pitfalls to be avoided.

It should be noted that use of the information gleaned from the benchmarking (hospital visits) exercise was not just used in the design development for the new hospitals but has also been put into practice as part of the Accelerated ASR. For example AAU models have recently been put into place in the West

of the city and are planned to be in place at the Glasgow Royal Infirmary at the start of 2011. In addition an Admission on day of service unit has recently commenced in the north of the city, this will allow these service models to be implemented, tested and further refined: with the out turn experience transferred to the New South Glasgow Hospitals.

The Clinical Briefs, Schedules of Accommodation and exemplar drawings described above formed a key element of the Employers' Requirements.

Following contract award in December 2009 the User Groups have worked closely with the Project Team and contactor architectural team to further develop and refine individual department layouts (1:200) and, having signed these off, the layouts of the individual rooms (1:50 drawings).

Full size mock-ups were built to assist users in developing the individual bedroom layouts (1:50 drawings) for the ward bedrooms and critical care. These consisted of an adult bedroom and en-suite, child's bedroom and en-suite with staff touchdown and a critical care space. The mock up rooms simulated in spatial terms the location of furniture, sanitary fitments, location of wall mounted equipment and bed head services. This has assisted clinical users in 'bringing architectural drawings to life', ensuring that the bedroom & en-suite design is fit for purpose, safe for patients and creates a healing environment. The mock-ups were also used to confirm high levels of visibility of patients from the corridor and staff touch down.

The mock-ups have also been visited by ward Senior Charge Nurses to assist them in understanding how the new wards will function in preparation for the move from multi-bed rooms to single bedrooms.

As previously mentioned the design of the ward and model of nursing are very much interdependent, the following (as well as the Change Management narrative at Chapter 6C) describes both in more detail and explains what action in being taken to prepare the nursing workforce for the move to the new environment.

6A.4.1 *Development of the Ward Design (Adult)*

A number of UK sites were visited in support of design development, including the Bevan Ward at the Hillingdon Hospital NHS Trust which is a pilot site for different layouts of 100% single rooms. The main elements of an effective design were identified as the maximisation of patient visibility, good access to natural light and minimising travel distances

Other key concepts taken from site visits were:

- the layout & design of the ward is crucial – especially in terms of the impact on nurse staffing and patients
- good design can facilitate the shift from multi-bed to 100% single accommodation within current staffing levels

- central positioning of support services such as clean & dirty utilities, disposal hold, linen bay and equipment /storage areas can reduce nurse walking times therefore increase time spent at the bedside
- provision of single rooms can facilitate staff to deal sensitively and privately with patient issues allowing private conversations and discussion of diagnosis and care
- single rooms give greater flexibility in isolating patients. This decreases patients ward transfers and boarding resulting in less staff time spent trying to find a single room for patients
- access to natural daylight and use of colour is very important to provide a healing environment
- observation panels into bedrooms increase patient visibility
- the use of touchdown spaces (mini nurse stations) support a devolved nursing model which allows the nursing staff to be closer to, and more in contact with, the patient; and
- including clinicians, nurses, allied health professionals, patients and families in the ongoing design process will maximise opportunities to improve staff workflow and patient safety and to create patient-centred environments

The following describes firstly the typical layout of a current ward within the existing estate and then the new ward design generated as a result of the benchmarking visits and subsequent work between the users, project team and architects.

6A.4.2 *Current typical Ward layout*

Across the Board area the majority of the hospital estate was built within in late 19th & early 20th century. The current design of ward areas consists of a variety of multi-bedded wards, ranging from nightingale wards to four bedded rooms.

Wards are commonly designed with a centralised nursing station with heavily used areas (clean & dirty utilities) at the end of or outside the ward area. Increased workload caused by travel back and forth to the nursing station and utility areas is inherent in current nursing care models which is not time efficient and inhibits care delivery.

Bottlenecks caused by full occupancy in gender specific multi-bed rooms can lead to challenges in managing beds and the result in knock-on impacts of delays in patient flows from emergency wards, Intensive care unit and post surgery recovery rooms.

6A.4.3 *New Ward Design*

The adult hospital is planned with each of the 8 floors of the ward stack comprising 112 bedrooms, all of which will be single bedrooms, each with en-suite shower and toilet facilities. Each floor is subdivided into four wards comprising 28 bedrooms.

The layout of each ward is a longitudinal triangular shape which provides the optimal design solution to support patient safety & reduce risk, enable social interaction between staff and patients and facilitate good observation. To enable effective operational management and minimise walking distances for staff regularly used rooms e.g. clean & dirty utilities, linen & equipment bays are centrally located. This will reduce walking times for nurses and maximise the amount of time spent with patients at the bedside.

The provision of hot desk facilities, interview rooms, staff change and seminar & medicines management rooms close to ward areas are also key to the smooth operation of the new service model. All bedrooms are placed on the perimeter affording all patients access to natural daylight and extended views. The design affords maximum flexibility allowing specialties to 'flex' across into another ward during peak activity. The wards will have staff touch down bases spread through the ward and near patient access to patient records.

6A.4.4 *Bedroom Design*

All single rooms can provide flexibility to manage differing levels of acuity even within a single speciality ward. Technologically the rooms are state of the art. All equipment required for the needs of patients including medical gases, access to computer technology and patient call systems are easily accessible on the bed-head services. It is anticipated that patient data entry will be done at the bedside.

A key design principle is good visibility from the corridor into the bedrooms. The design achieves good lines of sight into all rooms, achieved by incorporating large observation panels to give direct line of sight into the bedroom. Privacy issues will be addressed by the incorporation of interstitial blinds into the observation panel.

A key aesthetic and safety feature is that each patient will have his or her own en-suite toilet & shower room. The layout as designed, utilising interstitial en-suites provides good outward views for patients and high levels of daylight into rooms.

Although toilet & shower rooms are not the sole source of nosocomial infections, they are certainly important contributors. The design has an added benefit of an uncomplicated route from bed to en-suite in every room, giving patients direct access to toilet facilities.

6A.4.5 *Touch-Down Bases*

In addition to a centrally located nurse's station, multiple touch-down bases are a key design feature. These mini communication bases will allow nurses to complete handovers, communicate within the ward & other departments and enter data onto the computerised Patient Management Systems.

Decentralised Nurse Bases will reduce walking distances for nursing staff and will support good lines of sight into single rooms. The National Patient Safety Agency supports this view and suggests that walking time per shift can be reduced from 6km to 2.9km per shift, therefore increasing the time spent at the bedside.

There will be a devolved 'Team Nursing' model, whereby rather than working from one nurse station, nursing teams will be assigned to clusters of bedrooms supported by touchdown spaces to enable a safe and efficient model of care delivery.

6A.4.6 *Children's Ward*

There are wards on 5 floors of the new children's hospital and the design for each level is different reflecting the needs of that ward however, room bedroom sizes are the same and reflect the same principles as the adult wards, that is good vision, flexibility, and en suite WC and shower rooms.

There are not 100% single rooms in the children's hospital. This was agreed following consultation on the appropriate mix of single/multi-bed wards for children. The outcome of the consultation with children, young people and their carers was that there was a strongly expressed preference from both patients and their carers for the retention of a mixture of single and small bed-bays (2-4). This mixture was seen to offer flexibility in addressing a number of factors including the level of illness, the need for isolation, the need for company to aid recovery, and the preference of teenagers, in particular, for either privacy or companionship. The proposed build has 83% single rooms.

The current RHSC has a mixture of single and multi occupancy bedded areas and is therefore similar to the proposed design. There are not therefore the same challenges as the adult hospital around workforce training.

6A.4.7 *Information Management & Technology (IM&T)*

The provision of IM&T appropriate to the single room solution is a critical enabler to the nursing care model. To improve operational efficiency all single rooms are enabled for near patient data entry, with voice and data communications on the bed head services.

The new hospitals will include use of intelligent staff call systems, with the potential to link to the staff call, cardiac arrest, pager / telephone alert system. When the staff call is initiated, 'follow me' lights on digital panels sited at the staff base and at key points in corridor areas will indicate which patient is calling and allow the appropriate staff member(s) to respond. The Board has begun rollout of national patient management system (PMS) which will reduce duplication of effort and support communication systems for nursing staff.

In summary key ward design features such as near patient data entry, touchdown spaces and local support services will minimise staff movement by reducing supply trips, will significantly increase time spent providing direct care to patients and optimise nursing performance and efficiency.

Single bedroom accommodation will enhance patient flow whereas multiple bedded rooms paradoxically limit flow. The movement of patients will be reduced as bed management will be more efficient and productive, for example once a patient is admitted to a single room there is no need to transfer due to infection control, gender specific issues or end of life care

It is recognised that the move from multi-bed accommodation to 100% single rooms will be a significant change in practice for nursing staff, and this topic is discussed in more detail in Section 6C (Change Management). Substantial work has been undertaken to initiate cultural change by actively involving key clinical users in developing the ward design. As described the Generic ward user group has had, and continues to have, active ongoing involvement through the detailed design process during 1:200 and 1:50 stages for FBC. In addition the project team have held workshops, meetings and road shows to enable active input from wider professional groups.

6A.5 User And Stakeholder Consultation

As identified in Chapter 4, the procurement process was under pinned by the establishment of a clear brief of requirements from the NHS expressed in written and drawn format in the ERs.

Wide ranging and extensive consultation with Users, staff, patients, carers, other partners/stakeholders and the community was carried out (and continues through the design development process) in order that the specific requirements of the varied parties are considered and included where relevant.

Consultation activity in the following areas is identified and summarised below:

- Stakeholder User Groups;
- Technical & Facilities; and
- Community.

6A.5.1 *Stakeholder User Groups*

Stakeholder User Groups were formed in early 2007 for each of the departments within the Adult & Children's Hospitals, there are over 70 such groups and they will remain active throughout the design and construction of the project.

Membership includes Medical, Nursing, Allied Health Professions, Facilities Management, Diagnostic and Pharmacy staff. In addition the user groups are supported by input from medical physics and IT and, where required,

radiological protection officers. It should be noted that infection control have been fully involved in the design with a senior infection control nurse being a full time member of the Project Team and therefore part of the team liaising with the bidders, undertaking bid evaluation and working with the User Groups to develop the schedules and design.

Between 2007 and 2009, in preparation for the tender period, the User Groups were instrumental in identifying critical co-locations and developing the Schedules of Accommodation and Clinical Briefs. Since then, the Users have been involved in developing the 1:200 and 1:50 layouts.

6.A.5.2 *Technical & Facilities*

Specific workshops and consultations were arranged during the development of the ERs to ensure that the numerous specialist technical aspects of the requirements were discussed and agreed with the relevant individual(s) and groups in the Board (and out with where necessary).

This included mechanical & electrical workshop sessions with Senior Board Facilities Managers in order that the proposed output specifications were reviewed, adjusted where necessary, and agreed topic by topic as well as to support the setting of specific requirements for protection against critical failures (e.g. plant room floods and resilience to failures) which were embedded in the ERs. Similar such consultations included:

- infection control review of technical documents and outputs in relation to surface finishes and other aspects of the requirements;
- HFS in relation to draft SHTM standards and the updating of standards;
- Radiation protection officers in respect of gauss lines, building fabric and associated measures;
- the Board's procurement team in respect of equipment strategy and ADB codifying of the requirements;
- renal in relation to RO water and other specialised aspects of the department;
- fire and acoustic engineers to support the drafting of the specific requirements in relation to these specialised areas; and
- sustainability advisors in relation to the various energy and sustainability facets of the scheme.

6A.5.3 *Community Engagement and Benefits*

6A.5.3.1 Community economic benefits

As described in the Outline Business Case NHS GG&C commissioned a socio- economic analysis of the planned investment in South West Glasgow. The analysis concluded that the NSGH project is a catalyst for broader economic and social regeneration, contributing positively to the physical development of the local area and contributing significantly to the South West economy and that of the wider locality (see Table 32).

Table 31: NSGH Economic Impacts Summary (£m)

	Estimated future direct impact of services locating to NSGH (using scenario 2) (£m)	Estimated combined future impact, with multiplier effects (£m)	Estimated combined future impact of the site based on employment level of 8,400, with multiplier effects (£m)
South West Glasgow	£30	£30 – 40	£40-£50
Glasgow City	£90	£110 - £140	£140 -£175
Glasgow City Region	£170	£240 - £290	£300 - £370

Source: SQW Socio-Economic Impact Analysis

However, the analysis was also clear the potential impact of the new South Glasgow Hospitals Campus will only be realised through effective collaboration between partner organisations, building on existing partnership structures in South West Glasgow and Glasgow City. The approach undertaken by the NHS GG&C has sought to embed the activities described below within existing partnership structures.

6A.5.3.2 Economic impacts from the construction programme

In taking forward the recommendations from the socio-economic analysis NHS GG&C incorporated Community Benefit considerations in the procurement process for the New South Glasgow Hospitals project.

In doing so, the board aims to work in partnership with the successful bidder to ensure as far as possible, that investment supports local businesses, sustains local employment and creates new training and employment opportunities. The community benefit provisions within the procurement process focussed on:

- Targeted Recruitment and Training
- SME supplier development
- Social Enterprises development

In furthering the community benefit programme, BCL have entered into a partnership agreement with Glasgow South West Regeneration Agency, Glasgow City Council and Community Enterprise in Scotland. Through established partnership structures BCL will work with NHS GG&C to:

- Achieve target of 10% of total labour required to deliver the project (including those works delivered by specialists, or sub-contractors) to be delivered by New Entrants
- Devise a Local Labour Action Plan and establish requirements with Sub-Contractor/s to recruit and source supplies locally where these exist
- Establish an operational team to deliver services including: vacancy promotion, skills assessment and matching, general and vocational training and business development
- Establish a “Recruitment & Training Centre” in close proximity to the New South Glasgow Hospitals Project

- Adopt a recruitment protocol to support mainstream recruitment from communities in South West Glasgow
- Engage Small Medium Enterprises (SME's)/ Social Enterprises to assess and develop their capacity to participate in the project
- Establish a project portal, www.nsghproject.com for individuals and businesses to register for employment and procurement opportunities

To support the implementation of the community benefit programme, a Community Benefit Delivery Group has been established with partners and sub-contractors. This group is responsible for co-ordinating partners' activities, overseeing the implementation of the community benefit programme and ensuring the project is achieving the targets set out in BCLs bid submission.

6A.5.3.3 NHS careers

As described in the workforce section, NHS GG&C recognises that in order to deliver new models of care within the new provided hospitals significant workforce development will be required.

A partnership group including representation from NHS GG&C, South West Community Health Partnership, Community Planning Glasgow, Glasgow South West Regeneration Agency, Glasgow City Council Education Services and Cardonald College has been established.

The partnership aims to raise aspirations within South West Glasgow to pursue a career in healthcare and focuses on supporting individuals achieve the skills and competencies to access the workforce at NHS Carers Framework levels 1-4 (Scottish Curriculum and Qualifications Framework Levels 5-9).

Through the partnership, the board has already undertaken a number of early actions in South West Glasgow, these include:

- Presentations and briefings to Skills Development Scotland staff working with school age children and adult returners
- Programme of careers sessions undertaken by NHS recruitment in secondary schools in South West Glasgow
- Engaging secondary schools in South West Glasgow to increase number of pupils indicating a preference for NHS work experience placements
- In partnership with Job Centre Plus, Skills Development Scotland and NHS Recruitment deliver monthly NHS careers sessions in Govan and Shawlands Job Centres
- In partnership with Cardonald College establish HNC/D Applied Science to be delivered in 2011
- Increase participation on the HNC/D programme through piloting Skills for Work: Laboratory Skills qualification in South West Glasgow.
- In partnership with workforce development establish HNC/D Health to be delivered through Cardonald College in 2011

- Increase participation on the HNC/D programme through piloting Skills for Work: Health qualification in South West Glasgow

As the final configuration of services on the NSGH is implemented, NHS GG&C will work in partnership with employability services in South West Glasgow and Glasgow City to maximise opportunities for communities and co-ordinate activities with partners to implement a long term strategy.

6A.5.3.4 Housing sector

Through established partnership structures, NHS GG&C continues to work closely with Glasgow City Council, GHA and local housing providers in South West Glasgow. The focus of this engagement has been to inform future housing investment and improve access to affordable housing for NHS staff in South West Glasgow. This includes planning for the East Govan/Ibrox transformational area and Central Govan.

To support this programme, Govan and Elderpark Housing Associations and Crudens Homes in partnership with the NHS Credit Union and Glasgow Credit Union launched Unique Property Solutions. The project aims to provide financial support through the NHS Credit Union to support NHS staff access affordable housing in South West Glasgow.

In doing so, the board aims to retain the economic impacts in South West Glasgow through increasing the proportion of staff employed in the NSGH resident in South West Glasgow.

6A.5.3.5 Life sciences

Life science has become a key sector in Glasgow due to the benefits it derives from being part of a comprehensive national life sciences strategy, backed by industry, academia, the National Health Service and the government.

The redevelopment of the NSGH will bring significant benefits in terms of infrastructure and the co-location of clinical and academic staff.

Subject to FBC approval, NHS GG&C will engage Scottish Enterprise and the University sectors to establish a site commercialisation strategy based on the future configuration of university services to be delivered on site. This will be supported through existing planning structures to establish a land use strategy conducive to supporting investment in life science related industries.

6A.5.3.6 Conclusion

The approach undertaken by the NHS GG&C has sought to embed the activities described above within existing partnership structures. Subject to Full Business Case, NHS GG&C will continue to engage with partners and embed activities within established partnership structures.

For further information regarding the community benefits please see Appendix L.

6A.6 Community Engagement In The New South Glasgow Hospitals Project

As described in the Outline Business Case, NHS GG&C established dedicated engagement structures to support the continued engagement of stakeholders and communities throughout the design, build and commissioning phases of the project. These include:

- A Community Engagement Advisory Group (CEAG) to support engagement around the new South Glasgow hospital
- The Better Access To Health (BATH) disability advisory group to support engagement on physical access issues around the New South Glasgow Hospitals
- A Community Engagement Advisory Panel to support engagement of families, children and young people in the planning processes for the new children's hospital
- A Youth Panel to engage young people in the design of the new children's hospital
- A Family Panel to engage families in the design of the new children's hospital

Through these engagement structures, the board aims to ensure that:

- Patients, carers and community interests have been appropriately engaged in the design of the new South Glasgow Hospitals
- Patients, carers and community interests' views have informed the design of the new South Glasgow Hospitals
- Patients, carers and community interests have developed the necessary skills and knowledge to engage in the design process
- Neighbourhood stakeholders and geographic communities have participated in engagement and partnership processes, thus ensuring awareness of progress with the planning of the new South Glasgow hospitals
- The engagement of patients and carers met Scottish Government Health Department guidance on participation and involvement

As described in the Outline Business Case, the board undertook extensive engagement through these established structures to inform the Outline Business Case and Employers requirements, with an emphasis on the themes outlined below:

- Access & Wayfinding
- External landscapes
- Wards and Single Rooms
- Accident & Emergency

- Family & Carer facilities
- Children's Play Areas
- Out patient areas
- Main entrance
- Bereavement Pathway
- Renal Facilities

6A.6.1 *Detailed Planning*

Building on the work described in the Outline Business Case, NHS GG&C has supported a process to engage stakeholders in the 1:200 and 1:50 detailed planning for the new hospitals. This has included:

- A presentation from design team on 1:500 designs and treatment of identified themes and incorporation in 1:200 designs
- Group work and 1:1 interviews with over 100 Renal patients on the 1:50 design of the dialysis unit and renal inpatient accommodation
- Patient/carer/family engagement and commentary on the detailed design of mock up rooms and engagement on 1:50 design
- BATH Group engagement with the design team to consider the key access and way-finding themes identified during their work on the New Victoria and New Stobhill Hospitals
- Engagement with the NHS GG&C Spiritual Care Committee to assist in the development of the bereavement pathway and to finalise the 1:200 and 1:50 drawings for the design of spiritual care facilities in the new hospitals
- Youth and Family Panel participation in the planning meetings for 1:50 designs for family, adolescent, spiritual care and public areas
- Youth and Family Panel participation in the detailed planning of design installations for distraction, well-being and personalisation in treatment areas, bed rooms and public facilities

The above activity was supported by fact finding visits and training events to develop participants' technical understanding of the design process and capacity to engage in the process.

6A.6.2 *Engaging Communities in South West Glasgow*

Engaging communities around the hospital campus has focussed on raising awareness of NHS GG&C proposals within the South West Glasgow area and engaging partners in developing joint working opportunities. This will remain the focus as the project moves forward.

Working with the New South Glasgow Hospitals Project Team and partners, community engagement has participated in outreach activities and local events to brief community stakeholders on proposals for the new South Glasgow Hospitals. Briefings on the New South Glasgow Hospitals Project have regularly been provided for Area Committees, Community Reference Groups and Community Councils.

Community Engagement also works in partnership with the South West Public Partnership Forum to disseminate information and engage with their membership on the new adult and children's hospital.

In addition to the above, NHS GG&C continues to undertake outreach activity in local venues and utilise local newspapers, community based publications and events to raise awareness of the project.

In relation to the construction programme, BCL, supported by NHS GG&C have established a Good Neighbour Agreement, this includes a commitment to provide regular briefings to neighbours and notification of future activities, via a newsletter and website.

The programmes outlined above have established the foundations future engagement activity. Subject to Full Business Case, future community engagement will continue to reflect the ongoing commitment of NHS GG&C to keep patient and community stakeholders informed and involved in the delivery of the NSGH Project.

6B. PROJECT MANAGEMENT

6B.1 Previous Arrangements

The Outline Business Case identified the governance arrangements (including therefore those for project management of the process) relevant at that point in time. Post appointment of preferred bidder, the Governance Arrangements were reviewed and refreshed in order to meet the changing requirements and dynamics of the next stage of the project.

The new governance arrangements oversee the Acute Services Review (ASR) acceleration programme as well as the next phase of the Project. The arrangements are described below:

The key changes proposed included:

- Creation of a bi-monthly Acute Services Strategy Board with the amalgamation of the ASR Programme board and New South Glasgow Hospitals and Laboratory Executive Board;

- Creation of a weekly Acute Services Strategy Board Executive Sub-group (to be responsive to NEC3 Contract arrangements)

- Creation of a number of client/contractor groups to manage and control stages 1 and 2 of the project

- The Acute Services Redesign Group to undertake the necessary system modernisation, to work in achieving service and clinical transformation, also to obtain buy-in from the service directors who will be responsible for the new hospitals' operation.

The proposed arrangements were approved, in turn, by the New South Glasgow Hospitals and Laboratory Project Executive Group, the ASR Programme Board and the Performance Review Group (as well as subject to audit by PricewaterhouseCoopers UK) – the diagram below illustrates the arrangements which now form the framework for the project management of the project. Further information regarding the membership and remits of the various groups and sub-groups is attached at Appendix M.


Preformance Review Group
Acute Services Strategy Board
Acute Services Strategy Board Executive Sub Group
ASR Redesign Group
Joint Project Steering Group
Project Team
Project Management Group
Commercial Group
Construction Interface Group
Technical Design Group
Art Group
Joint Commissioning Group
Medical Planning Groups
IT Group
Equipment Selection Group
Communication and Marketing Group
NCH Project Group
Adult / Children's Users Groups
Laboratory Medicine Project Group
Site Co-ordinating Group

6B.2 Project Management

At a project level, the Project Director oversees and has responsibility for the progress and delivery of the Project on a day to day basis. He is supported by the Deputy Project Director, Project Team and Adviser teams as well as the interaction and partnership working between the Board and BCL which is inherent in the NEC contract and facilitated by the combined nature of the workgroups (i.e. resourced by a mixture of Board, Adviser and BCL personnel with the correct skills and experience) that have been established. The requisite daily activity and communication between the parties is encouraged and supported by the co-habitation on site of the Board (including Adviser personnel) and BCL delivery teams.

As is noted in the organogram above, a specific and particular structure of workgroups and hierarchy has been established in order to manage the day to day operations of the project and ensure communications, control and effective use of resources are engaged in progressing the delivery of the Project. As the Stage 2 activity has progressed, the Medical Planning Group and Technical Design Group have come-together and meet jointly to ensure the necessary coverage and interface between the concurrent technical design and medical planning matters. This group meets monthly as a forum to report on progress and management of the issues arising in the design development process.

As is identified in the table below (Table 33 – Governance Workgroups and Remits), each workgroup is comprised of individuals from the Board, BCL and the Adviser team and has an established Remit, Membership, Frequency (day and time) of meeting, and clear reporting line as well as a clearly identified lead (Chair).

With the exception of the 'IT Group' and 'Design and Healthy Environment Strategy Group' (which are sub-sets of the 'Technical Design Group') all workgroups report to the Project Management Group (PMG). The PMG meets fortnightly to review and address matters arising on the project. This includes issues which have been reported/referred to the PMG from a workgroup as well as any other relevant issues affecting the Project no matter their origin (e.g. internal to the Project or from external factors/parties). In the circumstance where matters arise that require to be addressed out with the PMG setting (due to timing/urgency) these are addressed at either the weekly Early Warning (Risk Reduction) Meeting or the fortnightly Commercial Group meeting or, if necessary, by arrangement of a dedicated meeting/discussion. The ability to arrange meetings/discussions at short notice is benefited from the co-habitation on site of the Board, Adviser and BCL teams.

The PMG reports to the Project Steering Group (PSG) on a monthly basis, the PSG being a principles forum to facilitate escalation of matters between the Board and its partner, BCL. Critically, the BCL membership includes dedicated director attendance from out with the immediate BCL project resource thereby providing a corporate presence and visibility to the process and Project. The intention is to review the structure in October 2010 and

make necessary changes to continue to adapt the arrangements to suit the needs of the project.

The Project Director (supported by members of the Project Team or Advisers as necessary on a case by case basis) attends the fortnightly Acute Services Strategy Board Executive Sub Group (ASSB-ESG) meeting. The ASSB-ESG has senior Board representation, including the Chief Executive, Chief Operating Officer, Acute Director of Finance and Head of Capital Finance, and exists to ensure a continuity of communication and reporting between the delivery team and the Board with regard to programme, process and matters arising. The ASSB-ESG has delegated authority to make decisions on project issues to maintain programme as well as to commit funding through management of issues referred by the Commercial Group. In this regard the group has delegated authority in line with the Boards Standing Financial Instructions (SFIs) which provides an agreed delegated limit for the Project Manager, Project Director, Acute Services Strategy Board Executive Sub Group, and Performance Review Group. In turn the ASSB-ESG reports to the Acute Services Strategy Board (ASSB) on a bi-monthly frequency.

In addition to the project management framework noted above, the core Project Team has a weekly meeting at the end of every week which provides discussion of cross workgroup items, allows any matters of concern to be raised and provides a diarised session for the team to receive any essential briefings, information updates or instructions from the Project Director.

The PEP (Project Execution Plan) and the RACI (Responsible Accountable Consulted and Informed) for the Project are appended at Appendix N and O.

Table 32 – Governance Workgroups and Remits

NEW SOUTH GLASGOW HOSPITALS PROJECT CONSTRUCTION MANAGEMENT

Group	Project Steering Group	Project Management Group	Commercial Group	Construction Interface Group	Technical Design Group	Design and Healthy Environment Strategy Group *(Sub-group of Technical Design Group)*	Joint Commissioning Group	Medical Planning Groups	IT Group	Equipment Selection Group
Remit (refer to Group remits paper)	- On a monthly basis identify key Strategic Drivers for the coming quarter. - Carry out a monthly review of Project Strategic Drivers providing direction to the Project management Group as required. - Carry out a monthly review of project issues (reported from sub groups via the PMG) that have not been cleared at sub group level. - Provide direction to the sub groups on the resolution of issues. - Monitor and identify any shortfalls in Project resources. - Monitor critical path of Project Programme	- Manage change control - Monitor short term design, procurement and construction programmes - Monitor project administration ie diary, document control, meetings -Oversee work of sub groups - Monitor sign off progress of sub groups - Monitor Community Benefit progress - Unblock sub group issues - Report key issues to Steering Group	- Manage Changes to Brief - Manage Payment Process - Manage valuations and costs - Manage Risk Register - Manage Early Warning/Compensation Event process - Report key issues to Project Management Group	- Identify short term works on site particularly any that may impact upon the hospital activities - Identify short term Hospital activities that may impact upon the construction works - Communicate construction activities to relevant 3rd parties - Monitor impact of works on surrounding area - Report key issues to the Project Management Group	- Ensure that planning Applications are submitted on time - Ensure that Planning Conditions are discharged on time - Ensure that Building Warrant application is submitted on time and all queries closed out - Monitor design compliance with the ER's and CP's. - Monitor design sign off - Monitor progress of key design strategies – fire, access control, acoustics etc - Manage any derogations from ER's and CP's - Manage any clarifications required against ER's and CP's - Monitor design programme - Manage Mock up and samples programme and signoff - Report any key issues to the Project Management Grp	- Review how art can best be incorporated into the scheme - Agree Project Art Strategy - Advise the design process of opportunities for art - Advise the design process and spatial and technical requirements for art - Report any key issues to the Technical Design Group	- Monitor the production of a Project Commissioning Plan - Monitor the production of a Project Commissioning Programme including operational commissioning - Review the design for "commissionability" - Manage specialist validations required ie pharmacy, CSSD, mortuary - Ensure equipment installation programme co-ordinated with main commissioning programme - Report any key issues to the Project Management Group	- Monitor the Medical Planning Programme and clear any blockages - Monitor resource levels required to meet programme - Monitor the medical planning sign off process and identify any critical delays - Ensure that other sub groups ie IT and Equipment feed into the medical planning process - Manage mock ups for functionality sign off - Monitor production of Room Data Sheets - Report changes to the Project Management Group	- Produce Project IT Strategy in sufficient time to inform the main design - Ensure that IT spatial requirements are co-ordinated with the main design - Ensure that IT technical requirements are incorporated into the design - Ensure that Equipment IT requirements are identified sufficiently early to inform the main design - Report any issues to the Technical Design group	- Monitor the inclusion of Equipment spatial and technical information on the Loaded Plans and Room Data Sheets - Ensure that Equipment spatial and technical information is provided to meet the design programme - Ensure that Equipment selection and procurement is carried out in time to meet the design and construction programme - Manage the approval of Equipment Selection - Manage change control in relation to Equipment provisions - Ensure that Equipment installation and commissioning is integrated into the Joint Commissioning Group - Report key issues to the Project Management Grp
Member-Ship **(Leads indicated in red)**	**Alan Seabourne** Alan McCubbin David Hall Douglas Ross Peter Moir Chris Lovejoy Ed McIntyre Neil Murphy Ross Ballingall Steve Pardy Tim Bicknell	**Alan Seabourne** David Hall Peter Moir Douglas Ross Mark Baird Mark McAllister Ross Ballingall Paul Serkis David Bower Darren Smith Ed McIntyre Tom Allan	Alan McCubbin Alan Seabourne **Douglas Ross** Peter Moir Paul Serkis Eric Napier Tom Allan	Hugh McDerment Sam Suddese Shiona Frew Estates Dept Facilities Dept Health & Safety Supervisor **Alan Keeley** Dave Jordan Kevin Graham Dave Bower Norman Sutherland	Alan Seabourne David Hall Frances Wrath Heather Griffin Hugh McDerment Jackie Stewart Karen Connelly Mairi Macleod Peter Moir Supervisor **Darren Smith** Manny Ajuwon Chris Lovejoy Ed McIntyre Emma White Alastair Leighton Tony Duddy	Alex McIntyre **Anna Baxendale** Dan Harley David Hall Dorothy Cafferty Frances Wrath Heather Griffin Jackie Sands Kate Munro Louise Watson Mairi Macleod Peter Moir Darren Smith Neil Murphy Liz Petrovitch Tom Littlewood	**Fiona McCluskey** Frances Wrath Heather Griffin Karen Connelly Mairi Macleod **Peter Moir** Supervisor C&B Support Ross Ballingall Chris Lovejoy Ed McIntyre Dave Bower Ron King	Alan Seabourne David Hall Fiona McCluskey Frances Wrath Heather Griffin Mairi Macleod Mark Baird Jackie Stewart Karen Connelly **Darren Smith** Emma White Paul Britton Dave Bower	**Alan Seabourne (tbc)** Alasdair Finlayson David Hall Frances Wrath Fiona McCluskey Hugh McDerment Karen Connelly Kenny Birney Lorraine Pebbles Mark Greig Marion Stewart Chris Lovejoy Tony Duddy Ed McIntyre Steve Pardy Michael Frain	Frances Wrath Hugh McDerment Isobel Ferguson Karen Connelly Lorraine Pebbles Peter Moir **Robert Stewart** C&B Support Dave Bower Darren Smith Manny Ajuwon Chris Lovejoy Steve Pardy Michael Frain
Attendees	To be identified as required	To be identified as required	To be identified as required	TA Advisers as required	TA Advisers as required	To be identified as required	Clinical reps/ Technical Advisers as required	To be identified as required	To be identified as required	To be identified as required
Frequency of Meetings	Monthly – Last Tuesday of each month 4pm	Every 2nd Tuesday 12.30pm	Every Tuesday 9am	Every Thursday 2pm	Every week - to be scheduled out	By Agreement	1 per month - to be scheduled out	Every week - to be scheduled out	1 per month - to be scheduled out	3rd Friday of every month 1pm (TBC)
Reports to:	Acute Services Strategy Board through Alan Seabourne	Project Steering Group	Project Management Group	Project Management Group	Project Management Group	Technical Design Group	Project Management Group	Project Management Group	Technical Design Group	Project Management Group

The agenda of the Project Management Group may expand to create a separate Construction Group

These groups will merge at some point

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6B.3 Commercial Project Management

Reporting to the PMG, the Commercial Group meets fortnightly to discuss and consider the various commercial matters arising. The requirement to manage and agree commercial aspects of the project is a natural aspect of the design and construction process, provided for in the NEC form of contract governing the Project.

The group consider standing agenda items, such as the Assessment (payment application on a monthly cycle), Early Warning matters, potential Compensation Events and Risk. Issues of a commercial nature that are raised ad hoc by either party (whether through one of the workgroups or otherwise) are addressed where necessary at the meeting.

In order to support ongoing management and assessment of commercial issues, a weekly review of Early Warnings is also carried out (the Risk Reduction Meeting) with relevant individuals attending to supplement the Commercial Group attendees where necessary due to particular aspects within the coverage of EWs or impacting as a result of EWs. Early Warnings are the correct contractual process under NEC for the raising of matters (by either party) that may impact the project, with the weekly session arranged to ensure active and live management of matters raised under this aspect of the project governance.

As noted on organogram above, there presently exists a Construction Interface Group which provides a critical function in the identification of impacts on the existing (Southern General) hospital site, wider neighbourhood and access etc. This group meets weekly, as well as attending the immediate neighbourhood and the existing hospital site where necessary to plan, discuss or oversee activity or proposed activity (e.g. adjustment to parking arrangements on the Hardgate Road campus entrance, demolitions of existing buildings on the hospital campus).

6B.4 Data Management

Complementing the overall contract management of the project and commercial matters is the Sypro web tool, which is kept up to date by the Board and records all of the ongoing contract paperwork and forms between the parties. The use of a live-time process and toolkit allows review and analysis of the status of EWs and other key project management sources at any time during the process.

General data management of the Project is controlled by the use of a web-based system, Aconex, which hosts all drawn and technical information generated as part of the design development. This is managed by BCL with Board and BCL individuals accessing and utilising the system (following training) to issue and respond to design and other project matters such as information requests and the like.

In respect of management arrangements post-implementation, individuals from the Facilities team (Estates) at the Board will be integrated into the construction phase (Stage 3) of the project to work alongside the Supervisor team. This will provide for key individuals to be involved in the construction process, testing and handover (including commissioning) aspects of the Project and therefore have an operational understanding of the components and equipment as well as interfacing with manufacturers and being involved in training and awareness sessions. The Project Team currently includes Facilities representation and this will continue through Stage 3 and into the operational phase, allowing a continuity of understanding and awareness to develop, manage and implement the operational environment from a support services perspective.

6B.5 Communications

A Communications and Marketing sub-group has been formed to strategically plan for the handling of proactive communications milestones, staff communications, marketing, media and joint working with the PR/marketing departments of the contractor and others as appropriate.

The communications and marketing plan will aim to:

- Raise awareness of the plans for the new hospital and the wider redevelopment of the Southern General Campus
- Build and maintain enthusiasm for the project amongst the local community
- Ensure staff, patients, the general public and other key stakeholders are kept updated as plans progress – including key milestones and decisions
- Highlight benefits for patients, staff and the local community – including new or improved facilities and services, economic impact and contribution to the wider regeneration of the Govan area

The main methods which are, and will be, used to keep stakeholders involved include:

6B.5.1 *Internal Communications*

NHS Team Brief - the monthly message from the Chief Executive which is used as the basis for face-to-face communication throughout the organisation

NHS GG&C Core Brief – a real-time electronic bulletin, which is used to brief staff across the organisation on key developments, decisions and achievements

NHS GG&C SN (online and print) - the monthly NHS GG&C staff magazine, which is circulated to 44,000 staff across the organisation and available online via the intranet. This has already carried several features on plans for the new hospitals

NHS GG&C Staffnet – Attracting 71,000 visitors a day, the intranet has dedicated pages on the new hospitals to keep staff informed of progress

Staff Briefings – in recognition that there is no substitute for face-to-face briefings, all the above is underpinned and supported by a regular programme of staff briefings and open drop-in sessions to update staff on progress and activity

6B.5.2 *External Communications*

The NHS GG&C Website receives around 60,000 hits a month. Within one click, visitors are taken to key information about the Southern General Campus with links to the latest news and information on the two new hospitals. The web is undergoing a redesign to deliver a stronger emphasis on patient and public information. Over the coming months the hospital pages will be enhanced with video footage and flythrough and other available visuals to help promote the development.

Health News – the quarterly NHS GG&C newspaper is distributed with three titles, the Herald, Sunday Herald and Evening Times, and is widely distributed across Greater Glasgow and Clyde. It is also sent to the 5000-strong Involving People database which includes politicians, community representatives and other individuals with an interest in health. It has already carried a series of articles on the hospital modernisation programme and will be used to provide regular updates on the redevelopment of the Southern General Campus as plans progress.

Media relations – the Communications Directorate will work with project leads and others to identify promotional opportunities to maximise media coverage on the redevelopment of the Southern General Campus. There has already been widespread media coverage of the announcement of the successful bidder for the contract and of the sod cutting for the laboratory development. This proactive work will inform the development of an action plan of activities to promote the new hospitals on an ongoing basis. Communications will also explore opportunities to develop campaigns and joint initiatives with key media partners.

Stakeholder Briefings – regular one-to-one briefings with key stakeholders such as local MSPs, business leaders and university colleagues will also be arranged to ensure they are kept updated on the development of the Campus.

6C. CHANGE MANAGEMENT

6C.1 Defining the Organisational Development Strategy

NHS GG&C has a major capital programme and service change programme in place to continue to implement the Acute Strategy Review (ASR) agreed in 2002. The key areas of focus over the next 3 years are:

- Continued planning for the New Glasgow South Hospitals, the new Children's Hospital and the Laboratory Strategy
- Redesign of services for the North East of the city to transfer inpatient services from Stobhill to Glasgow Royal Infirmary
- Centralisation of Vascular and Renal Services to the West and the rationalisation of Urology Services to 2 sites
- Continued integration of Clyde services
- Continuing to support a single system culture
- Integration and flow of patient information through the implementation of the Electronic Patient Record and the Patient Management System

The Organisational Development function will support these priorities by developing capability and capacity within the organisation to redesign services and manage change/support individuals and teams through significant change while also promoting and developing a culture of continuous improvement, in line with the Quality Strategy for NHS Scotland, through a strategic approach to LEAN.

The Head of Organisational Development (OD) is responsible for ensuring the development and implementation of divisional and directorate level OD Plans on an annual basis to support both short term and longer term change management processes arising from service modernisation and ongoing continuous improvement, aligned with board priorities and targets. OD Advisors provide local support to individuals and teams within each of the directorate management teams to develop capability and capacity for leading and managing change on an ongoing basis.

There is considerable experience of managing large scale change within the organisation and we are keen to ensure that lessons learned from previous change, e.g. the recent opening of 2 Ambulatory Care Hospitals/hospital closures and transfer of services to new sites, are incorporated into the overall planning process for the new south build. In addition we will work closely with other health boards through formal and informal networks to ensure continual sharing of experience and learning from other large scale change initiatives across NHS Scotland.

The overall strategic approach and planned programme of OD support is discussed and approved via the ASR Group, of which the Head of OD is a member and which reports to the Acute Services Strategy Board.

OD plans will be based on an Organisational Effectiveness Model capturing four workstreams: People and Other Resources; Structure and Infrastructure; Business/Service Processes; Values and Culture. Each of the areas impacted by change will be mapped to define the current position and undertake a gap analysis that will enable OD interventions to be identified and delivered in partnership with other support functions including H&IT, HR, Learning and Education. This will ensure that staff are well informed of proposed changes to service delivery and have the opportunity to provide input and feedback as the change is being planned and incrementally implemented over the next few years.

6C.2 The Change Management Framework - Summary of Core OD Themes

The ASR Group has agreed that the following areas will form the focus of any planned organisational development activity to support the change management agenda:

a) Supporting the engagement/communication strategy

There are significant workforce issues arising from the development of new service models and workforce planning which will be achieved through proposed centralisation, modernisation and redesign of services and the planned re-alignment of services at the Vale of Leven and the Royal Alexandria Hospital and between Stobhill/GRI and West Glasgow Hospitals.

In addition the implementation of the Electronic Patient Record and the Patient Management System (PMS) are significant change programmes which also require the adoption of new ways of working as well as changes to existing roles and practice.

The Head of OD participates as a member of the HR Workforce Engagement Group to identify how OD can best support communication and engagement processes aligned to the transitional arrangements. Senior OD Advisors are required to participate in local workforce engagement groups and continue to work closely with directorates to agree appropriate OD support at local level. All working groups and senior committees have staff side representation to ensure full consultation on any proposed changes that impact on staff.

b) Managing change

The acceleration of the ASR is a major change programme for the Acute Services Division and we will work closely with identified managers to ensure that they build on existing skills to lead change effectively through the use of a range of tools/techniques and OD interventions as well as providing advice and support on typical reactions and resistance to change and strategies for addressing these.

There is a variety of leadership development opportunities currently in place ranging from modular programmes, breakfast seminars, action learning sets in addition to coaching and mentoring arrangements. We will continue to provide leadership development opportunities based on annual needs analysis to ensure managers and clinical leaders at all levels possess the necessary skills to lead and manage change within their area of responsibility. This includes promotion and raised awareness of national and local organisational change policies and the Change Management Toolkit recently developed by NHS GG&C. Focused work is planned in the autumn of 2010 to consider the overall organisational culture, aims and aspirations and ensure appropriate leadership styles and behaviours are in place to support this.

Through discussions with Directors we will define specific teams requiring OD facilitation to further support them throughout the change process. Typically this type of approach will be used to flush out issues using tools/techniques such as SWOT Analysis/Current vs Future Landscape, Commitment Planning and the Change Curve to help understand resistance and reactions to the change process and to provide an awareness of the human behaviours associated with change.

c) New teams/integrated teams

It is clear that all of the changes will result in the integration of existing teams and in some cases the establishment of new teams. The OD function has considerable experience in supporting teams through transformational change and it has been agreed that work will be undertaken early in the change process to identify concerns/issues and address typical reactions and resistance to change. This may include:

- Exploring the practical issues arising from integration and the merging of 2/3 teams into 1 by establishing different ways of working, challenging traditional thinking and seeking agreement and commitment to newly defined ways of working to support effective integrated models of delivery
- Identifying values and addressing cultural and identity issues within this large and complex organisation e.g. attitudes and behaviours and unpicking the unwritten rules which define " how we do things around here"
- Clarifying new roles/responsibilities and standard operating procedures or integrated processes required in the new model
- Expressing and addressing fears/anxieties/hopes and aspirations and assumptions/misconceptions arising from planned change interventions
- Considering how best to ensure that staff moving from previous site(s) are not just expected to "be made to fit "into an existing site
- Ground rules/action plans to support all of the above and gain commitment to integrated team working

d) Redesign/LEAN

NHS GG&C is in the early stages of implementing a strategic approach to continuous improvement based on LEAN methodology. Initial work is focussed on defining priority areas for improvement activity across the board and the Head of OD will work closely with the Executive Sponsor, the Joint Operational Leads and Directors to identify priority improvement initiatives aligned to the ASR and implementation of PMS which will be undertaken during 2010/11, and on annual basis thereafter, to support the longer term strategy and ensure that services are appropriately designed prior to the transfer of services and the opening of new hospitals. An example of this is the recent Rapid Improvement Event within Renal Services which will inform both the short term centralisation of renal services on the Western Infirmary

General site as well as the longer term planned transfer of this service to the new south hospital.

We will continue to develop the capability and capacity across a range of managers and clinicians through the provision of a variety of training interventions. Building on existing redesign activity and the central provision of a core curriculum of redesign training we will place stronger emphasis on a whole system approach to redesigning patient pathways and administrative processes to shift the balance of care.

Desired outcomes for all improvement activity will be clearly defined at the outset and monitored through defined management structures and the Board's performance management arrangements to ensure sustainable change is achieved and provide evidence of benefits realisation and return on investment.

e) Longer term implications

While much of the initial focus has been on changes planned in the short term with specific emphasis on the transfer of inpatient services from Stobhill Hospital and centralisation of services to the West there have also been detailed discussions with directors/senior clinicians and the Head of OD to begin to consider longer term issues arising from the new South Glasgow build including Laboratory Services and the New Children's Hospital.

Planned OD interventions are in the process of being defined as pilot areas of work to consider operational issues and the full implications of the proposed service model and involve key stakeholders at the onset to ensure that individuals and teams have an opportunity to engage in the detailed plans required to support the full business case.

These areas of planned work will examine the cultural and workforce implications arising from the change, identify training and development requirements, agree areas for redesign to develop new processes and clarify changes to working practice and how this impacts on individual and team roles and responsibilities.

Examples of planned OD interventions include an initial session scheduled for November 2010 to consider the operational issues arising from the proposed Acute Assessment Unit which will capture key lessons learned from the opening of the Ambulatory Care Hospitals and reflect on ongoing progress with the planned transfer of services from Stobhill Hospital, in addition to a large focus group event scheduled for October 2010 focused on the implementation of the Laboratory Strategy.

Outcomes from these events will be reported via the ASR Group to inform future recommendations and ongoing implementation of the Organisational Development Strategy. This will ensure that all activities are targeted towards the delivery of the necessary service changes required to facilitate the

projected bed model and provide valuable learning early on in the planning process.

6C.3 Change Management Plans:

6C.3.1 *A Planned Approach to Organisational Change*

The overall emergent picture is one of continuous change and redesign impacting on individuals and teams at all levels. Experience has shown that often the people issues associated with change are addressed once the change is implemented or after the change has been introduced. It is therefore intended to have a more planned approach to change management in place. This will be an incremental process of change management and plans will evolve over the next 3 years (which will inform and be informed by local OD plans produced and reviewed annually) to support mangers and clinicians address resistance to change and challenge attitudes and behaviours to ensure effective implementation of the defined changes whilst redesigning key services prior to the opening of the new south hospitals.

A wide range of management groups and working groups are already in place and have informed the proposals set out in the full business case. A detailed programme of planned OD priorities is currently being defined to support the imminent transfer of inpatient services from Stobhill Hospital to GRI and the centralisation of identified services to the West early in 2011. During July and August a series of meetings were scheduled with the Head of Organisational Development, directors and key stakeholders to scope out the requirements to facilitate these transitional arrangements and consider potential targeted areas of OD work to support the New South build and the planned implementation of the Patient Management System.

We are in the process of discussing this in more detail with the relevant directors as executive sponsors of the change process and with relevant clinicians and managers to identifying wards/departments affected by change and plan a series of multi-disciplinary focus groups and/or events to be scheduled between September 2010 – January 2011 and then longer term, which the internal OD team will facilitate.

All planned interventions will focus on existing and planned clinical pathways to inform future model(s) of service delivery and consider the workforce implications arising from any proposed change. The multi-disciplinary approach will be designed to engage clinicians, staff side representatives and staff throughout the process to inform the final model and ensure effective communications of the intended change(s). Key support services (e.g. Medical Records, Facilities and Diagnostics) will also be represented in any planned interventions to ensure consideration is given to wider service implications.

The range of OD interventions designed to support this will include facilitated team sessions, one to one coaching and leadership development through an overarching OD Framework to ensure a consistent whole system approach to the change process.

Processes are in place to ensure close working with the HR and Learning and Education functions both informally and formally via HR Workforce Engagement Groups to ensure both transactional and transitional change management arrangements are fully considered throughout the process.

Measurable outcomes will be defined in the overall OD Strategy for all planned OD interventions to track progress and monitor the effectiveness of OD support in the implementation of the ASR. Clearly defined objectives and outcomes will be defined for all planned OD interventions and will be evaluated throughout the process with regular reports via the ASR Group to ensure delivery of the overall change plans and that corrective action and/or additional OD support is identified where necessary thus ensuring that the overall aims and objectives are achieved within agreed timescales. Benefits realisation arising from the change will include efficiency savings, increased productivity and improvements to the quality of patient care.

6C.3.2 *Change Management Planning – Current Activity and Initiatives*

As noted above, planning and readiness for service activity is under way in a range areas and activities. Two specific and essential areas of preparation in respect of the project are in nursing and facilities management, where the following activity is under way and planned.

6C.4 Nursing Readiness For Service Change

Professional nursing is about delivering a service that embraces the human values of caring and compassion alongside the necessary technical and decision making skills. The report *Modernising Nursing Careers: Setting the Direction (2006)* defines four priority action areas:

- Developing a competent and flexible nursing workforce.
- Updating career pathways and career choices.
- Preparing nurses to lead in a changing healthcare system.
- Modernising the image of nursing careers

The nursing workforce for the new hospitals is predicated on the agreed Board wide bed model. The generic ward establishments have been calculated using nationally validated tools in conjunction with the national Nursing & Midwifery Workload and Workforce Planning Programme.

Consensus amongst Nurse Directors within Scotland is that single room accommodation in itself should not increase the number of nurses required to care for patients and high quality nursing care should be achieved by appropriate staffing levels. Over the build period the Board will work towards

achieving the appropriate nursing workforce profile to support the operational management of single rooms.

With reconfiguration onto one site there will be economies of scale leading to increased efficiencies and better use of senior nurse resources.

Clinical leadership is vital to the delivery of safe and effective care within the new hospital. The Senior Charge Nurse (SCN) role is a key focus of Modernising Nursing Careers in order that the leadership of care quality is at the front line of patient care. The SCN has a pivotal role in ensuring safe and effective clinical practice, managing and developing their clinical teams and enhancing the patient experience. Each ward will have a SCN, the ward leader, who will play a key role in maintaining standards of high quality care and supporting continuous improvement. The SCN will be supported by a team of Registered and Unregistered nursing staff.

There will be a greater focus on the contribution & productivity of Clinical Nurse Specialists (Band 7/6). There will be a realignment of resources within the Band 5 Generalist Registered Nurse Co-hort, Assistant Practitioner and Housekeeper roles are currently being developed & piloted within NHS GG&C supported by an Education and Development Framework that describes the key capabilities, knowledge and skills required for the role. This has been designed to enable a flexible approach to learning and development and has been aligned to the NHS Knowledge and Skills Framework.

Assistant Practitioners work at level 4 of the NHS career framework developed by Skills for Health and will carry out some tasks traditionally undertaken by a Registered Nurse releasing those staff to deal with more complex cases.

6C.4.1 *Quality and Productivity*

Nursing quality & productivity is vital to the delivery of safe and effective care within the new hospital. The Board has ensured that the leadership of care quality is at the front line of patient care by the implementation of *Leading Better Care* to develop the pivotal role of the SCN in ensuring safe and effective clinical practice.

6C.4.2 *Leading Better Care*

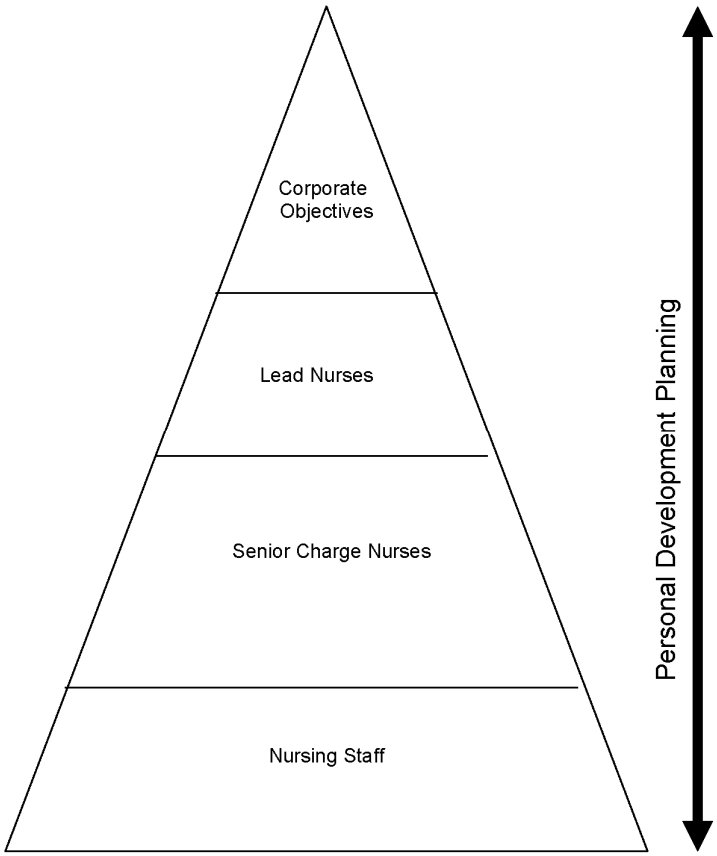
The Board has a strong focus on ensuring SCNs have the skill and tools to allow them to prioritise improving the patient experience. The aim of *Leading Better Care* is to create a modern clinical leadership role to enable frontline Band 7 Senior Charge Nurses (SCN) to maximise their contribution to delivering safe and effective care by developing their leadership capacity and capability. A national role framework has been developed which reflects four areas of SCN responsibility;

- to ensure safe and effective clinical practice
- to enhance patient experience

- to manage and develop the performance of the team
- to contribute to the delivery of the organisation's objectives

Through *Leading Better Care* Senior Charge Nurses are being empowering to be clinical leaders and guardians of safety and quality in their area. *Leading Better Care* establishes a national role framework (developed in partnership with NHS Education for Scotland) for SCNs working in hospital settings across the Board area. This has been rolled out across the Board as a key priority of the Nursing & Midwifery Strategy with key milestones and timetable co-ordinated by the assistant Director of Nursing. Further, the associated development, testing and roll-out of *Clinical Quality Indicators* (CQI) for *Falls Prevention*, *Pressure Area Prevention* and *Nutrition* provides real support to the SCN in improving care quality and provide direct read across to associated national workstreams. Close links have also been made between Leading Better Care and the roll-out across the Board of *Releasing Time to Care (Productive Ward)*. Together these initiatives are driving and sustaining real changes in care quality.

The Board has successfully delivered 8, with the 9th and last cohorts of Leading Better Care being delivered in October 2010. All SCN's will be working within the revised role by 2010. During the build cycle one cohort per year of Leading Better Care will be delivered to ensure any new SCNs in post have the key clinical leadership knowledge and skills for the role and it is expected that after attending this programme SCNs will develop and be supported in their leadership role. SCN's will facilitate ongoing Personal Development Planning with staff members through the KSF Framework to achieve organisation goals and the change process throughout the commissioning period. The cascade of objectives in the personal development planning context is illustrated below.



Leading Better Care reflects the need for SCNs staff to be clearly identifiable and visible to the public therefore the Board have adopted the national navy blue uniform for Senior Charge Nurses as described in CEL 36 (2009) and CEL 46 (2009).

Clinical leadership is a key driver for improving the quality of care that the patient receives. In conjunction with this, NHS GG&C are supporting senior nursing staff through the 'Prepare To Lead' programme. This programme creates a co-hort of leaders equipped to view issues strategically when delivering high quality healthcare. This means that nursing staff will be appropriately prepared to deal with changes in the nursing model.

6C.4.3 *The Releasing Time to Care Programme*

Research carried out by the NHS Institute found that ward nurses in acute settings say that they do not spend enough time on direct patient care, and that patient care suffers as a result. In 2007, the NHS Institute for Innovation and Improvement launched a programme that aimed to combat this. The 'Releasing Time to Care: Productive Ward' programme is being implemented across NHS GG&C alongside Leading Better Care.

Continuous quality improvement through the application of LEAN methodology, *Releasing Time to Care & Clinical Quality Indicators* will be consolidated to support the single room approach during the build & commissioning period to improve patient journeys, increase efficiency and contribute to more effective ward processes and procedures.

The Releasing Time to Care programme provides a structured framework for the use of continuous improvement methodologies with the ultimate aim of 'releasing time to care' in ward areas. This Programme has the potential to support SCNs to use a variety of quality improvement tools in their areas with the aim of having more capacity within the current resource envelope. The Releasing Time to Care Programme aims to combine factors to produce an environment that will:

- Increase the proportion of time staff spend on direct patient care
- Enhance the patient experience
- Reduce costs and all forms of waste
- Improve safety
- Increase staff well being

The Releasing Time to Care programme is split into parts, three foundation modules and eight process modules. To date, the Board have rolled out 2 cohorts of the programme and have concentrated on the three core modules:

- Knowing how we are doing (recording, displaying and using key measures)
- The well organised ward – (workplace organisation)
- Patient status at a glance – (improving the patient status display board)

Whilst the Productive Ward is a 'bottom up' methodology, its success depends on clear and visible links to the organisation's strategy. The objectives of the programme reflect clearly Board's mission and values and an improvement culture aimed at achieving a high quality experience for every patient.

6C.4.3 *Clinical Quality Indicators*

Four initial clinical quality indicators have been developed which are supported by a national electronic quality improvement programme. The background to Clinical Quality Indicators (CQI) is *Planning Ward Nursing - Legacy or Design?* (Audit Scotland 2002). This report emphasised that despite high numbers of nursing and midwifery staff in the NHS workforce, there was limited information available to compare nursing numbers, costs and impact on quality.

This is linked into the Scottish patient Safety Programme & Leading Better Care. These indicators are:

- pressure ulcer prevention,
- falls prevention,
- food fluid and nutrition,
- and monitoring and observation.

The SCN is responsible for ensuring measurement takes place but this can be delegated to anyone in the team as they deem appropriate. This provides SCNs nurses, when they are completing their CQIs compliance, with real-time reports and data to support where they are doing well, and highlight areas that require further work and are an important tool for senior charge nurses to establish a continuous quality improvement culture in their areas.

6C.4.4 *Clinical Nurse Specialists*

In the Board area 75% of the working week is spent on clinical activity however the aim is to increase this to 80%. In order to achieve this target, the Board is undertaking a CNS Workload Project to develop a principled approach to CNS's job planning. CNS's will be closer aligned to specific clinical areas and the aim is to allow one ward based clinical shift per week. In addition these nurses can provide a visible role model, support and advise ward staff whilst maintaining their own clinical credibility and competence.

6C.4.5 *NHSScotland Healthcare Quality Strategy*

The Quality Strategy has been incorporated into the Board's Nursing & Midwifery Work Plan 2010/11 and will be embedding into Directorate work streams.

6C.4.6 *Education*

Pre- and post – registration nursing and midwifery education is at the centre of nursing care delivery for patients, their families, relatives and carers. This entails the development and delivery of nursing care packages to ensure high standards of care are maintained and developed within a continuous quality cycling approach. Significant investment has been made in the clinical educator and practice development role to support the development of the registered practitioner and support staff to continue to deliver high quality patient care.

There are close links with the Schools / Departments of Health, Nursing and Midwifery within the University of Glasgow, University of the West of Scotland and Glasgow Caledonian University to support the clinical practice experience of undergraduate and pre-registered nurses, midwives and Allied Health Professionals. The clinical areas and environment enable undergraduate students to develop the skills required to care for patients under the supervision of a registered practitioner. There are many areas with international recognition for clinical practice within NHS GG&C, consequently practice placement experience is frequently requested from nursing students from other countries within the United Kingdom and the European Union.

6C.4.7 *Research*

There is a growing cadre of nurses developing research skills who are employed within the within the Clinical Research Facility and some specialist clinical areas, e.g. Oncology. However, in general nurses and midwives involved in clinical research tend to undertake this as a component in their academic studies, with an increasing number of nurses / midwives undertaking academic study at post graduate level. Although research activity within nursing and midwifery continues to develop there is a commitment for Clinical Nurse Specialists and Advanced Nurse Practitioners to be actively involved in nursing research to further develop the nursing care of patients and their families, relatives and carers.

6C.5 Facilities Management

The Facilities Management strategy for the New South Glasgow Hospitals and Lab Building has been developed to ensure that operational processes are enhanced in order to provide a patient focussed service delivery and that this service evolves through investment, innovation and acquired experience. The Board wish to provide a sustainable service through appropriately designed and well maintained facilities and also to be flexible and responsive to accommodate future change. FM user groups were established with representation from Catering, Portering, Domestic, Procurement and Decontamination Services to agree the design and layout of the FM accommodation in the 1:200 and 1:50 design process and FM were also represented on the Clinical Planning User Groups.

Highlighted below are some of the key developments which will allow FM to provide effective and efficient services to the patients and staff in the new hospitals

6C.5.1 *Automated Guided Vehicles*

The FM strategy for the Lab and New Hospitals has been developed through the design process and the key strand of this strategy has been the detailed design and the functionality of the system of Automated Guided Vehicles (AGVs). The installation of automated material handling systems is rapidly becoming a worldwide standard within large new build health care facilities. The installation of such systems can produce higher standards of service performance as well as leading to substantial whole life revenue cost savings, predominantly staff savings. The system also reduces the risks associated with the moving and handling of goods and services undertaken by FM staff.

Through dialogue with members of the Project Team, FM Staff and the BCL design team the Board have developed a programme of AGV movements which will transport the majority of goods around the hospitals; these goods will be transported in dedicated segregated clean and dirty FM lifts and in non patient/public areas.

This dialogue was undertaken through one to one meetings with heads of services, workshops and simulations as well as a visit to St Trondheim's Hospital in Norway where the system was seen in operation in a large acute hospital setting and information was gleaned from staff about their experiences.

Through design development the 'carts' used to transfers goods will be compatible with the AGVs and will allow the transport of trolleys used for, catering, linen/laundry, sterile supplies, and general supplies. There will also be the ability to exchange waste bins on a full for empty basis and remove the double handling of waste by FM staff.

6C.5.2 *Pneumatic Tube System*

Pneumatic tube systems are currently used in some areas within acute hospital sites across NHS GG&C but the installation of 92 send and receive stations in all wards and department within the new hospital will provide a comprehensive system for high speed delivery of specimens to dedicated labs in the new laboratory building. The system also includes a direct link between the emergency Department and Pathology to provide a high priority service. This system will improve the efficiency and speed of the specimen delivery service and free up portering time for patient movement duties. The location of the stations has been agreed through the user group meetings and the use of the system has been developed in consultation with the Laboratory Medicine Planning Team.

6C.5.3 *Service Yard/Waste Compound*

A key lesson learned from previous healthcare projects has been the location of the FM service yard to ensure that the transitioning of goods into and out of the hospital is undertaken quickly easily. This was the key factor in the decision to locate the service yard within the footprint of the new Laboratory Medicine Building with an underground tunnel to link to the new hospitals. This location allows the high volume of goods and service deliveries to be made separately from the main hospital and that roads and entrance are kept for 'clinical' traffic. The service yard provides a dedicated area for goods to be received, checked and then efficiently despatched to their destination with the majority of these transported by the automated guided vehicles. The service yard also accommodates the waste compound which is capable of sustaining a wide range of waste products which are generated from the new buildings and also the waste from the whole of the Southern General campus. Waste from wards and departments will be stored temporarily in waste disposal holds in wheeled carts which will be taken to the AGV hold area and then transferred into dedicated 'dirty' lifts and taken directly to the waste compound. As a full waste cart is removed a clean, empty cart replaces it. The service yard/waste compound will operate 24/7 to ensure that goods and services are available to wards and departments as required.

6C.5.4 *FM Readiness*

As indicated above the new hospitals will include systems which will allow FM to deliver more effective and efficient service delivery and in order for the FM team to be prepared a detailed commissioning plan will be developed. The first step of this will be to ensure that the appropriate staff are identified and supplied with the correct level of training to ensure the systems are maintained and operated to the optimum efficiency. This programme of training will be planned well in advance and will involve NHS FM staff working closely with the BCL team as the buildings are commissioned in readiness for handover. In order to prepare the appropriate staff identification of the tasks and duties that require to be undertaken and a review of the skills needed will be developed and the appropriate job descriptions compiled. The training programme will include: sub-contractor introductions, classroom and hands on training, geographical familiarisation and control system user training.

The handover of the building from BCL to the Board's Director of FM will include an asset register, operation and maintenance manuals, as-built drawings, health & safety files and training manuals which will be used to set up a preventative maintenance schedule for ongoing operations.

6D. CONTRACT MANAGEMENT ARRANGEMENTS AND PLANS

This Section considers the arrangements in place to mange contract change, both during the construction phase and into the operational phase. This outlook therefore considers known/expected change as well future, as yet unknown, contractual change.

6D.1 Construction Phase Change

The Stage 3 and 3A construction activities are governed by the NEC contract, as identified and discussed in Section 4.4 of this document. As is normal practice in construction related agreements, the contract makes provision for change – detailing the procedures to be followed and how any associated risks, costs and impacts are to be addressed and treated between the parties to the contract.

Notwithstanding the provision for change in the contract, the process around change requires to be managed and governed by the Board. To that end the governance and project management framework identified in Section 6.2, above, are integral.

It is possible that a Change is required or requested during the construction phase, with the origin of the proposed adjustment being service led (i.e. clinical) or technical. No matter the origins of such a proposed Change, the business justification requires to be determined and clear and approvals are necessary in line with the established delegated authority provisions.

- Project Manager approval of expenditure up to £10,000;
- Project Director approval of expenditure up to £100,000;
- Acute Services Strategy Board and Executive Sub-Group approval of expenditure up to £1.5m; and
- Performance Review Group approval of expenditure over £1.5m.

Notwithstanding the approval levels and guidance, it is important to note the regular contact between senior personnel in the Board project team, adviser team and the contractor through the meeting and communications structures, including specific provision of time dedicated to the review, discussion and agreement of potential change on a weekly basis. This is carried out in a partnering arrangement and environment, with individuals aligned as to the aims and objectives of the project as well as well sighted on the remit and vision to be delivered.

6D.2 Potential Future Change

The lifetime of the facilities will see change, driven by differing requirements, aims and outcomes. These may be internal to the Board (service led) or external due to regulatory, legislative or other factors, for example.

Service led change during the operational phase of the hospitals will manifest itself in the ASR Redesign Group (or equivalent established forum) and from a governance perspective will require to pass into the approvals structure for consideration based upon business justification proposals.

The role of the Chief Operating Officer is therefore critical in the look forward consideration of Change and management of change, with business cases (business justification) for proposed change of any origin requiring to be

assessed, considered and approved (or rejected) by the COO (supported by directors as necessary).

The ongoing remit of the Board, with regular meetings including directors and organisational development teams, as well as linkage and responses to national initiatives and requirements are all important and relevant in the approach to and consideration of potential future change. That is, the Board being a cohesive and collaborative entity supports the identification, consideration, management and decision making around future change a defined activity which should assist in the management of uncertainty and continuity of appropriate service delivery.

6E. BENEFITS REALISATION

A description of the anticipated benefits of the project and how they will be measured is given in chapter 2H and appendix D.

6F. CONTINGENCY PLANS

As is illustrated and described in Chapter 6B, the Project is well resourced and managed with an appropriate set of workgroups and reporting lines such that progress and matters arising are visible and addressed by the appropriate individuals and groups (which may be a combined Board/contractor/adviser group).

Given the structure as well as the frequency and detail of reporting, there is therefore an in-built risk management of progress in the project and awareness of key dates and deliverables throughout the various individuals and teams.

From a construction (including commissioning and handover) perspective the achievement of key dates and ultimately having the hospitals complete and ready for occupation is a managed activity that is reported accurately and frequently – which will allow identification and reporting to be escalated and contingent steps implemented should the service delivery dates be threatened.

As the clinical services will (with the exception of some aspects of new service) be being delivered on other sites (including the existing Southern General) prior to the new hospitals being opened, the ultimate contingent position should the new facilities not be completed on time would involve continuity of clinical service through continued delivery at the current sites and re-appraisal of the timing and implementation of the Board's transfer programme and plans. This would have communication and logistics (as well as cost) impacts, but does provide an overall contingent position.

In order to minimise loss of service/business interruption once the hospitals are operational, the Board requested inherent aspects of resilience to critical failures and mitigation of operational interruptions to be a key feature of the

planning and design of the hospitals. The requirements within the ERs include, for example, plant rooms being sectionalised with waterproof floor slabs and services on raised grids.

Additionally, the treatment of defects in the contract provide for a 24-month defects period with a prioritisation of timescales for correction of defects dependant upon the nature of the defect in question. This approach again provides a contingent position to minimise loss of service and impact on service once the hospitals are operational.

6G. POST PROJECT EVALUATION

This Section considers both Scottish Government Gateway reviews as well as Post Project Evaluation (PPE) as considered by the *Scottish Capital Investment Manual* (SCIM).

6.G.1 Scottish Government: Gateway Reviews

A Gateway 3 Review was undertaken by the Scottish Government Gateway Review Team between 4th-6th October 2010. The project was awarded a green level of Delivery Confidence Assessment, defined as successful delivery of the project/programme to time cost and quality appears highly likely and there are no major outstanding issues at this stage that appear to threaten delivery significantly.

The Gateway report is very positive and recommends that the project should develop a case study of the procurement approach (so this could be shared with other NHS and Government organisations). There are two actions highlighted to be completed before the next gateway review and these are to add some indirect risks (e.g. political risks) to the risk register and continue to develop the benefits management plan to define targets and gather baseline data.

6.G.2 Post Project Evaluation (PPE)

The Project Evaluation requirements are a very important feature in the lifecycle of the hospitals and in accordance with SCIM allowances have been made within both the project plan and budget to undertake evaluations throughout the construction phase, and 12 months after commissioning. There will also be a requirement to undertake follow up evaluation at 5 year intervals and this is recognised by the Project Team.

The construction phase evaluation will be continuous and will involve the Project Team preparing monitoring reports at regular intervals covering:

- Management procedures
- Design Solutions
- Contractor's Performance
- Expenditure forecasts

Upon completion, an initial review of delivery and functional suitability will be undertaken prior to occupation by a multi disciplinary group representing a wide range of stakeholders in the project.

Key issues that will be addressed in this review will include:

- Was the project completed on time?
- Was it completed within the agreed budget?
- What were the reasons for any delay?
- What action would management recommend to prevent future problems?
- Functional suitability of the building?

The Post Project Evaluation will commence once the buildings are fully occupied and the services have been allowed to bed-in. It is anticipated that this will be approximately 12 months after practical completion and handover of the facility, and will be undertaken by the same group which will assess the performance of the facility against the objectives as agreed.

The project evaluation will be aligned with timelines for the Laboratory facilities, such that the reviews are taking a holistic view of the hospitals, laboratories (including FM areas) and energy centre on a look forward basis. This is seen as a suitable and relevant approach in order that benefits are considered collectively and issues to be recorded and managed are identified with consideration of the wider facilities and impacts.

CONCLUSION

This FBC revisits and revalidates the proposals for a new adult and a new children's hospital on the Southern General Campus. These proposals are fully in line with the phased construction contract signed between NHS GG&C and BCL in December 2009. The new adult and children's hospitals form the pivotal phase of the ASR Strategy and therefore the key transitional aspect of the transformation of service delivery by the Board.

Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHSScotland

Date: 20/12/18

Status: Final v2

Contents

Executive summary

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating and managing a contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with probable linked cases of bloodstream infections associated with wards 2A/2B RHC.

Wards 2A/2B RHC is a haemato-oncology unit, also known as Schiehallion, and houses the National Bone Marrow Transplant Unit. In 2016 a patient within ward 2A RHC was identified as having a blood stream infection (BSI) as a result of *Cupriavidus pauculus*. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition received by the child was prepared. *Cupriavidus pauculus* was isolated from water samples taken from a tap on a wash hand basin within this area. The wash hand basin was subsequently removed as a result. A further single case of *Cupriavidus pauculus* was identified in September 2017 however no environmental or water sampling was undertaken at this time.

Between the period of 29th January and 26th September 2018, 23 cases of blood stream infections (11 different organisms) with organisms potentially linked to water contamination were identified. As a result further testing of the water supply was undertaken across both hospital sites early in the investigation. This testing identified widespread contamination of the water system. Control measures implemented included sanitisation of the water supply to ward 2A, installation of the use of point of use filters in wash hand basins and showers in ward 2A/B and other areas where patients were considered high risk. Drain decontamination was undertaken and on 26th September 2018 wards 2A/B were closed and patients decanted to ward 6A QEUH and 4B QEUH. There have been no new linked cases identified since the decant of the patients.

NHSGGC requested support from Health Protection Scotland (HPS) with this incident on 16th March 2018 and Scottish Government invoked the national support framework on 20th March 2018 which requires HPS to lead an investigation and provide board support. This report is a summary of the findings from this ongoing investigation for the period of 29th January 2018 – 26th September 2018. Further technical work is being undertaken for NHSGGC by Health Facilities Scotland (HFS).

Background

Health Protection Scotland

HPS plan and deliver effective and specialist national services which co-ordinate, strengthen and support activities aimed at protecting the people of Scotland from infectious and environmental hazards.

They do this by providing advice, support and information to health professionals, national and local government, the general public and a number of other bodies that play a part in protecting health.

HPS is a division of NHS National Services Scotland which works at the very heart of the health service across Scotland, delivering services critical to frontline patient care and supporting the efficient and effective operation of NHS Scotland. The specialist group involved in supporting NHSGGC in this investigation is the antimicrobial resistance and healthcare associated infection (ARHAI) group. The lead from HPS in this investigation and author of this report is a Consultant Nurse in Infection Prevention and Control with a specialist qualification in water and ventilation and is also the national HAI built environment and decontamination lead. HPS have been supporting NHSGGC with this incident since 16th March 2018. This report has been produced with full support from colleagues across NSS.

National Support Framework

The National Support Framework[1] is a structure that sets out the roles and responsibilities of organisations in the event that a healthcare infection outbreak/incident, is deemed to require additional expert support. The National Support Framework may be invoked by the Scottish Government HAI/AMR Policy Unit or by the NHS Board to optimise patient safety during or following any healthcare incident/outbreak(s)/data exceedance or Healthcare Environment Inspectorate (HEI) visit/report. Scottish Government invoked the national support framework[1] on 20th March 2018

NHS Greater Glasgow and Clyde

NHSGGC is the largest health board in Scotland serving a population of approximately 1.2 million people and employ circa 38,000 staff. The main hospital sites covered by this NHS Board are:

- Inverclyde hospitals campus
- Royal Alexandra campus
- Gartnavel campus
- West Glasgow ambulatory care Campus
- Glasgow Royal Campus
- New Victoria Hospital
- Stobhill campus
- Vale of Leven
- Queen Elizabeth University Hospitals Campus

Queen Elizabeth University Hospital (QEUH)/Royal Hospital for Children (RHC)

NHS Greater Glasgow and Clyde's (NHSGGC) Queen Elizabeth University hospital (QEUH) is a 1109 bedded hospital with 100% ensuite single side room. Construction commenced on the £842 million hospital in 2011 which was handed over to the Board on 26th January 2015 with patient migration commencing from 24th April 2015 until 7th June 2015. The adjoining Royal Hospital for Children (RHC) is a 256 bedded childrens hospital which was handed over to the Board on 26th January 2015 with migration of patients occurring between 10th and 14th June 2015. The QEUH and RHC were both fully occupied from 15th June 2015. There are a number of additional healthcare facilities in the surrounding grounds including the maternity unit, neurosurgical unit, elderly care unit and the national spinal injuries unit. The QEUH/RHC is Scotland's largest hospital and replaced a number of existing hospitals from the NHSGGC area including:

- Southern General Hospital
- Victoria Infirmary
- Mansionhouse Unit
- Western Infirmary
- Royal Hospital for Sick Children (Yorkhill)

Introduction

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating and managing a contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with 23 probable linked cases of bloodstream infections associated with wards 2A /2B RHC. NHSGGC requested support from HPS with this incident on 16th March 2018 and Scottish Government invoked the national support framework[1] on 20th March 2018 which requires HPS to lead an investigation and provide NHS board support. It is recognised that this investigation and remedial action is still underway and may be ongoing for a considerable period, therefore this report is a summary of the findings from this investigation and includes cases and findings for the period 29th January – 26th September 2018.

An initial report was produced by HPS and submitted to Scottish Government (SG) and NHSGGC on 31st May 2018. Due to the ongoing and complex nature of this incident and investigation a further report was requested. This report is a summary overview of this investigation however due to the large volume of data and complexities associated with this incident further technical work is being undertaken by HFS. HPS worked with the support of HFS as the technical engineering experts to support this investigation and report production. In addition the HAI Policy Unit Scottish Government (HAIPU) has requested a separate detailed review of wards 2A/B to be undertaken. This is currently underway and will form a separate report for HAIPU and NHSGGC.

Summary of clinical cases associated with this incident

Case definition

The case definition in place since January 2018 is:

"*any child linked to wards 2A/B RHC with a blood stream infection (BSI) caused by a gram negative bacillus that had been identified from organisms identified within the water system"*

Ward 2A RHC is a haemato-oncology unit, also known as Schiehallion, and houses the National Bone Marrow Transplant Unit and teenage cancer trust. Ward 2B is the day care component of ward 2A. In total there have been 23 cases identified during the period 29th January and 26th September 2018.

2016-2017

In February 2016 a patient within ward 2A RHC was identified as having a bloodstream infection (BSI) as a result of *Cupriavidus pauculus*. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition was made that the child had received. *Cupriavidus pauculus* was isolated from water samples taken from a tap on a wash hand basin within this area. Typing by Colindale reference laboratory confirmed the isolate from the washhand basin and the patient were the same. The wash hand basin was subsequently removed as a result. A further single case of *Cupriavidus pauculus* was identified in September 2017. NHSGGC reported that a second hand hygiene sink was found to be positive but following assessment was unable to be removed. Silver hydrogen peroxide treatment was undertaken and repeat testing resulted in zero total viable counts from this outlet.

2018

On 29th January 2018 *Cupriavidus pauculus* was again identified from a bloodstream infection (BSI) in a patient in ward 2A. Following identification of this case a series of investigations were undertaken including water sampling from outlets within the ward area. On 21st February *Pseudomonas fluorescens* was identified from a BSI and between 11th and 16th March 2018, 3 cases of *Stenotrophomonas maltophilia* were identified from patients in ward 2A. On 7th April a further case of *Stenotrophomonas maltophilia* was identified. *Cupriavidas*, *pseudomonas* and *stenotrophomonas* (amongst other gram negative bacillus and fungi) were identified from water samples obtained within wards 2A/B and therefore all cases considered to be linked to the water system. No further cases were reported until April, when between April and June, a further 10 cases were reported: 5 *Enterobacter cloacae*, 3 mixed gram negative bacilli, 2 S*tenotrophomonas maltophilia*. This cluster of mixed organisms, which were present from drain samples prompted the investigation in to the drains within ward 2A/B. Following drain sanitisation and environmental decontamination using hydrogen peroxide vapour, no further cases were reported until 2nd August and between the period 2nd August and 20th September 6 further cases were identified: 1 *Chryseomonas indologenes/Stenotrophomonas maltophilia*, 1 *Serratia marsescens*, 1 *Klebsiella oxytoca*, 2 S*tenotrophomonas maltophilia,* 1 *Enterobacter cloacae.* This latest cluster resulted in immediate further drain decontamination and a temporary decant facility for wards 2A/B being identified, with the patients transferred to wards 6A and 4B on 26th September to allow for investigative and remedial works to be undertaken in wards 2A/B.

In total there have been 23 patient cases identified. A number of patients have multiple organisms so the organism total is greater than the case number.

The organisms linked to cases include:

- *Cupriavidus pauculus* (1)
- *Pseudomonas fluorescens (1)*
- *Pseudomonas aeruginosa* (3)
- *Stenotrophomonas maltophilia* (12)
- *Acinetobacter ursingii* (2)
- *Enterobacter cloacae* (7)
- *Klebsiella oxytoca* (1)
- *Serratia marcescens* (1)
- *Pseudomonas putida* (1)
- *Pantoea sp* (1)
- *Klebsiella pneumonia* (1)
- *Chryseomonas indologenes*(1)

In addition to the organisms detailed above there is evidence of fungal growth in the water system however there have been no associated clinical cases reported.

A timeline of cases is detailed in Appendix 1. This incident has resulted in a number of children requiring additional intervention and some delays in chemotherapy treatment, however, there has been no associated mortality. There have been no associated cases since the temporary closure of wards 2A/B and the decant of the patients to ward 6A QEUH on 26th September 2018.

The clinical component of this incident is considered as occurring within two phases:

- Phase one relates to the water contamination and the clinical cases associated at that time relating to the water system. Following installation of point of use filters, the water system was acknowledged as being of suitable quality for use by patients and staff. Whilst work was ongoing to investigate and manage the water contamination incident the clinical component of this phase was considered over with a debrief held on 15th May 2018

- Phase two relates to the environmental contamination and subsequent associated clinical cases occurring as a result of the contaminated drains and the impact caused by the fitting of point of use filters. Phase two is currently ongoing and will remain open until wards 2A/B have re-opened

Summary of initial findings

Following identification of the potentially contaminated water system in wards 2A/B and the resultant possible linked cases in March 2018, NHSGGC considered the decant of these 2 wards to allow for a full investigation of the source of water contamination in wards 2A/B and consider remedial action. At that time ward 4B QEUH was being prepared for the transfer of adult BMT patients from the Beatson oncology unit. Water sampling was undertaken in this ward prior to decant as a precautionary measure. Results identified the presence of *Cupriavidus pauculus* (and other gram negative bacilli) in water outlets within this ward and was the initial suggestion that there may be widespread contamination of the water system that serves both QEUH and RHC. Further testing across the site provided confirmation of this, with positive samples being identified in a number of areas across both sites at both outlet level and within the water system in the basement level (risers). Within the same timeframe staff within wards 2A/B also reported they had witnessed “black effluent” around the rim of the drain in some wash hand basins. Following visual inspection and laboratory testing, this was considered to be biofilm and sampling identified significant contamination of the drains with microorganisms and fungi. Drain contamination is not unexpected however the level of biofilm evident was not in keeping with a water system of less than four years old.

In an attempt to establish the extent of the water system contamination and any causative factor NHSGGC, supported by HFS and HPS initiated a detailed investigation into the contaminated water system within QEUH/RHC. Support was also requested from a number of external companies experienced in water incident management: These included Leegionella, Public Health England (PHE), water solutions group and Makin & Makin. The detailed investigations led by NHSGGC and supported by HFS/HPS included reviewing commission, installation and maintenance records provided by the contractor. This proved to be challenging due to the archiving of data and there were very few members of the initial project team available who are technically qualified to retrieve data and provide verbal clarification. The detailed findings from these records are included within the technical review.

Results from ongoing water testing were reviewed on a weekly basis and highlighted there was evidence of regressional seeding of contamination which supported NHSGGCs view that a whole system remedial approach was required.

Commissioning and design of the hospital water system

As part of the normal water system commissioning water samples were obtained. Initial preliminary findings have identified that prior to handover from the contractor there were a number of water samples taken that produced results with high level of total viable counts (TVCs). TVCs are indicators that there are hygiene issues within the water system and are quantified as a generic indicator for microbial contamination. Specific microorganisms which can be tested for include: Coliforms, *Escherichia coli (*including O157), *Pseudomonas aeruginosa, Salmonella spp*, *Campylobacter spp* and Environmental Mycobacteria. Testing for these is not conducted as standard within current guidance and typically occurs in response to a suspected or confirmed outbreak, or due to identification of a series of sequential cases.

In response to the high levels of TVCs found as part of the pre handover commissioning sanitisation of the water supply was undertaken by the contractor, with some impact and a reduction in TVCs in most areas, however there are a number of reports which indicate that

there may still have been a number of areas with higher than normally acceptable levels of TVCs.

Design and installation of taps and clinical wash hand basins

The design and construct of wash hand basins, showers and taps in these hospitals were agreed with NHSGGC in line with the Scottish Health Technical Memorandum (SHTM) in place at the point the hospitals were designed (commencing 2009), this included the installation of taps with flow regulators. HFS and HPS were involved in this decision making process as were NHSGGC Infection Control team. The SHTM (SHTM 04-01)[2] was revised in 2015 and no longer supports the use of flow regulators in clinical wash hand basins.

Biofilm formation in flow regulators has been identified in a previously published outbreak.[3] The manufacturers of the taps/flow regulators in place across the QEUH/RHC recommend regular removal of the flow regulators for cleaning/decontamination however do not offer more specific guidance on frequency of decontamination of the flow regulators. The flow regulators in use have a number of components and potentially create ideal conditions for the development of biofilm.

NHSGGC provided an external company (Intertek) with some flow regulators to carry out microbiological testing. This confirmed that flow regulators have the ability to harbour a significant number of micro-organisms with the presence of biofilm being detected on all flow regulators tested and 50% showing high levels of contamination. It is also worthy of note that biofilm was present on some flow regulators which was not immediately obvious on visual inspection.

The taps in place across all clinical wash hand basins in both hospitals are also reported to be non compatible with silver hydrogen peroxide, a product which was used during commission stage to sanitise the water system in view of the high TVC results. It is unclear whether this has caused any degradation of the taps. A tap was deconstructed by NHSGGC and examined for the presence of biofilm, in addition to microbiological sampling. Several components of the tap exhibited microbiological contamination.

The presence of high levels of gram negative bacteria and fungus in the water system may indicate that temperature control required has not always been achieved. Temperature control is included as part of the wider technical review being undertaken for NHSGGC by HFS.

Other aspects discussed in the detailed technical review include:

- Flushing
- Contract/project team
- Roles/responsibilities
- Design and construction
- Guidance and specifications
- Specification of water system
- Flexible hoses
- System description

- Pipe work
- Post handover and maintenance

There are a number of local and national recommendations within this review for both NHSGGC and Nationally. The key NHSGGC and National recommendations from the technical review are included within the recommendation section of this report.

Infection Control at design commissioning and handover

HAI-SCRIBE

Healthcare Associated Infection System for Controlling Risk in the Built Environment (HAI-SCRIBE) [4], reference has been designed as an effective tool for the identification and assessment of potential hazards in the built environment and the management of these risks. HAI-SCRIBE (2007) was in place during the construction and handover of both buildings.

Implementation of HAI-SCRIBE should be the responsibility of a multidisciplinary team of specialists with appropriate skills.

Compliance with HAI-SCRIBE requires an accurate record of the process of hazard assessment and risk management which is essential ‘due diligence’ information.

Evidence has been reviewed in relation to the infection control sign-off of results and the system at commissioning/handover. Whilst there is evidence of involvement with initial results and sanitisation there is no evidence of ongoing input or sign off from the Infection Prevention and Control Team (IPCT). It is noted that there is lack of clarity in current national guidance relating to roles and responsibilities of the IPCT in the commissioning, design and handover of new or refurbished builds. Water was first placed on the Infection prevention and control (IPCT) risk register in 2018. The IPC risk register is reviewed on an annual basis with risks considered and prioritised using a risk scoring system. Water safety was added to the risk register in 2018 in response to the emerging evidence of potential issues associated with this incident. Prior to 2018 water safety did not feature in the IPC risk priorities when scored.

NHSGGC employed a robust approach to the design stage of the hospital project by means of a dedicated Infection Prevention and Control Nurse (IPCN) seconded as part of the project team to support the IPCT aspect of the design stage, commissioning and handover stage.

Whilst there was dedicated resource allocated to the project team, there is no documented evidence of NHSGGC Infection Prevention and Control Team involvement in the commissioning or handover process of the project. However NHSGGC has provided a statement from the Lead Infection Control doctor at the time to confirm that they were involved in reviewing some aspects of the initial water testing methodology and the results for QEUH and RHC during commissioning and handover. The Lead ICD has confirmed being involved in:

- Quality assurance of the water testing methodology used by the commissioning engineers.
- Liaising with Facilities Colleagues in reviewing the water testing results supplied by the commissioning engineers.

- Recommending further actions (dosing), for a small number of outlets with TVCs above the acceptable limits.

In addition to a nurse consultant being seconded as a dedicated resource to the project team with involvement in design, commissioning and handover, the project team were supported by the IPCT. This support included regular review of the new builds hospital project at the infection control committee and senior IPC meetings. NHSGGC reported that both the infection control manager and associate director of nursing (infection control) liaised regularly with the project associate nurse director and ensured the numerous commissioning groups established were supported by a member of the IPCT. In addition all wards were reviewed by a member of the IPCT prior to occupation by patients.

Current management of situation/Control measures

In addition to holding regular incident management IMT meetings (IMT) NHSGGC established a multi disciplinary water technical group which is a sub group of the incident management team. This group is supported by HFS, HPS, with monthly representation from water solutions group and Makin & Makin.

A number of control measures have been instigated during this incident and in particular in wards 2A/B. These included parent and staff education sessions, daily visits to the ward from members of the infection prevention and control team (IPCT), increased domestic hours, environmental monitoring by means of audit, including Standard infection control precautions (SICPs) audits.

Limiting access to water

In the initial investigation the use of water within wards 2A/B was limited with portable wash hand basins being supplied for hand washing. Patients were requested not to use wash hand basins or showers and wipes were provide as an alternative. Drinking water was provided by means of bottled water. Access to water was re-established once point of use filters were in place in showers and wash hand basins/sinks. BMT patients continue to receive sterile water.

Point of Use filters.

Following the identification that the water contamination was widespread across both RHC and QEUH an additional control measure of point of use (POU) filters for high risk areas was implemented to ensure a safe water supply at the point of use. In addition if a high risk patient was being nursed in an area deemed to be of low risk, a point of use filter was fitted to water outlets in their room. POU filters require to be changed every 30 days and are a costly approach, however in the interim until the water contamination can be addressed, is considered the only feasible approach to ensure safe delivery of water. A number of studies found that installation of point of use filters reduced either infection rates in associated healthcare settings[5;6] or pathogen counts within tested water samples.[7]

Once the POU filters were in place the restrictions on access to water within wards 2A/B was removed and patients were able to access washhand basins and showers. It was noted that following the fitting of the POU filters there was a greater splash evident from the wash hand basins as the point of entry of the water from the outlet was closer the basin. This splash was noted more from clinical wash hand basins than ensuite wash hand basins and trough sinks.

Drain Sanitisation

Following the identification of the second phase of cases associated with this incident and the hypothesis that the cases may be related to drain contamination, the drains were inspected by the IPCT. Once the drains were identified as being visibly contaminated with what was thought to be biofilm, a programme of drain sanitisation was undertaken across high risk areas commencing with wards 2A/B.

Environmental decontamination

Prior to and following completion of the first drain decontamination process in wards 2A/B, a terminal clean of all areas using hydrogen peroxide vapour was carried out.

Water treatment

It is well recognised that drinking water distribution systems contain a diverse range of microorganisms.[8-10] The presence of microorganisms is affected by various factors including; the disinfection processes employed, the location and age of the system as well as pipe material.[11]

There were a number of options explored for longer term water treatment by NHSGGC. These options included:

Chlorine dioxide

A number of studies were identified which utilised chlorine dioxide systems within hospital settings, and use of these was found to reduce bacterial numbers.[10,12,13] Various advantages and limitations associated with use of chlorine dioxide are known, with the most relevant summarised below.[14,15]

Advantages**:** Known to be effective against a wide range of bacteria, viruses and some protozoa including Giardia.

Limitations: Production of disinfection by-products (DBP's). Although potential production of DBP's always needs to be considered, the efficacy of water disinfection should not be compromised in trying to eliminate these.[16]

UV light

A number of drinking-water treatment technologies are available which employ UV light radiation to inactivate microorganisms.[15] As with chlorine dioxide, various advantages and limitations associated with use UV are known, with the most relevant summarised below.[14-16]

Advantages: Bacteria, fungi and protozoa (considered to be more effective at killing Cryptosporidium than chlorine dioxide) are readily inactivated at low UV doses, with higher doses required for virus inactivation. In addition, UV disinfection does not result in the formation of DBP's like chlorine dioxide.

Limitations: UV disinfection does not leave any residual compound in treated water and therefore does not offer protection against possible microbial re-growth in distribution pipe-work.

Thermal disinfection

Very limited information was identified in the published literature in relation to advantages and limitations of thermal disinfection. One study found that heat shock treatment at 80˚C reduced Gram negative bacteria in a hospital water system but did not lead to complete eradication.[17] Copper silver ionisation was also considered however this was discounted due to pH levels.

Preferred solution

The NHSGGC preferred method of choice for water treatment was continual dosing chlorine dioxide. This was supported by HFS and HPS. Shock dosing of the system was considered and it was agreed that due to safety issues and the potential impact on both hospitals ability to function during the process, this was not the most appropriate approach. It was also recognised that in the absence of initial shock dosing it may take up to two years for the process to be effective from tank to tap level. The procurement process is well underway and installation expected to commence November 2018.

Temporary closure of wards 2A/B

A recommendation was made by the IMT to pursue the temporary decant of wards 2A/B to allow investigative and remedial work to be undertaken. A number of options were explored resulting in the transfer of patients from wards 2A/B to ward 6A of the QEUH. Adult patients within ward 6A QEUH were transferred to Gartnavel General. Three rooms within the adult BMT (4B) were identified and allocated to the paediatric BMT unit. The patients were transferred on 26th September 2018. It is anticipated that the decant facility will remain in place until mid/late December.

Remedial work/Investigations wards 2A/B

The planned investigations/remedial works planned during the decant period include:

- Drain Survey
- Ventilation review
- Replacement of clinical wash hand basins
- Replacement of taps (with no flow regulator)
- Review of any little used water outlets with a view to remove
- Replacement of sections of pipework where biofilm noted
- Review of toilet cisterns and adaptation to reduce potential toilet plume effect.

Hypothesis

There are a number of workable hypotheses being explored; it is currently considered the most likely cause of the widespread contamination is a combination of hypothesis B and C

A: Ingress contamination

A small low level number of micro-organisms may have been present in the water supply at the point of entry. Lack of temperature or chemical control may have enabled biofilm formation. Due to the increasing biofilm throughout the system this may have allowed any subsequent micro-organisms present at point of entry an opportunity to flourish and cause widespread

contamination of the system.

B: Regressional contamination

This may have occurred due to contamination occurring at the taps/outlets or flow straighteners and contamination has regressed backwards throughout the system causing widespread contamination. The widespread positive results and array of bacteria point to contaminated outlets at installation or contamination of high risk components in the tap from ingress as opposed to the patient contact route.

C: Contamination at installation/commissioning

Contamination may have occurred due to presence of contaminated pipework or outlets. Prior to handover the system required to be sanitised due to high TVC counts. It is unclear if a robust flushing regime was in place from installation to handover and from handover to occupancy to prevent contamination.

Secondary Hypothesis

It is recognised that in many situations control measures or actions taken in an attempt to minimise the risk of HAI there can be unintended consequences. In this scenario the secondary hypothesis is linked to the unintended consequence of the point of use filter use:

POU filters.

In an attempt to provide water of a safe microbiological quality NHSGGC applied point of use filters to all clinical and patient wash hand basins in high risk areas and areas where high risk patients were being treated. These filters meant the exit point of the water from the taps was closer to the washhand basin and as a result caused more splash which may also lead to disruption of any drain biofilm as well as potential environmental contamination. (Pictures 1, 2). At the time of fitting the filters, the issue of biofilm within the drains and the associated risk or the resultant splashing that was being caused had not been identified and therefore the subsequent increased risk of environmental contamination and potential exposure of the children was not recognised.

Picture 1

Picture 2

Additional potential considerations to minimise impact

Ensuite single side rooms/hand hygiene practice

Since 2008 it is recommended that all new build hospitals have 100% en suite single side rooms.[18] As a result this has substantially increased the number of wash hand basins and therefore the frequency with which a wash hand basin is used and the water volume in each basin reduced when compared to multi occupancy wards with a single wash hand basin. Since the introduction and widespread use of alcohol gel, the need for hand washing as a first approach has greatly decreased, as alcohol gel may be used on hands that are not visibly soiled. This requires further exploration and consideration and review of flushing regimes and number of wash hand basins required.

Disposal to drain

A number of drain samples were sent to Intertek for analysis. A report has highlighted that in addition to the general presence of biofilm, there was biofilm noted around the aluminium spigots. There was also some occlusion reported as a result of adhesive and pooling noted between the back of the sink and the pipework. All aluminium spigots in wash hand basins in wards 2A/B were replaced with PVC spigots. In addition a number of foreign objects were identified within the drains. It was also reported that there was evidence of a yellow fluid present suggestive of urine being disposed to the drain. The biofilm has a mustard yellow colour and an odour of ammonia was detected. There was a small amount of yellow liquid in the base of the bowl trap which when removed and looked at in isolation also had an ammonia smell. Parents, families and clinicians are advised that hand wash basins are for hand washing only and additional activities such as fluids being disposed of to drain via a handwash basin should not occur. Staff are aware that this is not acceptable practice however the positioning of a wash hand basin in every ensuite single side room may encourage patients or visitors to expel fluids such as contents of a drink bottle. Items such as coffee, sweet drinks encourage the growth of

bio film and microorganisms within a drain. The large open horizontal drain may also encourage the accidental disposal of foreign items.

Summary

There have been no new reported cases since the decant of patients to ward 6A on 26th September 2018. The IMT will continue to meet regularly until the patients have been transferred back to wards 2A/B. The water subgroup will continue to meet until early/mid 2019 and will be supported by HFS/HPS. It has been evident to HPS that since the identification of this widespread incident and clinical impact on wards 2A/B, patient safety has been paramount with NHSGGC clinicians, facilities, IPCT and management team. A significant financial investment has been made to minimise ongoing risks including widespread use of point of use filters in addition to remedial work planned. A number of lessons can be taken from this incident for NHSGGC and NHSScotland as a whole in relation to water safety and commission, handover and maintenance of buildings. The national work and learning for NHSScotland will be driven via the HAI built environment steering group which is widely represented and chaired by the associate director of facilities (NHSGGC) and deputy chair is the lead ICD (NHSGGC).

Recommendations

A number of local and national recommendations have been made based on the investigation to date. This includes recommendations for NHSGGC which have been identified from a detailed HFS technical review. NHSGGC/HPS/HFS will produce an action plan based on the recommendations as follows:

1. NHSGGC

- To produce a detailed action plan addressing ALL points identified within the HFS technical review and should cover as a minimum:
  - Decontamination
  - The management of the water systems
  - All required rectification work
  - Management of recording systems
  - Routine and reactive maintenance schedules

2. All NHS Boards

- All NHS boards should ensure facilities teams are adequately resourced to ensure maintenance of all aspects of the water system are maintained in accordance with policies and guidance.
- All maintenance undertaken should be recorded and maintenance records should be reviewed regularly to ensure all aspects of the water system are maintained in accordance with policies and guidance

3. HPS/HFS

HPS (supported by HFS) to undertake an urgent national water review of all healthcare premises built since 2013 to provide assurance that a similar incident has not and is not likely to occur elsewhere.

HPS (supported by HFS) to establish a national expert group to:

- Review NHSScotland current approach to water safety including as a minimum:
  - Review NHSScotland current approach to water testing in healthcare settings.
  - Review NHSScotland current surveillance and reporting of potentially linked water related HAI cases.
  - Based on findings develop risk based guidance on water testing protocols, results interpretation roles and responsibilities and remedial steps to be considered.
- Give consideration to the development of a best practice built environment manual which will be evidence based and cover as a minimum current and emerging evidence

and the technical requirements from a clinical, patient safety and HAI perspective that will be adopted by all NHS boards. This will include as a minimum:

- Review existing national and international guidance relating to water safety.
- Develop robust requirements/guidance for all aspects of water safety.
- Develop robust handover requirements in relation to water systems.
- Review of the role of the IPCT into the built environment, and produce clear guidance on roles and responsibilities.
- Establish a risk based approach to water testing and any remedial action required, including roles and responsibilities that NHS boards will adopt.
- Review the requirement for 100% ensuite single side rooms the number of clinical wash hand basins per patient/bed.
- Review the use of flow regulators across NHS Scotland and identify and associated risks and recommend any remedial actions required.

- HPS/HFS will continue to provide support to NHSGGC relating to the current water incident and provide input into the weekly meetings until mid 2019 (and reviewed thereafter).
- Further develop the existing Scottish expertise in the built environment programme (mainly water and ventilation) at national level.

HFS (supported by HPS) to:

- Review all relevant water technical guidance to ensure all aspects are covered within the guidance including as a minimum:
  - Thermal disinfection in sections of water distribution systems
  - Handover checklists
  - Contract management procedures
  - Design guides to eliminate thermal pickup in cold water systems
  - Update advantages and disadvantages of chemical disinfection techniques
  - The organisms Boards should test for and action to take on defined levels
  - Drain cleaning regimes
  - Biofilm growth in drainage systems

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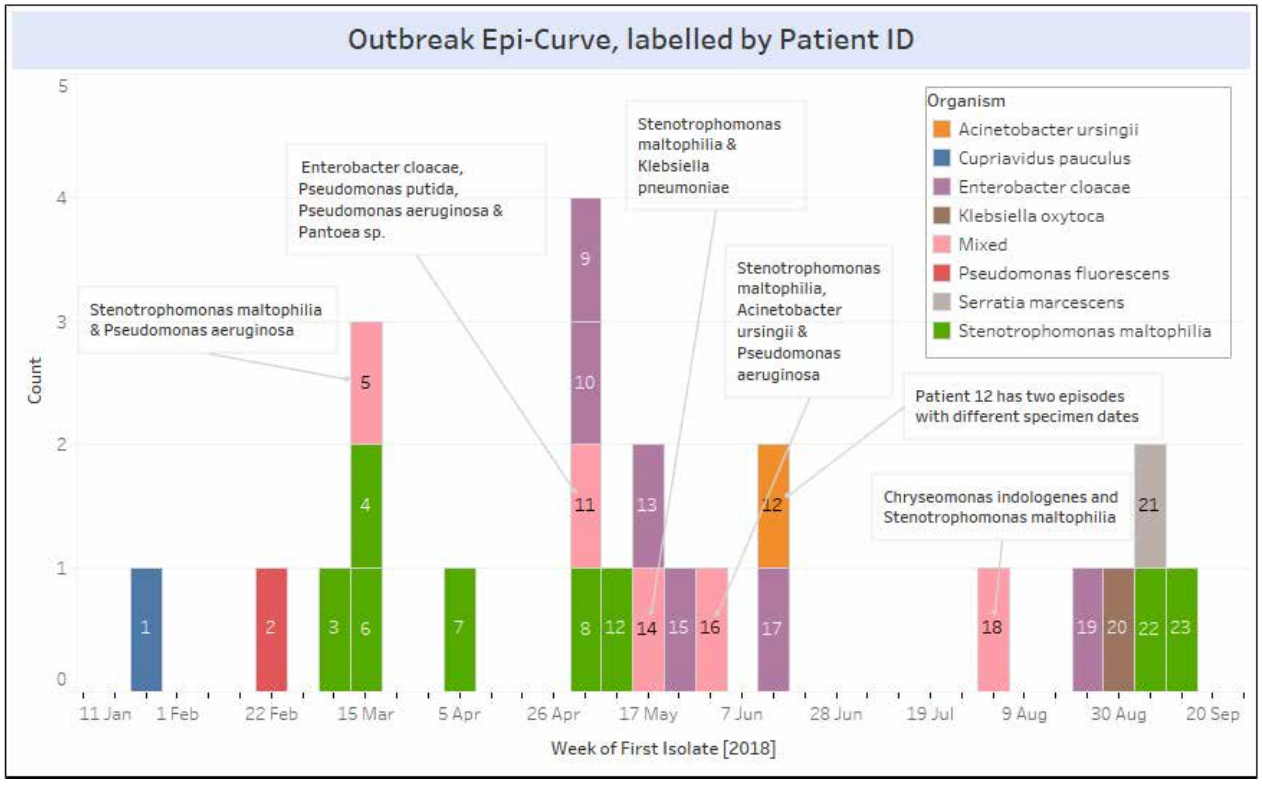
Appendix : 1 Timeline of cases

The epi-curve demonstrates that only one case of *Cupriavidus pauculus* was reported from 26th January 2018, with the other associated cases being *Stenotrophomonas maltophilia* and/or *Pseudomonas aeruginosa* positive between 21st February 2018 and 5th April 2018.



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Glossary

Alcohol gel	A gel, foam or liquid containing one or more types of alcohol that is rubbed into the hands to inactivate microorganisms and/or temporarily suppress their growth.
Aseptic Suite	An ultra clean environment within a department, (for example pharmacy) where sterile solutions are prepared such as chemotherapy under strict measures.
Bacteria	Microscopic organisms (germs).
Bib taps	A tap or stop cock which has a nozzle bent downwards.
Biofilm	Collective of one or more types of microorganisms, including bacteria, fungi and protists, that stick together and can become embedded on a surface.
Blood stream infection	The presence of bacteria in the bloodstream.
Chemotherapy	A cancer treatment where medication is used to kill cancer cells.
Chlorine dioxide	A chemical compound used for a variety of antimicrobial uses, including the disinfection of drinking water.
Clinical wash hand basins	A sink designated for hand washing in clinical areas
Cluster	A group of similar things located around the same location
Copper silver ionisation	A disinfection process where positively charged copper and silver ions are added into the water system. It is primarily used to control control Legionella, the bacteria responsible for Legionnaires' disease.
Decant	Temporarily transferring people to another location.
Decontamination	Removing, or killing pathogens on an item or surface to make it safe for handling, re-use or disposal, by cleaning, disinfection and/or sterilisation.
Drain	A fixture that provides an exit-point for waste water or water that is to be re-circulated.
Ensuite single side room	A room with space for one patient and containing a bed; locker/wardrobe, clinical wash-hand basin, en-suite shower, WC and wash-hand basin.
Flexible hoses	A flexible hollow tube designed to carry fluids from one location to another and are used to connect taps to the water supply
Flow regulators	Point of use regulators designed to provide constant and maximum flow rates at taps and showers etc. irrespective of changes in demand or water pressure

Flushing	The process of cleaning or “scouring” the interior of water distribution mains (pipes) by sending a rapid flow of water through the mains.
Gram negative bacilli	Gram-negative bacteria are bacteria that do not retain the crystal violet stain used in the gram-staining method of bacterial differentiation; examples include E.coli, and Pseudomonas aeruginosa.
Hydrogen Peroxide Vapour	Vaporized hydrogen peroxide is an airborne disinfectant and infection control measure that can be used for room decontamination after patient use.
Ingress	The act of entering.
Microbiological sampling	Sampling for harmful bacteria, parasites, fungi and viruses including those in water, environment and equipment.
Micro-organism	Any living thing (organism) that is too small to be seen by the naked eye. Bacteria, viruses and some parasites are microorganisms.
Organism:	Any living thing that can grow and reproduce, such as a plant, animal, fungus or bacterium.
Parenteral nutrition:	The giving of special liquid feeding products to a person using an intravenous catheter and bypassing the normal digestion process of the stomach and bowel.
Pathogen:	Any disease-producing infectious agent
Point of use filters:	A device that incorporates an integral filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow therefore protecting the end user from exposure to harmful waterborne pathogens.
Portable wash hand basins	A sink that is not connected to the mains water supply but connects to a water tank which is filled locally.
Regressional seeding	Where micro-organisms from contaminated water outlets/biofilm regress ‘back’ through the water system and seed other areas (pipes/tanks/outlets). The microorganisms embed themselves and multiply contaminating other areas of the system.
Sanitisation	Use of antimicrobial agent on objects, surfaces or living tissue to reduce the number of disease-causing organisms to non-threatening levels.
Shock dosing	The use of large quantities of chemicals to the water supply to break down organic waste and get rid of bacteria and contamination.
Silver hydrogen peroxide	A solution of stabilised silver in hydrogen peroxide that is used for surface and water decontamination.

Sterile water	Water free of all microorganisms – bacteria, viruses, fungi.
Terminal clean	Cleaning/decontamination of the environment following transfer/discharge of a patient, or when they are no longer considered infectious, to ensure the environment is safe for the next patient or for the same patient on return.
Thermal disinfection	The use of water and heat for the disinfection process for example washer-disinfectors.
Toilet plume effect	The dispersal of microscopic particles as a result of flushing a toilet.
Total viable counts	A quantitative estimate of the concentration of microorganisms such as bacteria, yeast or mould spores in a sample.
Trough sinks	A long, narrow basin designed for communal handwashing with water delivered at hand-washing temperature via mixer taps in conjunction with a thermostatic mixing valve. Usually used for surgical scrubbing.
UV light	A disinfection method that uses short-wavelength ultraviolet (UV-C) light to kill or inactivate microorganisms.
Water outlets	Any hole or opening where water is released for example taps, showerheads.
Water sampling	The analysing of the water supply for harmful bacteria, parasites, and viruses.
Water system	A system of engineered hydrolic and hydraulic components to supply water.
Spigots	A short cylindrical pipe which connects the Clinical Wash Hand basin to the main pipework.
Occlusion	Obstruction or blockage

NHS Greater Glasgow and Clyde

New South Glasgow Hospitals (NSGH) Project

INVITATION TO PARTICIPATE IN COMPETITIVE DIALOGUE

VOLUME 2/1

EMPLOYER'S REQUIREMENTS (Hospitals)

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Section 1.0 Development Context

1.1 Introduction

The provision of new facilities at the Southern General Hospital site in Glasgow represents the second phase of the Acute Services Strategy of the Board.

As illustrated in Appendix A, the Hospital Campus extends to some 28.6 hectares and is located within the Govan area, lying to the south-west of Glasgow City Centre adjacent to the residential neighbourhood of Drumoyne and the industrial areas of Shieldhall and King George V Dock. The site is located 500 metres south of the River Clyde. The sites northern boundary is defined by Renfrew Road/Govan Road with the eastern boundary defined by Moss Road/A739 (Clyde Tunnel approach road). Langlands Drive and residential developments delineate the southern boundary and Hardgate Road runs north-westwards to identify the western boundary of the Hospital Campus.

The Site extends to some 8.6 hectares and is located in the west-central area of the Hospital Campus (see Appendix A). The Site is bounded by operational healthcare buildings to three sides, with boundaries to neighbouring industrial areas to the north/north-west. The existing buildings within the Site (excluding the Surgical Block) are to be demolished by the Board in advance of the scheme, as described in Section 2.3 below.

The scheme includes the provision of 1,109 adult and 240 children's beds. The bed numbers are illustrated in *Table 1 – Proposed Bed Numbers – Adult and Children's Hospitals.* Key elements of the project include:

a. Development of an integrated adult acute and children's hospital proving the full range of acute health services;

b. Development of a new Laboratory facility including Mortuary and Post-Mortem Services, Biochemistry, Microbiology, Haematology and Medical Genetics;

c. Provision of a rooftop helipad; and

d. The supply and installation of Group 1 equipment, location and/or fitting of Group 2 equipment supplied by the Board and provision of structural, space and services requirements to support Group 3 and 4 equipment.

It should be noted that Information Management and Technology (IM&T) is outwith the project, the Board is procuring software and end-use hardware as part of a separate IM&T project. The Contractor shall, however, provide the required space within the building and the requisite hard infrastructure and containment, in accordance with Section 8.0 and Appendix M, to support the Board IM&T requirements

Adult Hospital		**Children's Hospital**	
Specialty	**Beds**	**Specialty**	**Beds**
General Medicine (incl MHDU + AAU)	405	Inpatient (incl critical care areas) (*12 beds in maternity facility)	193*
CCU	20	Short-stay (observation ward)	20
Stroke	26	Day Care/Day Surgery	27
Haematology	14	**Total Inpatient Beds**	**240**
Dermatology	18		
Nephrology	80		
Geriatric Medicine	93		
Surgery & Vascular (incl AAU)	164		
Urology	39		
Orthopaedics/rehab	139		
ENT	31		
ITU	20		
SHDU	23		
Clyde/Contingency	37		
Total Inpatient Beds	**1,109**		

Table 1 – Proposed Bed Numbers – Adult and Children's Hospitals

1.2 **Accommodation Overview**

1.2.1 **New Adult Hospital**

This will provide A&E services and acute specialist in-patient care as well as medical day services and out-patient clinics serving the local population.

Key components of the facility will include:

a. In Patient Accommodation
Surgical beds (general surgery, orthopaedics, urology, vascular, ENT and renal); Medical beds; Acute Assessment Unit – 118 beds, ICU/HDU/CCU – 79 beds, Acute Stroke – 26 Beds and Care of the Elderly 93 beds;

b. Out Patient Accommodation
Full range of general outpatient clinics including, among others, diabetic unit, respiratory, orthopaedics and urology;

c. Day Services
22 medical day bed area; 30 station dialysis unit;

d. Treatment & Diagnostic Services
Emergency Department, 20 operating theatres, imaging, and endoscopy;

e. Clinical Support Services
Pharmacy dispensary, medical physics, medical illustration. Laboratory services linked to the hospital by underground route and pneumatic tube system, aseptic unit within the children's hospital. The pneumatic system to extend across the abutment with maternity and the link to neurosciences to provide for expansion of the system to these areas; and

f. Non Clinical Support Services
Main entrance, medical records, administration, chaplaincy, social work, staff changing, switchboard, estates, facilities, security, catering, portering, domestic, management and energy centre.

1.2.2 **New Children's Hospital**

This will provide A&E services and a comprehensive range of inpatient and day case specialist medical and surgical paediatric services on a local, regional and national basis. The new development will also have outpatient facilities. The care strategy is that all of Glasgow's Children's Services (up to the age of 16 and up to 18 years where appropriate) will be provided at the New Children's Hospital. Of the 240 beds planned, around 20% of the beds will be for day patients and the balance for in-patient requirements.

Key components of the facility will include:

a. Outpatient Accommodation
Full range of Children's outpatient clinics including audiology, general paediatrics, orthopaedics, ENT etc;

b. Day Services
Circa 10 medical day beds; 4 dialysis stations and circa 25 day surgery beds;

c. Treatment & Diagnostic
Accident and Emergency, minor injuries, Imaging, 9 theatres, rehabilitation;

d. Clinical Support Services
Aseptic unit, pharmacy, medical physics, medical illustration (laboratory services linked to hospital by underground route and pneumatic tube system – tube system to be extended across abutment with maternity/neo-natal to provide for potential expansion of the system); and

e. Non Clinical Support Services
Facilities, ancillary services, administration, spiritual services, medical records, staff change, staff dining.

1.2.3 **Laboratory Facilities**

The new facilities will be one of two major Laboratory sites in Glasgow (the other at Gartnavel General). The services planned to be delivered from the new Laboratory build at the New South Glasgow Hospitals include Biochemistry, Microbiology, Haematology, Medical Genetics, Mortuary and Post Mortem. The mortuary and post mortem facilities include the re-provision of the Glasgow City mortuary which also provides forensic services for the City of Glasgow. The Employer's Requirements in relation to the laboratory facilities form Volume 2/2 of the ITPD and laboratories (buildability and interfaces) shall form a workstream of competitive dialogue between the Board and bidders.

1.2.4 **Facilities Management Building and Energy Centre**

These key support accommodation areas shall be developed in line with the operational needs of the Board and the energy strategy adopted for the project. The Facilities Management accommodation is located in the Laboratory building and the requirements in this regard are included in Volume 2/2 of this ITPD.

1.2.5 **Retained Services**

The Southern General Hospital site will retain approximately 630 beds within the institute of neurological sciences, Maternity, Spinal Injuries and Langlands buildings. The Langlands facility provides older people's services, dermatology and services for the young physically disabled.

1.3 **Elements of Procurement**

1.3.1 As detailed in Volume 1 of the ITPD, the procurement is following a competitive dialogue route. The areas for inclusion in the competitive dialogue have been established, with the following topics identified:

a. Design;

b. Logistics;

c. Laboratories (incl FM accommodation); and

d. Commercial.

Volume 1 of the ITPD provides further detail on the scope, extent and requirements of the competitive dialogue, including identification of the issues and aspects of each topic that shall be considered.

1.3.2 As detailed in Volume 1 of the ITPD, the Works are comprised of several Stages, namely:

a. Stage 1 – Laboratory Design & Construction;

b. Stage 2 – Hospitals Detail Design to FBC;

c. Stage 3 – Construction of Hospitals; and

d. Stage 3A – Landscaping Completion (including demolition).

Section 2.0 Responsibilities of the Parties

2.1 Introduction

The Board wish to procure Works which shall enable it to carry out its clinical functions, to combat health acquired infection and to maintain physical assets and clinical and non-clinical functionality with ease; and it shall be the responsibility of the Contractor to deliver a design and construction solution that optimises these requirements. The Board wish to provide its clinical functions in a high quality care environment which is accessible to the community, welcoming, safe and aesthetically pleasing. Innovative design and construction proposals, which as a minimum meet the requirements of the Works Information, Site Information and Employer's Requirements are sought from the Contractor.

2.2 Responsibilities of the Contractor

The Contractor shall be responsible for the following:

2.2.1 Providing Works that are fit for purpose;

2.2.2 Meeting all of the requirements of the Board stated in the Works Information, Site Information and Employer's Requirements as a minimum requirement;

2.2.3 The tasks, risks and aspects of the project identified as owned by the Contractor in the Risk Register;

2.2.4 Assisting the Board with the management of the risks identified as owned by the Board in the Risk Register;

2.2.5 Working with the Board and it's advisers in fulfilling all of the requirements and good practice inherent in the NEC3 contract;

2.2.6 Compliance with the requirements of the Construction (Design & Management) Regulations;

2.2.7 Providing a design that meets the relationships identified in the Adjacency Matrix;

2.2.8 Diverting the culverts that cross the Site and the other remaining services;

2.2.9 Obtaining all Consents required for the construction of the Works, including but not limited to the under noted. With regard to the under noted the Contractor shall provide to the Board copies of the following documents within 10 working days of all purification and discharge notices from date of issue by the appropriate authority:

2.2.9.1 Planning Approvals;

2.2.9.2 Building Warrant (incl Stage applications if applicable);

2.2.9.3 Building Warrant – Certificates for full occupancy;

2.2.9.4 Pre-construction Information and Construction Phase Health &Safety Plan;

2.2.9.5 Health and Safety File;

2.2.9.6 Utilities Suppliers Consents;

2.2.9.7 Other Local Authority Consents, including Building Control, Roads Construction Consent, Fire Strategy etc;

2.2.9.8 Certification for PMG installation;

2.2.9.9 Relevant Civil Aviation Authority and Strathclyde Fire and Rescue documentation in relation to the provision by the Contractor of a rooftop helipad;

2.2.10 Procuring that the Works are at all times performed:

a. In compliance with all Law and Consents;

b. In a manner that is not likely to be injurious to health or to cause damage to property;

c. Without injury, nuisance, interruption to, or other detriment of the existing clinical and support services current on the site;

d. In a manner consistent with the Quality Plans;

e. Except to the extent expressly stated to the contrary in the Works Information, Site Information or Employer's Requirements in compliance with all NHS Mandatory Documentation, NHS Guidance Documentation and Additional Guidance contained in Section 5.1;

f. In a manner consistent with the Board discharging its statutory duties and other functions undertaken by it as the same may be notified to the Contractor from time to time;

g. In accordance with all British and European Standards; and

h. In accordance with Good Industry Practice.

2.3 **Responsibilities of the Board**

The Board is responsible for the following:

2.3.1 The provision of the area of the Site agreed between the Board and the Contractor clear of buildings and known utilities unless otherwise illustrated. This to include the grubbing out and removal of foundations and underbuildings. Remaining utilities to be addressed by the Contractor are identified on the drawing illustrating same in Appendix M; and

2.3.2 The provision of access (agreed by the Board in writing in advance) to areas of the Hospital Campus to allow the Contractor to make utility connections, corridor/building linkages and other relevant activities identified to carry out the Works.

Section 3.0 The Site

3.1 The Site

The Site is located at 1345 Govan Road within the Hospital Campus. The boundary of the Site is identified in Appendix A.

Site Investigation (SI) work has been undertaken by the Board. The relevant SI information and associated interpretative reporting is located in Appendix N.

3.2 Travel Plan

The draft Travel Plan developed by the Board is located in Appendix W.

3.3 Planning

Outline planning permission has been secured by the Board (a copy of the communication issued by GCC in relation to the permission is attached at Appendix D.1). The outline permission has forty-three conditions attached and was conditional to the Section 75 Agreement being concluded in respect of transportation issues.

The Section 75 Heads of Terms (HoTs) are agreed between the Board and the Council, the HoTs for a proposed Fastlink service will be concluded by the Board as an aspect of the masterplanning prior to the conclusion of the competitive dialogue process.

The status of planning matters are identified in Appendix D.2, with details of the Masterplanning carried out by the Board in Section 7.0 of the ERs. As noted in Section 2.2, above, the Contractor is responsible for gaining and discharging Detailed Planning Approval.

3.4 Live Hospital Site

The Hospital Campus is a live hospital site, and as such will place restrictions on the Contractor in the construction of the Works. Essential 'blue light' and other access routes will require to be unobstructed by the Contractor 24hours per day, every day.

The 'blue light' and other access routes/site constraints are identified in Appendix A.

3.5 Other Projects On-Site

In addition to the ongoing access and operational requirements of the Board to deliver medical and related services, there shall be other construction projects and programmes ongoing on the Hospital Campus at varying times when the Contractor will be constructing the Works. This may include (but not be limited to) works to create a new-neo natal facility, multi-storey car parks and university facilities as well as a variety of site enabling, ongoing maintenance, utilities and demolitions works.

3.6 Site Logistics

Site Logistics shall form a Dialogue Issue during the Bid Period, this will include discussions in respect of both the live hospital site and other projects on-site, with relevant responsibilities, interface protocols, communications plans and emergency/contingent planning to be discussed and agreed with the Board.

Section 4.0 General Design Requirements

The following section provides an overview of the Board's key objectives for the Works. The Contractor's proposals should clearly demonstrate cognisance of these objectives in relation to the design and the construction process. In particular, the operational, functional and equipment issues contained in the Employer's Requirements must, as a minimum standard, be met by the design and construction solutions of the Contractor. Further to this, the Contractor shall ensure the design delivers a solution which indicates acknowledgement and understanding of the types of patients that are planned for the facility.

The Contractor must take cognisance of the following documentation in his design solutions and shall require to demonstrate in his bid return strategies to embrace the ethos of the documentation in the development of the design:

a. Scottish Government's Policy and Design Quality for NHSScotland;

b. The NHS Greater Glasgow and Clyde Design Action Plan;

c. Achieving Excellence in Design Toolkit (AEDET Evolution);

d. Scottish Planning Policy SPP6; and

e. Planning Advice Note 84.

Further, the Contractor shall design the Works to address the following issues:

4.1 Uses

4.1.1 Functional Requirements

The design of the Works shall:

a. Function efficiently, effectively and economically;

b. Optimise the Board's operating costs;

c. Demonstrate that the design fully reflects the special needs for each patient group in terms of access, functional relationships and planning. Patient groups are described and their particular requirements are defined in the Clinical Output Specifications in Appendix B and the mandatory and relevant guidance listed in Section 5.1. The facility as a whole should be fully accessible to the widest variety of patient groups, ambulatory, assisted and non ambulatory patients of all ages providing access to specialist services led by medical staff, allied health professionals and nursing staff;

d. Interface easily with other service providers in particular the wider services provided by the Board; and

e. The design shall be able to do this in terms of environment, scale, comfort, privacy, reassurance, style and security.

4.1.2 Human Dignity

To achieve appropriate levels of privacy, the Contractor shall provide Works which allow adequate space around patients. This may include space for relatives to sit with patients, adequate space between chairs, and seating in rest bays along corridors to provide rest places along the route of the patient / visitor journey. The privacy afforded to patients, staff and visitors shall not be compromised by inappropriate or inadequate sound reduction measures in the design or in the build standard.

Sill heights for windows shall enable outward visibility, in particular for children, patients in wheelchairs and in beds. Special consideration shall be given to the needs of the elderly and those with poor sight. Some doors and internal glazed screens shall require vision panels or other glazing systems, which may be obscured or controlled for privacy. The ability to use vision panels to view objects / small children on the other side is desirable.

4.1.3 Functional Relationships

The design shall offer all users of the Works the highest level of efficiency in their operations by way of relationships and adjacencies between functional units. Layouts shall reflect the workflow and logistics inherent in the Clinical Output Specifications in Appendix B; the parameters identified in the Adjacency Matrix; and the requirements of the housekeeping and domestic staff, catering, staff welfare and related management needs.

4.1.4 Work Flows & Logistics

Workflows within and between departments shall be direct and the routes for patients and staff as short as possible. Internal traffic cross-flows which could be inefficient or conducive to the transmission of micro-organisms either through airborne or other means shall be avoided.

The movement of people and the distribution of supplies and waste shall be carefully considered and the circulation routes shall be clear and appropriately sized, with the use of automated material transfer systems where relevant.

4.1.5 Adaptability & Expansion

The design shall consider the needs for departments to be adapted or expanded. This will require a range of approaches to be taken including the allocation of soft space adjacent to clinical spaces. The design shall demonstrate that potential change or expansion has been considered by the provision of adequate space either at the external perimeter and / or between functions and departments.

The structural grid, construction technique, structure, service penetration and engineering services strategy shall demonstrate that the design proposals for expansion, adaptation and flexibility are co-ordinated.

The provision of engineering, telecommunications infrastructure and building services shall be appropriate for the provision of anticipated changes in medical equipment.

4.2 **Spaces**

4.2.1 Space Standards

The Contractor shall provide designs which are efficient, economical and flexible for immediate and future use, and which can be managed efficiently to cope with seasonal and strategic variations in activity.

Appropriate space provision shall be given to circulation, waiting and sub-waiting space for the movement of patients, pedestrians and the storage and transportation of goods.

Space shall be considered to allow informal discussion, therapy and interaction within open and reception areas in the clinical environment, such as consultation and main waiting and reception areas. Consideration shall also be given to making use of open space areas within clinical areas and main circulation routes for 'break-away' space such as corridor recesses and courtyards.

The Contractor shall recognise that patients' and staff's perception of the spaces created may assist with their feeling of belonging and of not being intimidated, and may help with their orientation, mobility, confidence, privacy and their ability to socialise.

4.2.2 Floor Layouts

The design of departmental and unit layouts shall reflect the demand for space defined by occupancy and usage as described in the Clinical Output Specifications and reflected in the Exemplar Design/SoA. Where areas and shape of rooms results in undesirable spaces, the Contractor shall discuss with the Board alternative solutions, which may or may not result in shared space providing a more appropriate environment as well as optimising the available use of space. These may include locker rooms, sitting areas, seminar rooms etc.

4.2.3 Character & Innovation

4.2.4 Excellence for Patients

The design of buildings, external and internal appearance as well as the design of the external works, and landscape can have a positive or a negative effect upon patient care, staff experience at the work place and the way NHS healthcare buildings are perceived. The Contractor shall develop design solutions which by the use of materials, lighting, shape, scale, mass and form of the building elements make a positive contribution to engendering well-being of patients and staff.

4.2.5 Healthcare Excellence

Healthcare buildings should fit within their community and be compatible in design and the use of materials with their neighbourhood and have a strong NHS identity. The Contractor shall develop building design solutions that:

Reinforce the dependability and reassurance that the NHS means to the local community;

Respect their local environment but at the same time make a positive contribution to the urban context that they are in;

Clearly expresses their function in external and internal appearance;

Allows patient diagnostic and treatment areas that can be differentiated in design concept and detail from inpatient areas; and

Reflect that design considerations such as the distribution, size and proportion of windows and the use of materials can reflect the clinical function.

These elements shall be expressed in the scale and mass of the buildings, as well as the disposition of functions.

4.2.6 Architectural Vision

The Contractor shall develop building design solutions, which create an ordered composition of building elements in a stimulating form that successfully combines good standards of space, height, form, scale and use of materials and colours / images with associated functional requirements and its surroundings.

4.2.7 Stimulating Design

The Contractor shall develop building design solutions which create a high quality, good working environment, both externally and internally, which shall provide a reassuring, enjoyable, convenient and safe environment for all patients, their families, visitors and staff. This objective shall not be in conflict with the desire to produce a stimulating design. The Contractor shall meet this objective and shall develop a design which will not date and be capable of coping with future changes in a way that does not destroy the original design vision / concept. Further, the design shall incorporate best practice in terms of aspects of design that positively impact on health and recovery.

4.2.8 Design Innovation

Innovation in design can range from whole concepts of healthcare facilities' planning, distribution of functions etc to detail design of components, materials, spaces, use of technology etc. The Contractor shall develop designs at the concept level which shall translate the NHS modernisation agenda, and new forms of service delivery into new and innovative building solutions.

4.2.9 Recognisable Quality

The Board expects high quality design to match the best national standards of healthcare provision it intends to implement.

Materials shall be substantial and of high quality. They shall be carefully detailed and constructed such that the quality is appreciated throughout the life of the Works. They shall retain their appearance within a compatible maintenance regime. For example, detailing of external materials shall not cause unsightly staining.

The lifecycle plan and design detailing shall allow for replacement of elements in a way that does not impair design quality or service provision. A schedule of required life expectancies of building elements can be found in Section 5.3.

4.3 Citizen Satisfaction

4.3.1 Design Concept

The visual forms shall enhance the sense of place. They shall make best advantage of the environmental qualities of the Works and the wider Site.

The design concept shall be clear, and will not be compromised by the subsequent detailed design development. The design concept shall be complete and well balanced, with all parts relating to the whole.

4.3.2 Scale & Proportion

Appropriate scale and proportions shall reflect the human scale, adjoining urban surroundings and any existing buildings / structures retained on the Site. Plant rooms, lift and stair towers shall express form and function, but they shall not be perceived as dominating and oppressive.

4.3.3 Composition

The composition of the buildings shall be complete, cohesive and well balanced in massing. The visual form shall enhance the Site and sense of place. This can be done in a number of ways including by linkages to surroundings in plan form, expressions in the design of local character and including natural features of the Site in the composition.

The overall form of the buildings shall be designed to demonstrate the special needs of the function of each unit. The design shall clearly express in the form of the buildings the individuality and special nature of parts of the Works, yet the parts should harmonise with the Works and the overall site. The Contractor should give particular consideration to the architectural composition and expression of the following key aspects of the facility;

a. The form of the Adult Acute and Children's Hospital while mutually compatible should have an identifiably distinct character expressed both externally and internally as befits the nature of the patient groups; and

b. The Contractor will be require to ensure that the new Works are consistent with the overall masterplan strategy and with the existing facilities on the site, as such particular consideration should be given to the adjoining neonatal unit (which requires to be co-joined by an abutment) and the provision of a link to the institute of neurological sciences.

4.3.4 Aesthetics

The overall visual form of the buildings shall combine good standards of space, height, form and scale. The form of the buildings shall appeal to the aesthetic senses of patients, visitors and staff as follows:

The lines of the design shall clearly define forms and surfaces of the buildings;

The skyline shall reflect the mass of the buildings but not be out of scale and dominating;

The sky line shall not be monotonous;

The solid forms shall be in scale and have harmonious shapes; and

The interplay of light and shade shall add to the definition of the building form and the balance between solid and glazed elements should be carefully considered.

4.3.5 Colour & Texture

Colour decoration and motifs shall be used to facilitate identity of the Works; and its designated areas / zones and in addition improve wayfinding. It can also be used to create an immediate and distinct 'image' of the Works to visitors, which is interesting and stimulating.

The use of colour shall be co-ordinated and adapted with the lighting to the activities of each area, toned down in certain areas e.g., quiet areas, seminar rooms; but bright and stimulating in others, such as waiting and corridor areas.

The Board shall be entitled to choose the colour scheme in consultation with the Contractor and the Contractor shall liaise with the Board and nominated User groups and other representatives (e.g. BATH – Better Access To Health) in this regard.
An interior designer shall be included in the Contractor's design team to secure a clear co-ordination of the interior materials within the Works, matching the furniture, furnishings and equipment being procured by the Board. The colour scheme should be selected with due regard to integration with the Art Strategy as identified in Section 7.17.

4.4 Internal Environment

4.4.1 Quality Environment

The design of the Works shall create a high quality, good working environment, both externally and internally which will provide a reassuring, enjoyable, convenient and safe environment for all patients, their families, visitors and staff.

4.4.2 Light & Colour

The design shall provide quiet, comfortable areas with pleasing outlook easily accessible from clinical areas where patients and their families / visitors can "escape" from the clinical environment. Such areas may facilitate informal discussions with health professionals in the future, and be equipped for play / recreation. Where possible natural sunlight is to be brought into areas. The Contractor shall liaise with the Board and nominated User groups and other representatives (e.g. BATH – Better Access To Health) with regard to light and colour aspects.

4.4.3 Views

The Works shall provide quiet, comfortable areas with pleasing outlooks and easy access from clinical areas.

4.4.4 Internal Wayfinding

Design solutions shall incorporate an integrated, comprehensive wayfinding strategy that enables patients, visitors and staff to self-navigate with ease and lack of stress throughout the buildings.

The wayfinding strategy shall be designed to meet the needs of patients and visitors but routes shall be clearly defined to ensure that parts of the buildings that are restricted to staff are not used as short cuts by patients and visitors. The use of enclosed internal courtyards as an integral part of a route shall be considered. The Contractor shall liaise with the Board and nominated User groups and other representatives (e.g. BATH – Better Access To Health) with regard to the use and detailing of internal wayfinding.

Internal signage shall be easily understood and consistent throughout the journey from the entrance to the department reception and on to rooms. It shall not create clutter and the use of pictograms and graphic art should be considered.

Proposals shall be developed which acknowledge the multi-sensory process used in wayfinding and which address the need of people with impairment in touch, smell, sight or sound. The proposals should be developed with due regard to the requirements of the NHS Identikit guidance.

4.4.5 Internal Spaces

All internal spaces shall be well planned and appropriate within clinical areas.

Some spaces shall be designed to encourage social interaction for patients, visitors and staff.

Public spaces shall be used to integrate the various parts of the buildings, and shall be designed to avoid being a space joined by long, narrow corridors.

4.5 Urban & Social Integration

4.5.1 The Contractor should recognise that the design of the new hospital offers the opportunity for a responsive design which addresses the requirement for the sharing of Works with the wider community for the mutual benefit of both the functioning hospital campus and the local community at large.

Embodied in this approach will be the Travel Plan which addresses issues of local and regional access to the new Works in terms of

a. Car parking provision;

b. Public Transport Nodes;

c. Distance to Local Amenities;

d. Pedestrian routes and links;

e. Facilities for cyclists; and

f. Segregation of emergency servicing and visitor access routes.

The Contractor's objective should be to create an easily accessible healthcare facility which incorporates a Green Transport Strategy, segregates traffic flows and prioritises pedestrian routes. The strategy will require to be jointly developed by the Contractor in conjunction with the Board and Glasgow City Planning Authority taking cognisance of the Board's site-wide masterplan requirements.

Given the nature of the patient group, the children's hospital shall be extensively accessed by family groups and parents at varying time of night and day. Accessibility and amenity in design should take cognisance of this consideration.

The Contractor should consider opportunities in the building for third party development of support facilities such as retail outlets, cafes, health clubs, sports injury clinics, gymnasiums etc.

4.5.2 Sense of Place

The Works shall be designed to compliment and enhance the quality of the design in the locality in which it is sited. It shall create a welcoming, inclusive and vibrant environment, and shall enable easy access by the communities and groups who will use it. It shall be seen as a leading edge community resource reflecting the objectives of a modern NHS in the regeneration of healthcare facilities.

The Works shall be organised to establish a continuity of building frontage and a clear definition of public and private spaces. The viewing of service areas or more “industrial” looking parts of the Works from public entrances or from adjoining public spaces shall be avoided.

4.5.3 Good Neighbour

The Contractor shall ensure they are considered as a ‘good neighbour’ throughout design and construction periods. It shall add value to the neighbourhood, not detract nor be a nuisance. The Contractor shall register with and fully comply with the requirements of the Considerate Constructors Scheme. All sites registered with the Scheme are monitored by an experienced industry professional to assess their performance against the eight point Code of Considerate Practice which includes the categories Considerate, Environment, Cleanliness, Good Neighbour, Respectful, Safe, Responsible and Accountable.

The three main areas that the Scheme’s Code covers are:

a. The Environment: Registered sites should do all they can to reduce any negative effect they have on the environment. They should work in an environmentally conscious, sustainable manner;

b. The Workforce: Registered sites should provide clean, appropriate facilities for those who work on them. Works should be comparable to any other working environment;

c. The General Public: Registered sites should do all they can to reduce any negative impact they may have on the area in which they are working. Sites should aim to leave a positive impression on those they affect.

The Contractor shall provide Works which contribute to improving civic design, sensitive to its relationship with its surroundings, public transport and overall visual impact.

4.5.4 Neighbourhood & Community

The building height, volume and skyline shall relate well to the surrounding environment.

The design shall reflect the importance of the project in the context of community healthcare in the heart of an urban conurbation. Attention shall be paid to detail in the elevations, to ensure that blandness and lack of relief is avoided.

The form of development shall follow any changing topography across the Site, neighbouring properties, existing streetscape and landscape. The design of the Works shall be sensitive to and maximise existing Site features. It is envisaged that the buildings should compliment other new building developments in the area.

4.5.5 Site Fit

New buildings, parking areas, other infrastructure and services shall be located with regard to the existing landscape and topography. Amenity space shall be planned around the buildings at appropriate places.

The Contractor shall ensure that the design of the Works shall take account of the ecological and landscape features of the Site and maximise the retention of trees. There shall be a clear programme for future environmental improvements e.g., an arboricultural strategy for tree management and replanting, dedicated access to external grounds by patients, visitors, local communities and staff.

The design of the Works shall identify areas of the Site as possible expansion zones.

Suitable provision shall be made for refuse storage including provision of appropriate refuse bins and recycling facilities. Full details to be submitted to, and approved by the planning authority prior to the commencement of works

4.5.6 Hard & Soft Landscaping

The landscaping scheme shall be of a high quality. It shall assist in knitting the Works into its surroundings, and provide an interlinked network of attractive public spaces for amenity and circulation for use by patients, staff and visitors. The soft landscape design and choice of species shall be sympathetic to the character of the existing parkland landscape.

External hard and soft landscaping (including courtyards) shall be designed for therapeutic use and provide patient access. The landscape scheme shall facilitate security of pedestrians and avoid ‘No-Go’ areas. The design shall contribute to improving the environment of the local community.

Both hard and soft landscaping design require to specifically accommodate the needs of children and family groups, particularly in the areas adjacent to/around the children’s hospital.

Courtyards adjacent to the amenity area require to be accessible to patients, visitors and staff, with the Contractor to co-ordinate fire escape solutions to support this function.

A comprehensive and integrated landscape strategy taking into account the existing landscape features shall be developed. A clear strategy shall be developed for appropriate formal and informal treatment of public and private areas.

For further detailed landscaping scheme requirements refer to Sections 7.13 and 7.14.

4.6 **AEDET and ASPECT**

Healthcare building design frequently involves complex concepts which are difficult to measure and evaluate. In order to assist both the Board and the Contractor, the Board expects the Contractor to utilise the Achieving Excellence Design Evaluation Toolkit, more commonly known as AEDET Evolution and the associated supplementary tool ASPECT which are recognised as the exemplars of Design Quality Indicator (DQI) tools.

AEDET and ASPECT are to be used to assist in achieving the appropriate level of project design management and will be specifically directed towards achieving excellence in design rather than ensuring compliance with legislation, regulation and guidance. The toolkit poses a series of clear, non-technical statements, encompassing the three key areas of Impact, Build Quality and Functionality as a tool for evaluating the quality of design in healthcare buildings which have been evolved from sources including the Commission for Architecture and the Built Environment (CABE) and the Construction Industry Council (CIC) to establish an industry-wide framework for assessing design.

AEDET shall be used at various stages during the design – as the level of detail of the information available increases it should be possible to respond to more of the statements in the tool. As a minimum AEDET assessments will take place on the return bids as well as in preparation for FBC.

To complement AEDET Evolution, the Department of Health (England) Estates and Facilities Directorate has developed the ASPECT toolkit. ASPECT stands for A Staff and Patient Environment Calibration Tool and is based on a database of over 600 pieces of research. That research deals with the way the healthcare environment can impact on the levels of satisfaction shown by staff and patients and on the health outcomes of patients and the performance of staff. This research and the ASPECT toolkit itself are set out under 8 headings. When used to support AEDET Evolution ASPECT enables the user to score the Staff and Patient Environment Heading of AEDET Evolution in a more detailed, accurate way.

Section 5.0 General Design & Construction Requirements

5.1 Minimum Design & Construction Standards

5.1.1 NHS Publications

General

5.1.1.1 The Board has considered the documentary advice and guidance provided by Health Facilities Scotland and the Facilities Directorate of the Department of Health in relation to Health Building Notes ("HBN"), Health Technical Memoranda ("HTM"), Fire Practice Notes ("FPN") and other National Health Service published material.

5.1.1.2 The Contractor in carrying out of the Works shall comply with the requirements of the documents listed in *Table 2 – NHS Mandatory Documentation* in Section 5.1.2. Specific statements of compliance form an aspect and element of the bid return and evaluation process and requirements, with the requirement for bidders to clarify their approach during the bid period as an aspect of the dialogue process.

5.1.1.3 The Contractor in carrying out the Works shall have regard to and take into consideration the requirements of the documents listed *Table 3 - NHS Guidance Documentation* in Section 5.1.3. Specific statements of compliance form an aspect and element of the bid return and evaluation process and requirements, with the requirement for bidders to clarify their approach during the bid period as an aspect of the dialogue process.

5.1.1.4 Documents listed in *Tables 2 and 3* (together part of "NHS Publications") are deemed to include all volumes, supplements and any other associated requirements, unless specific volumes, parts or the like are specifically noted or noted as excluded.

5.1.1.5 Any reference to HTM/HBN is deemed to include SHTM/SHPN. The requirements of SHTM/SHPN shall take precedence over HTM/HBN unless expressly required otherwise by the Board and noted in *Table 2 or 3.* Presently *Tables 2 and 3* include reference to HTMs in relation to services systems. It is the intention of the Board that the new SHTMs in these areas, due for release by HFS late April/early May 2009, will be adopted and require to be complied with, as shall other SHTMs issued during the procurement process (subject to 5.1.9 below) – this to be clarified by the Board during the bid period. Current draft documentation is marked in *Tables 2 and 3* in blue shading.

5.1.1.6 In the event of any conflict (including differing requirements or interpretations) between the requirements of the documents listed in *Table 2 or Table 3* and the requirements of building control officers, such conflict should be highlighted to the Board for agreement and resolution. The Contractor shall notify the Board in writing of any such conflict as soon as he becomes aware of same;

5.1.1.7 In the event of any conflict between the requirements of the documents listed in *Table 2 or Table 3* or any other drawn or written information issued by the Board and the Schedule of Accommodation (SoA) information issued by the Board in this ITPD, the SoA identifies the minimum area requirements of the Board (in relation to room sizes).

5.1.1.8 In the event of any conflict between the requirements of the documents listed in *Table 2 or Table 3* and any written or drawn information issued to the Contractor by the Board in this ITPD, the information issued by the Board shall take precedence.

5.1.1.9 All references in these Employer's Requirements to NHS Facilities Scotland Requirements, building and engineering standards, Building Regulations, legislation,

Statutory Requirements, Codes of Practice, Department of Health publications, NHS Publications and other published guidance shall be deemed to mean those in place at the date of signing the construction contract. Any date reference in *Table 2 or Table 3*, therefore, may be replaced/read as that in place at the date of signing the construction contract.

5.1.1.10 Except as noted in 5.1.7 or 5.1.8 above, the Contractor shall provide Works which comply at all times with the requirements of *Table 2, Table 3* and the Additional Guidance identified at Section 5.1.4.

5.1.2 **NHS Mandatory Documentation**

In relation to the architectural design, structural design, and services design of the new buildings comprised in the Works, the documents listed in the following *Table 2* below set out that guidance which the Board considers to be mandatory.

Document	Title
CEL 25	Fire Safety policy for NHS Scotland 2008
SHTM 81	Fire Precautions in new hospitals Version 3
SHTM 82	Alarm and detection systems Version 2
SHTM 82 SUPP A	Automatic fire control systems and voice alarm systems
SHTM 83	Fire safety in healthcare premises - general fire precautions Version 2
SHTM 85	Fire precautions in existing hospitals Version 3
SHTM 86	Fire risk assessment Part 2 Healthcare Premises Version 4
SHTM 87	Textiles and furniture Version 2
HTM 05 – 01	Firecode – Fire safety in the NHS
HTM 05 – 02	Firecode – Fire safety in the NHS
HTM 05 – 03 (incl.)	Firecode – Fire safety in the NHS
HSANs	All published Health and Safety Action Notices
NHSE 10	Cubicle Rails
NHSE HN04	Curtain Tracks
NHSE HN03	Centre Pivot Window
SAN05/08	Flooring Materials
SN(01)01	Cubicle Rail
HVHNs	All published High Voltage Hazard Notices
SHTM	EnCOde – making energy work in healthcare
	EnCOde resource material
CEL 18	Healthcare Associated Infection: SHFN 30 and HAI SCRIBE Implementation Strategy
	HAI SCRIBE
SHFN 30	Infection Control in the built environment:design and planning.

Document	Title
	Access Audit Survey Toolkit V1
	Access Audit Checklist V1
	Fully Accessible Toilets
	SHFN 14 Disability Access
	SHFN Access audits of primary healthcare facilities
SFPN 3	Escape bed lifts Version 2
SFPN 4	Hospital main kitchens Version 2
SFPN 5	Commercial enterprises on hospital premises Version 2
HBN 04-01	Adult in-patient Facilities
HBN 00-04	Common activity spaces: circulation areas
HBN 15 – 03	Hospital helipads
SHTM 00	Scottish Health Technical Memorandum 00: Best practice guidance for healthcare engineering
SHTM 2005	Building Management Systems Parts 1 – 4
HTM 06-01 Part A	Part A Elec Services Supply and Distribution
HTM 06-01 Part B	Part B Elec Services Supply and Distribution
Draft for Consultation SHTM 06-01 Part A	Part A Elec Services Supply and Distribution
Draft for Consultation SHTM 06-01 Part B	Part B Elec Services Supply and Distribution
SHTM 2007	Scottish Health Technical Memorandum 2007 (Part 3 of 4): Validation and verification Electrical services: supply and distribution
SHTM 2007	Scottish Health Technical Memorandum 2007 (Part 4 of 4): Operational management Electrical services: supply and distribution
SHTM 2009	Pneumatic Tube Systems Parts 1 – 2
SHTM 2010	Sterilization Parts 1 – 6
SHTM 2011	Emergency Electrical Services Parts 1 – 4
SHTM 2014	Abatement of Electrical Interference Parts 1 – 4
SHTM 2015	Bedhead services
	Part 1 Overview and management responsibilities
	Part 2 Design considerations
	SHTM 2015 forms
SHTM 2020	Electrical safety code for low voltage systems
	Volume 1 Operational management
	SHTM Volume 1 forms
	HTM Volume 2 forms

Document	Title
SHTM 2021	Electrical safety code for high voltage systems
	Part 1 Overview and management responsibilities
	Part 2 Operational management
	SHTM 2021 forms
HTM 02-01 Part A	Medical gas pipeline systems : Part A
HTM 02-01 Part B	Medical gas pipeline systems : Part B
Draft for Consultation SHTM 02-01 Part A	Medical gas pipeline systems : Part A
Draft for Consultation SHTM 02-01 Part B	Medical gas pipeline systems : Part B
SHTM 2022 March 2004	Supp 1 Dental compressed air and vacuum systems
	SHTM 2022 forms
SHTM 2023	Access and accommodation for engineering services
	Part 1 Overview and management responsibilities
	Part 2 Good practice guide
SHTM 2024	Lfts
	Part 1 Overview and management responsibilities
	Part 2 Design considerations
	Part 3 Validation and verification
	Part 4 Operational management
	SHTM 2024 forms
HTM 03-01	Specialised Ventilation for Healthcare Premises
HTM 03-01 Part B	Specialised Ventilation for Healthcare Premises Part B
HTM 03-01 Part A	Specialised Ventilation for Healthcare Premises Part A
Draft for Consultation SHTM 03-01 Part A	Specialised Ventilation for Healthcare Premises Part A
Draft for Consultation SHTM 03-01 Part B	Specialised Ventilation for Healthcare Premises Part B
	SHTM 2025 forms
SHTM 2027	Hot and cold water supply, storage and mains services
	Part 1 Overview and management responsibilities
	Part 4 Validation and verification
HTM 04-01 Part A	Control of Legionella...drinking systems Part A
HTM 04-01 Part B	Control of Legionella...drinking systems Part B
Draft for Consultation SHTM 04-01 Part A	Control of Legionella...drinking systems Part A
Draft for Consultation SHTM 04-01 Part B	Control of Legionella...drinking systems Part B

Document	Title
SHTM 2030	Washer disinfectors
	Part 1 Design considerations
	Part 2 Operational management
	Part 3 Validation and verification
SHFN	Access Audit Survey Toolkit V1
SHFN	Access Audit Checklist V1
SHFN	Fully Accessible Toilets
SHFN 14	Disability Access
SHFN	Access audits of primary healthcare facilities
SFPN 3	Escape bed lifts Version 2
SFPN 4	Hospital main kitchens Version 2
SFPN 5	Commercial enterprises on hospital premises Version 2
HBN 00 -02	Sanitary spaces
HBN 04-01	Adult in-patient Facilities
HBN 00-04	Common activity spaces: circulation areas
HBN 15 – 03	Hospital helipads
SHTM 00	Scottish Health Technical Memorandum 00: Best practice guidance for healthcare engineering
SHTM 2005	Building Management Systems: Parts 1 – 4 (incl)
HTM 06-01 Part B	Part B Elec Services Supply and Distribution
HTM 06-01 Part A	Part A Elec Services Supply and Distribution
SHTM 2007	Scottish Health Technical Memorandum 2007 (Part 3 of 4): Validation and verification Electrical services: supply and distribution
SHTM 2007	Scottish Health Technical Memorandum 2007 (Part 4 of 4): Operational management Electrical services: supply and distribution
SHTM 2009	Pneumatic Tube Systems: Parts 1 – 2 (incl)
SHTM 2010	Sterilization: Parts 1 – 6 (incl)
SHTM 2011	Emergency Electrical Services: Parts 1 – 4 (incl)
SHTM 2014	Abatement of Electrical Interference: Parts 1 – 4 (incl)

Document	Title
SHTM 2015	Bedhead services
	Part 1 Overview and management responsibilities
	Part 2 Design considerations
	SHTM 2015 forms
SHTM 2020	Electrical safety code for low voltage systems
	Volume 1 Operational management
	SHTM Volume 1 forms
	HTM Volume 2 forms
SHTM 2031	Clean steam for sterilization
SHTM 2035	Mains signalling
	Part 1 Overview and management responsibilities
	Part 2 Design considerations
	Part 3 Validation and verification
SHTM 2040	The control of legionellae in healthcare premises – a code of practice
	Part 1 Overview and management responsibilities
	Part 4 Validation and verification
	Part 5 Good practice guide
	Part 6 supplementary guidance applicable to intermittently used healthcare premises
	SHTM 2040 forms
HTM 08-01	Acoustics
MEIGaN	Medical Electrical Installation Guidance Notes (MEIGaN)
SHTM 54	User Manual
SHTM 55	Windows
SHTM 56	Partitions
SHTM 57	Internal glazing
SHTM 58	Internal doorsets
SHTM 59	Ironmongery
SHTM 60	Ceilings
SHTM 61	Flooring
SHTM 62	Demountable storage systems
SHTM 63	Fitted storage systems
SHTM 64	Sanitary assemblies

Document	Title
SHTM 66	Cubicle curtain track
SHTM 67	Laboratory fitting out systems
HTM 68	Duct and Panel assemblies
SHTM 69	Protection
Draft for Consultation SHTM 87	Textiles & Furniture

Table 2 – NHS Mandatory Documentation

5.1.3 **NHS Guidance Documentation**

In relation to the architectural design, structural design, and services design of the new buildings comprised in the Works, the documents listed in the following *Table 3* set out that guidance which the Board considers to be guidance.

Document	Title
	NHSSCOTLAND National Cleaning Services Specification
SFPN 6	The prevention and control of deliberate fire-raising in NHS Scotland healthcare premises Version 3
SFPN 10	Laboratories on hospital premises
SFPN 11	Reducing unwanted fire signals in healthcare premises
SHGN	Magnetic Resonance Imaging
SHGN	"Safe" hot water and surface temperatures
SHGN	Static discharges
SHGN	Structured cabling for IT systems
SHTN 2	Domestic Hot and Cold Water Systems for Scottish Health Care Premises
SHTN 4	General Purpose Estates and Facilities Model Safety Permit-to-Work System
SHTN 5	The Operation and Management of Emergency Electrical Generators in Scottish Healthcare Premises
SHTN 6	The Safe Operation and Maintenance of Thermostatic Mixing Valves
SHPN 03	General Design Guidance
SHPN 06 Part 1	Facilities for diagnostic imaging and interventional radiology
SHPN 08	Facilities for rehabilitation services
SHPN 13 Part 2	Decontamination Facilities: Local Decontamination Units
SHPN 20	Facilities for mortuary and post mortem room services
SHPN 22	Accident and emergency facilities for adults and children

Document	Title
SHPN 27	Intensive care unit
SHPN 28	Facilities for cardiac services
SHPN 35	Accommodation for people with mental illness
SHPN 52	Accommodation for day care: Day surgery unit
SHPN 52	Accommodation for day care: Endoscopy unit
SHPN 52	Accommodation for day care: Medical investigation and treatment unit
SHPN 54	Facilities for cancer care centres - design and briefing guide
Draft for Consultation SHPN 06 Part 2	Facilities for Diagnostic Imaging
Draft for Consultation SHPN 23	Hospital Accommodation for Children and Young People
Draft for Consultation SHPN 28	Facilities for Cardiac Services
Draft for Consultation SHPN 57	Facilities for Critical Care
	Wayfinding: Effective Wayfinding and Signing Systems guidance for healthcare
	Handover checklist for buildings
HBN 04 Supp	Isolation facilities in acute settings
HBN 06	Facilities for diagnostic imaging and interventional radiology
HBN 06 Vol 2	PACS and specialist imaging
HBN 06 Vol 3	Extremity and open MRI
HBN 08	Facilities for rehabilitation services
HBN 10	Catering department
HBN 12	Out-patients department
HBN 22	Accident and emergency facilities for adults and children
HBN 23	Hospital accommodation for children and young people
HBN 26	Operating Departments – Facilities for Surgical Procedures
HBN 28	Facilities for Cardiac Services
HBN 29	Accommodation for pharmaceutical services
HBN 37	In-patient facilities for older people
HBN 40 Vol 1	Common activity spaces: public areas
HBN 40 Vol 2	Common activity spaces: treatment areas
HBN 40 Vol 3	Common activity spaces: staff areas

Document	Title
HBN 45	External works for health buildings
HBN 51	Accommodation at the main entrance of a District General Hospital
HBN 52 Vol 1	Accommodation for day care: Day surgery unit
HBN 52 Vol 1 Supp 1	Review of schedules of accommodation
HBN 52 Vol 3	Accommodation for day care: Medical investigation and treatment unit
HBN 54	Facilities for cancer care centres
HBN 57	Facilities for critical care
HBN 00 -02	Sanitary spaces
HBN 00 – 07	Resilience planning for the healthcare estate
HBN 07 – 01	Satellite dialysis units
HBN 07 – 02	Main renal units
HBN 09 – 02	Maternity care facilities
HBN 14 – 01	Pharmacy and radiopharmacy
HFN 05	Design against crime: a strategic approach to hospital planning (now archived)
NHS Estates Improving the Patient Experience	Friendly healthcare environments for children and young people
NHS Estates Improving the Patient Experience	Welcoming Entrances and reception areas
NHS Estates Improving the Patient Experience	The Art of Good Health : Using visual arts in healthcare
NHS Estates Improving the Patient Experience	The Art of Good Health : A practical guide

Table 3 - NHS Guidance Documentation

5.1.4 **Additional Guidance**

5.1.4.1 Further to the requirement noted in Section 2.2, that the Contractor shall comply with all Law and Consents, and the requirements in relation to NHS Mandatory Documentation and NHS Guidance Documentation above, the Contractor shall also comply with the standards and documents listed below.

a) Health and Safety Legislation, including Construction (Design and Management) Regulations 2007;

b) The Technical Standards complying with the Building Standards (Scotland) Regulations 1990 as amended by all subsequent Amendment Regulations;

c) Disability Discrimination Act 1995;

d) Current British Standards, European Standards, and Codes of Practice, as appropriate;

e) Strathclyde Fire Brigade and the Glasgow City Council's Fire Officer requirements;

f) The Board's Approved Codes of Practice, Procedure and Policy documents as listed in Appendix G;

g) Control of Substances Hazardous to Health;

h) Health Department Letters (or Management Executive Letters) as appropriate published by SEHD;

i) NHS QIS (Quality Improvement Scotland) 2003;

j) NHS Model Engineering Specifications;

k) The Building (Scotland) Act 2003;

l) The Building (Scotland) Regulations 2004;

m) Requirements of the utilities companies;

n) Building Research Establishment Digest Recommendations;

o) Local Bye-Law and Regulations;

p) Scottish Centre for Infection and Environmental Health guidance / recommendations;

q) All other bodies and authorities having jurisdiction;

r) Secure by Design;

s) The Ionising Radiations Regulations 1999 (IRR99);

t) The Radioactive Substances Act (1993);

u) Medical and Dental Guidance Notes: A good practice guide on all aspects of ionising radiation protection in the clinical environment, Institute of Physics and Engineering (IPEM), York, 2002;

v) Various related to the additional security required re use of radioactive materials e.g. IRR99, RSA93, NHS Security Management guidance note 001/2004;

w) Guidelines for the use of PET-CT in Children (UK PET-CT Advisory Board), British Nuclear Medicine Society (BNMS), London, 2008;

Healthcare interpretation of IEE Guidance Note 7 (Chapter 10) and IEC 60364-7-710 for Electrical Installations in Medical Locations. Annex to MEIGaN, Leeds, June 2005;

x) Releasing Time To Care (RTTC): The Productive Ward (NHS Innovations, 2008);

z) Delivering Quality & Value, Institute for Modernisation & Improvement;

aa) The Internal Environment: Evaluation of the King's Fund, Enhancing the Healing Environment Programme (NHS Estates, 2004);

bb) Lighting and colour for hospital design, Dalke et. Al. (NHS Estates, 2004);

cc) The role of hospital design in the recruitment, retention and performance of NHS nurses in England, CABE, July 2004;

dd) Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources, Administration of Radioactive Substances Advisory Committee (ARSAC);

ee) Provision of Paediatric Radionuclide Imaging Services, British Nuclear Medicine Society (BNMS), London, 2003;

ff) Published papers on operational radiation safety e.g. Zanzonico P et al, Operational Radiation Safety for PET-CT, SPECT-CT and cyclotron facilities. Health Physics 2008;

gg) Standards for Intensive Care Units, A Joint Document for the Intensive Care Society and the Intercollegiate Board for Training in Intensive Care Medicine, May 2006;

hh) Leather P, Pyrgas M, Beale D and Lawrence C. Windows in the Workplace: Sunlight, View and Occupational Stress. Environment and Behaviour 1998; 30: 739 – 762;

ii) Leslie RP. Capturing the Daylight Dividend in Buildings: Why and How? Building and Environment 2003; 38: 381 – 385;

jj) Heerwagen J. Green Buildings, Organizational Success and Occupant Productivity. Building Research and Information 2000; 28: 353 – 367;

kk) National Overview – Adult Renal Services (March, 2003) NHS Quality Improvements Scotland;

ll) Adult Renal Services (Feb, 2002) Clinical Standards Board for Scotland;

mm) Treatments of Adults & Children with Renal Failure – Standards & Audit Measures, 3rd Edition, Renal Association (August, 2002);

In addition the renal COS notes that water treatment should reach a minimum of the following standards:

nn) The higher European Pharmacolela (EP) XV1 standard :'Water for diluting concentrated haemodialysis solutions';

oo) ISO 13959: 'Water for haemodialysis and related therapies' or
AAMI (Association for the Advancement of Medical Instrumentation) standards; and

pp) European Renal Association Best Practice Guidance – 4th Edition 2007. NB New guidelines are due in 2009 and should be considered at that time.

5.1.4.2 The Contractor shall provide to the Board at Completion a certificate confirming that the Works comply with the requirements of NHS Scotland Firecode.

5.1.4.3 The Contractor shall provide all fixed and portable fire fighting equipment to comply with statutory requirements and the requirements and recommendations of NHS Scotland Firecode.

5.1.4.4 The Contractor shall ensure that the Works comply with the relevant requirements of Building Better Healthcare Volume 3 (published by NHS Estates); except insofar as there are NHS Scotland publications, which shall take precedence over the respective elements of Building Better Healthcare.

5.2 **Hierarchy of Standards**

5.2.1 Where there is any conflict between two or more documents, the more onerous standard shall be complied with by the Contractor, at no additional cost to the Board.

5.2.2 NHS Scotland standards shall take precedence over equivalent NHS England & Wales standards unless the NHS England & Wales standard is specifically identified in *Table 2 or Table 3*.

5.2.3 In certain instances, NHS Publications include a number of options or alternative solutions. Where the Board has defined their preference in *Table 2, Table 3* or in these Employer's Requirements the Contractor shall adopt these preferences as a mandatory requirement. As is noted in 5.1.1.2 and 5.1.1.3, the Contractor shall identify their interpretation and choice (of any options within documents) in NHS Publications during the bid period (to which the Board will review and respond) with compliance statements required in their bid return.

5.2.4 While the Board has placed a clear obligation on the Contractor in relation to NHS Publications, it also wishes to acknowledge that in certain cases the subject matter, guidance and advice included therein has been further developed and improved since the date of publication. While applying the foregoing as a base position, the Board does not wish to limit the use of current best practice or innovation in relation to the adoption of design standards. Consequently, the Board therefore wishes the Contractor to actively engage the Board in an on-going dialogue during the design process in order for the Board to review and agree to any proposed alternatives.

5.2.5 The Board considers NHS Publications reflect minimum standards and any alternatives proposed by the Contractor shall provide an equivalent or enhanced level of service and quality.

5.2.6 Further to the statements above in relation to NHS Publications, it should be noted that the Schedules of Accommodation (SoA) in Appendix C take precedence with regard to room sizes. The room sizes therein must be provided by the Contractor as a minimum requirement.

5.2.7 Further to the statements above in relation to NHS Publications, the following hierarchy of other design related documents shall apply (in order of precedence):

a. 1:50 drawings;

b. Room Data Sheets; and

c. Equipment Lists.

5.3 Life Expectancies & Lifecycle Requirements

5.3.1 The buildings, including building services components, shall be designed with materials, components and techniques that are readily available, reliable, sustainable and easily maintainable in use. The Board supports buildings constructed of proven technology components, with high life expectancy, leading to minimum cost in use.

5.3.2 Good Industry Practice for a design life at Completion for the elements listed below shall as a minimum be as indicated in the table below:

Table 1 – Component Life Expectancies

Building Element	Expectancy
Structure, including substructure	70 years
Floor structure	70 years
Roof structure	70 years
Drainage and below ground civil engineering infrastructure	70 years
External walls	45 years
External openings, windows, doors and curtain walling	25 years
Roof finishes	40 years
External Wall finishes	25 years
External hard surfaces (inc roads/carparking/footpaths etc)	Not less than 20 years to first maintenance
Internal partitions including openings	30 years
Internal doors	15 years
Internal finishes	15 years
Internal fixtures and fittings	15 years
Ironmongery	15 years
Engineering plant Volume B	CIBSE Guide
Engineering services distribution systems Volume B	CIBSE Guide

5.3.3 The Contractor shall demonstrate that the theoretical design life proposed for any element will be achieved.

5.3.4 Materials and components forming part of the Works, which require maintenance and replacement within the life of the Works, shall be selected, located and fixed in such a way as to minimise future inconvenience, disruptions and to avoid temporary closure of the Works.

5.3.5 Lifecycle Costs

5.3.5.1 It is a requirement of the Bid that a detailed Life Cycle Cost Plan (LCCP) be provided for the new facilities – it is envisaged that 3no.separate LCC Plans will be required for the project;

a. Acute Adult Hospital;

b. Childrens Hospital; and

c. Laboratory Block.

NB – it is assumed that External Works and FM/Energy Centre etc buildings will be separately identified and incorporated into the Acute Adult Hospital LCCP.

5.3.5.2 It is a requirement that the LCCP's be produced in accordance with the methodology as detailed in the following documentation;

a. BS ISO 15686 – 5 2008; Building & Construction Assets – Service Life Planning – Part 5 – Life Cycle Costing; and

b. Standardized Method of Life Cycle Costing for Construction Procurement

5.3.5.3 LCCP submissions to follow the formats as detailed in the above documentation, utilising the following base criteria:

Table 2 – Life Cycle Cost Plan component elements

REF	ELEMENT	DESCRIPTION	REQUIREMENT
1.0	Design Life	n.a.	60 years
2.0	LCCP Duration	Period to be considered within LCCP (NB – excluding Construction Period)	30 and 60 years
3.0	Discount Rate	NVP rate	3.5%
4.0	Base Date	Base Date for Costs	Acute & Childrens Hospitals – 1Q2015 Laboratory Block – 1Q2012
5.0	Client On Costs	Bidders to **exclude** Client On Costs to LCCP values	n.a.
6.0	LCCP inclusions	Schedule of LCC Information and Assumptions	
6.1	LCCP Summary Sheet	Elements for inclusion in Life Cycle Cost Plan	All as detailed in Standardized Method Appendix F.3&4, with the following **exclusions:** 1.3 – Client Definable Costs 2.7 – Client Definable Costs 3.1.2 – Internal Cleaning 3.1.3 – Specialist Cleaning 3.3. – Administrative Costs 3.4 – Overhead Costs 3.5 – Taxes 3.6 – Client Definable Costs. 4.17 Occupancy Costs 5.3 – Reinstatement & Dilapidations 5.4 – Client Definable Costs

6.2	LCCP Data Sheets		Data sheets to itemise: • Component Description • Work Description • Quantity • Unit • Component Cost Rate (£) • % Allowance of Cost Rate for Replacement • % Allowance for Replacement • Replacement Factor • Life Expectancy of Component • Number of Replacements • Cost per Replacement (£) • Total Cost of Replacement (£)
			All above elements to be provided in BCIS Elemental format
6.3	FM Data Sheets (Hard FM only)	Bidders to allow for the following FM Services: • Minor replacements, repairs & maintenance costs • Unscheduled repairs, replacement & maintenance costs • Grounds Maintenance	Data sheets to itemise: • Management Costs • Staff/Contracted Costs • Materials • Equipment Bidders to **exclude** Client On Costs to FM Services values

5.3.3.4 Although the Contractor will not be involved in the provision of FM Services, the proposed Design will impinge on the Boards operation of the facilities, and to this end the evaluation of the Bidders overall submission will take into account proposals to minimise the potential operating costs;

5.3.3.5 Bidders should therefore indicate where measures in relation to the following criteria have been utilised

a. 'Spend to Save' specification enhancement;

b. Design detailing;

c. Controls;

d. Standardisation; and

e. Modular construction.

5.3.3.6 All Innovation & Sustainability initiatives proposed by the Bidder, should be supported by a full Lifecycle Cost Plan as detailed above, and include;

a. Items as detailed in Section 6.1/2 – of the above LCC table;

b. Projected Energy & Carbon savings;

c. Payback period; and

d. Items as detailed in Section 6.1/3 – FM Data Sheets of the above LCC table.

5.3.3.7 The Bidders attention is drawn to the BREAAM LCC requirements, which need to be encompassed as part of the overall LCCP submission – all as detailed in Appendix U.

5.3.3.8 In connection with the above, and for bid comparison purposes, Energy consumption/savings calculations should utilise the following base cost and associated allowances;

a. Electrical consumption – 10p / KwH;

b. Gas consumption – 3.5p / KwH;

c. Oil consumption – 41p / litre;

d. Water consumption – £2.20 / m3;

e. Waste material disposal (bagged) – £60/ton;

f. Carbon production/reduction data to be provided to support above proposals; and

g. Payback periods to be provided.

5.4 Integration of Design

The Contractor is responsible for the integration of the various aspects and elements of the design of the Works.

5.4.1 Architectural / Structural Interface

5.4.1.1 Structural floors shall be designed to have penetrable zones co-ordinated with the modular framework for partitions and services.

5.4.1.2 Structural timber floors shall not be permitted.

5.4.1.3 Columns shall be located in-so-far, as is reasonably practical to coincide with corridor walls in order to minimise intrusion into rooms or corridors. The relationship of column ducts and walls shall permit clear internal room surfaces and not obstruct equipment or fittings.

5.4.1.4 As far as practical, the walls to vertical service shafts shall be non-load bearing and therefore maximising opportunity for future services installation, alteration and maintenance.

5.4.1.5 The elevation design shall facilitate distribution of services at the building perimeter.

5.4.2 **Integration with Engineering Services**

5.4.2.1 Internal walls, partition systems, ceiling voids and service risers shall be capable of integrating services, e.g. wiring, plumbing, medical gases and service terminals as required without detriment to the performance of any building services and other Works performance criteria such as fire resistance or acoustic properties. Services shall be co-ordinated and a satisfactory means of maintenance access shall be provided.

5.4.2.2 So far as is reasonably practicable, vertical service shafts shall not be surrounded by load bearing structural walls, to facilitate services installation and future alterations.

5.4.2.3 The Contractor shall be responsible for bunding and waterproof slab construction above theatres and in plant rooms to provide resilience and avoid flooding whilst ensuring functionality of engineering services.

5.4.3 **Manual Handling**

5.4.3.1 The Contractor, in the design of the Works, shall give due consideration to the obligations contained in the Manual Handling Regulations 1992 and ensure the appropriate allocation of space and structural capacity for the inclusion of mechanical devices, i.e. fixed and mobile hoists, robotic equipment and all FM, staff and patient lifts.

5.5 Sustainability

5.5.1 The Board has a significant asset base and, as a responsible healthcare provider and employer, it is committed to sustainability and carbon reduction in line with relevant and appropriate guidance and directives in this area. The Board has targeted an 'Excellent' BREEAM rating for the Project.

5.5.2 The specific sustainability considerations with regard to the Project and the requirements of the Contractor in this respect are detailed in Section 10.0 and Appendix M.

5.6 Control of Infection

5.6.1 Prevention and control of infection shall remain a primary consideration of the Contractor in the design and construction of the Works. The whole hospital design shall place a high priority on infection prevention and control in relation to the movement of goods and in particular the segregation as far as is reasonably practicable of clean linen, food trolleys and the removal of waste, soiled linen and empty food trolleys. The Contractor will be required to demonstrate to the satisfaction of the Board's Infection Control Team that the design and construction of the Works fully reflects and incorporates the following key infection control challenges;

a) Segregation of clean and dirty – laundry, food, healthcare waste;

b) Ventilation system – including the use of natural ventilation in relation to the affect by neighbourhood sources of environmental pollution;

c) Selection of Fixtures/fittings/flooring that are easy to clean and maintain;

d) Appropriate Isolation facilities;

e) Incorporation of appropriate workflows;

f) Handwash hygiene;

g) Wastewater and sewage/body fluid disposal;

h) Heating and lighting;

i) Water systems;

j) Food preparation.

5.6.2 The Contractor shall provide that all aspects of the Works allow the control and management of an outbreak and spread of infectious diseases in accordance with the following;

a. Infection Control in the Built Environment: Design and Planning (SHFN 30);

b. NHS Scotland HAI Scribe (Healthcare Associated Infection System for Controlling Risk In the Built Environment);

c. Scottish Infection Manual – 'Managing the Risk of HAI in NHS Scotland';

d. Guidance provided by Clinical Standards Board NHS QIS;

e. Textiles and Furniture (SHTM 87);

f. Ventilation in Healthcare Premises (SHTM 2025); and

g. The location of maintenance access to services and requirements of SHTM2023.

5.7 Design for Disability

5.7.1 The design shall comply with the requirements of the Disability Discrimination Act 1995, and take full consideration of HFN14 "Disability access", HFN20 "Access audits for primary healthcare facilities" and BS 8300:2001 “Design of buildings and their approaches to meet the needs of disabled people – code of practice”. Further guidance is provided in the NHS publication "Doubly Disabled: Equality for disabled people in the new NHS - Access to services”.

5.7.2 The Contractor shall ensure that the design and functionality of the Works meets the requirements of the Disability Discrimination Act 1995 as relevant and set standards of best practice to enable full access and use of the services and facilities available.

5.7.3 Entrances to the Works shall be clearly identified to promote ease of wayfinding and distinctive ‘landmarks’ shall be incorporated into the design particularly for the main entrances.

5.7.4 The Works’ environment, both externally and internally, shall be designed to be accessible to everyone. The journey onto the Site, from pedestrian / vehicle routes, through the main receptions, into the Works and to the desired locations shall follow a safe, logical and clear system.

5.7.5 Attention shall be paid in the design to all aspects of the physical environment relating to the accessibility of the Works as follows:

a. Access to buildings, such as level or ramped entry;

b. Emergency evacuation arrangements, in particular for the visually impaired, the disabled and the frail, such as fire refuges or alternative escape routes for people with mobility impairments;

c. The accessibility of external paths and landscaping;

d. Circulation within buildings, including their interior layout;

e. Effective lighting and signage and colour or tone contrast on doors to aid orientation;

f. Desks, laboratory benches, work surfaces and reception desks at varying or flexible heights;

g. Appropriate seating;

h. Accessible toilets; and

i. Convenient and reserved parking spaces for those who need them.

5.7.6 The Contractor shall ensure, as far as practically possible, that the Works design draws upon and endeavours to further develop improve and exceed current best practice and standards achieved in other similar projects, and incorporates full accessibility for the prospective patient groups, staff and public. This shall include aspects of both physical environment and visual and audio aids to enable full use of the Works for all groups. This philosophy of design shall be extended across all parts of the Works including access to the landscaped and external areas as well as the essential patient treatment and residential areas.

5.7.7 The Contractor shall ensure the design complies with the general accessibility ethos detailed above, whilst also addressing the detailed requirements listed elsewhere. It should be noted

that the requirements detailed are not exhaustive, and it is also recognised that specific clinical needs will determine the nature and design of Works in some areas.

In particular it is highlighted that the Works will be used by a high proportion of wheelchair users. The Contractor shall ensure that any fire evacuation procedures take full account of this.

In meeting the overarching obligations with respect to accessibility, The Contractor shall comply with the following non-exhaustive list of standards:

a. BS8300:2001 “Design of buildings and their approaches to meet the needs of disabled people – Code of practice”;

b. HFN 14 “Disability Access” and HFN20 “Access audits for primary healthcare Facilities”;

c. HFN 20 “Access audits for primary healthcare Facilities” ;and

d. HFN 21 “Car parking”.

5.7.8 BS8300:2001 is widely referred to by consultants advising on general building design in relation to the Disability Discrimination Act (1995). The Contractor shall therefore refer to this document and give full regard to its standards. It will, however be necessary to match the standards of BS8300 with others laid down in NHS guidance notes etc.

5.7.9 The Contractor shall also comply with further guidance contained in the NHS publication “Doubly Disabled: Equality for disabled people in the new NHS - Access to services”.

5.7.10 The obligations with respect to accessibility, as described in this Part 8 Section 3, are intended to reinforce the principles established within BS8300. Some, however, stand as requirements that deliberately exceed the minimum stated within BS8300. For the avoidance of doubt, specific accessibility requirements listed in this Part 8 Section 3 shall take precedence over the standards laid down in BS8300.

5.8 Equipment Requirements

5.8.1 The Equipment List is contained in Appendix F. This identifies equipment by Group (for pricing in bid returns), with location of equipment ascertained via the ADB Room Data Sheets (for all rooms) and exemplar 1:50s for those drawn at this stage. Group 1 Equipment shall be supplied and fitted by the Contractor, with Group 2 Equipment provided "free issue" to the Contractor by the Board and fitted by the Contractor. The Board are responsible for the supply and installation of Group 3 and Group 4 Equipment.

5.8.2 Notwithstanding the party who provides/supplies equipment, the Contractor shall identify and provide all necessary fixings and supports (to walls, ceilings and floors) connections and infrastructure (including supply, extraction and removal of waste) for all items of equipment listed in Appendix F.

5.8.3 The Contractor shall provide a suitable environment for each item of equipment as set out in the Room Data Sheets, this shall include accounting for temperature and ventilation requirements.

5.8.4 For the avoidance of doubt, this requirement specifically includes MEIGaN compliance and specialist service requirements by the Contractor, including for example 3-phase electrical supply, surge protection, standby power supply, ups, special water supply requirements and separation of contaminated waste.

5.8.5 For the avoidance of doubt, this requirement specifically includes the installation of renal water equipment and supplies by the Contractor to the meet the requirements of the Board.

5.8.6 Irrespective of the party responsible for the supply, installation, maintenance and replacement of each item of equipment, the Contractor shall provide Works that satisfy the following criteria:

a) allow Equipment and associated systems to be installed, commissioned, operated, maintained and replaced in accordance with:

i) Good Industry Practice;

ii) Manufacturer's instructions; and

iii) The Board's, statutory health and safety requirements.

b) Allow Equipment and associated systems to operate efficiently, effectively and in accordance with its intended function for the whole of its design life when operated in accordance with the manufacturer's requirements;

c) Take due account of the impact on the environmental conditions within the Works;

d) Take due account of the potential impact of future equipment changes through either refresh or replacement. In particular, allowance for equipment of different sizes, weights, service requirements or environmental impacts;

e) Allow the Board to provide their Clinical and Non-Clinical Services with a minimum of disruption during installation, commissioning, operation, maintenance and replacement; and

f) Provide safe and unencumbered access for maintenance and replacement of equipment during the buildings life, to include pulley hoists, barrier walkways and

landings and reinforced routes and areas as necessary to assist the safe removal and replacement.

5.8.7 The construction, structure, plant and services shall be designed to meet the specific requirements for Special Equipment and associated services. The design of the Works shall meet these requirements with regards to mechanical and electrical servicing, wall and floor loads, structural movement and deflections, the need for special (including protected) floors, wall supports, ceiling grids and other such measures to allow for the installation, maintenance and replacement of Special Equipment and associated services. Specific Special Equipment is identified in Appendix F.2. The particular interface arrangements between the Contractor and the Board with regard to the provision and fit-out of Special Equipment shall be finalised during the Competitive Dialogue process.

5.8.8 The Contractor shall not change the Group designation of any Equipment. The Equipment List issued at Appendix F.1 shall be priced and submitted in the bid return with no additions, omissions or changes unless requested in writing by the Board as an aspect of the bid period.

5.8.9 The procurement, delivery and installation of Group 2 Equipment shall be as follows:

a) The Contractor shall procure and deliver, or arrange for the delivery to Site, all Group 2 Equipment to a secure central holding area (suitable for the equipment to be stored) to be provided by the Contractor. The holding area requires to be accessible by vans, 7t trucks and articulated vehicles – with vehicle movements in the operation of dropping off or picking up from the holding area to be managed by the Contractor;

b) The off loading or up loading of any Group 2 Equipment will be attended by the Contactor who shall acknowledge receipt of every delivery and sign the relevant delivery receipts to that effect. The Contractor shall manage and carry out the conveying of all Group 2 Equipment into the holding area;

c) The Contractor shall manage the movement and delivery of all Group 2 Equipment from the holding area to the point of installation in time for installation the same day;

d) The Contractor shall prepare and maintain a log of all Group 2 Equipment delivered to Site in an electronic and paper format, providing monthly updates to the Board of the status of delivered, stored and installed Group 2 Equipment; and

e) Should the Contractor arrange for a secure central holding area off or adjacent to the Site the Contractor remains responsible for the Group 2 Equipment that has been delivered and the movement of same to the Site for installation.

5.9 Materials

5.9.1 The Contractor shall ensure that all materials incorporated into the Works shall comply with the requirements of the Construction Products Regulations 1991, and all aspects of the Employer's Requirements.

5.9.2 The Contractor shall ensure that all products and materials to be incorporated into the Works shall be new unless otherwise agreed by the Board.

5.9.3 Where materials and components are not specifically identified as complying with the Construction Products Regulations 1991, The Contractor shall ensure that they comply with the relevant British Standards and Codes of Practice.

5.9.4 The Contractor shall ensure that the whole quantity of each product and material required to complete the Works is of a consistent type, quality and overall appearance and is fit for its intended purpose. The Contractor shall ensure all products and materials are handled, stored, prepared and used or fixed strictly in accordance with the manufacturers' written instructions or recommendations and not be damaged when incorporated into the Works.

5.9.5 The Contractor shall not construct the Works utilising substances which are hazardous to health, including but not limited to substances referred to as being hazardous to health and safety in "The Control of Substances Hazardous to Health Regulations 2002".

5.9.6 The Contractor shall not specify or include products or materials that do not comply with relevant British or European Standards, Codes of Practice or which are generally known within the European Union at the time of specification to be deleterious to health and safety or to the durability of buildings and / or other structures and / or finishes and / or equipment, plant and machinery in the particular circumstances in which they are used. Such materials include but are not limited to:

a) High alumina cement in structural elements;

b) Marine aggregates or their derivatives where the chloride iron content by mass of cement exceeds the requirements of Table 4 of BS 5328: Part 1;

c) Aggregates where the drying shrinkage characteristics, when tested in accordance with BS 812: Part 120, exceed a value of 0.05%;

d) Aggregates for use in reinforced concrete which do not comply with BS 882 or with the provisions of BS 8110;

e) Water used in construction or manufacture which is not clean, fresh or free from chemical or organic impurities or does not otherwise comply with BS 3148;

f) Concrete where the total mass of the reactive alkali in the concrete mix exceeds the recommendations set out in the Concrete Society Technical Report No 30;

g) Woodwool slabs in permanent formwork to concrete or in structural elements;

h) Calcium chloride in admixtures for use in reinforced concrete or reinforced masonry construction;

i) Calcium silicate bricks incorporated within any load-bearing part of the structures, or other areas of the construction which are deemed to be load-bearing in any way;

j) Asbestos or asbestos-containing products;

k) Lead, or any material containing lead, which may be ingested, inhaled or absorbed, except where copper alloy fittings containing lead are specifically required in drinking water pipework by any statutory requirement or in architectural design features (e.g. weather flashings, radiation protection);

l) Urea formaldehyde foam, or materials which may release formaldehyde in quantities which may be hazardous with reference to the limits set from time to time by the HSE, at the time of incorporation in to the Works comprising the project;

m) Softwood used externally, except for non structural landscaping or in areas agreed with the Board (e.g. pressure treated pine decking);

n) Slipbricks;

o) Polyisocyanurate foam;

p) Polyurethane foam;

q) Extruded polystyrene other than low ozone depletion materials;

r) Other substances, which at the time of their incorporation into the project, have been designated by the Building Research Establishment and published in their Digest, as deleterious to health and safety or deleterious to the building fabric, including both substructure and superstructure, in the particular circumstances in which these substances are used;

s) Products associated with the destruction or depletion of tropical rain forest or threatened animal species;

t) Products or manufacturing processes which cause the emission of pollutants, armful radiation or ozone depleting chemicals, as identified in the Montreal Protocol;

u) Use of noxious substances including DoE “Red List” and EC “List 1” substances;

v) Materials which are generally composed of mineral fibres, either man-made or naturally occurring, which have a diameter of 3 microns or less and a length of 200 microns or less, or which contain any fibres not sealed or otherwise stabilised to ensure that fibre migration is prevented;

w) Lightweight or air-entrained concrete bricks;

x) Iberian roof slates; and

y) Fibrous boards, including MDF board, in any external construction work.

5.9.7 The Contractor shall obtain confirmation that all timbers are “Certified Wood”.

5.9.8 The Contractor shall certify at Completion that none of the materials, products or constructions listed has been used in the construction of the Works, or incorporated in them, other than where specific written consent from the Board has been obtained. The Contractor shall also notify the Board of any other material which may become designated as prohibited at any time after incorporation into the project, during the Defects Period.

5.9.9 The Contractor shall provide samples and prepare mock-ups of external cladding systems or building components as requested by and for the approval of the Board as follows;

a) Sample panel of curtain walling/external wall construction, nom 4m x 4m to include a sample window and any associated bris soleil or sun shading detail. To remain as reference sample until envelope complete;

b) All external finishes;

c) External and internal doorsets;

d) External and Internal windows and curtain walling, including all standard ironmongery;

e) Ironmongery;

f) Typical bed head arrangement for Adult and Children's Wards (could be part of mock up);

g) Nurses Station design and materials – mock up;

h) Floor, wall and ceiling finishes – samples and colour schemes indicating interior design strategy intent;

i) Light fitments;

j) Power, voice and data switches outlets etc;

k) Sanitaryware, taps outlets and IPS proposals, (part of a mock up);

l) All signage and Wayfinding proposals;

m) Lifts and other key M&E installations;

n) Wall protection and handrail systems;

o) Public art; and

p) Hard and soft landscape proposals and external works.

5.10 Energy Strategy

5.10.1 In accordance with best practice, the Contractor shall consider key design features including, but not limited to:

a) Use of passive ventilation where appropriate whilst minimizing mechanical cooling;

b) Use of heat recovery for exhaust air;

c) Use of redesigning processes and products to close the technical loop using recovered and bio-based materials;

d) Use of natural daylight into areas which require continuous illumination such as central/circulation areas;
e) Use of natural daylight through maximum use of lighting dimmer controls; and

f) Implementation of renewable energy sources – solar, wind, landfill gas, biomass and low impact hydroelectric, geothermal, low carbon heating systems and heat pumps.

5.10.2 The Contractor shall demonstrate that their proposals will effectively reduce water consumption below the average consumption data contained in SHTM 2027 for the type of accommodation being developed by the Board. The Contractor's proposals shall include estimated consumption for the Works in Litres/Bed/Day and measures that they propose allowing the Board to minimise consumption.

5.10.3 In the consideration of design for energy generation and use Bidders are requested to be aware of and consider possibilities around alignment with the "Sustainable Glasgow" initiative. The Bidders are to demonstrate such consideration and report on their findings. The contact point for Sustainable Glasgow is:

Richard Bellingham
Senior Research Fellow
Energy Policy
Fraser of Allander Institute
University of Strathclyde
richard.bellingham@strath.ac.uk

5.10.4 The Contractor shall submit a Mandatory Variant bid providing for a Maximum Temperature provision (26degC).

5.10.5 The specific energy requirements of the Board are detailed in Section 8.0 and Appendix M.

5.11 Fire Strategy

5.11.1 Fire safety in the proposed facility shall be controlled by Building Regulation, Health Technical Memoranda Firecode, and Fire Practice Notes, subject to approval by the Board's Fire Safety Advisor.

5.11.2 The Contractor must comply with the requirements of these publications, as a minimum standard, although it is recognised that alternative solutions based on a fire engineering approach may be more appropriate to the Contractor's design. Should the Contractor pursue an alternative approach it shall be their responsibility for meeting the minimum standards set out in the publications, fully satisfying the regulatory authorities of the appropriateness of its proposals and obtaining the necessary approvals.

5.11.3 The Contractor is required to prepare a Fire Safety Strategy document, including Fire Strategy drawings to demonstrate compliance with the relevant regulations. This document shall cover all aspects of fire safety, fire fighting and building management, including compartmentation and the ventilation implications of the Building.

5.11.4 The Contractor shall be required to ensure that all premises to be occupied by the Board have been appraised prior to occupation by competent persons appointed by the Board for compliance with Firecode and all Legislation are being met and shall provide the Board with an Annual Certificate of Firecode Compliance. For the avoidance of doubt the Contractor shall provide all fixed and portable fire fighting equipment to comply with statutory requirements and those of NHS Scotland Firecode. For the avoidance of doubt the Contractor requires to accommodate all fire fighting equipment which will be located within secure lockable containers housed in the wall construction, and operated by the same key throughout the development.

5.11.5 The Contractor shall provide a fully operational fire alarm system to meet the needs of the Works.

5.11.6 The specific requirements of the Board with regard to Fire Strategy are detailed in Appendix R.

5.12 Flexibility and Adaptability

5.12.1 The Contractor shall in the design of the Works consider opportunities which present themselves for the future expansion of Clinical and Non-Clinical Services.

5.12.2 The Contractor shall ensure, as far as is practical, that the Works structure and envelope, services, partitioning, ceiling, and flooring systems are consistent with a co-ordinated methodology which facilitates future flexibility for re-planning and change in the layout of departments, rooms, services outlets and equipment. In particular, it shall be possible to install or relocate fittings, fixtures, equipment and service outlets with minimum disruption to the use of the Works.

5.12.3 The design for the Works shall take full account of, but not be limited to:

a) Changes in technology, both clinical and non-clinical (e.g. systems of care and volume of work);

b) Building structures shall be designed by the Contractor to facilitate ease of alteration to the internal layout of the building, or to its plant, services or equipment, during the lifetime of the buildings. This shall be achieved by;

i. Selecting structural forms in which future builderworks holes for building services distribution, both vertically and horizontally (including ductwork), or equipment, may be cut simply and economically, minimising the installation of secondary framing;

ii. Providing knock out panels to permit the formation of holes not exceeding 150x150mm through suspended floors, adjacent to 50% of the internal columns on all floors. These knock out panels shall be positioned close to columns distributed across all areas of each floor;

iii. Designing the floors for imposed loadings that will permit the reallocation of space within the Works, so that each area of floor is structurally capable of supporting the imposed loads of offices, wards, corridors, general storage areas or waiting areas, together with their appropriate partition walls, finishes, ceilings, services and medical Equipment;

iv. Providing removable access panels within the structure, where these are required for the installation or removal of plant, services or equipment;

v. Internal room walls to be constructed such that they can be readily removed or altered i.e. the structure is not reliant on the walls for structural stability;

vi. Designing the structure of the buildings so that any future extensions can be constructed and brought into service with minimum disruption to the operation of the Works; and

vii. Designing plant space and riser space so that a future 25% services capacity expansion can be accommodated.

5.12.4 The structure and foundations of the buildings shall be designed by the Contractor to permit the construction in the future of further accommodation by extending the buildings horizontally or constructing further new buildings adjacent to them.

5.13 Facilities Management

5.13.1 The SoA and exemplar design have taken cognisance of the operational requirements and space/location requirements of the Board. The Contractor requires to comply with as well as design the Works to support and comply with the Board Policies (contained in Appendix P).

5.13.2 The specific requirements with regard to automatic material handling equipment (robotics), and the development of the Board's requirements and design in that regard, will be addressed during the competitive dialogue process. Details with regard to automatic material handling equipment is contained in Appendix M.

5.13.3 The Board shall have personnel integrated into the project development and the Works operations in relation to familiarisation and FM operations. The Contractor shall at all times liaise and support the integration and requirements of the Board in this respect at no additional cost.

5.13.4 The Contractor is required to provide space for maintainable, replaceable building services and plant.

5.13.5 The Contractor shall ensure that plant and equipment is suitably identified in line with the NHSScotland asset management system or equal and approved system/technologies.

5.14 Design Development

5.14.1 The bid period has specific bid return requirements (detailed in Volume 3 of the ITPD) with regard to written and drawn design information. Once the Contractor is appointed, the period to Full Business Case (FBC) approval comprises design development of the Contractor's Proposals in relation to the Hospitals, concurrent with the design and construction of the Laboratories. The design development to FBC will be fully programmed and demonstrable in a priced Activity Schedule forming an aspect of the bid returns from bidders.

5.14.2 The procedure for the review of design development will be agreed with the Contractor prior to the return of bids and the commencement of the design development.

5.14.3 The Contractor shall, as a minimum requirement, provide the information detailed in Appendix K (Design Development) as an output of Stage 2 (Hospitals Detailed Design to FBC). The satisfactory production of completed Appendix K information to the Board is one of the pre-conditions to the approval to proceed to Stage 3. More information relating to Stages 2, 3 and 3A are contained in Volume 1 of the ITPD.

5.15 Extended Defects Period

5.15.1 Due to a number of factors, including double-running/transition from other hospital sites, the Board are desirous of a defects period that provides management and physical benefits to the Project. In this regard a period in excess of the 'traditional' one year defects will be sought, with particular associated requirements in relation to:

a) Training and handover to Board personnel;

b) Correction times/periods for defects;

c) Seasonal commissioning;

d) Management activities; and

e) Performance requirements.

5.15.2 Volume 1 of the ITPD details further particular Extended Defects Period (EDP) requirements of the Board and identifies that this will form an aspect of Competitive Dialogue with bidders under the Commercial workstream.

5.16 Critical Failures

5.16.1 The Board require that the Works have inherent aspects of resilience to critical failures and mitigate operational interruptions.

5.16.2 In this regard, the Board have identified particular considerations and requirements that the Contractor shall adopt and develop as an aspect of bid return and design development. In addition to the resilience requirements of NHS Publications and the design requirements stated elsewhere in the Employer's Requirements, specific areas that the Board have prepared as exemplary are identified in Appendix X (Critical Failures).

5.16.3 The Contractor is required to comply with the provisions of Appendix X in their design, as well as provide for a developed strategy in relation to mitigation of critical failures in their bid return.

Section 6.0 Construction Phase Requirements

6.1 Site Logistics, Welfare and Board Accommodation

6.1.1 The Contractor is responsible for the provision of all temporary site accommodation/welfare and associated requirements, including the provision of car parking for site operatives during the design and construction stages. All such accommodation requires to be metered to provide readings of all utilities usage separately at any time.

6.1.2 No Contractor staff or personnel (including any sub-contractors, suppliers, supply chain members or other personnel providing any goods or services to the Contractor) are allowed to park on the Hospital Campus (except where attending as a patient or visiting/assisting a patient) during the Works.

6.1.3 The Board require the Contractor to provide dedicated site accommodation for the exclusive use of the Board and its representatives. This requires to be in the immediate environs of the Contractor accommodation on/adjacent to the Site to support joint working and meetings, but must facilitate segregation such that the Board area has a dedicated access for their use.

6.1.4 The Board require dedicated fully serviced accommodation including:

a) an open plan area with workstations, sockets and IT + telecoms connections for 10 persons;

b) an open plan area with workstations, sockets and IT + telecoms connections for 20 persons;

c) cellular offices with workstations, sockets and IT + telecoms connections for 5 persons;

d) a meeting room to accommodate 15 persons, serviced with sockets and IT + telecoms connections;

e) a suitably serviced room to accommodate a 1GB router;

f) secure wireless connectivity;

g) male, female and disabled toilet facilities;

h) a kitchen area with seating for 10 persons; and

i) adjacent dedicated parking for 30 cars.

6.1.5 The Contractor accommodation adjacent but separate from the Board accommodation will provide shared meeting rooms for 30, 20 and 10 persons separately as a minimum requirement.

6.1.6 The provision of site welfare and accommodation will form an aspect of Competitive Dialogue with the Board under the Logistics workstream. This workstream will also consider other logistics issues such as deliveries to site, site traffic and storage provision. The specific logistics, requirements, constraints and parameters of these aspects of the Project will be discussed and considered in detail to allow the generation of relevant information and potential solutions by bidders for the Board to consider and discuss. This will include proposals for the location of welfare, storage and parking solutions as well as layouts for site accommodation and welfare.

6.1.7 Further, specific requirements of the Planners to be met by the Contractor are identified in the Outline Planning document in Appendix D.1.

6.1.8 The Contractor shall be responsible for the cost provision and maintenance of all site signs and hoardings during the construction phase of the works. The requirements of NHS Scotland signage guidelines will require to be met by the Contractor, for the avoidance of doubt the key requirements are as follows;

a) Principal signage required at 3 no.key locations around the site as NHS Scotland signage guidelines;

b) Principal signage size will be no less that 6 x 4 metres;

c) NHS Greater Glasgow and Clyde identity prominently displayed (no less that 350mm in height) on hoardings enclosing entirety of site;

d) Graphics should be made from vinyl or other suitably durable material; and

e) All hoardings must be 2400mm high solid panels (metal or timber) with viewing panels painted white and maintained in good condition, free from graffiti and posters at all times.

6.1.9 All signage to include space for signage boards provided by the Board project manager for display and use – particular numbers and sizing of boards in this regard to be clarified to bidders by the Board.

6.2 Site Preparation Works

6.2.1 The Contractor shall be responsible for identifying and undertaking all preparation works necessary in order to make the Site suitable for the development of the Works. These works shall be undertaken prior to commencement of, or integrated with, the Stage 1 and Stage 3 activities.

6.2.2 For the avoidance of doubt, this obligation covers but is not necessarily limited to:

a) The identification of all protected trees to be removed from the Site by virtue of their condition and / or position in relation to the proposed Works. The Contractor shall be responsible for seeking the approval of Glasgow City Council for any such removal proposals, and the proposed mitigation / replacement strategy, in accordance with the conditions of Glasgow City Council's requirements and the associated Local Plan;

b) The identification and implementation of protective measures required to remaining trees, including their root systems, in accordance with BS 5837:2005, "Guide for trees in relation to construction";

c) In accordance with the Wildlife & Countryside Act 1981, any tree felling and shrub clearance shall be carried out outside the bird breeding season (March to August). Contractors shall take due cognisance of this requirement in any work programming. Where this is not possible a qualified ecologist shall be appointed to examine all potential breeding sites before any clearance takes place. If occupied nests are found, clearance and felling works shall cease until the nest is no longer in use. The contractor shall formally confirm to the Planning Authority in writing if clearance is in order following the ecologist's inspection;

d) Japanese Knotweed (JK) - Areas of the site have been the subject of contamination by Japanese Knotweed. The Board have embarked on a programme of eradication, details of which will be made available to the Contractor. The Contractor shall be

required to dig up any JK plant material and transport to a separately identified bunded area on the site (to be formed by the Contractor) where the JK shall be treated by the Board. The Contractor shall provide wheel washing provision for the vehicles utilised in the transportation and removal of JK (including Board vehicles involved in ultimate removal from the site);

e) The identification, decommissioning, removal and / or protection / relocation of live (and used), live (and redundant) or redundant (and disconnected) buried services crossing the Site;

f) The identification and removal of old foundations, drainage runs, basement structures and other below ground obstructions present following demolition of previous structures occupying the Site that are not removed by the Board (e.g. some steam duct lines);

g) Upon the finding of any medical waste or other contaminants on the site the Contractor shall advise the Board of such discovery for discussion and agreement of the necessary removal and/or protection steps to be taken; and

h) Diversion of the culverts.

6.2.3 Where relevant, the Contractor shall carry out all site preparation works (if necessary) in accordance with BS 6187:2000 “Code of Practice for Demolition” and the following:

a) Issue a method statement identifying the scope and methodology for undertaking the enabling works (if any), for approval by the Board in accordance with (TBC);

b) Break up and remove offsite all foundations, temporary accommodation, and other below ground and surface obstructions in accordance with, but not limited to, BS5528 “Demolition in open spaces”;

c) Decommission and / or break up and remove all redundant underground structures, chambers and redundant surface water and foul water drains, telecommunications, electric cables, gas mains, water mains and ducts within the Site. For the avoidance of doubt, this obligations includes for making safe all redundant works left in-situ, and sealing of voids, where left, against vermin;

d) Protect remaining services against damage or disruption; and

e) Minimise vibration and noise produced by the demolition works, and agree appropriate limits for such with the Board and neighbours.

6.3 Workmanship, Construction Accuracy & Tolerances

6.3.1 The Contractor shall ensure that general workmanship conforms to current revisions of BS 8000: – “Workmanship on Building Sites”, which covers typical building construction activities. Where specialist design proposals require construction activities outside the scope of this document, The Contractor shall propose specific quality procedures relating to these activities based on Good Industry Practice current at the time, as a minimum.

6.3.2 The buildings and the external works shall be designed and set out by The Contractor in accordance with BS 5606:1990 “Guide to Accuracy in Building”.

6.3.3 In some situations the tolerances identified in BS 5606 may not be appropriate for the particular elements or combination of elements in the Works. Where special levels of accuracy are required in relation to The Contractor’s proposals these shall be stated by The Contractor. The Contractor shall consider the recommended procedure set out in Figure 8, Section 4, Appendix B, of BS 5606.

6.3.4 The Contractor shall identify critical dimensions and setting out points on all its drawn information.

6.3.5 The Schedule of Accommodation contained in Appendix C of the Employers Requirements details the number and net floor area (as defined in paragraph 2 below) of the all relevant rooms or spaces in the Works, and the Gross Floor Area (as defined in paragraph 2 below) of the departments within The Works.

6.3.6 The actual floor area (as constructed) of a room or space may vary by up to 2% less or greater than the net floor area of the relevant room or space recorded on the Schedule of Accommodation (which actual floor area shall be measured on the same basis as that referred to in the definition of net floor area in paragraph 2 below) always provided that the proportion of the room remains generally unchanged. However the Contractor should note that the Single Bedrooms (as constructed) are required as a minimum to comply with the Schedule of Accommodation space requirements.

6.3.7 The net floor areas of rooms and spaces/departments and the other areas shown in the Schedule of Accommodation shall only be amended insofar as an Approved Project Managers Change Instruction varies such areas.

6.3.8 The Contractor will remain entirely responsible for procuring that the net floor areas of rooms and spaces/departments as shown in the Schedule of Accommodation applicable to the Works are capable of being achieved within the total gross floor area of the Works specified in such Schedule of Accommodation. The overall as built net floor area of the Works shall be not less than the total net floor area shown in the Schedule of Accommodation by more than1%.

6.3.9 The net floor areas of the individual rooms and spaces listed in this Schedules of Accommodation shall be calculated using a manually operated electronic measurement computer programme from a Computer Aided Design (CAD) system.

6.3.10 The number and identification of rooms listed on a department by department basis in the Schedule of Accommodation are as noted and identified on the 1:200 Departmental Layout plans identified in Appendix I.

6.3.11 For the duration of the Works the Contractor shall;

a) maintain computerised electronic versions of the Schedule of Accommodation and shall regularly update the areas shown in the Schedule of Accommodation from time to time in order to, inter alia, properly record the net floor areas and gross floor areas stated in all items of Design Development;

b) Afford the Board's Representative and Project Manager an opportunity to access and view such computerised Schedule of Accommodation at any time during normal working hours; and

c) As soon as reasonably practicable following finalisation of the 1:50 scale Room Layout Drawings, shall prepare and issue to the Board (in hard copy and electronic format) the final Schedule of Accommodation for the Works.

6.3.12 In connection with the above the following definitions apply;

a) Net floor area

In relation to a room the area bounded by the internal face of the walls or partitions enclosing the room. Or in relation to the space the area bounded by the internal face of

the walls or partitions and boundary(s) to any adjoining space(s). This area shall be measured elctronically from the approved plans that relate to the room or space. The net floor area is measured with deductions for:

i) column encasures

ii) pipe boxing

iii) service zones

b) for the avoidance of doubt the actual floor area may not be the net floor area of the room or space. The net floor area shall include the area of furniture, fittings and equipment within the room or space;

c) The net floor area for the department will be the sum of the individual net floor areas for the relevant rooms;

d) Gross floor area

Gross Departmental Area means the area bounded by the internal face of the external walls, centre line of partitions or boundary to adjoining departmental and/or communication space(s) that enclose that department. This area shall be measured electronically from the 1:200 scale Department Layout Plan that relates to the department. The Gross floor area shall include all elements of construction, spaces or rooms and circulation, but exclude:

i. service ducts

ii. lift shafts or other communication spaces contained within the boundary of the department.

e) Other areas means all other areas not included in a department, the balance of all service ducts, lift shafts, communication spaces (not included in department areas), corridors, plant rooms and the like measured electronically on the same basis as a Department from the 1:200 scale Department Layouts. The department areas are identified in Appendix I;

f) In relation to the Works, the Gross floor area is the sum of items d) and e) above; and

g) The departmental areas are identified in Appendix C.

6.3.13 Control of Noise & Dust

6.3.13.1 The attention of The Contractor is drawn to the provisions of Section 60 of the Control of Pollution Act 1974, with reference to the control of noise and dust in relation to any construction works. Where such works are adjacent to occupied property, The Contractor shall ascertain from the relevant authorities what requirements or restrictions, if any, shall apply, particularly in relation to Aspergillus. The restrictions may relate to the type of plant to be used, siting of plant, methods of working to be adopted, the hours of work permissible and may, in addition, impose a maximum noise level that must not be exceeded.

6.3.13.2 The Contractor shall make applications as early as possible to the utility company for the relevant connections in order to avoid the use of site generators.

6.3.14 The Contractor shall fit compressors, percussion tools and vehicles with effective silencers of a type recommended by the manufactures of the compressors, tools or vehicles but in any event to the requirements of BS 5228: Part 1: 1997 in accordance with Good Industry Practice.

6.3.15 Any equipment of a semi-permanent nature used by the Contractor, which produces noise on a regular basis, shall be positioned to cause the minimum disturbance to adjacent areas in agreement with the relevant authorities. The Contractor shall take all reasonable measures throughout the course of the Works to prevent the egress of water, dust, debris or any microbiological contamination out of the Site and into adjacent buildings. In particular, the Contractor shall establish any specific requirements for the control of dust identified.

6.3.16 The Contractor must comply with the specific planning requirements with regard to the control of noise and dust.

6.3.17 Continuity of Existing Services

6.3.18 The Contractor shall plan and execute the Works to ensure the Works activities do not affect the operational continuity of the Hospital Campus and the immediate neighbours to the Site.

6.3.19 The Contractor shall ensure that all reasonable safeguards are incorporated to ensure continuity of utility supplies to the Hospital Campus and adjacent users of the Site in-so-far as they may be affected by the Works. For the avoidance of doubt, utility supplies include, but are not limited to, gas, medical gases and air, electricity, water, sewerage and communications services.

6.4 Live Hospital Site

6.4.1 The Hospital Campus is a live hospital site, and as such will place restrictions on the Contractor in the construction of the Works.

6.4.2 As is noted in Section 6.1, above, logistics of the Site will form a workstream under the Competitive Dialogue to take place between the Board and the Contractor and this will extend to the consideration, discussion and agreement in regard to particular constraints, routes, timings and the like that will and will not be possible in the carrying out of the Works due to the 'live' nature of the environment.

6.4.3 Specific site constraints and access type requirements of the Hospital Campus and the Site have been considered in advance by the Board. These are contained in Appendix A and identify, amongst other issues, 'blue light' routes, FM delivery points and roadways that require to be unobstructed by the Contractor 24hours per day, every day.

6.4.4 The use of tower cranes on site by the Contractor may be restricted by the Board, Planners and the CAA. The Contractor is required to establish any relevant constraints and shall be responsible for implementation of craneage as permitted. This will include no oversailing of areas out with the Site and shall require the Contractor to demonstrate his management proposals in this regard, including modelling of swing-arcs and the like. Specific CAA requirement for aircraft warning lights are to be installed by the Contractor with regard to temporary and permanent structures. This will extend to, but may not be limited to, tower cranes, the flue to the new energy centre, other flues and chimneys to the Works;

6.4.5 In addition to the physical logistics and constraints in respect of the live hospital environment, the Contractor shall require to observe and comply fully with specific Board Policies for the duration of the Works when on the Hospital Campus or Site. The relevant Board Policies are listed in Appendix P.

6.4.6 The Contractor will require to carry out dilapidation surveys prior to the commencement of the Works, during the Works and at the completion of the Works – the extent, format and location of such to be agreed with the Board. Hard and electronic copies of all dilapidation surveys to be provided to the Board by the Contractor.

6.4.7 An aspect of the surveys to be carried out by the Contractor prior to the commencement of the Works is a full photographic survey of the boundary of the site, adjacent buildings, main roadways and approach roadways. Hard and electronic copies of all photo surveys to be provided to the Board by the Contractor.

6.5 Standardisation and Prefabrication (incl modular and off-site)

6.5.1 In order to take advantage of the repetitive nature of construction, maximise productivity and efficiency and minimise construction periods and waste, consideration shall be given to off-site prefabrication. It shall specifically be applied to repetitive elements e.g., sanitary assemblies, bathrooms or complex equipment such as plant assemblies.

6.5.2 The Contractor shall where reasonably practicable use standardised and / or pre-fabricated components and elements of construction which improve product quality, guarantee consistency of performance, optimise maintenance, and provide for reasonable flexibility for future changes, ease of replacement and value for money.

6.5.3 The use of standardised / prefabricated elements and building components to achieve good quality control, ease and speed of installation and flexibility for future use are welcomed. Their use shall not constrict the Board achieving clinical functionality and offer value for money. Items which may be considered include, bathroom pods, bedroom pods and other repetitive elements.

6.6 Room Mock-ups

6.6.1 The Contractor shall construct exemplar room mock-ups during the design development stage of the Works (Stage 2) for the hospitals. This will allow the Board's Representative to witness the quality standards of workmanship according to Good Industry Practice. Exemplar typical room mock-ups will be constructed for the rooms listed below in order to demonstrate important or unusual design elements of rooms i.e. integral bespoke furniture.

6.6.2 The Contractor shall provide mock-ups of the following rooms for use in the design development and approval process:

a) Single bedroom (standard) with en-suite (adult hospital);

b) Single bedroom with pull down bed for parents (children's hospital);

c) Single bed space (Critical Care) including all services and screening; and

d) Any modular accommodation proposed by the Contractor.

6.6.3 During the construction phase of the Works (Stage 3), the Contractor shall prepare a number of exemplar rooms as part of the Quality Control process, this is in addition to or a development of the mock ups noted above. The Contractor shall provide exemplar rooms of the following rooms:

a) Generic treatment room;

b) Single bedroom (standard) with en-suite;

c) Standard Outpatient Consulting Room;

d) Theatre suite;

e) Renal dialysis station and example of renal media panel;

f) Staff base; and

g) Reception point/counter.

6.6.4 These will establish minimum quality standards for the main areas and shall include main building services elements including lighting, heating, staff call, fire alarms, patient entertainment systems and all power and data accessories. This shall, where appropriate, include 3D computer illustrations.

6.6.5 The exemplar rooms to be prepared in the construction phase of the Works (Stage 3) shall portray doors, windows and the principal fitments and furniture. They shall allow definition of floors and walls, reflect the ceiling arrangements and identify the engineering services terminals. These shall be provided in a timely manner, to ensure they add value to the design development and approval process. The Contractor shall agree the content of and construct the exemplar mock-up rooms to a timetable to be agreed with the Board.

6.7 Witnessing and Testing

6.7.1 Witnessing and testing duties will be carried out by the Supervisor, all as detailed in relevant Clauses of the current NEC3 Engineering and Construction Contract, namely;

TITLE	DESCRIPTION	CLAUSE REFERENCE(S)	SUPERVISOR and CONTRACTOR DUTIES
Section 1	General	10.1; 11.2(6); 13.1; 13.3; 13.6; 14.1; 14.2; 14.4	10.1 – to act as stated in the contract and in a spirit of mutual trust and co-operation. 13.1 – to communicate in a form which can be read, copied and recorded. 13.3 – to reply to a communication within the period for reply 13.6 – to issue certificates to the Project Manager and Contractor 14.1 – Contractors duty to provide the works and be responsible for design. 14.2 – to notify the Contractor before delegating any actions or cancelling any delegation. 14.4 – replacement of Supervisor.
Section 2	Contractors Main Responsibilities	27.2; 27.3	Contractor's duties in relation to site access/action on legitimate instructions
Section 3	Time	n.a.	
Section 4	Testing and Defects	40.3; 40.5; 41.1; 42.1; 42.2; 43.1; 43.3	40.3 – to notify the Contractor of his tests and inspections before they start and afterwards of the results. 40,5 – to do tests and inspections without causing unnecessary delay to work or payment. 41.1 – to notify the Contractor of the results of the test or inspection on Plant and Materials required by the Works Information to be tested or inspected before delivery. 42.1 – instruct the Contractor to search for a Defect and to give reasons for searches which are instructed. 42.2 – to notify the Contractor of defects found before the Defects Date. 43.1 Contractor duty to correct Defects whether notified by Supervisor or not.

			43.3 – to issue the Defects Certificate at the later of the Defects Date and the last Defect Correction Period.
TITLE	**DESCRIPTION**	**CLAUSE REFERENCE(S)**	**SUPERVISOR and CONTRACTOR DUTIES**
Section 5	Payments	50.1	Project Manager duty in relation to assessing amounts due.
Section 6	Compensation Events	60.1(6)(8)(10)(11); 61.1	Actions/inactions of Supervisor in connection with Compensation Events.
Section 7	Title	70.1; 71.1	70.1 – Supervisor signing for marked Plant and Materials outside Works Area. 71.1 – Contractor action to allow Supervisor signing for marked Plant and Materials outside Works Area.
	Dispute Resolution	W1.3(5); W2.3(4)	Actions/inactions of Supervisor in connection with dispute Resolution Procedure.

6.7.2 It is envisaged that the Supervisor role will be carried out by a number of delegated parties – parties will be delegated by named Supervisor all as Clause 14.2, and are likely to comprise the following;

a) Civil & Structural Engineering;

b) Mechanical & Electrical Services;

c) Board Personnel (FM Services); and

d) Civil/M&E/Fabric Clerks of Works

6.7.3 In relation to the above duties as detailed under Section 4 – Testing and Defects, the Supervisor will carry out the following functions;

a) Design Compliance Check

i) Review the Design Data and detailed design information for general compliance with the terms of the Contract;

b) Procedure Review

i) review the quality assurance procedures proposed by the Contractor before work begins on the Laboratory and Hospital sites and review the operation of the procedures at regular intervals during The Works;

ii) regularly check to see whether the procedures employed by the Contractor are generally in accordance with the terms of the Contract; and

iii) review the proposed procedures and programmes for testing, commissioning and hand-over of The Works.

c) Construction Review

To the extent necessary to carry out the services referred to in Section 4 of the NEC3 Contract:-

i) enter the Laboratory and Hospital sites to monitor The Works to view the general state and progress of the Works to review overall workmanship, samples of goods and materials used or about to be used in The Works and to ascertain generally that the terms of the Contract have been and are being complied with by the Contractor;

ii) the frequency and timing of the Supervisor's visits are dependent on the progress of construction on the Laboratory and Hospital sites;

iii) regularly check to see whether the Contractor's work is being undertaken in accordance with Method Statements, Works Information and in a workmanlike manner;

iv) witness the testing, review and consider the suitability of all M & E and Building Management Systems, test results and certificates and other procedures within the Contractor's commissioning activities (all test results and certificates and other relevant commissioning and snagging paperwork to be collated by Independent Commissioning Engineer and provided to the Supervisor). In the event that a test carried out by the Contractor does not satisfy the terms of the Contract, check to see whether suitable remedial actions have been implemented and satisfactory results have been obtained on any re-tests;

v) generally inspect rectification works which have previously prevented the Supervisor from issuing a Defects Certificate; and

vi) undertake a visual inspection as appropriate of The Works before hand-over, to see whether the appearance is generally acceptable and in accordance with the terms of the Contract.

d) Reports

i) Report on the status of The Works following each site visit (and at any other time as appropriate) identifying any work that is non-compliant with the Contract; and

ii) Produce a weekly report following each site visit to ensure that the Employer is kept fully and properly informed on all aspects of the Works.

e) Familiarisation with Other Project Documents

i) The Supervisor shall familiarise itself with the Design Data and the Project Documents to the extent necessary to carry out the Supervisor role as provided for in accordance with the terms of the Contract;

f) Familiarisation with Quality Manuals

i) The Supervisor shall familiarise itself with and understand the Quality Manuals for the design and construction of the Project as set out in the Contract;

g) Monitoring and Inspection Procedure

i) The Supervisor and the Contractor shall agree an ongoing monitoring and inspection procedure, with reference to the Contract's key construction and

commissioning activities and the completed Works, and shall operate the same so as to ensure the efficient monitoring of construction and the efficient operation of activities;

h) Certification

i) The Contractor shall give the Supervisor (and Project Manager) sufficient notice in accordance with the Contract, of the date (the Completion Date") when it anticipates that Completion in respect of any Project Phase will be achieved;

ii) The Supervisor shall issue the relevant Defects Completion Certificate(s) in accordance with Clause 43.3 of the Contract; and

iii) As soon as practicable following the issue by the Project Manager of the Completion Certificate in respect of the final Project Phase to be completed in accordance with the Construction Programme, the Supervisor shall (provided that the Contractor has complied with its obligations to remedy any works listed in the Defects List) issue a final Defects Certificate.;

i) Snagging Items

i) The Contractor shall produce a Snagging Protocol detailing the process and individual party inputs, to cover the Phases of the Works. It is expected that this Protocol will be developed in conjunction with all interested parties e.g.:

- Board Representatives/Users/FM Team
- Supervisor
- Independent Commissioning Engineer
- The Contractor

and be provided at least six months prior to Phase Completion Date(s);

ii) The Contractor will provide for a computer/software based integrated snagging management system to be utilised during the snagging process, Provision to include all necessary peripheral equipment (PDA/Pens) and include for necessary training for Board Users and their advisors;

iii) The system will be managed and maintained by the Contractor, with appropriate access granted to project personnel; and

iv) Under the NEC3 Contract, there will be a "zero defects" approach to the project, and the Snagging Protocol will reflect this approach;

j) Notification of Completion of Defects

i) The Supervisor shall when requested by The Contractor attend any meetings convened about any part of the Works for the purpose of inspecting whether the Defects items applicable thereto have been remedied and/ or rectified; and

ii) The Supervisor shall issue a Defects Certificate, with copies of such notification also being issued, once all the works and other activities required in order to remedy and/or rectify Defects have been completed to the standards required by the Contract;

k) Miscellaneous

The Supervisor shall:

i) monitor the progress of the Contractor's design production;

ii) observe and monitor mock-ups, fabrication, construction and installation works on the Sites so as to satisfy itself that the Works comply with the Contract;

iii) audit the Contractor's Quality Assurance and the Contract control systems and procedures;

iv) issue Defect/Non-compliance notices and oversee the resolution of non-compliant matters;

v) review the commissioning of components of the Works in accordance with Contract/Works Information (as appropriate). The Supervisor will audit and monitor the commissioning work and report on the commissioning and testing of the Works;

vi) inspect and sign for marked up Plant & Materials outside of Works Area in accordance with Clauses 41.1/70.1/71.1; and

vii) hold regular meetings to discuss compliance and progress matters with the Employer and his Technical Advisors and the Contractor and attend meetings between the Employer and the Contractor as appropriate.

6.7.4 In order to assist the Supervisor in the performance of the above duties, the Contractor shall, as a minimum provide the following information;

a) the Accepted Programme;

b) copies of the Contractor's working programmes showing when the Contractor intends to carry out key activities whether off or on Site;

c) copies of all relevant documentation in connection with Plant & Materials outside of Works Area;

d) copies of such working drawings, schedules and specifications prepared for tender issue to the Contractor's sub-contractors as may reasonably be required by the Supervisor;

e) access to designs, drawings and documents register, technical and audit reports, consents, certificates and specifications to a level necessary to allow the Supervisor to assess compliance;

f) copies of correspondence relating to Building Control matters;

g) access to all quality control and quality assurance records, including procedures and method statements for the Project;

h) copies of all non-compliance reports generated by the Contractor and evidence of the clearance of the same;

i) copies of commissioning reports;

j) access to draft and final building/O&M manuals at the same time as the same are required to be provided to The Contractor under the Contract and otherwise as may reasonably be required by the Supervisor;

k) a copy of the health and safety plan and health and safety file and access to safety reports;

l) The Contractor's progress reports;

m) Any available completion check-lists prepared by the Contractor;

n) Change orders/requests prepared by the Contractor relating to the Works;

o) Copies of any reference or notice of intention to refer a dispute to the dispute resolution procedure in relation to the Works; and

p) The Defects List.

6.8 Commissioning and Handover

6.8.1 It is envisaged that the Contractor will appoint an Independent Commissioning Engineer to manage/programme/collate all M&E Testing and Commissioning processes, all as detailed in Appendix M, M&E3 Section 5 of the Employers Requirements

6.8.2 The Contractor will be required to provide the following in relation to the Commissioning and Handover process.

a) Final Commissioning Programme

i) A Final Commissioning Programme shall be prepared for each Phase to replace the Outline Commissioning Programme. The Final Commissioning Programme relating to the relevant Phase shall be prepared in consultation with the Board, in accordance with the requirement of the Completion Process;

b) Pre-Completion Commissioning

i) The Contractor's Pre-Completion Commissioning shall comprise the activities described as such in Table A Commissioning – Outline Commissioning Programme;

ii) The Contractor shall give written notice to the Project Manager/Supervisor and the Board's Representative of the commencement of The Contractor's Pre-Completion Commissioning in respect of each Phase when The Contractor (acting reasonably) considers that it shall commence The Contractor's Pre-Completion Commissioning in respect of the relevant Phase;

iii) The Contractor shall, at the times set out in the Final Commissioning Programme (and in relation to Manufacturer's Training, Induction Training and Building Familiarisation, when the Board Employees are made available for training by the Board pursuant to the Manufacturer's Training Programme, Staff Familiarisation Training Programme, Induction Programme and/or Staff Training Programme, as appropriate) undertake and complete The Contractor's Pre-Completion Commissioning in respect of the relevant Phase;

iv) The Board's Commissioning shall comprise the activities identified as such in Table A Commissioning – Outline Commissioning Programme;

v) The Contractor shall give written notice to the Board's Representative of the date upon which the Board shall be entitled to commence the Board's Commissioning in respect of each Phase, such notice to be given at least 1 month prior to the date when The Contractor (acting reasonably) considers that the Board should commence the Board's Commissioning in accordance with the Final Commissioning Programme; and

vi) The Board shall undertake and complete the Board's Commissioning for the relevant Phase, within the time period permitted within the Final Commissioning Programme, the Manufacturer's Training Programme, Staff Familiarisation Training Programme, the Induction Programme and/or Staff Training Programme (as appropriate) and shall comply with the Contractor's Site Rules and shall not cause any damage to the Works and/or Facilities or delay to the Works, in the carrying out of such activities;

c) Completion

i) The Contractor shall, no later than two months prior to the date that it anticipates (acting reasonably) a Phase will achieve the Completion Date, notify the Supervisor and the Board's Representative of such anticipated completion;

e) Post Completion Commissioning

i) The Contractor's Post Completion Commissioning shall comprise the activities identified as such in Table A Commissioning – Outline Commissioning Programme;

ii) The Contractor shall undertake and complete the Contractor's Post Completion Commissioning for the relevant Phase as follows:

- in relation to staff training, when Board Employees are made available to The Contractor for training in accordance with the Training Release Schedule, Induction Programme, Staff Familiarisation Programme and/or Staff Training Programme (as appropriate);

- in relation to clinical cleans, in accordance with the Final Commissioning Programme;

- The Board's Post Completion Commissioning shall comprise the activities identified as such in Table A Commissioning – Outline Commissioning Programme; and

- The Board shall undertake and complete the Board's Post-Completion Commissioning for the relevant Phase in accordance with the Final Commissioning Programme, Training Release Schedule, Induction Programme, Staff Familiarisation Programme and/or Staff Training Programme (as appropriate) and shall not cause damage to the Facilities in the carrying out of such activities.

e) Equipment and Training

i) The Contractor shall not clean, or move to enable general cleaning, items of equipment so identified by the Board unless in agreement with the Board's Representative. This shall include but not be limited to:

- physiological monitoring equipment;

- patient medical equipment when in use (e.g. respirators, air tanks, infusion pumps);

- department based computers, visual display units and radiographic equipment or machine consoles including anything bearing radiation or hazard Warning signs; and

- equipment that is plugged in for re-charging; and

ii) The Board shall ensure that any equipment of the Board that is transferred from an existing site is cleaned and disinfected prior to being transferred to the Facility.

OUTLINE COMMISSIONING PROGRAMME

Table A: Commissioning

Area comprised within a Phase	**Pre Completion Commissioning**		**Post Completion Commissioning**	
	The Contractor's Pre-Completion Commissioning	**Board Commissioning**	**The Contractor's Post Completion Commissioning**	**Board Post Completion Commissioning**
Rooms/areas which only contain the Contractor's equipment and movable equipment to be installed/commissioned by the Contractor in accordance with Appendix F (*Equipment*)	The Contractor to install Board Specialist Equipment as required in accordance with Appendix F2 (*Equipment*) The Contractor to commission and test equipment as required in accordance with Appendix F (*Equipment*) The Contractor to carry out Handover clean The Contractor to carry out Staff Familiarisation Training when Board Employees are made available to The Contractor by the Board for training, in accordance with the Staff Familiarisation Training Programme, Manufacturer's Training Programme,	Board to make available Board Employees for training in accordance with the Staff Familiarisation Training Programme, Manufacturer's Training Programme, Induction Programme and/or Staff Training Programme. The Board shall witness such testing as required by Approved Persons e.g.: • medical gas testing including provision of gas for such testing purposes • Clinical Cleaning in accordance with The Board's obligations as set out in the Completion Criteria of The Supervisor Contract.	The Contractor to train Board Employees made available for training pursuant to the Training Release Schedule, Induction Programme, Staff Familiarisation Training Programme and/or Staff Training Programme The Contractor to carry out Clinical Clean in accordance with the Commissioning Programme Clinical Clean of Board Equipment	Board to install, commission and test equipment as required pursuant to Appendix F (*Equipment*) and the Commissioning Programme Board to make available Board Employees for training in accordance with the Training Release Schedule, Induction Programme, Staff Familiarisation Training Programme and/or Staff Training Programme Board decant of patients to be carried out in accordance with the Commissioning Programme

Area comprised within a Phase	Pre Completion Commissioning		Post Completion Commissioning	
	The Contractor's Pre-Completion Commissioning	**Board Commissioning**	**The Contractor's Post Completion Commissioning**	**Board Post Completion Commissioning**
	Induction Programme and/or Staff Training Programme			
Rooms/areas which contain items of fixed equipment which are installed/commissioned by the Contractor and items of fixed equipment which are installed/commissioned by the Board in accordance with Appendix F (Equipment)	The Contractor fixed equipment installed, connected, commissioned and tested in accordance with Appendix F (Equipment) and the Commissioning Programme The Contractor to carry out Handover clean Completion of Works after Board Equipment installation The Contractor to insure Equipment in accordance with Appendix F (Equipment) The Contractor to carry out Staff Familiarisation Training when Transferring Board Employees are made	Board Specialist Equipment and fixed equipment installed, connected, commissioned and tested in accordance with Appendix F (Equipment) and the Commissioning Programme Board fixed equipment protected/mothballed until after the Phase Completion Date for the relevant Phase Board to protect and maintain the Board Equipment placed, and / or installed. Board to make available Board Employees for training in accordance with the Staff Familiarisation Training Programme, Manufacturer's Training Programme, Induction Programme and/or Staff	The Contractor to train Board Employees made available for training pursuant to the Training Release Schedule, Induction Programme, Staff Familiarisation Training Programme and/or Staff Training Programme The Contractor to carry out Clinical Clean in accordance with the Commissioning Programme Clinical Clean of Board equipment	Board to install, commission and test equipment as required pursuant to Appendix F (Equipment) and the Commissioning Programme Board to make available Board Employees for training in accordance with the Training Release Schedule, Induction Programme, Staff Familiarisation Training Programme and/or Staff Training Programme Board decant of patients to be carried out in accordance with the Commissioning Programme

Area comprised within a Phase	Pre Completion Commissioning		Post Completion Commissioning	
	The Contractor's Pre-Completion Commissioning	**Board Commissioning**	**The Contractor's Post Completion Commissioning**	**Board Post Completion Commissioning**
	available to The Contractor by the Board for training, in accordance with the Staff Familiarisation Training Programme, Manufacturer's Training Programme, Induction Programme and/or Staff Training Programme	Training Programme. The Board shall witness such testing as required by Approved Persons e.g.: • Medical gas testing including provision of gas for such testing purposes • Clinical Cleaning in accordance with The Board's obligations as set out in the Completion Criteria of The Supervisor Contract.		
ICT Board are responsible for installing hardware (server, PCs printers etc) and the Contractor responsible for infrastructure (containment, cabling, computer rooms etc)	The Contractor infrastructure installed, commissioned and tested in accordance with Employers Requirements (*ICT*)	Board hardware installed, commissioned and tested (Network, servers, critical clinical workstations) in accordance with Employers Requirements (*ICT*) and the Commissioning Programme	The Contractor to train Board Employees made available for training pursuant to the Training Release Schedule, Induction Programme, Staff Familiarisation Training Programme and/or Staff Training Programme The Contractor to carry out Clinical Clean in accordance with the Commissioning Programme	Board hardware installed, commissioned and tested in accordance with Employers Requirements (*ICT*) and in accordance with the Commissioning Programme Board to make available Board Employees for training in accordance with the Training Release Schedule, Induction Programme, Staff Familiarisation Training Programme and/or Staff Training Programme

OUTLINE COMMISSIONING PROGRAMME

Completion Process

A. Final Commissioning Programme

A.1 The Final Commissioning Programme shall be in accordance with the Outline Commissioning Programme and shall impose no greater or more onerous obligation on the Board or the Contractor than those set out in the Outline Commissioning Programme, unless otherwise agreed. The Final Commissioning Programme shall be developed by the Contractor in conjunction with and having consulted:

1.1.1 the Contractor;
1.1.2 the Board;
1.1.3 the Supervisor; and
1.1.4 the Board's FM Team.

A.2 The draft Final Commissioning Programme shall contain, amongst other things, full details of the following (including timing and sequence of events) for each Phase:

1.1.5 Contractor's Pre Completion Commissioning;
1.1.6 Board's Commissioning;
1.1.7 Contractor's Post Completion Commissioning;
1.1.8 the Board's Post Completion Commissioning; and
1.1.9 the Supervisor's Completion Criteria applicable to the relevant Phase.

A.3 The Contractor shall provide the Board with a draft of the Final Commissioning Programme relating to each Phase not less than 12 months prior to the anticipated Phase Completion Date.

A.4 If the Board has any comments on the draft Final Commissioning Programme, it shall issue comments on the draft Final Commissioning Programme to The Contractor on receipt of the draft Final Commissioning Programme by the Board from The Contractor, pursuant to paragraph 1.3 of this section (Outline Commissioning Programme).

A.5 If the Board raises comments on the draft Final Commissioning Programme in accordance with paragraph 1.4 of this section (Outline Commissioning Programme), the parties shall meet in good faith to discuss the terms of the Final Commissioning Programme), in order to agree the terms of the Final Commissioning Programme.

A.6 If the parties cannot agree the content of the Final Commissioning Programme, the matter shall be referred for determination in accordance with the Dispute Resolution Procedure.

A.7 Where any amendments to the scope and/or timing of the Board's Commissioning and/or the Board's Post Completion Commissioning are agreed or determined pursuant to paragraph 1.5 and/or 1.6 of this section (Outline Commissioning Programme) such change shall be treated as a Compensation Event.

OUTLINE COMMISSIONING PROGRAMME

Staff Familiarisation Training

B. Manufacturers' Training

B.1 The Contractor shall provide Technical Manufacturer's Training to such numbers of Board Employees as is agreed between the parties as being appropriate to allow for a cascade training regime, in accordance with the Manufacturer's Training Programme, which shall be submitted for agreement with the Board 4 months prior to a Phase Completion Date. The training shall be carried out prior to each Phase Completion Date, in accordance with the durations per system required pursuant to Table 1 (Outline Commissioning Programme), and in accordance with the Manufacturer's Training Programme. The Contractor shall only be responsible for those Board Employees directly trained by it. Systems requiring such manufacturer's training and thus more direct staff exposure to the manufacturer, are listed (but are not limited to those set out in) in Table 1 (Outline Commissioning Programme). The Board shall make available the relevant staff for training in accordance with the Manufacturer's Training Programme.

C. Building Familiarisation Training

C.1 Building Familiarisation Training shall be provided to each Board Employee by The Contractor to provide staff with general building and Site Familiarisation, general Site orientation and Building Health and Safety Induction. This shall be organised in small groups for half a day so that the impact on the existing sites is minimised, and subject to paragraph 2.2 below, shall comprise part of The Contractor's Post Completion Commissioning "Building Familiarisation"). The Building Familiarisation shall be programmed on a training plan, prepared by The Contractor and agreed with the Board not less than 40 Business Days of the anticipated Phase Actual Completion Date.

C.2 Board Employees at each Phase Completion Date shall receive this training leading up to their transfer, in a time period agreed with the Board and shall comprise part of the Contractor's Pre Completion Commissioning.

C.3 The Board shall make available the relevant staff for training in accordance with the Staff Familiarisation Training Programme.

D. Department Induction

D.1 Board Employees shall receive a department induction prior to the Relevant Service Transfer Date. This training (comprising two half days) shall be provided by the Contractor at the existing sites. Should the Board require this to be undertaken off site the costs associated with this shall be borne by the Board. This training shall cover department operational procedures and risk assessments.

D.2 The Induction Training shall be programmed and set out in a Training Plan with the Board Employees receiving the training in the period leading up to the Relevant Service Transfer Date. The Training Plan shall take into account the Board's responsibility for delivering the Services at the existing sites and shall therefore be designed to limit the impact on operational delivery and shall be prepared by The Contractor and agreed by the Board not less than 12 months prior to the anticipated Phase Completion Date.

D.3 The Board shall make available the relevant staff for training in accordance with the Induction Programme.

Table 1: Systems requiring staff direct manufacturers' training (to familiarise Transferring Board Employees with new plant and equipment)

Systems	CarPark Operative	Switchboard Operator	Receptionist	Helpdesk Operative	Security Officer	Porters	SoftFM Managers	SoftFM Supervisors	Energy Manager	HardFM Managers	HardFM Supervisors	Technicians	Electrical Craftspersons	Mechanical Craftspersons	Building Craftspersons	Maintenance Assistants	Administrators
Access Control	1				1		1	1									
CCTV (Operator)	1				1		1	1									
CCTV (Maintenance)										1	1	1	1				
Other Alarms	1	1	1	1	1												
Switchboard System		2	2	2													
Helpdesk System (Front Line process)		2	2	2													
Helpdesk System (Workload & record keeping process)							2	2		2	2						
Helpdesk System (Task Management & Feedback))						1	1	1		1	1	1	1	1	1	1	
Passenger Lift Evacuation (Competent Person)										1	1	1	1	1		1	
Passenger Lift Evacuation (SOP)	½	½	½	½						½	½	½	½	½	½	½	
Computer Aided Facilities Management System		2		2			2	2		2	2	2	2	2	2	2	
Asset Management System							2	2	2	2	2						
MiCAD									2	2	2	1	1	1	1		
Training in construction & operation of PPM									2	2	1	1	1	½	½	½	

Scheduling																	
AHU									1	1	1	1	1	1			
Airtube (Operator)						½	1	1			1	1	1	1			
Airtube (Maintenance)										1	1	1	1	1			
Systems	**CarPark Operative**	**Switchboard Operator**	**Receptionist**	**Helpdesk Operative**	**Security Officer**	**Porters**	**SoftFM Managers**	**SoftFM Supervisors**	**Energy Manager**	**HardFM Managers**	**HardFM Supervisors**	**Technicians**	**Electrical Craftspersons**	**Mechanical Craftspersons**	**Building Craftspersons**	**Maintenance Assistants**	**Administrators**
Auto Doors/Barriers										½	½	½	½	½	½		
BMS									2	2	2	2	2	2			
BMS Access Control (Operator)	1				1		1	1		1	1						
BMS Access Control (Maintenance)										2	2	2	2	2			
BMS Technology maintenance/trouble shooting									3	3	3	3	3				
BMS Technology Input/output Alarms & Scheduling									2	2	2	2	2				
BMS Technology - Report writing									2	2	2						
BMS Energy Management & metering functions									3	3	3	1	1	1			
Boilers MTHW									1	1	1	1	1	1			
Chillers/Local DX Units									1	1	1	1	1	1			

CHP									1	1	1	1	1	1			
Fire Systems	1	1	1	1	1					2	2	2	2	2	2		2
Generators									½	1	1	1	1	1			
Systems	**CarPark Operative**	**Switchboard Operator**	**Receptionist**	**Helpdesk Operative**	**Security Officer**	**Porters**	**SoftFM Managers**	**SoftFM Supervisors**	**Energy Manager**	**HardFM Managers**	**HardFM Supervisors**	**Technicians**	**Electrical Craftspersons**	**Mechanical Craftspersons**	**Building Craftspersons**	**Maintenance Assistants**	**Administrators**
Refrigeration									1	1	1	1	1	1			
Security Systems (Operational)	1			1	1		1	1		1	1						
Security Systems (Maintenance)										1	1	1	1				
Renewable Energy resources – where provided				1		1			3	3	3	3	3	3	1	1	
Decontamination – RO Plant operation & maintenance.				1		1			1	1	1	1	1	1	1		
Sterilisers/Washer Disinfectors										1	1	1		1			
Switchgear HV											1	1					
HV infrastructure and operation											1	1					
Switchgear LV										1	1	1	1				
LV infrastructure and operation										1	1	1	1				

UPS/Battery Cubicles										½	½	½	½				
MGPS infrastructure and operation										1	1	1		1			
Robotics							1			1	1	1	1				
Nurse Call											1	1	1				

6.8.3 Handover Procedures

6.8.3.1 The Contractor's Commissioning Programmes to include for sign off of relevant Testing and Commissioning elements by other parties, e.g.:

a) Board Approved Parties

i) Fire Officer;

ii) Control of Infection Officer;

iii) Radiation Protection Officer; and

iv) Medical Gases Officer;

b) Supervisor; and

c) Independent Commissioning Engineer

6.8.3.2 It will be the Contractors responsibility to programme the above sign off requirements to ensure relevant Completion Date achieved.

6.8.3.3 In connection with the above, the Supervisor will expect the Contractor to provide the following documentation in connection with Handover/Completion;

6.8.4 General

6.8.4.1 General Requirements

The Contractor shall provide such labour, materials, stores, test equipment, tools, instruments, apparatus and assistance as are reasonably required for the purpose of the inspection by the Supervisor and shall be responsible for the provision of such electricity, fuel, water and other consumables and materials as may be reasonably required for the same. Invitations shall be furnished to the Board, its Project Manager and the Supervisor to witness such works inspections, testing and commissioning activities as the Board deems necessary. Adequate notice of testing shall be given.

6.8.4.2 The Contractor shall ensure that major items of plant shall be tested at the works for both performance and safety prior to dispatch. Major items of plant shall include, but not be limited to, the following: boiler plant, generators, chillers/refrigeration machinery, large pumps, HV/MV switchgear, large pressure vessels etc. The Contractor shall arrange to witness all factory testing and shall furnish the Board, its Project Manager and the Supervisor with the opportunity to witness all factory testing, and sign off marked items of Plant and Materials. The Board, its Technical Advisors and the Supervisor shall be given at least fourteen days notice of such testing.

6.8.5 Works inspection, testing and acceptance activities

6.8.5.1 Completion Criteria

6.8.5.2 The Contractor shall demonstrate that the following criteria have been achieved:

6.8.5.3 The building is structurally complete, all external fabric is complete and internally all the finishes are complete in accordance with the ADB Room Data Sheets;

6.8.5.4 All incoming Utilities including all associated back up systems is tested, commissioned and operational;

6.8.5.5 The Mechanical and Electrical plant and systems operate satisfactorily in accordance with the specified design criteria, and the ADB Room Data Sheet;

6.8.5.6 The Building Management System is complete, tested, commissioned and operational;

6.8.5.7 All furniture and equipment shown on the Loaded Room Layout drawings (as supplemented by Appendix F (Equipment) have been installed (and commissioned if appropriate);

6.8.5.8 The Board has been supplied with keys, access codes, swipe cards and other access devices for access to and within the Works;

6.8.5.9 Safe access and egress to and within the relevant Laboratory and Hospital sites has been established;

6.8.5.10 The relevant Laboratory and Hospital sites shall be free from all surplus materials, plant and equipment that could materially affect the completion of the Tests on Completion and shall comply with the standards and requirements of Section 3;

6.8.5.11 All internal and external drainage systems are installed and are operational;

6.8.5.12 External works as appropriate have been completed and are available for use by the Board;

6.8.5.13 All hard-landscaped external works, including roads, car parks, pavements and boundary walls/fences are complete and available for use by the Board;

6.8.5.14 Lift and Escalator systems are complete, commissioned and operational;

6.8.5.15 All building directional departmental, general information and room numbering signage as indicated within Employers Requirements/the Contractor Proposals and/or Reviewable Design Data and necessary to all the operational Services to commence has been provided and installed. This includes both internal and external signage;

6.8.5.16 The Fire Management Strategy has been finalised, The Contractor to complete and submit fire safety risk assessment in accordance with the Fire (Scotland) Act 2005;

6.8.5.17 The Fire Detection, Alarm and Suppression Systems are complete, tested commissioned and operational

6.8.5.18 All External Lighting is installed, tested, commissioned and operational;

6.8.5.19 All IT and Communication Systems are complete, tested, commissioned and operational;

6.8.5.20 All Security and Surveillance Systems, Access Controls and Call Alarms are complete, tested, commissioned, operational and available for use by the Board;

6.8.5.21 Acoustic Testing has been completed to prove compliance with the Employers Requirements and the Contractor Proposals;

6.8.5.22 The medical gas and vacuum system is complete, tested, commissioned and witnessed by NHS Greater Glasgow and Clyde's Chief Pharmacist and Medical Gases Approved Person;

6.8.5.23 A proving and training period for the Board has been offered by the Contractor, and subject to the Board making themselves available within agreed timescales, this training has been completed;

6.8.5.24 A proving and training period for the Service Provider has been completed;

6.8.5.25 The Contractor has provided all documentation to the Supervisor in accordance with the Supervisor's Contract and Section 4; and

6.8.5.26 A draft hard copy and electronic format of the relevant As Built Specification Documents, Operational & Maintenance Manuals and Health & Safety Files for the Facilities (containing, as a minimum, all the testing and commissioning information so far as it is reasonably practicable) have been issued by the Building Contractor.

6.8.6 Clinically clean

6.8.6.1 On completion of the Works, The Contractor shall provide the Facilities as "clinically clean" in accordance with NHS Scotland National Cleaning Services Specification and to the satisfaction of the NHS Greater Glasgow and Clyde's Control of Infection Officer.

6.8.7 Testing and commissioning documentation

6.8.7.1 All documentation associated with the Tests on Completion shall be collected and collated by the Contractor/Independent Commissioning Engineer and shall be presented as a bound, indexed document to the Board. The following list is indicative of the test documentation expected to be provided:

Test Documentation
Building Warrant Completion Certificates
Evidence that all Conditions attached to the detailed Planning Consent have been discharged to the satisfaction of the Local Authority.
Roads Construction Consents
Design Warrants
Flushing Cleaning and Chlorination test certificates
Boiler Plant Manufacturers Factory Test and Commissioning Sheets in accordance with CIBSE Commissioning Code B, including all steam systems
Ductwork Systems pressure test and volume flow rate Certificates
Laundry Equipment Commissioning Certificate
Kitchen Equipment Commissioning Certificate
Electrical Installation Completion and Inspection Certificates in accordance with BS 7671 and

Test Documentation
NICEIC requirements
Robotics Equipment Commissioning Certificate
Lighting and Power Certificate of Test
Fire and Intruder Alarms Commissioning Certificates, including intruder detection and alarm, access control system(s)
General Electrical Earth Loop and Insulation Resistance Test Sheets
Testing of all hot water service thermostatic mixing valves (TMV's) in accordance with BS6700 and tests to comply with HSE Document L8 and HGN 'Safe Hot Water and Surface Temperatures
Emergency Lighting Completion and Test Certificates
Certificate of Compliance/Testing of Radiation protection
Security Systems Commissioning Certificates
Certificate of Soundness Testing of Gas Installation
Gas Pipework Pressure Test and Purge Certificates
Medical Gas Pipework Pressure Test and Purge/Commissioning Certificates
Fire Suppression System Certificates (in accordance with BS6266 and tests to comply with CIBSE Guidance E)
Fire Alarm Sound Record Sheets
Lighting Calculation Sheets and Lux Level Test Results (Internal & External)
Machine (Generator/UPS/CHP etc) Specialist Commissioning and Factory Test Sheets
Acoustic Test sheets (in accordance with BS 5821)
Lift Commissioning in accordance with BS EN 81 and Factory Test Sheets
Lightning Protection Risk Analysis and Test/Commissioning Sheets
Boiler Plant Manufacturers Factory Test and Commissioning Sheets in accordance with CIBSE Commissioning Code B
Works pressure test certificates for all pressure vessels
Mechanical Pipework Systems Pressure Tests
A/C Equipment Performance Tests
Condensate Clearance Tests for A/C Equipment
BMS/EMS Tests/Commissioning Records in accordance with CIBSE Commissioning Code C
Air Distribution Systems in accordance with CIBSE Commissioning Code A
Water Systems (heating & domestic water) in accordance with CIBSE Commissioning Code W
Legionellae Testing (to include an organic check on the incoming mains) within tolerances given in HSE ACOP test sheets
Domestic water systems bacteriological quality test sheets
Rainwater harvesting systems test and completion and bacteriological quality test sheets
Plant (Calorific, Treatment etc.) Specialist Commissioning and Factory Test Sheets
Nurse Call Test Certificate
Disabled Toilet Alarm Test Certificate
Fire Alarm Test Certificate
CCTV and Access Control Test Certificate
TV Aerial Certificate
Patient Entertainment System Certificate
Telephone Cabling Test Certificate
ICT Cabling Test Certificate
Induction Loop Test Certificate
Pipeline Pressure and flowrate Test Certificates including drainage and all steam systems
Steam boiler/generator test factory test and commissioning certificates in accordance with

Test Documentation
CIBSE Commissioning Code B
Ground Source Heating installation pressure and Test Certificates
Chiller factory test and commissioning certificates in accordance with CIBSE Commissioning Code R
Chemical clean and inhibitor dosing certification to heating/chilled water systems
Ductwork physical and bactericidal cleaning certification

Section 7.0 Architectural Requirements

7.1 Masterplan

7.1.1 The Masterplan for the New South Glasgow Hospitals has been developed in consultation with various stakeholders, including User Groups, Architecture + Design Scotland, the Carbon Trust, Strathclyde Passenger Transport, Civil Aviation Authority (CAA) and Glasgow City Council Planning Department. The aims of the Masterplan are to achieve a clarity of spaces and routes within the existing Southern General Hospital Site.

7.1.2 The proposed Masterplan design seeks to improve the entrances to the site, traffic flows around the site and enable all visitors to the new hospitals to orientate themselves quickly with the campus. A new main boulevard entrance will be created from Govan Road, which will border the new Laboratory, FM & Mortuary and Energy Centre Site. However, the traffic flows have been separated and all service access to this area will be off Hardgate Road. Public Access and drop off via private car become immediately clear on the approach to the building and the traffic flows allow drop off adjacent to the relevant entrances and then onwards to the respective car parking zones. A new transport 'hub' located centrally on the site provides direct and sheltered access to the new hospital entrance. This hub will allow 'Fastlink', taxi and private car drop off within immediate walking distance to the entrances. Public Bus routes will remain on the existing road network with additional bus stops being provided at key entrances.

7.1.3 Blue Light traffic routes into and within the site are clearly identified and provide the quickest access points from whichever direction the ambulance approach.

7.1.4 Upgrading and Replacement of car parking provision has located 4 new major car parks strategically around the site:

a) Adult Hospital x 2nr;

b) Children's Hospital; and

c) A&E Entrance

7.1.5 Pedestrians and cycle routes through the site and the interaction with the building have been developed to provide clear designated routes to the new main hospital and surround buildings, while the punctuation of the site with pockets of landscaped spaces supplement the main park area situated immediately in front of the new main hospital entrance. The 'green space' within the campus is designed to provide a functional retreat for patients, visitors and staff.

7.1.6 As the final design develops within the parameters of the Masterplan, there is a requirement to update the Development Control Plan for the entire Southern General Site to identify future uses, expansion and redevelopment.

7.1.7 The Masterplan presents the Board's vision of the New South Glasgow Hospitals on the Southern General Hospital Site and requires to be followed and implemented by the Contractor.

7.2 Exemplar Design

7.2.1 The exemplar design has been developed in consultation with the Board and User Groups. The exemplar design is intended to reflect these discussions and provide an advanced level of briefing that will enable the Contractor's response at the end of the bid period to be more advanced in terms of understanding of the Board's and User's functional, clinical and quality requirements. As well as reflecting the requirements of the Clinical Brief the design exemplar is also intended to represent a design quality benchmark against which the Contractor's proposals will be measured. The exemplar demonstrates the aspirations of the Board in terms of the graphical and technical representations of the Contractors.

7.2.2 Whilst the exemplar design has not been developed with the intention of constricting the Contractor's proposals to a particular solution nor has it been developed in order to stifle innovation or creativity, it should be noted that the functional relationships indicated in the exemplar does represent the culmination of a process of detailed consultation with the Board and Users to determine their requirements and as such it is not expected that the Contractor will require to revisit the functional relationships or design principles as set out in the following exemplar information;

a) 1:500 departmental relationship drawings for all levels of each building indicating functional relationships, entrances and main circulation routes (Appendix H);

b) 1:200 departmental drawings for 7 no. key departments in the Adult's Hospital and 4no. key departments in the Children's Hospital indicating room adjacencies, circulation layouts, corridor widths, entrances and links to other departments/facilities. (Appendix I);

c) 1:50 Room Layout Drawings indicating clinical functionality, room size and shape and compliance with ergonomic data. (Appendix J); and

d) ADB Room Data Sheets (Appendix E).

7.2.3 Described in more detail below are the key features of the exemplar design which will require particular consideration by the Contractor;

a) Adult and Children's Hospital Identity;

b) Podium;

c) Ward Tower;

d) Main Entrance; and

e) Atrium including retail space;

Adult and Children's Hospital Identity

7.2.4 The exemplar proposes a single overall building footprint subdivided into the Adult and Children's facilities, creating two distinct but adjoining hospitals. This is in acknowledgement of the benefit to be exploited through the co-location of the Adult and Children's Hospitals, a great deal of consideration has been given to identifying these in the brief and in the design of the two hospitals.

7.2.5 It is important to stress that the Children's Hospital will operate as a hospital in its own right with its own clinical staff and management, with some shared facilities. It is therefore a requirement of the brief for the Children's Hospital not only that there should be an appropriate degree of clinical and patient separation between the two hospitals but also that the distinct identity of the Children's hospital shall be maintained both externally and within the patient and public areas. This requirement is expressly reflected in the exemplar design which indicates two separate entrances for the Adult's and Children's Hospital.

Building Typologies

Podium

7.2.6 A significant proportion of the overall building footprint is dedicated to integrated acute facilities which will be housed in the 3 storey podium. The podium will house such departments as Operating Theatres, Radiology, Critical Care and Outpatients Departments. The key drivers behind the location of departments are the necessities of co-location for functionality along with appropriate public/private zoning of the facilities. For example Outpatients and Accident Emergency Departments are located on the ground floor towards the external boundary of the footprint to ensure an appropriate level of public accessibility is achieved while the core of the footprint is reserved for private treatment and diagnostic areas such as Radiology.

7.2.7 Departments located in the podium;

a) NSGH Main Entrance and Discharge Lounge;

b) NSGH Emergency Department;

c) NSGH Rehabilitation;

d) NSGH Radiology;

e) NSGH Acute Assessment;

f) NSGH Critical Care;

g) NCH Main Entrance;

h) NCH Emergency Department;

i) NCH Rehabilitation;

j) NCH Radiology;

k) NCH OPD;

l) NCH Cardiology;

m) NCH Inpatient Wards;

n) NCH DCFP;

o) Operating Theatres;

p) Endoscopy;

q) Aseptic Suite;

r) Renal Dialysis;

s) Nuclear Medicine;

t) Medical Physics;

u) Dining Area;

v) Retail and Café; and

w) Pharmacy.

Ward Tower

7.2.8 Located above part of the footprint of the podium will be the 13 storey 4-wing ward tower providing single bedroom ward accommodation across a range of departments including Renal, Vascular, Haemato-Oncolgy etc. In total the facility includes the provision of 1,109 adult and 240 children's beds. While not all bed spaces noted will be accommodated in the ward towers, the ward tower typology was developed as being the most appropriate and achievable method by which these bed numbers could be accommodated. The towers are positioned and orientated to provide best use of views across the site, provide appropriate levels of natural light and to achieve patient privacy by preventing overlooking from other ward accommodation.

7.2.9 Tower Wards include;

a) Generic wards;

b) Haemo-oncology wards;

c) Vascular wards;

d) Renal wards;

e) Dermatology; and

f) Stroke;

Main Entrance

7.2.10 There are 6 staff/patient/visitor entrances on the ground floor;

a) NSGH Main Entrance;

b) NCH Main Entrance;

c) NSGH 24 Hour/Staff Entrance;

d) NCH 24 Hour/Staff Entrance;

e) NSGH Acute Assessment Entrance; and

f) NSGH / NCH Emergency Department Entrance

7.2.11 At each of the above entrances a robust glazed canopy will require to be incorporated in order to provide shelter from the elements for staff, visitors and patients and to assist in the prevention of wet contamination of flooring within the building. Entrance canopies will require to be sized appropriately to accommodate ambulances as necessary. A methodology for the maintenance and cleaning of the canopies will also be required.

7.2.12 The ambulance entrance of the Emergency Department (ED) will be expected to have the ability to be converted into an external decontamination facility. This would include the requirement to incorporate roller screens as part of the ambulance canopy and multiple water mixer points to allow shower attachments. The area will also require the ability to isolate drained water under decontamination procedures.

7.2.13 The main entrances to the Adult's and Children's Hospitals will be expected to have a light, spacious and welcoming atmosphere and the main entrance shall be immediately apparent to all users. The main entrances for the Adult's and Children's Hospitals should reflect in form, scale, space and use of materials the aspirations and design quality promoted by the Board resulting in a meaningful expression of the Board's intent for the facility; that is to deliver first class healthcare to the local population and provide a focal point for community activities and education welfare. The entrances should demonstrate the required benchmark of architectural design quality while at the same time incorporating practical considerations, for example the provision of appropriate shelter and adequate accessibility of entrances.

7.2.14 The façade of the main entrances should be fully glazed for the full height and width of the entrance area including automatic sliding entrance doors to allow views in and out of the main entrance and reception. It is important that large glazed areas such as this should be clearly identified as such for safety purposes and must be safety glass. Solar shading devices should be incorporated as necessary to achieve the Board's stated Sustainability and Energy Targets. The size and numbers of automatic entrance doors should be sufficient for the expected number of users to pass comfortably and safely through them. A glazed canopy should be incorporated in order to provide shelter across the full width of the entrance at a height that provides appropriate shelter while also coordinating as required with the façade design. The structure and glass forming the canopy shall be robust and shall incorporate all appropriate standards of security, and where reasonably practicable, limit the potential for exposure to crime and vandalism.

7.2.15 Entrance lobbies should be provided as Section 7.5.2 including the requirement for a minimum of 6 metres of barrier matting to prevent the ingress of dirt and wet contamination to flooring. Any lobby enclosure provided requires to be fully glazed to allow users to proceed safely and confidently.

7.2.16 Once inside the building the reception areas and information points are key to orientation. The tone of a building is set by the entrance and reception to the building, therefore the Contractor's design should achieve a balance of openness with patient confidentiality and staff safety, resulting in reception areas skillfully combining a friendly welcome with low-key oversight of public areas. The expected quality of the main entrance spaces should be akin to a large hotel foyer, this expectation should be reflected in the choice of quality robust materials for flooring, walls, ceilings, balustrades etc. The quality of the space should also be enhanced by interesting shapes and forms, lighting techniques and the incorporation of art.

7.2.17 The reception area and main entrance generally will be busy places, both in terms of footfall and hours worked. Materials, finishes and furnishing therefore need to be robust, as well as attractive. The Contractor's design should cater for well selected, fit for purpose furnishings which will complement a clear approach to design. One such component of the main entrance design is the flooring, it is vitally important that the floor finish in the main entrance area should combine robustness and attractiveness with slip resistance. A material such as natural stone/ceramic tiles which have a high micro-surface roughness should be used.

7.2.18 One of the most important features of the reception area is the reception desk which should be close to the entrance and should be an open well lit counter/desk with a feature or identifying sign at high level. The reception counter requires to reflect and enhance the quality of the surroundings in terms of form, quality of materials and lighting.

7.2.19 In order to provide staff, patients and visitors with access to information especially at the key points of entry to the Building it is the Board's intention that Contractor's should incorporate electronic information points utilising touch-screen technology in addition to the manned reception points and stations and the PA system. These information points should present information (in a variety of languages) on the hospital for orientation and wayfinding purposes along with information in relation to the public transport hub which should be adjacent to the main entrance giving real time information on bus/fastlink timetables. The Contractor will be required to provide a clear strategy for the provision of these information points.

7.2.20 The main entrance requires to incorporate well planned waiting rooms which can help to relax patients, thereby reducing fear and increasing confidence. Upholstered seating set out in the style of a hotel foyer with spacious waiting should be the goal, these areas allow patients, carers and visitors to relax, chat, wander or simply enjoy the space and any views afforded. This is especially valuable where the patient may be accompanied by friends or relations.

A Changing Places facility which combines a toilet, shower and changing room for use by people with complex and multiple disabilities will require to be located at the Adult and Children's entrances. The space should be provided in accordance with the requirements of BS8300:2009 item 27 and should incorporate an adjustable changing table and fixed track hoist system.

7.2.21 A requirement throughout the hospital especially within entrance areas shall be to incorporate appropriate standards of security, and where reasonably practicable, limit the potential for exposure to crime and vandalism. Guidance is provided in HFN05 -"Design against crime-a strategic approach to hospital planning".

7.2.22 Atrium including retail space

a) The exemplar indicates a linear atrium linking the main entrances of the Adult's and Children's Hospitals. This concourse performs a number of different functions;

b) Provide a link between Adult and Children's Hospitals;

c) Provide clear horizontal and vertical links to all areas of the hospital facilities with the incorporation of stairs, lifts and escalators as necessary;

d) Provide a clear route for patients, staff and visitors to frequently attended departments such as the outpatient's department;

e) Provide access to pharmacy;

f) Provide access to retail facilities such as the cafeteria to allow users to purchase drinks, food and to consume them in a pleasant and relaxing environment;

g) Continue the quality of the main entrance spaces which will be reflected in the choice of quality robust materials for flooring, walls, ceilings, balustrades etc; and

h) Provide opportunities to incorporate art, lighting techniques and tv/video display screens to enhance the quality of the space and provide a welcome distraction.

7.2.23 The multi-level linear atrium space will be formed between the outpatient department and the remainder of the departments contained in the podium such as day surgery and radiology. The atrium will contain link bridges, escalators, lifts and stairs providing all vertical and horizontal communication links across the void space providing the necessary connections between departments. The lifts should be fully glazed to all sides providing views over the atrium space for the purposes of orientation. A high level of finish will be expected for all stairs and balustrades, any handrail, barrier or guarding to stairs or corridor links should be glazed to allow views for children and those in wheelchairs. The roof to the atrium should be fully glazed to provide a light, bright welcoming environment. Solar shading devices should be incorporated as necessary to achieve the Board's stated Sustainability and Energy Targets. The atrium will also provide fully glazed areas of façade to courtyards where available, to allow users views out to external landscaped courtyard spaces. The expected quality of the atrium concourse space should be akin to a high quality shopping mall and continue the quality of the main entrance. This should be reflected in the choice of quality robust materials for flooring, walls, ceilings, balustrades etc. The quality of the space should also be enhanced by interesting shapes and forms, lighting techniques and the incorporation of art.

7.2.24 The form of the atrium shall clearly express the individuality and special nature of parts of the Works including the retail facilities, yet the parts should harmonise with the facilities as a whole. The Contractor should give particular consideration to the architectural composition and expression of the form within the atrium which should reflect an identifiably distinct character for the Adult Acute and Children's Hospital as befits the nature of the patient groups.

7.2.25 The atrium also provides opportunities for retail facilities including pharmacy and cafeteria facilities, these areas should be clearly expressed.

Helipad

7.2.26 The Contractor will require to provide a rooftop Helipad and the associated services, access requirements and safety facilities in full compliance with the following guidance;

a) HBN 15-03 – Hospital Helipads;

b) British Helicopter Advisory Board – Helicopter Site Keepers Guidance Document; and

c) Structural Design Criteria - ICAO Heliport Manual

7.2.27 The Helipad will also require to be provided in line with all requirements of Glasgow City Council Planning Department including the following requirement;

a) A detailed noise and environmental assessment regarding the relocation of the heliport landing area shall be submitted to the Planning Authority for its written approval prior to its siting and operation. The Contractor requires to consult the Director of Land and Environmental Services, Public Health Unit concerning the methodology and approach to any assessment.

7.2.28 It is understood that this type of Helipad does not require to be licensed by the CAA (Civil Aviation Authority), however due to the congested nature of the surrounding area the Helipad operator will require a Rule 5 permission from the CAA and therefore the Contractor must consult the Operator and Board to ensure compliance.

7.2.29 The Helipad Operator(s) and Board will require to be consulted on the type of helicopters that will be expected (including size and weights). However as general guidance for the size of Helipad required a rectangle with sides at least 25 m long (or a circle at least 35.4 m in diameter) will be a minimum requirement to accommodate all helicopter types likely to make use of the facility.

7.3 Ceilings Heights & Voids

7.3.1 The floor to ceiling heights, or to services level where there are no ceilings, shall be designed to accommodate the nature and use of the accommodation, but as a minimum shall be at least 2700mm irrespective of location. The ADB room data sheets define ceiling heights on a room by room basis.

7.3.2 All circulation and communication spaces shall have a minimum ceiling height of 2700mm;

Room Type	Department	Minimum Ceiling Height
All Corridors	Wards	2700mm
Lift Lobbies	All Departments	2700mm

7.3.3 Certain special types of room should be 3000mm or above in height to suit their medical or equipment needs;

Room Type	Department	Minimum Ceiling Height
All Operating Theatres	All Departments	3000mm Where Laminar Flow curtains are present – 2100mm required to u/side of curtain from ffl.
Radiology and scanning Rooms (CT and MRI)	Radiology	3000mm
Endoscopy Rooms	Endoscopy	3000mm
Therapy Room	Rehabilitation	4500mm

7.3.4 Additionally there are a number of departments where all ceiling heights should be as a minimum 3000mm – including all main communication and interdepartmental circulation routes;

Department	Minimum Ceiling Height
Operating Theatres	3000mm
Critical Care	3000mm
Imaging	3000mm
Rehabilitation	3000mm

7.3.5 The following criteria require to be incorporated in the Contractor's Proposals:-

a) Areas such as circulation spaces, patient corridors, waiting areas, reception areas, entrance areas and atria should be given particular consideration in terms of ceiling form, material and with particular regard to maximising the height of ceilings to offer a light, spacious and welcoming character. For the avoidance of doubt a suspended ceiling tiled solution throughout will not be acceptable in these areas. Where higher ceilings are present a maintenance strategy will require to be clearly demonstrated;

b) An appropriate and safe void allowance above all ceilings shall be provided, including appropriate and safe points of access for maintenance of services. The void allowed shall be adequate for the full co-ordination and installation of engineering, cabling (including IT)

and other services. Co-ordination with the electrical, mechanical and communication services shall be an inherent part of the ceiling and building design. A full and appropriate strategy for the coordination of services requires to be clearly demonstrated to the Board through the use of 3D Modelling techniques;

c) It is imperative that the Contractor shall demonstrate their solution to the above requirement to the satisfaction of the Board by providing a clear and identifiable strategy for the installation of these services , providing satisfactorily accurate sizing and positioning for ducts , cable trays etc, including access points in plan and section to confirm compliance with this key Board requirement. As part of this requirement a clearly identifiable zoning strategy will require to be demonstrated by the Contractor regarding the location of access points to ceilings or roof voids;

d) The Contractor shall also ensure that the ceiling voids are designed to accommodate the specific requirements of the fire strategy for the Facilities -and in particular, the provision of cavity fire-barriers within compartments;

e) Services access through all Category 1 ceilings will not be acceptable (ceiling categories will be as defined in the ADB Room Data Sheets). For these areas the ceiling services should be capable of being accessed from an adjoining activity space. For the avoidance of doubt services should not be accessed from below (i.e. through the ceiling) in these areas. The following list of areas is indicative only and not exhaustive;

i) Aseptic suite;

ii) Decontamination unit;

iii) Operating theatres;

iv) Anaesthetic rooms;

v) Plaster room;

vi) Post operative recovery; and

vii) Preparation;

f) Ceiling or roof voids must not be accessible to patients or visitors. Access will be by Maintenance personnel only;

g) Modular ceilings are not acceptable in the operating theatre but may be required in associated areas for maintenance purposes. The ceiling in the operating theatre should also be able to withstand regular washing and have a completely sealed finish to maintain microbiological standards in compliance with SHTM, SHPN, HBN guidance;

h) If an acoustically absorbent ceiling is considered in any location it is essential that this does not present an infection hazard in compliance with SHTM, SHPN, HBN guidance;

i) Designated access points shall be fitted with a self-contained Ramsey-style ladder or similar where appropriate to facilitate access for maintenance purposes – this should be clearly demonstrated in the Contractor's approach to access and maintenance;

j) Demountable suspended ceilings shall be readily demountable without suffering undue damage and shall be capable of being easily cleaned;

k) Ceilings will be constructed in a proprietary suspended plaster board system in areas demanding specific hygiene criteria as defined in the ADB Room Data Sheets;

l) Ceiling mounted booms required for patient support and monitoring systems in theatres, treatment or x-ray rooms shall be co-ordinated with the ceiling layouts. E.g. Background fixings within ceiling void. Access to check and maintain fixings to all structurally mounted equipment requires to be provided by the Contractor in a clearly demonstrated strategy;

m) In line with the requirements of HAI Scribe coving will be required at the junction of wall and ceilings within all theatre suites and endoscopy rooms;

n) A minimum of 2100mm clearance is required under any suspended fixtures e.g. Signage;

o) The protrusion of light fittings, radiant panels or any other fittings will not be accepted in clinical areas;

p) Consideration may be given to making use of the ceilings to provide additional natural light by way of roof-lights. However, careful consideration should be given to the implications of incorporating these, e.g. rain noise, and to how they will be cleaned;

q) Emergency egress from roof void areas into patient areas is not acceptable (this includes any garden areas internal to the facility);

r) Suitable service maintenance walkways, incorporating handrails, shall be provided within roof voids with access hatches where walkways pass through fire barriers. Services require to be entirely clear of this walkway;

s) Floor to ceiling heights must be carefully considered in relation to the overall height restriction placed on the building by the granted Outline Planning Consent; Additionally floor levels are required to tie in with adjacent building levels where clearly required e.g. Neonatal;

t) Where Laminar flow canopies are present, a height of 2100mm will be required from finished floor level to the underside of canopy curtain for headroom; and

u) Washable ceilings are required in all clinical areas.

7.4 **Corridor Widths**

7.4.1 The table below identifies the Board's minimum requirements for corridor widths on a departmental basis with which the Contractor must comply;

Corridor Type	Department	Minimum Corridor Width (clear between handrails)
Hospital Street	Communication	Requirements for Means of Escape will dictate width – however minimum of 3000mm required
General Traffic – Staff Only	All Departments	1500mm
General Traffic – Patient Areas	All Departments	1800mm – two independent wheelchair users to pass
Patient Bed/Trolley Traffic	Wards	2150mm – straight movement with passing places width 3330
Patient Bed/Trolley Traffic	Theatres/Endoscopy	2960mm – two beds to pass regularly
FM Tunnel	Links buildings	8000mm - to be developed with robotics design and requirement.

7.4.2 Corridor widths shall be as required by the nature and use of the accommodation. Minimum widths shall apply along the whole length of the corridor. Main interdepartmental corridors in areas that patients may travel in beds shall be of sufficient width to allow two beds, with any attached equipment, to pass. Departmental corridors shall have passing places and all corridor widths shall be subject to specific agreement with the Board.

7.4.3 The following criteria require to be incorporated in Contractor's proposals:-

a) the utilisation of corridor widths and profiles is an integral element of the Clinical Brief and requires to be addressed in design solutions. This may be achieved through the use of informal seating areas and the like, whilst avoiding areas where patients may be obscured from staff view where possible;

b) corridors in patient areas shall not be less than 1800mm (clear between handrails or other protrusions), with corner protection to be provided and handrails to both sides, where appropriate as defined in Section 7.16 - Protection;

c) wherever possible reduce lengths of circulation routes and provide open areas and stopping/resting points along the length of travel;

d) avoid isolated columns in open plan areas or on circulation routes where practicable; and

e) avoid dead ends to circulation routes, particularly in patient areas;

7.5 **Doors**

7.5.1 Door widths shall be identified in the relevant ADB Room Data Sheet and Schedule of minimum door widths below (in the eventuality of a conflict between the RDS and Schedule below the wider provision will apply).

Room Type	Department	Minimum Coordinating width of Door
Ensuites	All Departments	1980 mm
Recovery	Operating Theatre	1900mm
Corridors	All Departments	1900mm in corridors greater than 1800mm wide i.e. Corridors with patient access
Operating Theatre	Operating Theatre	1900mm
Endoscopy Room	Endoscopy	1900mm
Assisted Bathrooms	All Departments	1500mm
Patient Bedrooms	All Departments	1500mm
Treatment Rooms	All Departments	1500mm
DSR	All Departments	1500mm
Disposal Hold	All Departments	1500mm
Equipment Store	All Departments	1500mm
MRI Room	Imaging	1450mm (refer to HBN 06)
Interview/Sitting Rooms	All Departments	1000mm
Consult/Exam Rooms	All Departments	1100mm
Clean/Dirty Utility	All Departments	1000mm
Offices	All Departments	1000mm
Seminar Rooms	All Departments	1000mm
General Stores	All Departments	1000mm
Staff Rest Rooms	All Departments	1000mm
Staff WC	All Departments	1000mm
Patient WC	All Departments	1100mm

7.5.2 For the avoidance of doubt, the minimum coordinating width indicated above is as defined in SHTM.

7.5.3 Notwithstanding the above, the Contractor shall be responsible for establishing, through detailed consultation with the Board, additional specific requirements for door widths in all areas of the Works. Consideration shall be given to providing sufficient door width in areas where the Board's operations rely on the use of larger items of Equipment such as waste containers and regeneration trolleys.

7.5.4 Door widths and door configuration shall be provided to allow for the delivery and removal of Equipment to each area. The Contractor shall require to demonstrate replacement planning for

major items of kit including navigation routes through corridor and other doors (e.g. replacement Imaging equipment). In this respect the Contractor shall ensure that the relevant corridor and door opening widths can accommodate the replacement of plant and materials along designated routes (identified by the Contractor). This to allow the passage of new/replacement Equipment and Specialist equipment without the need for the removal of any doors, door operating gear/equipment or handrails/protection.

7.5.5 The following criteria require to be incorporated in the Contractor's proposals:-

a) doors from the single bedrooms to en-suites in all ward accommodation should comply with the requirements of both HBN 04-01 Adult Inpatient facilities and HBN 00-02 Sanitary Spaces. The double door to the shower room should consist of a sliding/folding door and a hinged door. The sliding/folding door provides staff and unassisted patient access. Both doors need to be fully open for assisted use of the facilities. The sliding/folding door should be designed to release from the overhead track in order to provide mobile hoist access to the room and transfer to one side of the toilet. The hinged door should be able to open unhindered. To maximise the free space in the bedroom, consideration should be given to making this a folding door;

b) doors will require to accommodate overhead tracks (including supporting structures as necessary) for patient hoists in all bedrooms, with patient hoists to be installed in six bedrooms per ward generally and all bedrooms in elderly wards as well as in one room per OPD cluster in the Children's hospital;

c) all main entrance doors shall be automatically operated with break-out facility in the event of fire and have an effective draught lobby;

d) internal door leaves to all areas shall be of solid core construction, reinforced with damage protection plates; They must be resistant to all damage which would be reasonably expected for the building use. In line with BS8300 requirements the Board would expect that as a minimum all doors where there will reasonably expected to be wheelchair access – 400mm high kickplates will be provided. Refer to Section 7.16 - Protection for further details;

e) doors to some rooms shall be of a security rated construction, particularly areas where medical drugs are likely to be stored as indicated in ADB Room Data Sheets;

f) all door frames must be of solid or metal construction, and must be securely fixed in to the adjoining construction;

g) all doors to bedded areas shall be minimum width of one-and-a-half size openings to allow access for hospital beds, with double width doors required in ward area corridors. In addition to the requirements of the Disability Discrimination Act, careful consideration needs to be given as to the clear opening size of doors due to the need to transport patients and items through. Patients may be supervised, with an individual on either side of them (some patients may be evacuated in their bed to a place of safety, therefore pinch-points at rooms and corridors need to be avoided);

h) doors shall incorporate vision panels as per the ADB Room Data Sheets, to permit staff observation; of these, some will require integral blinds to obscure the vision panel for privacy reasons, this will also be indicated in ADB Room Data Sheets. Integral blinds to the vision panel are to be operable only from the inside of the room where a member of staff will

be constantly present, where a member of staff will not be constantly present (bedrooms for example) the integral blind should be operable form both inside and outside the room. Integral blinds in door vision panels require to be vistamatic type (horizontal blinds are not acceptable);

i) doors should have low-level viewing panels to ensure that a baby, toddler or young children or those in wheelchairs can see and be seen from either side of the door. Where a door has a single viewing panel, the minimum zone of visibility should be between 500 mm and 1500 mm from the floor. If a door requires an intermediate horizontal section for strength or to accommodate door furniture, the door should have two viewing panels, one accommodating a zone of visibility between 500 mm and 800 mm from the floor and the other accommodating a zone of visibility between 1150 mm and 1500 mm from the floor. Doors requiring vision panels are indicated in the ADB Room Data Sheets;

j) all doors to patient bedrooms, en-suites and bathrooms shall be fitted with a break-out (anti-barricade) facility which may be achieved by a combination of outward opening doors and ironmongery solutions. The Contractor will be expected to comply with anti-ligature/anti-barricade requirements in the Children's DCFP;

k) fire doors fitted with door closers are heavy and awkward to open and hamper easy circulation. All fire doors on circulation routes, and those not needing to be closed for security reasons, should be fitted with electromagnetic stays or swing-free door closers, which will close in the event of a fire alarm and be linked to the BMS to close at night. Door holds and door closers utilised in any location must not de-rate the fire rating of the door set to below that require for the location;

l) all bedroom doors which shall have free swing door closers (as HBN 00-04);

m) swipe card access and video plus audio door access will be required at the entrances to all departments, at links between departments to provide the necessary segregation, at all ward entrances, access points to staff only areas and access to FM/back of house areas;

n) all interview and consulting room doors to have a suitable level of acoustic performance to achieve the dB rating required by the ADB Room Data Sheets. Also refer to Section 7.8 – Acoustics. No air transfer grilles shall be permitted in these particular rooms and must comply with all requirements of the ADB Room Data Sheets;

o) the requirements for Radiofrequency shielding to doors within Radiology department shall be based on the requirements of the MRI scanner supplied and the siting of the device within the room and wider environment. Door leafs will typically incorporate copper or aluminium sheet materials and special details such as compressible brass finger strips at the head, sill and door jambs to maintain the continuity of the Rf cage electrical conductive construction. For the avoidance of doubt however it is required that the Contractor must seek advice from and agreement with the Board and the Board's Radiation Protection Adviser in this matter;

p) door closers to shielded doors require to be agreed with the Board and the Board's Radiation Protection Adviser;

q) all Radiology, Imaging and Nuclear Medicine x-ray rooms require lead lined doors as do all Theatres, dental (Children's hospital) and areas of A&E. The requirements for radiation protection shall be based on the designation and nature of the area, size of the room,

location of the door in relation to equipment and other risk factors. For the avoidance of doubt it is required that the Contractor must seek advice from and agreement with the Board and the Board's Radiation Protection Adviser in this matter;

r) doors must be fire resistant in line with fire regulations but, where connected to the fire and security alarm systems, must fail closed. Any alarm system linked to doors must not be compromised by even a short term power loss or surge;

s) doors to Theatres and Recovery areas require to open automatically upon activation of a push pad (not switch). Push pads to be sited to the left and right of both approaches to the door (i.e. 4 pads per door set). It should be possible to stand automatic doors in the opening position;

t) signs on or adjacent to all doors should be at a height of 800–1500 mm and tactile so that they can be easily read by touch;

u) external doors to non-public access areas should be metal-faced, solid timber core construction, other than louvred doors to plant areas, where ventilation is required;

v) any locked fire exit doors must have the capability of release on the activation of the fire alarm, or a local release facility of a type not likely to tempt patients to misuse it in line with Building Control requirements;

w) in the Children's Hospital doors to rooms that should not be entered by young children must be fitted with high-level latches. Where rooms require privacy, the doors should be fitted with 'free-to-escape' emergency release. In this case thumb-turn locks are not appropriate as young children can easily tamper with them, which could then cause panic in an emergency;

x) all external main entrances require to fitted with automatic sliding doors which protect both ends of a draught lobby. The entrance, doors and draft lobby must be designed to ensure that all normal hospital traffic can safely enter the building without compromising the inner environment (temperature and cleanliness, etc) or security of the building, throughout all weather conditions all in full compliance with HBN 00-04. For the avoidance of doubt all main entrances should allow for bed access/egress with a minimum clear width of 1740mm and doors should open automatically in the event of fire or power failure in line with the requirements of the Technical Standards requirements;

y) all fixings to ironmongery, fixtures and fittings in the Children's Hospital must be either securely concealed or be of a tamper-proof form (e.g. non-return screws);

z) the Contractor shall provide ironmongery which shall compliment the overall quality of the interior design concept. The Contractor shall ensure ironmongery is of robust construction suitable for its specific purpose and usage characteristics and in accordance with the Room Data Sheets. For ease of use by elderly or disabled persons the Contractor shall ensure handles are colour contrasted with the door background colour and of easy grip design. For ironmongery requirements refer to Section 7.11.1 Ironmongery;

aa) in 'back of house' areas such as catering, mortuary and all FM areas doors should be wide enough for trolleys and equipment to pass through easily and will need additional protection at heights related to equipment likely to cause damage. Any external doors to catering areas will require to be pest and insect-proof. All doors in food handling areas should have vision panels. Some doors may require security devices to allow access for designated staff only. For economy of space, chilled food stores and cold rooms may be fitted with sliding doors; flush thresholds are required to facilitate the passage of trolleys. Automatic cold air curtains should be fitted to maintain the temperature when the door of chilled food stores and cold rooms is open;

bb) Consideration should be given to providing doors within the children's hospital of different shaped vision panels, ironmongery and colours to provide a less clinical feel; and

cc) all doors within circulation and communication routes require to provide as large as practicable an effective clear opening width to allow the free movement of all forms of traffic. For the avoidance of doubt, the effective clear opening width for a swing door is the available width measured at 90degrees to the plan of the doorway clear of all obstructions (such as protruding ironmongery) when the door is opened through 90degrees or more. In all main circulation and communication routes (corridors over 1800mm) doors should comprise door leafs which are floor to ceiling heights with no overpanels. At these locations any door nib should be of a transparent nature in order to provide for maximum visibility to the corridor beyond.

7.5.6 Additionally, the Contractor requires to comply with the following:-

a) ensure that door edges do not present a hazard to visually impaired people when in hold open position. Contrasting texture flooring should be considered to guide people into the line of doors, as an integral part of the way-finding strategy;

b) light pressure delay check door closers should be provided to self-closing doors;

c) colour contrasted easy grip lever furniture and ironmongery;

d) any fully glazed doors or associated screens to have additional visual identification, for example applied manifestations;

e) level access to all doors, including escape doors;

f) generally, intermediate doors across main circulation routes should be held open on electro-magnetic devices linked to the fire and security alarm systems and designed to fail closed in an emergency or power failure.

7.5.7 Door Security

7.5.7.1 Door security requirements shall be identified in the relevant ADB Room Data Sheet, however the following criteria will require to be met by the Contractor;

a) access doors to patient areas will require to be alarmed and linked to a suitable alarm system capable of being monitored by the duty room or ward manager. This is vital within the Children's Hospital where all entrance/exit doors will require door control systems to prevent unwarranted access/accidental egress. They must be controlled externally with close proximity cards and internally by a press-to-release switch at a high-level. They will also be operated from a communications base, coupled with an audio-speech facility between the entry door and the communications base for identification purposes. Door control systems must be capable of manual or automatic release on initiation of the fire alarm system;

b) security measures are also needed to control unauthorised access to all departments through the use of swipe card and video entry systems. It is recommended that access through the main entrance to all areas be controlled by use of an entry-phone or intercom system with CCTV, linked to the reception/clerical office and communications base. Programmable close proximity card or similar systems must be fitted to changing room doors and used broadly across all departments. Ideally the programmable system should grant different patterns of access to suit the needs and privileges of authorised staff and visitors. The security measures chosen should not inhibit emergency escape from the above areas or access by the staff at any time;

c) all doors must be master-keyed / carded, with allowance for a suitable quantity of sub-master suites to facilitate the security zoning arrangements within the building such that each department, ward and service area can be locked down separately and with a master key. All doors throughout the building to have the same lock to allow a single key to be used by all staff. Spare cylinder and key sets to be maintained by the Contractor to allow ease of replacement. Secure and 'staff only' areas are to be controlled by proximity card readers linked to electrical locking devices in the doors. The proximity cards are to be contained within the staff I.D. badges. Contractor to provide facility to enable alterations to cards. Twelve thousand cards and lanyards are required to be provided by the Contractor;

d) there will be a decontamination entrance leading from the ambulance bay into A&E, which can act as a decontamination "airlock" with internal drainage and integral showering facilities with a "dirty" end onto the ambulance entrance and a "clean" end into the department. This area should have piped oxygen and suction to be able to manage the rare situation of a contaminated patient requiring resuscitative measures. This area requires to have audio/intercom communication with the adjacent hospital area to allow communication between staff;

e) the A&E will have secure entry and exit points which can be locked if required. Electric swing doors will be configured to open automatically if approached by a patient trolley. All other access will be by proximity card access by staff members; and

f) the A&E will have facilities for the management of high security patients, access to the treatment area for patient transfers of this type to have a discrete external door, security rated and access controlled as agreed with the Board and Strathclyde Police.

7.5.8 Draft Lobbies

7.5.8.1 All main entrances will require a draft lobby, the enclosure to the lobby requires to be fully glazed to enable users to proceed safely and confidently.

7.5.8.2 The lobby area should have absorbent and dirt-retaining flooring, over a sufficiently large area, to minimise damp and dirt being taken into the hospital to further minimise the risk of slip accidents. Mats must be able to be uplifted and removed from matwells for cleaning. For details of these requirements refer to floor finishes section – Section 7.9.2. Further, draft lobbies require to have air curtains and consider further energy efficient design features.

7.5.8.3 The size and shape of the lobby should also:

a) allow the smooth flow of users into and out of the building;

b) allow for the fact that users may congregate there;

c) ensure that by the time the second doors are reached, the first are closed;

d) provide a “modifying” environment between the outside and inside of the hospital; and

e) if other facilities are provided within the draught lobby, such as seats and payphones, they should not obstruct the passage of users.

7.6 **Windows**

7.6.1 Bedroom windows shall be sized and positioned so that patients can view through the window from their bed while sitting up, from a seated position and when standing. In the Children’s Hospital windows must have a low-level sill, a maximum of 600 mm high, to enable small children to see outside from their bed or cot. Blinds, controlled from within the room, are required for all internal glazed screens and windows to ensure privacy and also give protection from glare and solar gain.

7.6.2 The Contractor shall ensure that appropriate solar glazing and/or solar shading is incorporated on windows on typically East, West and South facing elevations. The Board will expect the Contractor to implement solar glazing/shading strategies as part of the overall solar heat gain and ventilation strategies. Further to this the Contractor will require to clearly demonstrate compliance with the environmental/energy targets as defined in Appendix M.

7.6.3 Natural light shall be provided in public spaces and in occupied private and staff spaces within the Facilities as far as is practical. Natural and artificial light sources should be designed to avoid or minimise glare.

7.6.4 Where possible all windows shall be designed by the Contractor to be cleaned externally and internally from the inside, unless otherwise agreed by the Board. The Contractor shall ensure no portions of windows, either fixed or opening should come below the level of worktops or desks except in in-patient areas where bedrooms and day dining rooms cills may be lowered to facilitate better external views. Locking devices to enable the windows to be released for cleaning purposes shall be by key or other device such that they cannot be released by unauthorised persons.

7.6.5 The following criteria require to be incorporated in the Contractor's Proposals:-

a) windows must combine security with good natural light and ventilation;

b) window frames to be of a robust and secure construction;

c) provision of external window cleaning system to ward tower, podium and all other windows;

d) all windows (in a naturally ventilated building solution) to have robustly controlled, limited openings to a maximum of 100mm clear opening (as per ADB Room Data Sheets and SHPN 03) with a robust, secure method of restricting the extent of opening;

e) all windows (in a naturally ventilated building solution) should be capable of opening in order to meet the desire to naturally ventilate the building as far as is practicable. This is required to address seasonal changes, where external temperatures may dictate that it is not desirable to open windows to achieve ventilation. The opening operation of all windows also needs to balance the desire to open windows against compromise of the security of the building envelope. The Contractor must submit full details of the proposed trickle vent with their bid, consideration should also be given to the effects of opening windows at height in the tower;

f) there may also be reduced air flow within the building as, for security reasons, some windows may not open extensively. With this in mind, it is essential that the ventilation and temperature control systems are of a high standard. The use of passive methods is encouraged;

g) as part of any passive, natural ventilation scheme dependant on the opening of windows, The Contractor shall demonstrate through thermal simulation (IES, TAS or equivalent) the optimum window opening arrangement has been selected to optimise thermal comfort with due consideration to any restrictions on openings;

h) the Contractor shall consider use of integral blinds to windows as part of the overall external shading strategy for the building along with meeting the specific requirements of the room as indicated in the ADB Room Data Sheets. The use of Integral blinds is considered to be advantageous in the area of Infection Control offering a practical solution to a range of cleaning issues. The Contractor must demonstrate maintenance and replacement methodologies for any proposed integral blinds (to windows or screens) and include robust gear and switching/movement controls;

i) in the critical care department windows in the single bedroom should be sealed. This is essential to maintain mechanical cooling and positive/negative airflow;

j) in the critical care department integral window blinds must be installed that can provide 'black-out' which is essential for ultrasound examinations and other imaging procedures;

k) proposals for the external solar shading of the building should be considered in the context of the overall design and, only if necessary, should consideration be given to solar glazing to south elevations. No reliance on the fitting of internal blinds can be used when evaluating reduction in solar gains;

l) where any windows require external security shutters, these shall be electrically operated and fully concealed;

m) window ironmongery in the shall be anti-ligature in the Children's DCFP;

n) windows that open onto courtyards where children play may constitute a hazard. Raised planting, for example, beneath them can prevent children sustaining injuries while running. In areas where children and young adults will be present Centre-pivot windows are to be avoided. Windows should preferably be of the sash-type with restrictors;

o) In areas where children and young adults will be present child-resistant locks should be fitted to all windows;

p) cords on window blinds or curtains should be kept short and out of reach of young children;

q) in order to promote good observation and communication between staff and patients in single bedroom ward areas large internal glazed screens between bedrooms and corridors should be incorporated. This will enable staff to observe patients and equally importantly, patients to see staff. However, patients should have the means to obscure windows where required through the use of integral blinds to provide privacy when required;

r) it should be possible for cleaners to gain easy access to the inside and outside of windows. A cleaning and access strategy for all windows and curtain walling requires to be provided by the Contractor, with all necessary equipment and access included in the Contractor's Proposals;

s) selection of the type of glass is crucial for the effective control of security, and for thermal and solar glare control and should be selected in conjunction with the overall consideration of environmental modelling of the Works. Colour rendering – for diagnosis of patients should also be considered in the choice of glass type for windows and screens. The robustness of all glazing must be appropriate to the functionality, relative to safety and resistance to damage;

t) the Contractor shall ensure that all handles or control gear shall be placed at levels which enables them to be operated by staff without the use of loose poles, and which do not conflict with the location of the adjoining construction elements, including blinds and curtains. Where windows are placed over worktops or desks, or where the operation as described above is not achievable, mechanical or electrical means of opening shall be provided by the Contractor with controls located in a suitable position within the room concerned;

u) the Contractor will be expected to use toughened glass in all locations (windows, doors, balconies, balustrades etc) except areas which are vulnerable to vandals or intruders at ground floor locations. As toughened glass is inherently strong and when damaged breaks into small pieces this is deemed to be less dangerous in terms of falling shards of glass or risk to vulnerable patients at risk of self harm. Laminated glass at ground floor level only will provide greater security. Laminated glass when broken will remain in place with numerous cracks, but the fragments are held together and do not separate therefore no hole left in the window for an intruder to get in through for example; and

v) One way screens/viewing panels should be incorporated as identified in the ADB Room Data Sheets.

7.7 **Building Envelope**

Facade

7.7.1 The Board would confirm that a variety of building envelope solutions will be considered in response to the following diverse challenges;

a) Energy usage;

b) Environmental considerations i.e. Odour from the nearby sewage works;

c) Ventilation and overheating;

d) Infection Control;

e) Acoustics;

f) Natural Light;

g) Cleaning and maintenance; and

h) Solar Control strategy

7.7.2 The envelope solutions which will be considered as acceptable to the Board include:

a) a partially sealed air conditioned building working in tandem with natural ventilation;

b) mechanically ventilated building working in tandem with natural ventilation;

c) double skin facade solution.; and

d) a sealed building where a maximum temperature solution is provided.

7.7.3 The envelope solution(s) proposed by the Contractor will require to be fully developed and modelled clearly indicating compliance with the Board's stated Sustainability and Energy Targets. It is not envisaged that a fully air conditioned solution alone will be capable of meeting the stated targets, however if this option is proposed, as above, a the Contractor will require to provide to the satisfaction of the Board a fully developed and modelled solution clearly indicating compliance with the Board's stated Sustainability and Energy Targets.

7.7.4 The Contractor shall also ensure that the external envelope shall incorporate provisions for its cleaning and maintenance. The Contractor shall ensure that the external hard and soft landscaping around the buildings shall allow access for the appropriate cleaning system, whether by ladders, mobile platforms or cleaning cradles attached to the building structure. Appropriate provisions shall be incorporated by the Contractor to allow the safe use of ladders. The external skin of the building shall be designed by the Contractor to accommodate the point load access of ladders and operatives, where the cleaning and maintenance system uses this method.

7.7.5 The following criteria require to be incorporated in the Contractor's proposals:-

a) external finishes shall be durable and easily cleaned, with finishes which may be vulnerable to abuse / vandalism (including graffiti) to be avoided;

b) anti-climbing measures shall be carefully considered, specifically in relation to any external wall-fixed rainwater goods and solar shading;

c) protection / avoidance from vehicular impact at drop-off, delivery points and the like is required; and

d) external detailing to avoid;

i) nesting or perching sites for birds and other wildlife;

ii) Unsightly weather staining of facades; and

e) Method of cleaning and maintaining façade

7.7.6 The Contractor shall design the building envelope to prevent rainwater entry into the building structure and the internal accommodation. Where water penetrates cladding elements, as part of the functional design and construction techniques, the Contractor shall ensure it is controlled and drained externally.

7.7.7 The Contractor shall ensure that all building elements and retaining structures shall incorporate appropriate means to resist the passage of dampness, both into the building structure and fabric, and into the accommodation, including the resistance to any hydrostatic pressure. The Contractor shall ensure that all such construction shall be in accordance with the requirements of the Building (Scotland) Regulations 2004, BS 8102 and Code of Practice CP 102 for Protection of Structures against Water from the Ground.

7.7.8 The Contractor shall ensure that the buildings are constructed and the design is detailed to limit air infiltration to minimum levels to reduce energy consumption and improve internal environmental conditions.

7.7.9 Performance demonstration tests for all roof and wall elements shall be carried out by the Contractor in accordance with the following:

a) BS 5368, Part 2: 1986 (EN86) Resistance to Water Penetration;

b) BS 5368, Part 3: 1986 (EN77) Wind resistance; and

c) BS 5368, Part 4: 1986 (EN86) Test Report Format.

Roof

7.7.10 The roof construction shall be fully weatherproofed, designed for minimum maintenance and suitably braced and held down to resist the influence of gusting winds appropriate to their locations. All penetrations through the roof membrane or cladding shall be suitably sealed to prevent the ingress of water. The roof shall be laid to falls appropriate to the adopted membrane or cladding and shall include sufficient provision of guttering and down pipes to adequately discharge rainwater to the underground drainage regime.

7.7.11 As part of the Board's sustainability requirements a strategy for rainwater harvesting should be considered by the Contractor. Where rainwater harvesting is incorporated, full risk analysis shall be carried out and tabled for consideration, all actions shall be taken to mitigate risks to infection control requirements. Rainwater harvesting is likely to be restricted to use in areas of the FM, Energy and Laboratory buildings.

7.7.12 The Contractor shall also ensure that all roofs shall incorporate provisions for cleaning and maintenance. Appropriate provisions shall be incorporated by the Contractor to allow the safe use of ladders, guardrails, walkways, access solutions and fall protection solutions in line with all Health and Safety Guidelines to prevent fall from height. This is a fundamental aspect of the roof design and a clear strategy detailing access provision will require to be demonstrated by the Contractor as part of the overall roof design.

7.8 Acoustics

7.8.1 The Contractor shall endeavour to minimise and mask ambient noise sufficiently to preserve patient privacy, confidentiality and maintain a calming atmosphere in public and patient areas.

7.8.2 Audiology booths require to be provided to the necessary acoustic and other standards.

7.8.3 The specific requirements of the Board with regard to Acoustics are contained in Appendix S.

7.9 Finishes

General Finishes

7.9.1 All wall finishes and backgrounds shall be selected and installed in accordance with SHTMs and appropriate British and European Harmonised Standard Specifications, Codes of Practice and ADB Room Data Sheets.

7.9.2 Areas of the Facilities that are subject to potential damage from trolleys, vehicles, beds or other similar traffic shall have adequate protection to comply with as a minimum SHTM 69 and in line with the specific requirements of Section 7.16.

7.9.3 The detail design and finished quality standards of certain specific finishes will be subject to the construction of mock-ups during the design and construction stages. These will form the benchmark for quality control of Site operations.

7.9.4 The use of colour patterning, motifs and texture should be considered by the Contractor in appropriate areas throughout the buildings as an integral part of the wayfinding strategy.

7.9.5 The following criteria require to be incorporated in the Contractor's proposals for all areas:-

a) internal finishes shall be durable and easily cleaned;

b) internal wall surfaces shall be resistant to damage appropriate to the location. Certain areas will necessitate severe duty partitions in accordance with BS 5234 Part 2:1992 (or equivalent), with wall protection. Severe duty partitions will be required in major circulation and heavy industrial areas such as FM;

c) wall finishes must be in accordance with the relevant SHTMs, HTMs HBNs, Design Guides, the Scottish Building Standards, and ADB Room Data Sheets and should also be appropriate to the activity space that they serve, in terms of: imperviousness; hygiene; joints; smoothness; moisture resistance; resistance to cracking; and resistance to abrasion;

d) internal partitions finishes shall also be as required by the nature and use of the accommodation and shall incorporate radiation protection requirements, sound reduction, fire resistance, humidity, biological attack and duty as identified by relevant HBN, SHTMs and appropriate British and European Harmonised Standard Specifications, Codes of Practice and ADB Room Data Sheets and as identified elsewhere in this document;

e) all wall finishes in clinical areas in the Children's Hospital must be durable and able to withstand wet cleaning and the accidental impact of trolleys and heavy mobile equipment. Especially vulnerable points must have additional protection. Smooth paint surfaces are the easiest for cleaning, for example eggshell or vinyl silk emulsion;

f) all wall finishes in clinical areas in the Adult's Hospital should be durable and able to withstand wet cleaning and the accidental impact of trolleys and mobile equipment. Especially vulnerable points should have additional protection. Smooth paint surfaces are the easiest for cleaning – eggshell or vinyl silk emulsion. A matte finish is not acceptable;

g) as the use of ceramic wall tiles is not acceptable in terms of Infection Control, impervious wall cladding is required in shower areas and as splash backs in kitchens, toilets, cleaner rooms etc;

h) The infection control team must be consulted and involved with material specification and detailing;

i) columns should be located, insofar as is reasonably practical, to coincide with corridor walls in order to minimise intrusion into rooms or corridors. Columns or ducts must not protrude into corridors so that they reduce the required minimum width; and

j) external walls and internal partitions shall be provided with movement control joints, appropriate to their material, method of construction and anticipated movement. Where movement joints are required these are to be identified on the layout drawings, these will not be acceptable within rooms or in clinical areas.

7.9.6 Additional specific finishes requirements that must be met by the Contractor's Proposals are identified below;

a) all Radiology, Imaging and Nuclear Medicine x-ray rooms require lead lined partitions and doors as do all Theatres, dental (Children's hospital) and areas of A&E. The requirements for radiation protection shall be based on the designation and nature of the area, size of the room, location of the door in relation to equipment and other risk factors. For the avoidance of doubt it is required that the Contractor must seek advice from and agreement with the Board and the Board's Radiation Protection Adviser in this matter;

b) the requirements for radiofrequency shielding to walls and doors in the Radiology department shall be based on the requirements of the MRI scanner supplied and the siting of the device within the room and wider environment. Walls and door leafs will typically incorporate copper or aluminium sheet materials and special details. For the avoidance of doubt however it is required that the Contractor must seek advice from and agreement with the Board and the Board's Radiation Protection Adviser in this matter, however full floor to ceiling protection should be included in all patient treatment areas (as well as full protection to all doors leading to or from treatment areas) in Radiology, Imaging and Nuclear Medicine x-ray rooms as well as all Theatres, dental (Children's hospital) and areas of A&E;

c) all Theatres throughout the facility should have no reflective surfaces or bright door handles as laser surgery may be undertaken;

d) where interventional procedures are considered, or will be undertaken in any room within the Radiology Department, the room finishes should conform to operating theatre standards. Ceilings should be continuous and impermeable. The provision of specialist paint finishes for ceilings and walls is expected and will be identified on ADB Room Data Sheets;

e) in all cases in the Radiology Department, overlapped sealed joints should be used over architraves and skirtings. Floors should be finished with non-electrostatic vinyl sheeting in order to avoid electrostatic discharges that may affect the function of the MRI and associated equipment;

f) wall and ceiling finishes in operating theatres should be impervious, durable and able to withstand wet cleaning and the accidental impact of trolleys and heavy mobile equipment. Especially vulnerable points should have additional protection. Protection measures should be considered at the initial design stage to prevent the need for regular maintenance which

would require the unit to be closed for long periods. The provision of specialist paint finishes for ceilings and walls is expected;

g) in the mortuary the floor of the body handling and post mortem area must be very hardwearing, non-slip, and impervious to water and disinfectant. The floor should be self-draining towards gullies to allow for drainage after cleansing. Walls should be capable of withstanding regular washing or hosing down, and should meet the raised junction with the floor at a waterproof joint. Ceilings should be capable of withstanding frequent washing down; and

h) IPS solutions shall be required in all toilet areas and areas where wet/sink provision is required (e.g. utility rooms). The use of flexible hose connections is prohibited.

Flooring

7.9.7 The Contractor shall ensure all level and inclined flooring shall meet the following minimum slip resistance requirements:

a) "Rz surface micro-roughness of 20 µm*;* and

b) "Slip resistance pendulum value of 36 (when either dry or contaminated)

7.9.8 The choice of flooring for areas, which may foreseeably become wet or contaminated, needs careful consideration. An anti-slip floor may be an effective control in some areas, such as kitchens, bathrooms, WCs and shower rooms. The choice of flooring will be influenced by the likelihood of the floor becoming contaminated and other factors such as the use of, and levels of, pedestrian traffic in the area. Effective cleaning will be important in maintaining the performance of anti-slip floors, however, it is important to establish with suppliers and cleaning staff that anti-slip flooring can be cleaned to appropriate hygiene standards. In certain areas such as operating theatres, where hygiene is paramount, this is especially important.

7.9.9 The flooring is just one, albeit important element, in the slip potential model and in areas where contamination occurs only occasionally, it may be more appropriate to control the risk through enhanced cleaning and management regimes. Therefore the Contractor requires to comply with the following;

a) the Contractor will require to demonstrate that a Risk assessment has been carried out in accordance with SHTM guidance. This assessment will require to be conducted in conjunction with the Board since as noted above, cleaning and management issues are factors in the assessment;

b) the Contractor shall, in order to complete a thorough risk assessment, procure test results in the "installed" condition which are independently verified by the Health and Safety Laboratory, Buxton, Derbyshire or approved equivalent. The method of testing shall be performed using a pendulum-coefficient of friction instrument with "Four-S" rubber, in accordance with approved HSE test methodology. For the avoidance of doubt, the obligation to follow the pendulum-coefficient of friction methodology is a specific obligation and is derived from the HSE, which only recognises this type of test;

c) the Contractor shall also ensure adoption of similarly robust test methodology for other areas including stair treads and nosings;

d) the Contractor shall ensure that all entrances to the Facilities incorporate appropriate floor matting designed to remove contaminants including water, dirt and leaves from footwear, trolley wheels etc. Barrier matting is most effectively deployed in conjunction with other controls including effective or enclosed canopies and heating, in particular underfloor heating and ventilation or a water evaporation system such as a hot air curtain; and

e) the Contractor shall be identify a strategy proposal at each entrance for agreement by the Board. The matting must extend a minimum distance of 6 metres along the route of travel within the building in line with NHS Scotland Safety Action Notice SAN (SC)05/08. For the avoidance of doubt the Contractor shall comply with all of the recommendations provided in SHS Safety Action Notice SAN (SC)05/08;

7.9.10 The following criteria requires to be incorporated in the Contractor's proposals:-

a) floor finishes must be in accordance with the relevant SHTMs, HTMs, HBNs, Design Guides, and the Scottish Building Standards, and should be appropriate to the activity space they serve in terms of imperviousness; hygiene; joints; smoothness; anti-static; slip resistance; absorption of liquids; radius of ignition. Areas with special requirements such as Operating Theatres and ancillary accommodation require particular consideration;

b) care must be taken in the selection of the appropriate soft floor coverings, for the avoidance of doubt carpeting or soft flooring will not be acceptable in any clinical areas;

c) in all areas the floor material should be coved to form the skirting (minimum of 100mm) to avoid angles and corners where microbial colonisation can occur. All coving must have a proprietary cap strip to the upstand. This detail will allow easy cleaning of the floor finish. In areas where frequent wet cleaning methods are employed, the flooring material should be unaffected by germicidal cleaning solutions, the skirting material used should be integral with, and have properties similar to, the floor finish;

d) vinyl, linoleum or rubber are examples of slip-resistant flooring and should have welded joints. The flooring should be at least 2.5mm thick;

e) all joints between sheet floor finishes and between cove skirtings are to be hot seam welded with care taken particularly at doorways (all welded joints and set in coves, no open joints or sit on cove);

f) loose laid barrier matting is not permitted;

g) visually contrasting texture flooring surfaces should be utilised, wherever appropriate, as an integral part of the way-finding strategy;

h) zero profiles are required at external access points, including access routes to any garden/courtyard areas;

i) smooth vinyl/linoleum coverings shall not be permitted in areas susceptible to wetting and where it is not reasonably practicable to keep them dry such as all WC's , En-suites, Clean/Dirty Utility Rooms, Cleaners Rooms, Assisted Bathrooms , kitchens etc;

j) early cognisance should be taken in the positioning of construction joints in flooring bases to avoid seams in floor finishes in the centre of rooms or circulation areas, joints in these areas will not be acceptable;

k) continuous flooring to be provided as far as is reasonably practicable, with no patching and utilising welded joints and set-in coves;

l) where movement joints are required these are to be identified on the layout drawings and will not be acceptable within rooms or in clinical areas. Movement joints must by flush with the surrounding floor finish;

m) the continuity and integrity of surfaces is important in all areas and particularly in wet and more clinically sensitive locations. Surfaces should be easily cleaned and finished to avoid potential dirt trapping points;

n) in wet areas such as shower rooms with level access floors it is important to avoid tripping hazards such as floor gulley surrounds and lippings to contain water;

o) floor gulleys, gratings and associated finishes should be integrated within the overall floor build up in accordance with relevant manufacturer's recommendations and to achieve tight and continuous sealing to minimise potential for dirt traps;

p) vinyl, linoleum or rubber flooring is tolerant of small movements in the structural floor. The floor screed therefore should be perfectly smooth, crack-free and stable. Adhesives should be powerful enough to resist the formation of "waves" in the floor finish that can result when heavy equipment is moved;

q) sufficient time should be allowed for the adhesive to set prior to use. Thresholds at doorways between adjacent rooms require particular attention because they are points of stress in the floor finish;

r) in theatres with laminar flow ventilation, the floor area enclosed by the hood should be marked with lines or a contrasting coloured area of flooring;

s) in the mortuary area it is important that the floor covering is chosen can be effectively cleaned, maintained and, where necessary, repaired. Vinyl anti-slip floor is often difficult to keep clean (due to grit type surface) and its iron-based particles produce stains, particularly visible on light-coloured flooring. A slip resistant resin flooring will require to be provided;

t) sprung flooring is required in gym and other relevant areas; and

u) waterproof finishes are required in bunding to theatre plant rooms, energy centre plant rooms and other plant areas where resilience is required to prevent water damage to areas below.

7.10 Interior Design

7.10.1 The interior environment is fundamentally important in achieving a non-institutional and therapeutic environment. The Contractor should focus on creating the highest quality spatial environments, which respond to the Boards ethos and operational needs. The interior design should be developed in conjunction with the master plan and architectural solution, producing a fully coordinated and complimentary scheme.

7.10.2 The aim should be to create progressive environments which respond sympathetically to their setting, whilst creating the opportunity to develop contemporary methods of working practices, including the development of large scale dynamic public spaces. The design should respond to client and user needs, whilst emphasising quality of materials, light and space.

7.10.3 The Contractor should seek to exploit the sensory elements of design to provide both information and stimulus. It is a physiological fact that the majority of information that we receive is visual. For sighted people, promoting the sensory aspects of design adds depth and meaning to the environment whereas for visually impaired people whose ability to access significant amounts of information is substantially limited, this design approach is fundamental to understanding the environment and operating independently within it. Because most visually impaired people have some sight, the use of colour to create contrast between critical surfaces and key design features is perhaps the most powerful way of accurately describing the immediate environment.

7.10.4 The use of tactile information should also be clearly developed in the Contractors approach, to all lift signage and door signage. Audible information, including the range of sounds created by contact with different surfaces can be extremely useful and the senses of both sound and touch affect the aesthetic experience of the environment.

7.10.5 The Contractor should demonstrate colour differentiation in surfaces. Visually impaired people are generally less confident at differentiating colours that fully sighted people, but if the colour difference is above a certain threshold value their confidence improves significantly.

7.10.6 The Contractor should indicate an understanding of the principle that the nature of the light source can significantly affect the way we perceive colour contrasts that are applied to the critical surfaces of an interior. Ceilings, walls, doors and floors are all critical surfaces that should be sufficiently differentiated from each other. Navigation through a building is much easier if these large areas re differentiated sufficiently by colour or material.

7.10.7 The Works shall contain a mixture of public, semi-public, and restricted areas which should be designed and articulated to create a hierarchy of spaces, clearly identified and linked.

7.10.8 In addition to the general and special considerations consistent with good Healthcare design, designers and planners will need to recognise:

a) the need to combine the individual specialist requirements for the care of patients with an environment that is a good for staff and welcoming to visitors;

b) The Board's requirement for the Works to meet high standards of quality, efficiency, and cleanliness;

c) the requirements of the staff for an attractive and pleasant environment to work in; and

d) The Board's requirements to ensure designs recognise environmental and ecological issues;

e) For reasons of infection control soft furnishings must be covered in an impervious material within all clinical and associated areas;

f) The interior design represents a challenging opportunity to provide an interior environment appropriate for a friendly and important public building of this type; and

g) To develop this to an agreed solution it is anticipated that extensive consultation will take place with user groups to ensure that the final outcome is projected to be responsive to the specific requirements of each element of the building;

7.10.9 It is important that the interior environment should be welcoming, comfortable, and enjoyable for patients, thereby limiting the institutional atmosphere typical of many healthcare Facilities. Users should be provided with external views and views to landscaped courtyards, corridors with break out spaces providing glimpses out of the building should also be incorporated to give users orientation.

7.10.10 The scale and diversity of patient facilities to be provided means that it will be extremely important to create individual identities to key areas within the overall building design. This will not only help patients identify and orientate themselves within the facility but will also help foster a sense of ownership among staff and a community spirit within individual elements of the building. A distinct identity should be immediately apparent in the Children's Hospital which will require through the use of colour, shape and motifs to provide interest and distraction for patients, parents and visitors alike. This will require to be reflected in all aspects of the design including flooring, wall finish, doors and ceilings. The importance of play for children, and the unique role of the hospital play specialist are described in 'Friendly healthcare environments for children and young people' (NHS Estates, 2003, pp 37–38).

7.10.11 Play specialists should be included when designing the New Children's Hospital as spaces for play are an essential requirement in all patient areas and present a unique opportunity for designers to provide creative and stimulating environments for young patients. This and the use of varied colours, murals, cartoons, varied flooring and the like are of extreme importance in the design of the children's areas and will be an important aspect for bid return and consideration.

7.10.12 The use of colour will help to differentiate the separate functions which share a common structure, and the use of symbols, graphic devices, furnishings, fabrics and accessories when thoughtfully co-ordinated will provide comfortable, yet clearly identifiable, internal environments for patients and staff alike. Any approach to this area of design must be developed carefully within the exacting requirements of procurement and to ensure an easily maintained solution.

7.10.13 It is possible that the Board shall invite external patient support groups and family groups to assist in interior design solutions and activities. The Contractor shall require being aware of such, and engaging with such groups during design development and construction. Such groups shall have an ongoing role within the Works and shall be desirous of incorporating exhibitions and artwork/contributions in the Works. The Contractor shall require supporting such an interface and allowing works to be displayed on wall finishes and the like. The Contractor's Proposals shall reflect such interfacing and engagement.

7.10.14 The Contractor shall develop an interior design strategy to cover all areas of the Works. The interior design proposals shall promote the ideals of the Identikit guidelines.

7.10.15 Proposals shall be presented by the Contractor in room-by-room schedules with samples of finishes, colours, lighting fittings, materials as appropriate, and signage, supplemented by colour sketches or coloured computer images for agreement with the Board, in time to allow for consultation with the users, and for incorporating feedback into the final scheme.

7.10.16 It is expected that the Contractor will provide Interior 3D perspectives and an Interior Colour Strategy Report detailing the following – this is not an exhaustive list;

a) Internal Views of Atriums, entrances and key high profile public areas;

b) Views of Hospital street/Mall including retail area;

c) View of receptions and waiting areas;

d) Ward areas and bedrooms; and

e) Theatres.

7.10.17 The above information should indicate the following information;

a) Architectural vision – space, height, form, composition, scale, character and use of materials;

b) Finish type, colour;

c) Overall colour strategy;

d) Incorporation of Art; and

e) Wayfinding Strategy including images

7.10.18 Where the Contractor includes internal planting displays, associated irrigation and atmospheric controls shall be provided. The Contractor shall ensure that the building design and services allows for an appropriate level of light to ensure the growth and survival or any interior planting within their design.

7.11 Architectural Hardware

Ironmongery.

7.11.1 The following criteria require to be incorporated in Contractor's proposals:-

a) the locking system shall be fully suited across the Works and shall interface with swipe card / other entry systems where provided. Particular requirements with respect to electronic door access / security requirements are contained in Section 8.3.14;

b) ironmongery, fixtures and fittings in the Children's DCPF shall be anti-ligature and anti-barricade;

c) all fixings to ironmongery, fixtures and fittings (in patient areas) must be either securely concealed or be of a tamper-proof form (e.g. non-return screws);

d) where indicated in the ADB Room Data Sheets mirrors to be shatterproof glass, with concealed fixings;

e) all joints between flush fitting components and adjoining surfaces to be as tight as practicable; and

f) all fire fighting equipment to be located within secure lockable containers housed in the wall construction, and operated by the same key throughout the development (all fire fighting equipment to be supplied by the Contractor);

g) in the interest of children's safety door handles to the kitchens should be located at a high level to prevent unauthorised access;

h) the Contractor shall provide ironmongery which shall compliment the overall quality of the interior design concept;

i) the Contractor shall ensure ironmongery is of robust construction suitable for its specific purpose and usage characteristics and in accordance with the ADB Room Data Sheets. For ease of use by elderly or disabled persons the Contractor shall ensure handles are colour contrasted with the door background colour and of easy grip design; and

j) samples of all the ironmongery products shall be prepared in accordance with section 5.9. Details of lock suiting will be submitted by the Contractor to the Board to allow adequate time for discussion and amendment if necessary before the fittings are required for installation in the buildings.

Blinds & Curtains

7.11.2 The following criteria will require to be incorporated in the Contractor's proposals;-

a) the Contractor shall provide all fixings for blinds and curtains including integral blinds;

b) all blinds, curtains and associated fixings shall be Class 0 rated;

c) the Contractor shall ensure that materials for blinds and curtains (including any cubicle curtains) shall also comply with the requirements of the Board's Control of Infection Officer for cleaning, washing and maintenance, and comply with SHFN 30 and SHTM 87, and specific Safety Action Notes. For reasons of infection control curtains must be able to withstand washing processes at disinfection temperatures;

d) the Contractor shall provide integral blinds to windows, curtain walling and internal screens;

e) The locations and fixings for both blinds and curtain tracks and cubicle curtains shall be co-ordinated by the Contractor with the window and internal window sill design from the outset of the building design development and the fixings shall be designed by the Contractor to take the proposed maximum loadings possible for the tracks concerned and shall be non-weight bearing from an anti-ligature perspective in the Children's DCFP. For the avoidance of doubt all curtains, blinds, accessories including fixings are to be provided by the Contractor;

f) Curtain tracks shall be designed by the Contractor to overlap the window openings so that they do not allow light to pass into the room when drawn. Controls for blinds and curtains shall be co-ordinated by the Contractor with the window design and its opening gear, including any operating handles, levers or stays that may be required and shall be located conveniently for staff or patients to operate as appropriate;

g) The Contractor shall fix bed and cubicle curtain tracks at the height recommended in the relevant guidance and The Contractor shall ensure bed curtain tracks are co-ordinated with other service outlets and the window positions, where applicable. An adequate ventilation gap must be provided by the Contractor at the curtain head; and

h) All Single bedrooms should have glass partitions for observation purposes, complete with integral venetian blinds for privacy.

7.12 Staircases, Ramps, Balustrades, Walkways, Escalators & Lifts

Staircases and Ramps

7.12.1 Where staircases, ramps, balustrades, walkways and lifts are provided in addition to those required to satisfy means of escape criteria, these shall be designed to relate to the anticipated capacity of use and clearly designated for public, staff or service circulation.

7.12.2 For the avoidance of doubt, the Contractor requires to ensure that for all stairs the requirements of HBN 00-04 and Technical Standards are achieved. This includes the following key criteria;

a) the maximum number of risers between landings for a flight of internal stairs should be 12-14;

b) risers and goings uniform, riser height should be 150-170mm, going minimum of 280mm, 300mm preferred;

c) for steps not adjacent to a wall, a barrier, with a minimum height of 100mm above the level of the treads should be provided for safety reasons. This requirement should be developed in conjunction with the design of the stair / balustrade to viewed as a cohesive whole;

d) open areas on the underside of stairs should be avoided to eliminate the possibility of anyone walking into the overhang created;

e) to indicate that there are descending steps ahead, a hazard-warning zone should be provided on each landing. The zone should use a floor finish that contrasts visually with the general floor finish, but has the same slip resistance. The warning zone should be at least 400 mm from the nosing and a minimum of 800 mm deep and 1200 mm wide;

f) capable of achieving mattress evacuation; and

g) where ramps are provided in addition to those required to satisfy means of escape criteria these shall be suitable for independent and / or assisted wheelchair users, trolleys and ambulant disabled people. Ramps, however will not be considered appropriate for any significant changes in level.

7.12.3 The atrium will contain link bridges, escalators, lifts and stairs providing all vertical and horizontal communication links across the void space providing the necessary connections between departments. A high level of finish will be expected for all stairs and balustrades, any handrail, barrier or guarding to stairs or corridor links should be glazed to allow views for children and those in wheelchairs.

Lifts and Escalators

7.12.4 For the avoidance of doubt, the Contractor requires to ensure that for all lifts the requirements of HBN 00-04 and HTM 2024 are achieved. This includes the following key criteria;

7.12.5 The number, type, size and speed of lifts should be determined from a traffic analysis specific to the proposed facility, and should allow adequate flexibility of the lift solution to accommodate future changes. However as a guide the following dimensional requirements will be achieved;

Lift Type	Minimum Sizes
All lifts	1100mm (wide) x 1400mm (deep)
Small General Traffic	1600mm (wide) x 1400mm (deep)
Large General Traffic	2000mm (wide) x 1400mm (deep)
Patient Trolley/Stretcher Movement	1400mm (wide) x 2400mm (deep)
Bed Movement Lifts	1800mm (wide) x 2700mm (deep)

7.12.6 Handrails should be provided on both side and rear walls of lift cars to be used for general traffic, this includes where stretcher/trolley lifts are to be used for general traffic. The minimum dimensions noted in the table above will require to be provided clear of handrails.

7.12.7 In order to segregate traffic, for operational and infection control reasons, it is not anticipated that lifts for bed movement will be used for general traffic.

7.12.8 Dedicated vertical lift facilities will be required as part of the installation of the overall Automated Material Transfer System as outlined in Appendix M. A clear strategy for the incorporation of these systems will require to be provided by the Contractor in consultation with the Board. The use of public and personnel lifts by automated systems is not acceptable.

7.12.9 Lift doors for general traffic should provide a clear opening width of 1100mm and height of 2000mm. Lift doors for movement of patient trolleys/stretchers and beds should provide a minimum clear opening width of 1370mm and a height of 2100mm.

7.12.10 Additionally the following criteria should be met:

a) the lifts within the atrium should be fully glazed to all sides providing views over the atrium space for the purposes of orientation;

b) a protected lobby should be provided where a lift does not open off a hospital street;

c) wall-wash lighting, uplighting or perimeter lighting should be utilised in the lift car rather than direct downlighting to avoid dazzling patients being transported on beds, trolleys or stretchers;

d) a visually contrasting floor surface measuring at least 1500 x 1500mm should be provided outside the lift door area;

e) lifts, where provided, are to be suitable for disabled wheelchair persons and visually impaired, with tactile controls and audible warnings; and

f) the use of escalators within the atrium space to access the upper level of Outpatients department is considered as desirable. All aspects of the Escalator design should be designed to the requirements of BS EN 115-1:2008.

7.13 **Landscape Design**

General Design Approach & Aspiration

7.13.1 In accordance with the principles of 'Designing Places – A Policy Statement for Scotland' (Scottish Executive 2001) the site layout and landscape design shall create external spaces that are distinctive, safe and pleasant, easy to get to and move around, welcoming, adaptable and resource efficient.

Existing Site

7.13.2 The existing hospital campus generally presents a poor quality environment for visitors, patients and staff.

7.13.3 It is dominated by large expanses of blacktop roadway and vehicles, disparate and scattered buildings, open yards, service bays and large flat areas of featureless and exposed open space. The site does include a number of mature trees which are subject to a Tree Preservation Order (TPO). The majority of these are to the eastern side of the campus, visible from the approach to the Clyde Tunnel, away from the principal area of the proposed new hospital development. The few mature trees remaining on the proposed site of the new hospital will need to be removed to facilitate the required building footprint and infrastructure.

Landscape Masterplan

7.13.4 The masterplan prepared for the development of the Southern General Hospital seeks to address many of the negative landscape issues currently affecting the campus and to provide the framework for the development of a high quality, coherent, well organised and welcoming external environment to enhance the experience of staff and patients alike. This includes the provision of a major new access from Govan Road together with a significant rationalisation of internal roads and paths to provide clear and direct approaches to the proposed new hospital and improved links throughout the campus with its hinterland. The proposed layout attempts to integrate private vehicular access, public transport and the new Fastlink route with pedestrian and cycle circulation to provide a vibrant but coherent new public realm within the heart of the Campus. In particular, the masterplan sets out the framework for the creation of high quality public realm and street frontages to the entrances associated with the proposed hospital within a strong landscape framework of formal avenue and informal tree planting. This is essential to create both a high quality setting and to provide the human scale necessary to offset any negative influence from the visual dominance of the size and physical mass of the building envisaged.

7.13.5 In particular the masterplan creates a large, central open space within the heart of the campus to be developed as a park for the use of patients, visitors and staff alike. This is intended as a multi functional space providing for social interaction and relaxation as well as opportunities for informal exercise with marked walking routes and a trim trail. The Contractor is to also to include works of art and sculptures in this area.

Hard Landscape - General

7.13.6 Areas of landscape and public realm shall demonstrate a high quality of detailed design, utilising high hard quality sustainable and durable materials to achieve design life noted in Section 5.3 The choice of materials shall reflect both the quality and importance of the proposed new building as well as the aspirations in the masterplan to create, a people friendly external environment. The contractor's attention is drawn to the need to ensure long term sustainability and the requirement to achieve the BREEAM Healthcare "excellent" rating. In this regard due reference shall be paid to the BRE "Green Guide to Specification" to maximise the use of materials and specifications achieving an A rating or better as far as is practicable with regard to other technical and specification requirements in terms of adoption and compliance with standards and legislation noted elsewhere.

7.13.7 The masterplan envisages a hierarchy of spaces and circulation and consequently surface treatments and materials shall vary accordingly.

7.13.8 The minimum standard for a pedestrian footpath within the site shall be asphalt with pre-cast concrete flat-top pin kerb edges to GCC Roads Department adoptable standards as identified in Section 9.0. At the top end of the hierarchy in the spaces associated with the frontage of the building and the main entrances, high quality modular or unit paving shall be used that shall feature clean, crisp detailing and edging together with striking and vibrant paving patterns and designs commensurate with the very best of 21st Century urban design.

7.13.9 The contractor will be expected to demonstrate a clear gradation of hierarchy within their design and choice of materials, between these two in terms of intermediate public spaces and major footpath routes around the site and within the new public park.

7.13.10 Design of all hard landscape in terms of accessibility, surfaces and gradients shall conform to or exceed BS8300 as well as to maximise long-term sustainability and BREEAM Healthcare scores.

7.13.11 Hard landscape materials, specification and laying shall conform to the following minimum standards, where relevant.

a) BS 7533 (all relevant sections pertaining to the materials chosen);

b) BS EN 1342 (Setts of Natural Stone – Requirements and Test Methods);

c) BS EN 1341 (Natural Stone – Requirements and Test Methods); and

d) BS EN 1339 (Concrete flags – Requirements and Test Methods).

7.13.12 Maintenance of hard landscape areas shall be in accordance with BS 7370 – 2. The contractor shall develop and submit a fully detailed maintenance schedule for all areas of hard landscape and associated street furniture and play equipment.

7.13.13 New access roads and vehicular circulation routes shall be designed and constructed in accordance with current highway design standards and to Glasgow City Council Roads Department, adoptable standards to the extent identified in Section 9.0. This to include all road markings to all roads, cyclepaths and car parks (incl car parking bays/spaces and drop-off points, ambulance areas and the like) and all road signage. Raised kerbs to bus drop-off/stops to be included.

7.13.14 The detailed design of vehicular roads shall incorporate appropriate traffic calming and speed control measures to reduce vehicle speeds and contribute to a pedestrian friendly environment. Consideration requires to be given to the transport of patients (particularly spinal patients) in the design of traffic calming methods. Along the hospital frontage at drop-off points and where large numbers of patients and visitors will be expected to congregate and enter the building, a change in surface material for the carriageway shall be utilised that provides the appropriate visual signals for both pedestrians and vehicle users alike and is commensurate with the high quality paving design and external environment required for the building frontages.

7.13.15 Pedestrian crossing points shall be provided at frequent intervals as indicated on the masterplan. These shall be formed at footpath rather than at road level in order to both achieve BREEAM points as well as to provide a traffic calming measure.

7.13.16 Roundabouts and important junctions shall be landscaped distinctively to provide a clear visual orientation point within the site and to reduce the apparent expanse of road and hard standing in these areas. Where possible public art or sculpture shall be incorporated in the roundabout designs to reinforce their distinctiveness.

Cycle Access

7.13.17 The design shall include improvements and modifications to the existing cycle access points, as well as creating new cycle access at appropriate locations to the site as indicated on the masterplan. New or modified cycle access shall be off-road and shared with pedestrian traffic as far as possible. In this regard, cycle paths shall be a minimum of 3 metres wide in order to comply with current guidance from Sustrans and to gain BREEAM Healthcare points. Where cycle lanes are provided either as separate routes or on roadways, the minimum dimensions and layout shall be in accordance with the above noted guidance and to the minimum required in BREEAM Healthcare.

Cycle Shelters

7.13.18 Cycle shelters shall be provided in the numbers required to achieve BREEAM Healthcare points. Cycle shelters shall provide secure and sheltered space for the parking of bicycles and shall be in a secure and visible location. Cycle storage areas shall be located adjacent to or as near as possible to building entrances to ensure direct safe and easy access/egress. Cycle shelter areas and their approach paths shall be lit to adoptable street lighting standards and shall be capable of being overseen by CCTV both day and night. Consideration of cycle stacking systems should be pursued by bidders and proposed to the Board.

Courtyards

7.13.19 The design of the new hospital building envisages the creation of a number of external courtyards for use by staff, visitors and patients. The courtyards shall be designed to provide a variety of purposes including opportunities for meeting and social interaction as well as quiet reflection and privacy. Where appropriate, courtyards and external spaces within the building shall have a practical and or therapeutic purpose, for example the incorporation of steps and ramps to assist with physiotherapy, as well as simply providing a view of plants, green space and natural light within the interior of the building.

7.13.20 In order to comply with BS8300 and the principle of free access, the finished paving level at building entrances shall be the same as the adjacent internal floor level. The building design in this location shall utilise a raised, DPC detail in order to ensure finished levels within the courtyards are visually unobtrusive. A solution which creates a series of humps or rises and falls between doorways opening out into courtyard areas will not be acceptable.

7.13.21 The internal layout design of the courtyard shall allow for any requirements for maintenance access to the building edges.

7.13.22 The courtyard paving shall be formed from high quality modular and unit paving with detailing commensurate with scale of courtyard in question. Path widths and circulation spaces shall be in accordance with minimum standards set out in BS8300 and BREEAM Healthcare, whichever is the greater. Courtyards shall include high quality planting design that incorporates the opportunity to introduce a variety of domestic/garden scale plant material including a mixture of evergreen, deciduous and herbaceous material together with bulb planting. The extent and type of plant material shall reflect the nature and function of the courtyard in question. Courtyards shall include a variety of seating opportunities to ensure that there is provision for both quiet and private contemplation and social interaction for group discussion. All courtyards shall be provided with litter bins and low level external lighting. Seating shall be in a variety of forms but as a minimum at least half the seating provided shall include backrests and arm supports. The design of the courtyards shall not restrict seating opportunities to purpose made bench or seat provision only and seating opportunities and areas of social interaction shall be incorporated into the overall courtyard design, utilising a variety of means including low walls and edgings at seat height.

7.13.23 The courtyard design shall include wherever possible the provision of tree planting in order to provide some height and to offset the potentially oppressive effect of the courtyards being surrounded by tall walls on four sides. The courtyard designs shall also incorporate some undulations and changes in level and provide visual relief from the prospect of a flat plain. In detail, courtyard designs will be expected to provide both open and intimate enclosed spaces within their overall layout.

7.13.24 The detailed design and specification of the courtyards shall provide a variety of visually distinct spaces in order that they can contribute to the wayfinding strategy and orientation round the building for patients, visitors and staff.

7.13.25 Notwithstanding the above requirements, courtyard design shall provide low maintenance external space.

Children's Play Areas and Play Equipment

7.13.26 The masterplan envisages the creation of a children's play area adjacent to the main entrance to the Children's Hospital. The purpose of this provision is both to provide a relaxed and welcoming child friendly entrance whilst at the same time actively making safe provision for children's play, whether children are outpatients or visitors to the hospital.

7.13.27 All children's play equipment shall conform to the relevant parts of BS EN 1176 and be expected to provide a design life with regular maintenance of 25 years. The contractor shall offer a range of equipment that provides the best manufacturer's warranty available and for which the supply of spare parts in guaranteed for the anticipated design life of the equipment.

7.13.28 All play equipment shall be installed with an appropriate safety impact absorbing surface suitable for the equipment in question. All safety surfacing shall be of a 'wet pour' or other continuous type surfacing system rather than tiles or loose-fill materials such as bark or sand. The final choice shall be influenced by the materials' longevity and lifecycle costs.

7.13.29 Play areas shall include a mix of equipment suitable for a broad range of ages and abilities appropriate to the context of the Children's Hospital (from toddlers through to young teenagers) and include a degree of open or free space. Seating opportunities for casual supervision by parents and carers shall be maximised and include a sufficient quantity of litter bins. Seating may be varied but must include at least 50% with back support. Provision of equipment for young children and toddlers shall include coloured boundary fencing with non-slam self closing gates.

7.13.30 The provision of an area of the play zone to be under the neo-natal link, thereby providing for an outdoor visit or play space usable in wet or inclement weather, is to be developed by the Contractor and included in the design.

Street Furniture - General

7.13.31 Street furniture shall be robust, practical and fit for purpose whilst at the same time being of a contemporary high quality design. The specification of different materials shall pay regard to both cost and long term sustainability. Any timber utilised shall be from a sustainable source and be FSC Certified Timber, where it is not of the type that is inheritantly long lasting in external or wet conditions shall be preserved, treated with a minimum 15 year lifetime guarantee or better. Street furniture items shall form a key component of the external landscape design, especially in the public realm, at entrance areas surrounding the building and within the parkland. The contractor shall provide a well considered and coherent design that presents a suite of complimentary elements that are integrated into the overall public realm and landscape design. All mild steel components and fittings shall be galvanised to and polyester powder coated or otherwise factory painted and supplied with a minimum warranty of 15 years or better prior to any retouching or painting being required.

7.13.32 All street/external furniture requires to be securely fixed to the ground.

7.13.33 Bus stops and shelters require to be installed as necessary to comply with the relevant Planning and Travel Plan requirements;

7.13.34 Covered architectural pedestrian walkways are to be provided between the Fastlink drop off area and the adjacent entrance to the new hospital as illustrated on the masterplan drawings;

Litter Bins

7.13.35 All litter bins shall be of the type which includes a front facing door or hatch that allows the internal bin or receptacle to be removed and emptied easily

Seating

7.13.36 It is anticipated that a wide variety of seating and seating opportunities shall be incorporated into the final design. The majority of this will be purpose made seating or seat items however the contractor is also expected to incorporate into the design opportunities for seating within the landscape in the form of low walls, steps and grass mounds.

7.13.37 Where formal seating is provided at least 50% of this shall include backrests and armrests. Seating shall be designed and located as a key element of the overall landscape design. Seating and benches placed seemingly at random will not be acceptable. The contractor shall ensure that adequate seating and rest points are provided at regular intervals along pathways and walking routes.

7.13.38 All seating must be securely fixed to the ground.

7.14 Soft Landscaping Requirements

General Design Approach

7.14.1 In accordance with the principles of 'Designing Places – A Policy Statement for Scotland' (Scottish Executive 2001) the planting and soft landscape design shall contribute towards the creation of external spaces that are distinctive, safe and pleasant, easy to get to and move around, welcoming, adaptable and resource efficient.

7.14.2 The landscape of the existing campus is largely flat, featureless and unwelcoming. In accordance with the masterplan the new planting design shall include substantial tree planting to:

a) provide immediate and long term landscape structure and impact within the campus grounds;

b) create a distinctive and appropriate landscape setting for the new hospital complex;

c) mitigate against the visual impact of the buildings, roads, car parking and hardstanding across the site and provide human scale; and

d) mark progression along key routes and lend identity to the different spaces that will be created.

It is required that semi mature and larger nursery stock trees are utilised along principal avenues, paths and thoroughfares to achieve this requirement.

7.14.3 The detail planting design and specification shall provide an appropriate mixture of seasonal variety, height and colour for all year round interest. It shall provide both immediate impact and medium to long term growth and be capable of delivering a high quality landscape that will develop and mature over the medium to long term. The detail design layout and choice of plant material shall be appropriate to the immediate context, such as public realm, pathways and circulation zones, private/quiet space, spaces for adults, children, visitors and patients, whilst paying due regard to environmental and climate factors. The planting design shall help to provide shelter and shade as well as assisting users to orientate and locate themselves. The planting and landscape design should be developed to reinforce wayfinding strategies through the creation of readily identifiable and distinguishable spaces.

Retention & Protection of Existing Trees

7.14.4 As far as possible, the campus layout shall maximise the retention of existing mature trees on site and incorporate them into the overall layout and landscape design. In accordance with planning conditions and best practice, all trees to be retained in the medium to long term shall be protected in accordance with BS 5837:2005, the exact method to be agreed with the Planning Authority.

Felling of Existing Trees & Vegetation Clearance

7.14.5 In accordance with the Wildlife & Countryside Act 1981, any tree felling and shrub clearance shall be carried out outside the bird breeding season (March to August). Contractors shall take due cognisance of this requirement in any work programming. Where this is not possible a qualified ecologist shall be appointed to examine all potential breeding sites before any clearance takes

place. If occupied nests are found, clearance and felling works shall cease until the nest is no longer in use. The contractor shall formally confirm to the Planning Authority in writing if clearance is in order following the ecologist's inspection. A qualified Ecologist shall be as defined in BREEAM Healthcare.

7.14.6 Where any tree work is undertaken this shall conform to BS 3998 "Recommendations of Tree Works and current HSE/AFAG safety leaflets

CAA Restrictions

7.14.7 The site lies approximately 3 km from Glasgow Airport, well within it's 13km 'safeguard circle' and therefore detailed consultation with the CAA will be required to develop proposals that minimise any increased risk of birdstrike. The landscape and planting design shall form an integral part of the 'Bird Hazard Management Plan' which is required for submission to the Planning Authority. The Contractor shall comply with the CAA publications CAP 772 – 'Birdstrike Risk Management for Aerodromes' and Advice Note 3 – 'Potential Bird Hazards from Amenity Landscaping and Building Design'. It is likely that adherence to this guidance will impact on the specification of plant material and contractors are therefore required to consult early with the CAA to establish their requirements. Approval by the CAA of the detailed landscape proposals will be required to clear the Planning Conditions relating to the detailed landscape design.

Landscape Design and SUDs integration

7.14.8 Landscape design associated with SUDS shall comply with CAA Advice Note No.6 – 'Potential Bird Hazards from SUDS'. Any surface water features associated with a SUDS design for the site shall be fully integrated with the landscape design, as opposed to simply 'landscaped'.

7.14.9 The SUDS solution of the Contractor shall actively consider underground storage tanks which shall consider the use of the water for grey purposes on the site where possible.

Biodiversity

7.14.10 The detailed landscape and planting design shall be developed in accordance with the 'Biodiversity Action Plan' submitted to the Planning Authority as part of the Masterplan.

7.14.11 It is a Planning Requirement that the new landscape framework for the campus will link areas of established green networks within and beyond the site, SUDS proposals and movement networks (roads, footpaths and cycle paths) to habitat retention and creation, minimising the impact of the development on wildlife and vegetation. Contractors will require to reconcile the requirements of the Planning Authority with the restrictions that may be required by the CAA as noted above, together with maintenance regimes on site in the detailed landscape and planting design. Contractors will be required to undertake a detailed habitat assessment using a qualified ecologist to establish the baseline situation at the start of the contract to inform the detailed landscape design development.

BREEAM

7.14.12 The Contractor shall maximise BREEAM Healthcare points available through the landscape and external works as a key element of their designs. In conjunction with 'Biodiversity' above, a qualified ecologist will be required to undertake a habitat survey to establish the baseline situation at the start of the contract to inform the detailed landscape design development with a view to achieving maximum points available and contribute towards the required "excellent" rating.

Topsoil

7.14.13 Should topsoil stripped from the site be retained on site, this requires to be in a dedicated storage area, appropriately stored, protected from contamination, maintained and re-used within the final landscape works as required. The Contractor will be required to undertake a comprehensive soil analysis (BS 3882 Annex E) to determine whether there is any contamination present that would limit or otherwise restrict the use of site stripped topsoil within the final landscape works.

7.14.14 If it is determined that the material be taken off site, either on a temporary or permanent basis, this shall be agreed in writing with the Planning Authority in accordance with condition 9.

7.14.15 The soil analysis shall also determine nutrient deficiencies and the requirements for fertilizer and soil additives required to ensure the successful growth and establishment of the planting specified for the areas to which it is finally spread.

7.14.16 Imported topsoil shall be to BS3882 "multipurpose" grade or as required to suit the final choice of plant material. The use of peat shall not be permitted. All compost shall comply with PAS 100.

Topsoil Storage

7.14.17 Where imported or existing topsoil is to be stored in a single location for no more than 6 months (maximum) the height of storage mounds shall not exceed 2M. Where a period of more than 6 months is required the height of the mounds shall not exceed 1M high. Where existing topsoil is stripped and stored the soil shall be turned every 6-12 months.

7.14.18 All topsoil stored for longer than 6 months shall be re-tested to determine the degree of nutrients, fertilizer and ameliorants required immediately prior to re-spreading in its final location.

7.14.19 Topsoil depths for planting:

a) Shrub planted areas: 400mm minimum depth; and

b) Grass areas: 150 mm minimum depth;

i) General handling and contamination prevention; and

ii) Subsoil/ground preparation for landscape areas.

Plant Material

7.14.20 The specification criteria for plant material in general shall conform to either the National Plant Specification or BS 3936 and other related British Standards. The specification criteria for Semi Mature and Root-Balled Trees shall be to BS 4043.The handling, transportation, storage and establishment of plant material shall be in accordance with the Horticultural Trades Association publication 'Handling and Establishment of Landscape Plants'. Contractors will be responsible for developing a robust and technically competent specification for all the soft landscape and planting works in accordance with the best industry standards and practice.

7.14.21 The choice of plant species and provenance of plant material shall be appropriate to achieve the purpose required by the design and for the location, scale and situation in question. There is no general limitation on the type and range of plant material envisaged with the following exceptions:

a) Thorny or spiny plant material shall be avoided, especially within the body of the site within the ornamental species mixes. This type of material traps litter and debris which is then extremely difficult to clear and consequently encourages the nesting of vermin. Possible exceptions might include the use of Hawthorn or other native hedgerow plants along the site boundaries in association with structure or woodland planting, depending upon the final design layout.

b) Poisonous plants/skin irritants on contact with foliage/stems further definition required.

7.14.22 Planting densities and size at planting shall be appropriate to ensure a careful balance between immediate and short term impact and long term growth.

7.14.23 Tree planting pit/trench size and design shall be appropriate to ensure the long term establishment and future growth of all new trees. This shall include where required the use of drainage, irrigation tubes and root protection barriers adjacent to services. All semi mature trees shall be underground guyed using an approved proprietary product such as the Platipus system (or equivalent). All tree staking shall be double short stakes with cross bar.

7.14.24 All semi mature tree planting shall be provided with a 5 year establishment guarantee from the supplier(s) The defects period and contractors' liability for replacement planting shall extend to the full period of the guarantee, subject to standard industry limitations. The defect period for tree planting in general shall extend to a minimum of two growing seasons following agreed completion of the contract.

7.14.25 Extended establishment guarantees from suppliers shall be required in relation to semi-mature tree planting.

7.14.26 Any seeded areas are to be protected by secure temporary fencing (secure to the ground and securing the seeded areas from access) until such time as the seed takes.

7.14.27 Any grass adjacent to the children's play areas and entrance to the Children's Hospital to be turfed.

Maintenance

7.14.28 The contractor shall develop and submit a fully detailed management plan and maintenance schedule of the completed landscape design for approval. Maintenance shall generally conform to the relevant sections of BS 7370 and be designed to ensure the long term establishment and development of the new landscape and planting design.

7.15 Wayfinding & Signposting

External wayfinding strategy

7.15.1 The movement of people through a hospital site is one of the key factors to the successful scheme. Wayfinding considers the different aspects regarding this and creates a system which responds to the requirements of each separate situation. The Contractor should create a unique identity for the hospital by providing an integrated solution between signage, architecture, interior design, landscape and art. The solution should provide a clear strategy for patients, visitors and staff whilst also assisting people with restricted mobility, impaired vision and language difficulties.

7.15.2 The Contractor should in their wayfinding proposals consider the prominence of architectural and interior landmarks on the site as well as colour coding, imagery, sign types and fonts etc. to create a visually stimulating family of signs as well as providing a system which conforms to current legislation. The Planting and landscape design shall assist with wayfinding and route marking around the site and provide identity to the different spaces within and around the site.

7.15.3 The solution should eliminate doubt and uncertainty in a potentially anxious environment by providing information at the right points as well as architecturally designed areas of interest and comfort. The accessibility of the site will be enhanced by a successful wayfinding system.

7.15.4 It is the Board's intention that Contractor's should incorporate electronic information points utilising touch-screen technology in addition to the manned reception points and stations internal to the building and the PA system. These information points should be located externally at appropriate locations and should present information (in a variety of languages) on the hospital for orientation and wayfinding purposes along with information in relation to the public transport hub which should be adjacent to the main entrance giving real time information on bus/fastlink timetables. The Contractor will be required to provide a clear strategy for the provision of these information points.

7.15.5 The above should be integrated into a clearly defined arts programme, which from the beginning of the project develops a strategy considering the site as a whole.

7.15.6 The following criteria require to be incorporated in the Contractor's external signage proposals;

a) all signage (internal and external) to be provided by the Contractor;

b) the signs will be exposed to the elements and therefore will require to be robust, accident proof, vandal resistant and weather proof;

c) the signs will be mounted generally on grey ppc steel posts fixed to concrete bases, the signs are to be a matt aluminium finish;

d) all light units to signs should be externally located to be easily accessed and maintained;

e) overstuck lettering is not acceptable; and

f) traffic signage to be compliant with Transport Scotland guidance;

As a minimum the Board would expect the following external signage to be incorporated, signage to be a Hospital Campus (i.e. whole existing and new hospital) wide integrated solution:

Location	Function/Type	Identity Requirements
All vehicular, pedestrian, cycle entrances to the site	Facility Identification	All external signage requires to be as NHS Identikit Guidelines and as such feature the following ; • NHS Greater Glasgow & Clyde Identity incorporated. • Generally white background with NHS Scotland dark blue text in Stone Sans type face. • Colour on external signage to be NHS Scotland Dark Blue or Light Blue only. • If required to identify for example entry only for ambulances – this can be reversed to light/dark blue background with white text. • Signage size , height and text size should be appropriate to location and function • The limited incorporation of the caring device is acceptable. • Directional signage should indicate arrows and text ranged according to the direction. • All external signage will require to be clearly illuminated. • Matt Finish to all external signs. • Built up brushed stainless steel lettering or equivalent standard finish to signage will be expected to be incorporated at key areas of public prominence – entrances, receptions, atria, main circulation.
Vehicular routes through site	Building Identification	
Vehicular routes through site	Car Park Location – directional / Availability of Spaces	
Car Park entrances	Identification of Car Park entrances	
Car Park	Identification of disabled designated spaces	
Pedestrian and vehicular routes through site	Building Location - directional	
Building Entrances	Identification of Building entrances	
Building Entrances	Identification of Building	
Building Entrances	Building Directory – indicating key departments	
Vehicular routes through site	Identification of ambulance only / service only routes/entrances and helipad	
All locations	Statutory Signage	As guidance requirements

Internal wayfinding strategy

7.15.7 Design solutions shall present an integrated and comprehensive wayfinding solution that enables patients, visitors and staff to self-navigate the Facilities with ease. The wayfinding solution must comply with the DDA, meeting the needs of people with physical and/or sensory disabilities/impairments, and those with literacy difficulties. It shall add value to the internal environment and could be a component of the comprehensive arts programme.

7.15.8 Way-finding is a critical part of the building functionality, and must guide patients and visitors to their desired destination in the most efficient manner possible. It should be borne in mind that people using health buildings may be easily disorientated due to illness and / or upset; they may be in unfamiliar surroundings; they may have difficulties with sight, hearing, mobility or learning; they may not have English as their first language; or they may need information presented at a lower level because they are in a wheelchair.

7.15.9 An audit of the signage within the Facilities shall be completed with the Board prior to Completion to ensure that the signage is complete, and that no ad hoc signs are required to complete the wayfinding scheme.

7.15.10 The following criteria require to be incorporated in the Contractor's proposals:-

a) all lift and door signage should incorporate the use of braille;

b) all signage and signage fixings must be robust and vandal resistant;

c) colour contrasted or tactile variation flooring clues should be provided to main reception area to guide visually impaired people to reception desk point at 90 degrees from circulation route. Clear orientation markers/signals are required at changes in direction at all entrance routes and main entrance;

d) There is an expectation that the signage will require to incorporate additional colour and/or images in line with the overall wayfinding strategy. The Contractor will require to provide a clear demonstration of this approach, which may for example assign colour on a departmental or level by level basis or to identify and differentiate the Children's Hospital. However any colour strategy developed for signage should be within the standard colour ranges identified (including tints) within NHS Identikit Guidelines. Any adoption of images on signage as part of this strategy will require to be developed in conjunction with the Board; and

e) In order to provide staff, patients and visitors with access to information especially at the key points of entry to the Works it is required that the Contractor shall incorporate electronic information points utilising touch-screen technology in addition to the manned reception points and stations and the PA system. These information points should present information (in a variety of languages) on the hospital for orientation and wayfinding purposes along with information in relation to the public transport hub which should be adjacent to the main entrance giving real time information on bus/fastlink timetables. The Contractor will be required to provide clear proposals for the provision of these information points.

7.15.11 The Contractor is required to comply with the relevant NHS Publications in relation to signage and must include the following provision;

Location	Function/Type	Identity Requirements
Main Entrances	Facility Identification	All internal signage requires to be developed from NHS Identikit Guidelines and as such feature the following ; • NHS Greater Glasgow & Clyde Identity incorporated. • Generally white background with NHS Scotland black text in Stone Sans type face. Other background colours can be considered – within NHS Identikit colour ranges identified. • Signage size, height and text size should be appropriate to location and function. • Directional signage should indicate arrows and text ranged according to the direction. • Matt Finish to all internal signs • Monolith, ceiling fixed or wall mounted signage types are acceptable for internal signage. • Illumination should be incorporated for signage within areas of public prominence – for example main entrances, atria, key receptions etc.
Main Entrances	Building Identification	
Main Entrances	Reception Identification	
Main Entrances	Building Directory – Identifying department locations on a floor by floor basis – featuring building plan.	
Main Entrances	Department Locations - Directional	
Main Entrances	Identification of key facilities – Toilets , Stairs, Lifts etc	
External to Stairwells	Level Directory	
Inside stairwell	Stair Identification	
Lift Car	Level Directory	
Corridors	Departmental Locations - Directional	
Corridors	Identification of Exits - Directional	
Departmental Entrances	Identification of Departmental entrances	
Departmental Entrances	Departmental Directory	
Departmental Entrances	Reception Identification	
Departmental Corridors	Key Locations - Directional	
Departmental Corridors	Room Identifiers (Every Room)	Room signs to feature the following; • Signs should be adjacent to doors at a height of 800–1500 mm and tactile (Braille) so that they can be easily read by touch. • Room name • Room number • Occupant name (should be removeable)
All locations	Statutory Signage	As guidance requirements

7.16 Protection

7.16.1 The Contractor shall be required to demonstrate that their proposal provides the most effective height / location and orientation of protection that shall prevent direct impact with the building fabric.

7.16.2 The Contractor is required to comply with the relevant NHS Publications in relation to protection and must include the following provision;

Location	Protection	Handrail
All main communication routes/main corridors between departments	Heavy Duty ; Mid-height handrail and either durable material on lower part of walls, or lower height crash rail, and with splayed skirtings in main corridors. Corner protection also required.	Handrails required. Handrails should return into recessed doorways and openings, but otherwise be continuous to aid navigation.
Hospital Street / Building Entrances	Severe duty; Mid-height handrail or crash rail, lower height crash rails and splayed skirtings. Corner protection also required.	Handrails required. Handrails should return into recessed doorways and openings, but otherwise be continuous to aid navigation.
Departmental Corridors; All wards	Heavy Duty ; Mid-height handrail and either durable material on lower part of walls, or lower height crash rail, and with splayed skirtings in main corridors. Corner protection also required. Bed locators where required.	Handrails required. Handrails should return into recessed doorways and openings, but otherwise be continuous to aid navigation.
Operating Theatres	Rails may be omitted in favour of overall durable, washable finishes. In practice the greater care shown by the theatre users appears to compensate for the lower level of protection.	None required.
Workshops, storerooms etc	May be constructed of materials which are not necessarily given a decorative finish, or applied protection. These materials include brickwork, blockwork and concrete.	None required.

7.16.3 The Contractor will also be expected to provide, as a minimum the following provision;

a) where handrails and wall protectors are provided a minimum vertical clearance of 50 mm must be maintained between the handrail and wall protector and a minimum horizontal clearance behind the handrail of 75mm;

b) where the wall protector protrudes in front of the handrail, the clear width of the corridor will be to the wall protector; and

c) handrails should be easily visible, that is, contrast visually with the surface to which they are fixed, smooth and free of any abrasive elements, neither too cold nor too hot to the touch.

7.16.4 The Contractor shall undertake a detailed review of those pieces of mobile equipment both Clinical and Non-Clinical, that is expected to be used by the Board and The Contractor within the Works. This review shall include a process of risk assessment and shall be organised to determine the type and extent of protection that is required to the building fabric. This review shall be made available to the Board as requested.

7.16.5 The Contractor shall endeavour to minimise the extent of impact damage incurred by ensuring corridors are and free awkward comers / obstructions. The Contractor shall ensure that doors and lifts are of sufficient width to accommodate all forms of hospital traffic and shall, where necessary, be designed to be normally held in the open position or to automatically open where appropriate.

7.16.6 In line with health building guidance, continuous hand-rails should be fitted to both sides of all patient accessible routes and corridors. Certain proprietary handrails have also been developed as wall protection crash rails. A combination of these hand rails or some of the following forms of protection would be deemed appropriate in patient and non patient routes and corridors:

a) crash rails;

b) defensive coves; and

c) corner treatment and reinforcement.

7.16.7 Exposed services such as ducts, radiators and pipework can be badly damaged when struck by trolleys etc. The Contractor shall incorporate measures to avoid damage to these elements.

7.17 Integration of Healing Arts Strategy

7.17.1.1 Introduction

Art and Architecture is a key strand of the Board's Arts and Health Strategy. The Board recognises that good design in healthcare buildings makes a measurable difference to the experience of patients, visitors and staff.

7.17.2 As part of it's Design Action Plan, the Board are committed to the development and integration of Art and Therapeutic Design within the new developments at Southern General Hospital and this will include;

a. New Adult Acute Hospital;

b. New Children's Hospital;

c. New Laboratory Block (part of novated design); and

d. External space and general landscaped areas within the site boundary.

7.17.3 The Art strategy will be developed in the context of;

a. current Board arts strategy work already being undertaken in Glasgow as part of ASR I and the new Maternity Unit at Southern General Hospital;

b. the range of cultural, regeneration, funding partnerships already established within Greater Glasgow and Clyde; and

c. the need to ensure a local arts perspective is developed that reflects international level of quality.

7.17.4 Competitive Dialogue Stage (May - September 2009)

Bidders are asked to clearly demonstrate within their written and drawn responses how they will develop and deliver an Arts and Therapeutic Design Strategy that reflects:

a. Integrated art, specimen art, interior design and landscaping (e.g. stained glass, bespoke art, special lighting, floor designs, therapeutic colour choices, special procurement of non clinical looking furnishings, landmark way finding, gardens and sensory planting);

b. Art enabling works (e.g. electrical infrastructure, lighting, wall niches and strengthened walls and ceilings to host future art works);

c. The provision of programmable spaces (e.g. future exhibitions, performance or sculpture); and

d. Architectural elements (e.g. entrance canopy, art doors, curved walls, specially designed stairways and car parks);

7.17.5 Bidders are asked to prepare a detailed proposal of how they will provide resources and capacity to support the Board's aspirations to develop and deliver this strategy in conjunction with a wide range of stakeholders including patients, managers, clinicians and fundraisers ensuring that the Art strategy and design proposals are fit for purpose and in line with contract management/ build timelines.

7.17.6 Broad Plan for Developing and Delivering an Arts Strategy

The Arts strategy should be developed with a tiered approach based on priority areas for art and therapeutic design to be implemented on a discretionary basis reflecting levels of finance available. The table below gives an indicative format, but bidders should bring forward proposals which they feel will develop the most rewarding strategy.

Bidders are strongly recommended to have dedicated resource for the inputs below in terms of architecture, arts and technical requirements.

STAGE	TASKS	RESOURCES
Stage 0 Competitive Dialogue	Develop Art Strategy as part of bid proposals. The strategy developed by your team will form part of the evaluation process.	Identify bidder resources that will be provided during Stage 2 design and anticipated costs over the time period for stage, along with assumptions on frequency of meetings etc. The proposals should therefore ring fence money and time for Stage 2.
Stage 2 Design Development	The successful bid team will develop their strategy along with Board managers and other associated groups as noted earlier. • As a key member of the Board's Arts Development Group you will meet monthly to develop, plans and incorporate a full arts strategy into the detailed designs for the new builds. Prepare detailed costs and budgets for these works for Board consideration. • Working to the Arts Development Group will be the artists and designers who will meet weekly through design development forum to discuss concepts, plans, detailed and help prepare detailed costs.	The successful bid team will be required to take forward the strategy subject to Board involvement and work with teams to develop a workable proposal that is both achievable, realistic and affordable in the run up to FBC and approval to proceed with construction of the adult and children's hospitals. Note: costs for the arts strategy may be included within the contractors price, or funded by external Board source, or from a combination of these.
Stage 3 Construction of Adult and Childrens Hospitals	Incorporate the agreed art strategy design into the new builds	Manage the construction and full integration of the approved strategy on site by the successful bid team. Attend periodic meetings (quarterly) to review progress.
Stage 4 Commissioning	Fully commission any loose art works requiring service connections.	This would occur during post handover Board equip[ping stage, detail and input from bidders would be developed during Stage 2.

7.18 Secure by Design

7.18.1 It is important that security is effective but not visible and we would seek to avoid through good design the need for overt signs of security systems such as perimeter fencing and extensive CCTV provision.

7.18.2 The principals of 'Secure by Design' promote good practice, and encourage the adoption of design principles that reduce crime prevention as opposed to adopting 'active' preventative measures, The Contractor shall provide a report detailing compliance as far as is practicable with Secure By Design certification requirements. The Contractor should liaise with the local police in refining a strategic approach to the security of the facilities and the overriding safety of staff, patients and visitors.

7.18.3 While connections to the community are encouraged, not to the detriment of security Frequently, 'single point of access' is a strategy that is widely encouraged.

7.18.4 The following are extracts from the 'Secured by Design Principals' Document (2004):

a) Access design and escape routes;

To satisfy the requirements of individual developments, and in the interests of good urban planning, new development must provide adequate access to meet functional and recreational needs, including for example paths and inter-connecting open spaces, and access for emergency services. However multiple footpaths and points of access can make crime easier to commit by providing a choice of alternative escape routes from the scene of a crime. Careful attention to the disposition and design of access, and in some cases limiting the means of access to developments and to buildings, can assist in reducing opportunities for a crime, be it illegal entry, vandalism, crimes against the person or vehicle theft. Uncontrolled rear access ways to buildings and footpaths that are unduly secluded provide opportunities for crime with a low risk of detection and are to be strongly discouraged. It may on occasion be necessary to restrict access to a development to one main point, and it is always advisable to carefully consider the desirability and design of secondary access routes;

b) Footpaths and cycleways;

Public footpaths and cycle ways form a vital part of the communications network in both urban and rural settings. They also provide an important local or strategic recreational amenity. Their provision is strongly encouraged by current government planning guidance, but awareness is need of the potential problems that poorly located or poorly design footpaths can have. They can, for instance provide opportunities for unobserved access to the rear of buildings, means of escape for offenders and opportunities for crimes against people. Furthermore, poorly designed or sited footpaths may cause users to feel ill at ease and give rise to fear of crime, particularly after dark. This is likely to lead to reduced levels of use, which reduces the benefit to the community and will in turn exacerbate the problem. Well designed, well used and well maintained footpaths on the other hand provide fewer opportunities for crime and are likely to feel safer;

c) Relevant Secured by Design Key points:

i) Superfluous and unduly secluded access points and routes should be avoided;

ii) Access points to the rear of buildings should be controlled, for example by means of lockable gates;

iii) In terms of security, the design of the footpath of equal importance to the design of the building. The standard combined cycleway/footway should be 3m wide as a minimum and footways 2m wide as a minimum. Any shrub planting should start at the back of the verges;

iv) The position of the planting and choice of species should be such that hiding places are not created;

v) Good visibility should be maintained from either end, and along the route of footpaths and cycleways. Sharp changes in direction should be avoided;

vi) Footpaths and cycleways should not generally be routed to the rear of the buildings, but if this is unavoidable a substantial buffer should be planted between a secure boundary fence and the footpath margins, with planting designed so as to discourage intruders;

vii) Footpaths and cycleways shall be lit in built-up areas to adoptable street lighting standards except where the route is passing through woodland or and ecologically sensitive area, in which case an alternative lit route should be made available, such as a footway alongside a road; and

viii) Alternative routes to important destinations may be beneficial, although a balance has to be struck between advantages of greater choice and perceived security against the disadvantage of providing additional means of escape or of encouraging inappropriate movement of people.

Section 8.0 Building Services Requirements

8.1.1. Introduction

8.1.1.1. The Contractor shall in carrying out the Works comply with the following non-exhaustive list of Mechanical & Electrical requirements.

8.1.1.2. The Contractor shall provide an engineering system that utilises the latest technology to create a high quality working environment that will provide an efficient hospital for all patients, their families, visitors and staff. The Contractor shall ensure the services network is efficient, effective, flexible and unobtrusive to the clinical functions. The Contractor shall ensure that the system is easy to maintain and shall maximise the opportunities for flexible adaptation and extension of The Works.

8.1.1.3. The heating and cooling mediums shall be selected to ensure the most efficient systems are utilised taking into account integration of low carbon technologies and the site wide interconnectivity requirements.

8.1.1.4. Mechanical, Electrical, Public Health and Specialist services shall be designed to be an integral and co-ordinated part of the overall scheme. Services shall be clearly identified at regular intervals and at all locations where maintenance access is required.

8.1.1.5. Plant access shall be prioritised in all aspects of the building services design to minimise the requirement for the use of portable access equipment.

8.1.1.6. Permanent access equipment shall be provided by the Contractor to allow routine maintenance of all equipment within all plant rooms and associated areas where items of plant are located.

8.1.1.7. A systematic plant replacement strategy shall be provided by the Contractor, this shall detail the works required for the replacement of all major plant items and their major components.

8.1.1.8. All access equipment including lifting beams, access platforms, equipment cradles, slings, block and tackles and access ladders to allow all plant to be replaced in accordance with the strategy shall be provided by the Contractor with each item of equipment cross referenced to the plant items within the replacement strategy.

8.1.1.9. The location of engineering and utility services shall be co-ordinated with the structure and not constrain or conflict with clinical functionality.

8.1.1.10. Access to all services shall facilitate ease of maintenance which should be safe and able to be effectively undertaken. There shall be provision for space to give flexibility for future re-planning and / or re-modelling and replacement of the services.

8.1.1.11. The Board requires the buildings to be designed to achieve a very efficient level of energy and utility utilisation in accordance with the energy targets noted in Appendix M&E4 .

8.1.1.12. The Contractor shall take cognisance of all the building services implications of the requirements described in the Employers Requirements.

8.1.1.13. The power distribution systems and final circuits where required shall incorporate, IPS and UPS systems to meet the requirements of (S)HTM06-01 together with full compliance where appropriate with the MEIGaN requirements.

8.1.1.14. UPS to be provided from resilient platforms with N+1 redundancy with ability to transfer to shunt by-pass without loss of load, these shall be distributed throughout the works to ensure that reliable interruptible supplies are provided to suit the hospital operations.

8.1.1.15. Open protocol industry standard format must be used for all elements of the Electrical, Mechanical, Public Health Medical Gases, Security and Specialist systems.

8.1.1.16. All systems shall be warranted for support for an extended period and all software shall be retro compatible.

8.1.1.17. All Mechanical, Electrical, Public Health and Specialist system plant shall be designed and installed in modular arrangements incorporating plant N+1 redundancy to minimize disruption during planned maintenance.

8.1.1.18. All Mechanical, Electrical, Public Health and Specialist systems shall be designed and installed in resilient arrangements with dual distribution paths and appropriate isolation facilities to ensure that the completed installations meet all operational, maintenance, servicing together with plant replacement requirements and that local maintenance does not disrupt adjacent areas.

8.1.1.19. Where contradictory advice is apparent, the most recent guidance shall generally take precedence; unless indicated otherwise in the main compliance section of the Employer's Requirements – Volume 2.1 Section 5.1.

8.1.2. Engineering Services Interface with Building Fabric and Service Routes

8.1.2.1. The Contractor shall ensure that co-ordination of the Electrical, Mechanical and Communication services shall form an inherent part of The Works design.

8.1.2.2. Services provision, e.g. luminaires, fire alarms, security and mechanical services, shall be co-ordinated with the ceiling layout and allow simple relocation if required.

8.1.2.3. Access to services shall be provided and the services clearly identified at regular intervals and at all locations where maintenance access is required, for example at valves and electricity connection points. Access to building services shall be in accordance with SHTM 2023 "Access for Engineering Services".

8.1.2.4. It shall not be acceptable to require other services to be removed to allow access to services.

8.1.2.5. The positioning of sockets, light switches, alarm buttons and fire “break-glass” panels etc shall be consistently located throughout the hospital buildings and to specifications set out in BS8300, unless specific clinical needs take precedence.

8.1.2.6. Structural design shall ensure that structures are co-ordinated to ensure the logical and sequential installation and maintenance of services. For example the use of columns adjacent to vertical service voids shall be avoided.

8.1.2.7. All Mechanical, Electrical, Public Health and Specialist systems shall be fully co-ordinated in 3D with prefabricated plant, escalators, lifts, the building fabric and structural frame, secondary steelwork, façade systems, fit out to ensure that the completed installations meet all operational, maintenance, servicing and plant replacement requirements.

8.1.2.8. The Contractor shall provide secure utilities services connection to those services which are;

a) to be taken directly from public and other utilities; and

b) to the point of supply (inc connection) for those utilities which are to be taken from the Board.

8.1.3. Service Routes

8.1.3.1. All service voids, risers and other spaces shall allow for installation of additional services and shall provide a defined reserve of a minimum 25% of useable area through routing cross sectional area. All isolating valves and other items requiring particular access shall be positioned at convenient locations with permanent access provision and which do not impede execution of the clinical functions of the space.

8.1.3.2. The Contractor shall provide a compliance matrix indicating the level of provision of each service together with the means of calculation of the required 25% reserve capacity.

8.1.3.3. Services shall be arranged in a clearly zoned spatial hierarchy in ceiling voids, risers and plant spaces.

8.1.3.4. Generally access to services shall not be given in clinical areas, where this is unavoidable due to the requirement for local access the Contractor shall ensure that all services are co-ordinated and grouped to minimize the number of access hatches.

8.1.3.5. Ceiling void depths in Theatres shall be minimized, and in all cases be less than that required for void protection, with all power and data wired in a loop in basis to allow rewiring without the requirement to access the ceiling void, where access is required to allow periodic inspection of fixings, this shall be accommodated by the apparatus trims and via light fitting openings.

8.1.3.6. Services shall be configured to ensure local maintenance and isolation can be carried out in each room without the requirement to take other rooms out of use.

8.1.3.7. All service voids, risers, plant rooms and other service / plant spaces shall be designed to easily facilitate the future removal and replacement of building services within each space.

8.1.3.8. In order to minimise potential disruption to the Board due to maintenance of building services, The Contractor shall route services through common spaces such as corridors and avoid through routing within department areas.

8.1.3.9. All ductwork shall be provided to allow cleaning of internal surfaces and components to be undertaken in accordance with the Health and Safety Approved Code of Practice 33, and as detailed in the HVCA Document TR17 Cleanliness of Ventilation Systems.

8.1.3.10. Plant rooms shall be configured and constructed to minimize the risk of water penetrating into Critical operational areas. This is a pre-requisite of the design and the Contractor shall provide a detailed strategy document indicating the risk assessments and mitigation measures proposed e.g. water tanks not located above Critical operational areas, plant room floors constructed to prevent water seepage, tanking to be integrated in construction detailing rather than ad hoc post installation details, appropriate location of floor gulleys and sensitive routing of water and drainage pipework.

8.1.4. Server and Nodal ICT rooms

8.1.4.1. Major leak detection shall be incorporated complete with automatic zoned shut off valves.

8.1.4.2. Water proof ceilings to be provided in all Server and Nodal ICT rooms.

8.1.4.3. Resilient redundant environmental engineering services shall be provided within the Server and Nodal ICT rooms. The rooms shall be configured and located to minimise the risk of water damage from all sources with the following minimum requirements:

a) No overhead water, condensate or drainage pipework allowed within ICT rooms; and

b) No water tanks, tea points, DSR's, Cleaners rooms, toilets or showers etc. to be located directly above ICT rooms.

All ICT rooms to be clinically cleaned prior to the installation of active equipment, this deep clean shall be carried out by the Contractor's specialist cleaners to an agreed Board specification by the relevant Board Representative and a certificate issued. Special care shall be taken in advance of the deep clean with ongoing general cleaning being carried out at regular intervals to ensure that the cable termination works are carried out in accordance with the manufacturer's recommendations.

8.1.5. Engineering Flexibility and Zoning

8.1.5.1. All Mechanical, electrical, public health and specialist systems including medical gas zoning shall be configured to promote flexibility in order to enable re-modelling, re-planning and replacement to be undertaken at a future date.

8.1.5.2. All engineering services shall be zoned with isolation and safety provision for the whole of the the Works and for individual wards and departments. The Contractor shall also ensure that zoning accounts for:

a) The requirement for “dirty” / “clean” separation;

b) Solar movement; and

c) The necessity for isolation of part of the Works without affecting the entire facilities e.g. all theatre suite services including, ventilation, water, power, medical gases, lighting and controls etc. shall be capable of being independently isolated for maintenance with the remaining theatres still in service.

8.1.5.3. The Contractor shall ensure that all sections of the services distribution can be taken out of service for maintenance without interruption of the water, gas, medical gas and electrical supplies to the adjacent areas; this shall be detailed in the systematic plant replacement strategy noted in the introduction 8.1.1.

8.1.5.4. It is a pre-requisite of the design that all services to individual Theatres and other Critical operational areas can be isolated for maintenance, repair and replacement without the need to effect the ongoing operation of the other facilities.

8.1.5.5. Specifically each Theatre shall have individual air handling units and associated controls. The air handling strategy in Critical Care areas shall be developed with the design layout to minimize disruption during maintenance and each air handling unit must not serve more than one Critical Care pod. Also Air handling units in isolation facilities in Critical Care and general areas shall be configured in accordance with SHBN04.

8.1.5.6. Air handling strategy for the large recovery areas shall be developed with the design layout to minimize disruption during maintenance with the provision of interwoven duplicated systems and sectional controls.

8.1.5.7. Air handling strategy for the large decontamination areas shall be developed with the design layout to minimize disruption during maintenance with the provision of interwoven duplicated systems and sectional controls.

8.1.5.8. Air handling strategy for all large areas shall be developed with the design layout to minimize disruption during maintenance with the provision of interwoven duplicated systems and sectional controls.

8.1.5.9. No exposed pipework shall be visible in clinical areas.

8.1.5.10. Controls at nurse bases shall be co-ordinated with all alarm panels to improve aesthetics and ensure simple operation.

8.1.5.11. Patients operated environmental controls shall be provided to allow set point variation via a graduated slider with arrow type legend (rather than temperature levels); the local set point bandwidth adjustment shall be controlled from group settings at the BMS front end.

8.1.5.12. Emergency shut offs shall be provided at appropriate locations for all services.

8.1.6. Energy Targets

8.1.6.1. The buildings and building services solutions shall provide sustainable, low carbon, low energy facilities in accordance with Appendix M&E 4.

8.1.6.2. The Contractor shall comply with the requirements relating to energy targets as specified in Appendix M&E 4.

8.1.6.3. The Contractor shall provide a breakdown of how the target energy consumption shall be achieved. In particular, the Contractor shall provide details of the anticipated electrical and gas consumption of The Works.

8.1.6.4. In order to assist in meeting this target, the Contractor shall incorporate a high level of innovative building automation and equipment monitoring. The Contractor shall ensure that a central Building Management System (BMS) for The Works is in place, providing linked control and monitoring of the estate functions. Refer to Appendix M&E 5 for details.

8.1.6.5. The Contractor shall note that the Building Volume used in the calculation of Energy Consumption Performance Indicators shall be the “Heated Volume” as defined in Encode. The Contractor shall also include services within the calculation for determining the energy consumption.

8.1.6.6. The Contractor shall calculate the energy consumption for the new buildings using weather data from CIBSE Guides, and degree-day data. The Contractor shall submit all assumptions used to the Board for comment.

8.1.6.7. In order to assist in achieving the water consumption target noted in Appendix M&E 4. The Contractor shall use water saving measures including but not limited to:

a) Low Flush Toilets;

b) Automatic Sensor Taps;

c) Flush Controls to Urinal Facilities;

d) Major Leak Detection and Automatic Shutdown; and

e) Flow restrictors (if risk assessment accepted)

8.1.6.8. Consideration shall also be given to the possible use of borehole water.

8.1.7. Thermal Comfort

8.1.7.1. It is a requirement of the Contractor's Bid Submission that a maximum temperature (28 degree C) solution be considered for the whole of the Works. This will be discussed with bidders during the bid process. Such a solution would require to be produced with the following supporting information;

a) Capital Costs;

b) Lifecycle & Maintenance Costs;

c) Additional Electrical etc loadings; and

d) Projected Energy costs.

8.1.7.2. Where maximum internal summer time temperature calculations of ventilated rooms indicate that the internal temperature will exceed those limits set out in the Appendix M&E 3 for frequent periods, the Contractor shall provide means of reducing the temperature rise.

8.1.8. Air Quality

8.1.8.1. Internal

8.1.8.2. Air quality in all areas shall take account of occupancy levels, internal pollutants, heat gains, external pollutants, atmospheric conditions and shall be controlled to provide adequate comfort and fresh air levels appropriate to the functions of each department area.

8.1.8.3. Particular attention should be given to the risk of cross infection within the hospital / healthcare environment and shall be such as to minimise the spread of infection, all systems to comply with Hai-Scribe and infection control requirements.

8.1.8.4. The Contractor shall demonstrate how their proposals facilitate the control and management of an outbreak and spread of infectious diseases, and in particular shall comply with the requirements of SHTM 2025 (Ventilation in Healthcare Premises) and Hai-Scribe. In order to reduce cross-contamination, the design of The Works shall incorporate 100% fresh air supply systems only.

8.1.8.5. The Contractor's demonstration shall cover all aspects of the building, its services, spatial relationships, PPM Regime and incorporate requirements of the Board's Infection Control Team.

8.1.8.6. Consideration shall be given to the odours from the adjacent sewage works and appropriate filtration shall be included to reduce odours entering the facility.

8.1.8.7. Special consideration shall be given to the reduction of strong smells within the Children's hospital in accordance with SHPN23.

8.1.8.8. External

8.1.8.9. The Contractor shall comply with the requirements of Glasgow City Council and other Statutory Bodies regarding airborne emissions from the Site and shall undertake all studies necessary to prove that emissions and their dispersal will not have any adverse impact on the local community or staff, patients and visitors to the Site.

8.1.8.10. All works shall comply with the Clean Air Act. 1993.

8.1.8.11. The Contractor shall ensure that all Cooking Odours/Fumes are disposed off and do not cause a nuisance to the local community or staff, patients and visitors to the Site in accordance with Planning Condition 17 (see Outline Planning Conditions documents in Appendix D).

8.1.9. Vibration

8.1.9.1. The Contractor shall ensure that Building Services Plant and Equipment are suitably isolated from the building structure in order to prevent the transmission of vibration. The Contractor shall comply with the guidance on the satisfactory magnitude of building vibration with respect to human response given in BS 6472. The Contractor shall comply with the following vibration limits detailed below:

a) Plant rooms on occupied floors 0.015 m/s^2;

b) Plant rooms above and below occupied floor levels 0.050 m/s^2; and

c) Remote plant rooms 0.100 m/s^2.

8.1.9.2. All mechanical ventilation, air conditioning and electrical plant shall be suitably isolated from the structure of the building and fan units positioned in a ducted system shall be isolated from the ducting by means of flexible connections in accordance with Planning Conditions 12 (see Outline Planning Conditions documents in Appendix D).

8.1.9.3. To minimise structure borne noise or vibration lifts and/or hoists, including doors, guide rails and ancillary plant shall be suitably isolated from the structure of the building connections in accordance with Planning Conditions 13 (see Outline Planning Conditions documents in Appendix D).

8.1.9.4. The Contractor shall establish, in consultation with the Planning Authority, whether Best Practicable Means shall be employed as an approach to control noise or whether a baseline noise survey is required. If the latter is deemed necessary the procedures to be adopted shall be agreed in writing with the Planning Authority and thereafter implemented in the agreed manner. When detailed method statements for construction are available an assessment of hospital noise and vibration sensitivity should be undertaken and adequate controls put in place prior to the commencement of any construction demolition works in accordance with Planning Conditions 15(see Outline Planning Conditions documents in Appendix D).

8.1.9.5. All plant and systems shall be installed to meet the vibration requirement of the Clinical Equipment, including theatres and micro biology microscopes etc.

8.1.10. Acoustics

8.1.10.1. The Contractor shall ensure effective control of building services noise and provide a satisfactory acoustic environment in accordance with the following levels as per (S)HTM 08-01. This shall be developed with the Contractors Acoustician to ensure that a holistic approach is taken to prevent nuisance noise, as detailed in Appendix S – Acoustic Requirements.

Table 2 Criteria for internal noise from mechanical and electrical services		
Area type	**Example**	**Noise from mechanical and electrical services**
Ward areas, sleeping areas	Single-bed ward, multi-bed ward, on-call rooms, relatives' overnight stay	NR 30
Recovery	Recovery rooms	NR 35
Small office-type spaces	Private offices, treatment rooms, interview rooms, consulting rooms	NR 35
Open clinical areas	A&E	NR40
Circulation spaces	Corridors, hospital street, atria	NR40
Public areas	Waiting areas, dining, playroom	NR40
Personal hygiene (en-suite)	Toilets, showers	NR40
Personal hygiene (general access)	Toilets, showers	NR45
Small food-preparation areas	Ward kitchens	NR40
Large food-preparation areas	Main kitchens	NR 50 (NR 55 below extract hoods)
Large meeting rooms (>35 m2 floor area)	Lecture theatres, meeting rooms, seminar rooms, board rooms, classrooms	NR30
Small meeting rooms (≤35 m2 floor area)	Meeting rooms, seminar rooms, board rooms, classrooms	NR35
Operating theatres (excluding laminar flow theatres)	Operating theatres	NR40
Laminar-flow theatres	Ultra-clean theatre	NR50
Laboratories		NR 40 where laboratory has no fume cupboards NR 60 at 1 m from fume cupboard with open sash
Table 2 Criteria for internal noise from mechanical and electrical services		
Area type	**Example**	**Noise from**

		mechanical and electrical services
Utility rooms	Clean utility, dirty utility	NR40

8.1.10.2. As well as complying with the technical requirements noted within the various hospital documents, the Contractor shall develop a managed approach with all designers and the acousticians to provide a holistic solution in areas where low level noise could create potential problems e.g. courtyards, entrance halls etc.

8.1.10.3. The Contractor shall include active solutions were these are deemed appropriate e.g. provide piped music in atria, changing rooms to assist acoustic performance.

8.1.10.4. Noise from, or associated with the completed development (the building and fixed plant) shall not give rise to noise level, assessed with windows closed, within any dwelling or noise sensitive building in excess of that equivalent to Noise Rating Curve (NRC) 35 between the hours of 0700 hours and 2200 hours and Noise Rating Curve (NRC) 25 at all other times in accordance with Planning Conditions 11 (see Outline Planning Conditions documents in Appendix D). Refer to appendix M&E3 and the general acoustic requirements noted in section 7.8 - Acoustics.

8.1.11. Plant Life Cycle Costs

8.1.11.1. The Contractor shall ensure that all plant and systems are selected and configured to provide high quality, efficient, resilient, modular flexible and maintainable Building Services solution.

8.1.11.2. The Contractor shall provide evidence of plant life cycle costings including:

a) Capital Cost;

b) Energy Running Cost;

c) Maintenance Cost;

d) Replacement Cost.

8.1.11.3. Warranty costs for each of the building systems shall be benchmarked against industry standards and backed up by detailed costings in the extended warranty schedules.

Sustainability, Renewables, Low, Zero Carbon Technologies

8.1.11.4. The Contractor shall provide evidence of compliance with the Energy Target requirements as detailed in Appendix M&E4 and section 10 and shall develop the sustainability brief in conjunction with the Local Authority to ensure compliance with:

a) Building Regulations;

b) BREEAM Healthcare Excellent requirements;

c) Building Control;

d) Glasgow City Council requirements;

e) Scottish Government Planning Policies including SPP6;

f) Advice Notes including PAN84;

g) NHS/Board objectives.

8.1.12. Design Criteria

8.1.12.1. The Building Services shall be designed in conjunction with the development of the Architectural and Structural packages to ensure a holistic approach to minimise energy use while maintaining user comfort, fabric protection and statutory compliance.

8.1.12.2. All Mechanical, Electrical, Public Health and Specialist system plant shall be designed in modular arrangements incorporating plant N+1 redundancy.

8.1.12.3. All Mechanical, Electrical, Public Health and Specialist systems shall be designed and installed in resilient arrangements with dual distribution paths and appropriate isolation facilities.

8.1.12.4. The lighting levels shall be in accordance with CIBSE guides and Building Control requirements.

8.1.12.5. Power shall be configured to meet the Target Energy demands and also the design peak load plus 25% capacity for future growth.

8.1.12.6. The growth shall be provided in a modular configuration to allow plant cycling and high efficient running.

8.1.12.7. Fire safety systems shall be provided in accordance with the Fire Strategy.

8.1.12.8. Fire alarms shall be Fire Code and BS5839 CAT L1.

8.1.12.9. Refer to Appendix M&E 3 for Room Design criteria and internal temperature frequency periods.

8.1.13. Compliance with Health Service Notes and Memorandums

8.1.13.1. The Mechanical, Public Health, Electrical, Life Safety and Lift Services shall be designed and installed in accordance with the relevant SHTM's, HTM,s, SHBN's, HBN's, SHGN's and HGN's to meet the Employers Requirements.

8.1.13.2. Refer to Volume 2.1 Section 5.0 General Design & Construction Requirements for document hierarchy and Compliance Requirements.

8.1.14. Compliance with Planning/Building Regulations

8.1.14.1. The Building Services Installations shall generally comply with the Building Regulations and Planning Requirements.

8.1.14.2. If any deviations are proposed these must be highlighted in the contractors return documentation together with the details of the proposed mitigation strategy.

8.1.15. Incoming Services - Utility Connections

8.1.15.1. General

8.1.15.2. Discussions with the supply company have been commenced by the Client and contract details are included in Appendix M&E 1.

8.1.15.3. The Contractor will be responsible for the provision of all utilities and the energy supply infrastructure to and from The Works (whether this is internal or external to the Site boundary), including:

a) Confirmation of the capacity of the proposed system;

b) Liaison with potential suppliers;

c) System development and planning;

d) Any supplies modifications to the periphery of the Site;

e) Any supplies modifications within the Site;

f) Metering and sub-metering of power supplies;

g) Metering and sub-metering of heating usage;

h) Metering and sub-metering of cooling usage;

i) Metering and sub-metering of water usage;

j) Metering required for BREEAM;

k) Strategic planning in the context of the site environment;

l) Emergency systems; and

m) Power factor correction.

8.1.16. Security of Incoming Supplies

8.1.16.1. The Contractor shall provide back up to respond to the failure of the incoming supply of Electricity, Gas and Water supplies to The Works. This shall:

a) Provide full standby generator capacity for all electrical services on an N+1 basis in accordance with the requirements and recommendations of (S)HTM 06-01;

b) Ensure that The Works are provided such that all the requirements detailed in (S)HTM 06-01 are satisfied;

c) Ensure that energy, water, power supplies, medical gases and communication supplies to and within The Works are maintained by providing standby sources of supply (eg. dual fuel boilers, standby generators etc);

d) Develop a strategy to ensure the security of the supply. The Contractor shall be required to demonstrate the feasibility of the strategy to the satisfaction of the Board; and

e) Ensure their town's water connection to the Site maintains an adequate and robust service and shall provide connection details with their proposals;

8.1.17. Water

8.1.17.1. A robust alternative town's water supply is to be provided by the Contractor to the Site from a separate sector of the Scottish Water network.

8.1.18. Site Mains Water, Fire Water, Quality & Distribution

8.1.18.1. The Contractor shall develop the Site potable and fire water networks as separate systems each arranged with adequate valving to achieve robustness in continuity of supply.

8.1.18.2. The outcome of the water survey works is awaited, it is anticipated that The Works are to be supplied from dual supplies one from Govan Road and a second from Hardgate Road.

8.1.18.3. The Contractor shall filter the Site potable water to the criteria set out in SHTN02 with 0.2 micron filtration. Pipework shall be stainless steel.

8.1.18.4. The water filtration system shall be established within the Energy Centre to provide resilient filtered water to meet the requirements for The Works.

8.1.18.5. The Contractor shall provide external isolation of water supplies to the new Facilities.

8.1.19. Incoming Power

8.1.19.1. The overall site power systems shall be integrated with the Distribution Network Operator (DNO) incoming arrangement to provide a resilient system.

8.1.19.2. Scottish Power have advised that the existing 11kV network cannot accommodate the New Hospital load; they have been requested to provide proposals to enhance their network for the development. The Contractor shall negotiate with the supplier and ensure that an integrated solution is provided to meet the new building together with the additional site requirements detailed below.

8.1.19.3. The system shall also be configured to provide power for retained estate and new build areas as indicated in Appendix M&E1.

8.1.20. Fossil Fuels

8.1.20.1. The Contractor shall be responsible, in conjunction with SGN in determining the philosophy for the provision of fossil fuels to the Site.

8.1.20.2. Options the Contractor shall consider are;

a) Un-interruptible gas supply;

b) Provision of dual fuel burners and a heating oil standby facility;

c) Installation of CHP for base load;

d) Provision of CHP to provide full campus Electrical and Heating Loads in “Island” configuration with grid as standby.

8.1.20.3. Standalone Heating Boilers are not mandatory if the bidder identifies packaged CHP plant which does not require them to provide the required resiliency and dual fuel capabilities.

8.1.20.4. Irrespective of the option proposed by the Contractor the availability criteria described elsewhere in this document must be strictly adhered to.

8.1.20.5. Natural gas is required for;

a) Space heating;

b) Limited steam generation (for humidification);

c) Combined Heat and Power systems; and

d) Catering.

8.1.20.6. The gas supply shall be provided by a new mains connection from Govan Road. The pipework shall be routed to the Energy Centre to feed the Heating Boilers, CHP plant and routed to serve localised requirements within the Works.

8.1.20.7. Twin regulators shall be provided at the gas meter, non return valves shall be fitted at fire isolation valve to avoid back pressure shutting down regulator valve on activation of the fire valve.

8.1.20.8. Automatic Isolation facility to be incorporated in all gas fire valves during fire alarm testing. Valves shall be capable of being reopened and set to work remotely via the BMS.

8.1.21. Standby Power

8.1.21.1. Electrical Supplies to the Works shall be fully backed up by on site generation as noted above and in item 8.3.31 below. The Contractor shall provide the infrastructure and plant space to allow the extension of the generation capacity to meet the additional site loads as noted above together with a 25% capacity for growth.

8.1.22. Medical Gases

8.1.22.1. A new oxygen VIE compound is to be provided by the Contractor rated to supply the combined demand of The Works and the retained estate.

8.1.22.2. The existing site systems shall be extended by the Contractor to also be capable of supplying the combined site demand, this may be achieved by the expansion of the Maternity accommodation or the establishment of a further VIE compound site, which summated with the existing Maternity storage will meet the combined demand of the the Works and retained estate.

8.1.22.3. For the purposes of the Bid, the bidder shall assume that the latter is required and shall include for a further new VIE compound to be located as per drawing G1274/U(96)01.

8.1.22.4. The Contractor shall provide all civil, builderswork and distribution pipework via a ring main distribution circuit, which should be carried through to the new building risers.

8.1.22.5. The system shall be fully compliant with current SHTM requirements.

8.1.22.6. The Contractor shall liaise closely with the Boards Supplier who will lease the VIE tanks. The contractor shall carry out all builders work, foundations, bases, blast walls together with all pipe and electrical works.

8.1.22.7. Medical gases shall be supplied and configured to suit the new Hospital requirements and retained estate requirements including:-

a) Nitrous Oxide;

b) Oxygen (as above);

c) Vacuum (Split over two systems with valved off link); and

d) Surgical and Medical Air services (Split over two systems with valved off link).

8.1.22.8. Medical air plant should be provided from 2 separate sources of supply via a ring main distribution net work, carried through to the internal risers.

8.1.22.9. Within the Children's hospital special care shall be taken in the location and covering of medical gas equipment to reduce fear while retaining full operational abilities. The proposal shall be robust, simple to use and easily cleanable.

8.1.23. IT

8.1.23.1. IT equipment/server rooms shall be established in both the new Children's Hospital and Adult Acute Hospital. The two new rooms shall be interlinked, together with associated hub rooms via a star/mesh configuration of cabling.

8.1.23.2. Distributed secondary comms rooms shall be established to allow CAT 6A cables to be run to all positions within The Works within the 90m cable length restriction.

8.1.23.3. All new incoming services shall be duplicated and presented individually at the two server rooms. Ducting and manholes to be provided to up to four providers with diverse routes for each network provider.

8.1.23.4. Distributed secondary comms rooms shall be established to allow CAT 6 Augmented (CAT6A) cables to be run to all positions within The Works within the 90m cable length restriction.

8.1.23.5. The Contractor shall ensure that his works have no impact on the security of services to the existing hospital estate during the site construction works.

8.1.24. NHS Model Engineering Specifications

8.1.24.1. The Contractor shall ensure that systems are installed in accordance with all relevant NHS Model Engineering Specifications and amendments to ensure compliance with the Technical Memorandum.

8.1.25. Service Capacity Reserve

8.1.25.1. In accordance with Good Industry Practice, all plant, plant spaces and building services systems shall be specifically designed and provided with defined reserve capacity allowances and future expansion capabilities for The Works (e.g. distribution boards with 25% spare capacity, 25% additional containment, 25% spare capacity in distribution Pipework, 25% additional plant capacity, 25% additional cooling capacity, 25% additional air handling capacity etc. for the buildings as designed). As detailed in 8.1.3.2, the Contractor to provide compliance matrix detailing how this to be delivered.

8.1.25.2. With optimum for maximum temperature variant (MV2).

8.1.25.3. This shall be demonstrated within the calculations, plant room layouts and service route drawings provided with each stage of the design build project to ensure full compliance at project completion.

8.1.25.4. In addition to the reserved capacity allowances the Contractor shall also ensure reserve capacity, service termination, zoning and general arrangement supports any future extension of the building that may be an optional feature of the Contractors Proposals.

8.1.26. Commissioning, Testing and Demonstrations

8.1.26.1. The Mechanical, Electrical, Public Health and Specialist systems shall be fully tested and commissioned in accordance with:

a) CIBSE Commissioning Code;

b) The Institute of Hospital Engineers Guidance to Engineering Commissioning;

c) Requirements of SHTN’s and SHBNs; and

d) Requirements set out in the works documents

8.1.26.2. The Contractor demonstrations are to cover all aspects of the building, its services, and spatial relationships, Soft and Hard FM and incorporate requirements of the Board’s Infection Control Team.

Refer to section 6.8 – Commissioning & Handover for details.

8.1.27. Environmental Proving

8.1.27.1. During the design stage the Contractor shall provide the Computational Fluid Dynamic requirements of SHPN57 e.g. CFD shall be used to model and prove the ventilation strategy for the works.

8.1.27.2. On completion of the commissioning of all individual systems the overall performance of the combined systems shall be demonstrated within every room within the Adult Acute and Children's Hospitals.

The following parameters shall be recorded:-

a) Space Temperature;

b) Space Humidity;

c) Space Sound Levels;

d) Controls Operation & Achieving Set Points;

e) Domestic Hot and Cold Water;

f) Air Velocities (Comfort Criteria);

g) Lighting Levels; and

h) Fire Alarm Sounders.

8.1.27.3. Trend logs from the BMS system are to be used as a record of the local conditions achieved where possible, or hand held instruments with current Calibration Certificates. All readings shall be recorded, tabulated and issued.

8.1.27.4. Measuring instrument Calibration Certificates shall be forwarded for record purposes.

8.1.27.5. Room cooling capacities shall be tested on a department by department basis by introduction of temporary heat loads to prove the system design capabilities.

8.1.27.6. This shall be carried out by the Contractor at their own cost.

8.1.27.7. The Contractor shall also carry out seasonal commissioning as detailed in Appendix U – BREAAM Guidance, to ensure full system performance i.e. Main cooling plant operation in the summer and heating plant in the winter.

8.1.28. Asset Register

8.1.28.1. The Contractor shall include for a comprehensive Asset Register to be compiled on an open protocol industry standard format for all elements of the Electrical, Mechanical, Public Health Medical Gases and Specialist systems.

8.1.28.2. The Contractor is advised that an NHS Scotland (HFS) National asset management package is currently out to tender for development, this should fully developed and implemented by the time The Works are in the construction phase, failing this the Asset Register management package should revert to industry standard current at time of construction.

8.1.28.3. The register shall be linked to the As Fitted drawings via MiCAD drawing mapping, the MiCAD should also integrate with the Labour Management Systems (LMS) to provide a fully integrated system complete with interfaces to the PPM and Board's labour resource software systems (Apollo or Eclipse).

8.1.28.4. For ease of reference, all installed Mechanical, Electrical, Public Health Medical Gases and Specialist systems components shall be asset tagged by the contractor, entered into the PPM system and linked to its full specification and maintenance schedule.

8.1.28.5. IT provision for this functionality should include for server capacity to effectively store all 3 elements, PPM, MICAD & LMS packages.

8.1.28.6. The tagging system shall be capable of simple extension to allow the Bar Coding of Hospital Equipment, and the bidders shall provide technology proposals for Board consideration.

8.1.28.7. The asset tagging system shall be interfaced with the Personal Digital Assistant (PDA) System to be utilised for Managing Building Handover and Snagging.

8.1.28.8. The Contractor shall provide and manage a computer based electronic system for the management of the handover of the building. The system shall allow a file for each room to be established, with drawings linked to the file and marked to highlight snags or defects. This system shall be configured to provide management reports on zoned and room type selection basis.

8.1.29. Planned Preventative Maintenance PPM

8.1.29.1. The Contractor should provide, as part of the contract, a full PPM manual and system (computer based software package) for all the buildings and for all building and building services elements of the project. This system will incorporate the As Fitted drawings (MiCAD format) and specifications. This schedule shall have a full planned maintenance programme of works that the FM & Estates managers can review to plan and establish their annual maintenance schedules and annual budgets. The Contractor will be responsible for the purchase and installation of the full PPM system, including pc work stations, barcode readers and tablets.

8.1.29.2. The system to be compiled on an open protocol industry standard format for all elements of the Mechanical, Electrical, Public Health and Specialist systems.

8.1.29.3. The PPM system shall be compiled at an early date with time and input included for three iterations of comments and workshops with the Estates Department to ensure that the system meets the various requirements of the Hospital Technical Publications, CIBSE,

Clinical Services and Estate's Department. The system shall be fully linked to the As Fitted drawings via MiCAD drawing mapping, to provide a fully integrated system complete with interfaces to the PPM and Board's labour resource software systems (Apollo or Eclipse).

8.1.29.4. It is understood that there may be an iterative process involved in the preparation of the information, however it is a requirement that the Contractor allows for and ensures that all PPM, Asset register, tagging, management systems and MiCAD information is fully updated to "as fitted" condition.

8.1.29.5. The Contractor shall handover a fully working system including PC's hardware, barcode readers, tablets, printers and project specific software together with system training for the Client's operators.

8.1.30. Helipad

8.1.30.1. The Contractor shall include for all services including;

a) Fire fighting systems;

b) Suppressant storage;

c) Associated drainage, lighting and vertical access; and

d) All items required to allow operation of the helipad to ensure full compliance with HBN 15-03 and CAA guides.

8.1.30.2. The Contractor shall liaise with Glasgow City Planning and the CAA to agree the proposed location and height for Energy Centre Flue and ensure that warning lights are fitted to all required parts of the development including the flue.

8.1.30.3. All warning lighting shall be installed in accordance with the CAA requirements and the lamp replacement methodology shall be included in the main Plant Replacement Strategy.

8.1.30.4. The Building Services shall be designed and installed to accommodate Compliant Helipad Operation with the inclusion of:-

a) Lighting to main energy centre flue;

b) Appropriate location and height selected for;

i. Heat rejection plant to avoid flight path;

ii. Heat rejection plant to avoid hot air generated turbulence; and

iii. Air intakes to avoid contamination from downwash; and

c) Extract ducts to avoid contamination of operators and patient's in transit.

8.1.31. Automated Material Transfer System

8.1.31.1. It is anticipated that an Automated Material Transfer System installation will be provided to reduce the requirement for manual handling and increase service efficiency, all as detailed within Appendix M&E7. The Contractor shall set out the building service and vertical transport implications to ensure that space allocation and service requirements are incorporated for docking stations and controls.

8.1.31.2. All power, controls and equipment shall be configured to ensure EMC compatibility with the robotic solution.

8.1.31.3. The building fabric and general building services installations shall be designed to accommodate the Automated Material Transfer System.

8.1.32. Radiation Protection

8.1.32.1. All required protection and amendments to the Mechanical, Electrical, Public Health and Specialist Services shall be provided by the Contractor to suit the radiation protection regime in accordance with the manufacturer's guidance HSE regulations and Technical Memorandums.

8.1.32.2. Contractor to note that all Radiation Protection measures proposed to be discussed and agreed/endorsed with/by the Boards Radiation Officer

8.1.33. Telemedicine

8.1.33.1. The mechanics of Telemedicine system shall be provided by the Contractor via the ICT network cabling infrastructure and field cabling. The PACS equipment shall be provided by the Board.

8.1.33.2. As the principal tertiary children's hospital RHSC Glasgow is actively involved in all aspects of telemedicine and the new hospital requires to be arranged and equipped to facilitate telemedicine as part of normal practice. In practice this will require:

a) The ability to plug in mobile telemedicine units throughout the clinical areas to enable clinical consultations;

b) The equipping of all teaching facilities within the hospital for the transmission and receipt of educational activities;

c) A dedicated telemedicine suite; and

d) An IT infrastructure which will enable engagement in telemedicine activities from individual offices / PCs.

8.1.33.3. Telemedicine and teleconferencing play an increasingly important role in provision of children's hospital services in Scotland through:-

a) The transmission and receipt of educational programmes;

b) Support for networked models of service delivery (regional and national); and

c) Support for direct clinical care in remote locations.

8.1.33.4. Telemedicine and teleconferencing shall also play an increasingly important role in provision of adult's hospital with similar facilities being provided.

SECTION 8.2 – MECHANICAL SYSTEMS

8.2.1. General

8.2.1.1. The Contractor shall design, supply, install, test, commission and maintain all Mechanical Building Services necessary to support the clinical activities of The Works. The following systems are indicative of those anticipated by the Board but are not exhaustive and it shall be the Contractor's sole responsibility to determine that all necessary systems (excluding Medical Equipment) are included.

8.2.1.2. Systems shall be designed, supplied, installed, tested, commissioned, and put into service all in accordance with all relevant Regulations and Standards.

8.2.2. Building Management Systems & Controls

8.2.2.1. The Contractor shall ensure that all plant can be operated in automatic mode or manual mode should a corruption in BMS software occur. Furthermore, physical bypasses shall be provided where appropriate for maintaining service, for example at control valves for critical departments.

8.2.2.2. Network communications equipment for BMS, CCTV, Access Control Systems etc. shall be housed in racks, located within environmentally controlled secure rooms. If it is proposed that these share node rooms with the main network services then suitable control measures and rack locking shall be provided.

8.2.2.3. The system shall be fully integrated with the Building Services, refer to Appendix M&E 5 for BMS requirements.

8.2.3. Metering

8.2.3.1. The Contractor shall ensure the use of meters giving high accuracy at low flow rates and that metering points give consumption in SI units including any time bands as appropriate. The Contractor shall ensure data collection and report production is by electronic systems.

8.2.3.2. The Contractor shall allow sub-metering of electricity, gas, heating and cooling usage for each individual department / ward /unit. With water consumption measured in departments and wards with high usage.

8.2.3.3. Metering shall be provided in accordance with the targeted BREEAM credits.

8.2.3.4. The BMS shall be installed to automatically read and provide trend analysis to a range of energy and water meters. All meters including those of the utility supply companies and internal sub-meters shall be automatically read by the BMS at pre-determined intervals. The Contractor shall ensure that the BMS is capable of reading utility meters on a continuous basis in order to facilitate trend analysis. The energy metering shall include (but not be limited to):-

8.2.4. Electricity

a) Main incoming HV supplies;

b) Main LV Switchboard;

c) External lighting (separate sub-meter for each car parking area);

d) All distribution boards with separate meters for power and lighting;

e) Departmental power and lighting;

f) HVAC control panels;

g) Cooling plant; and

h) Tenant areas;

For the purpose of energy estimates, hours run meters shall be provided by the Contractor for all Air Handling Unit (AHU) fans.

8.2.5. Water, Gas, Oil, Bio Fuel

Water

a) Main incoming water supply; and

b) Internal sub-meters

Gas

a) Main incoming gas supply; and

b) Internal sub-meters

Oil

a) Delivered to Site; and

b) Used on Site

Bio Fuel (if proposed)

a) Delivered to Site; and

b) Used on Site

8.2.6. Asset Management & Tracking (AM&T)

8.2.6.1. The Contractor shall also arrange for the Utility metering systems to interface with the Board's AM&T system for fiscal metering, electronic invoice & validation process.

8.2.7. Heating System

8.2.7.1. The Contractor shall provide all heating systems required to support the Board's Clinical Output Specification and to;

a) Zone and control heating circuits to provide an efficient and comfortable environment;

b) Provide valve isolation such that isolation of circuits and sub-circuits shall have minimal disruption to the remaining departments;

c) Provide 24 hour occupied (and unoccupied) wards and departments with a night set back Facilities;

d) Provide a temperature and ventilation night set-back facilities so that when departments are unoccupied they will have frost and anti-condensation protection;

e) Good quality heat emitters shall be provided to ensure satisfactory heat distribution within the area served. Heat emitters and all heating pipework shall be arranged such that in all areas, the surface temperature limits as laid down in Health Guidance Note "Safe Hot Water and Surface Temperatures" are not exceeded. Heating pipework shall not be utilised as a heat emitter within patient areas;

f) The bidder shall provide catalogue details of all proposed heat emitters; and

g) Particular attention shall be given to effective use of warm air curtains in entrance / draft lobbies.

8.2.7.2. The Heating pipework shall be thoroughly examined and tested prior to the fitting of insulation. Any site welds shall be x-rayed and a certificate issued to confirm the suitability of the completed joint for operation within the test requirements

8.2.8. Water Systems and Filtration

8.2.8.1. Cold Water Supply

8.2.8.2. The water supply system for The Works shall include two new supplies and also incorporate on-site segregated bulk water storage (24-hours). Treatment of potable cold water supplies is not acceptable and the provision of a wholesome supply from Scottish Water's mains with the minimum of storage and handling is required.

8.2.8.3. The Contractor shall design and install the domestic cold and hot water supply installations to fully comply with the requirements of;

a) (S)HTM04-01;

b) SHTM 2027;

c) SHTM 02;

d) SHTM 2040 "The control of legionella in healthcare premises - a code of practice"; and

e) Health Guidance Note "Safe Hot Water and Surface Temperatures."

8.2.8.4. Pipework shall be stainless steel with compatible accessories.

8.2.8.5. The Contractor shall include for all specialist membrane filtration treatment plant (Replaceable cartridge systems are not acceptable). The Contractor shall provide water sampling points throughout the installation in accordance with the SHTM02. Renal water treatment shall be provided by the Contractor in accordance with Appendix M&E6 with due regard for clinical requirements.

8.2.8.6. Secure local isolation via manual shut off valves shall be provided by the Contractor at all sanitary appliances and at final connection points to Equipment.

8.2.8.7. Area leak detection shall be interlinked to zoned automatic shut down valves.

8.2.8.8. Secure external isolation to the buildings shall be provided by the Contractor. Sentinal taps for testing shall be clearly identified on drawings.

8.2.8.9. Pipework and valving shall be configured to allow isolation of local services whilst maintaining adjacent facilities e.g. resilient pipework routing and valve location to ensure that only one Theatre to be off-line at a time, one CCU bed, one renal bed, one standard bed etc..

8.2.8.10. Plumbed in water dispensers shall be provided at ward level and strategic areas including main reception/café areas etc.

8.2.8.11. Plumbed water shall be provided to specialist services such as, but not limited to;

a) Washing machines in specialised units;

b) Catering requirements;

c) Dishwashers in ward areas in accordance with the exemplar layouts and Equipment List; and

d) Retail Units.

8.2.8.12. Plumbed water shall be provided to all vending machines as required throughout The Works in accordance with the Employers Requirements.

8.2.8.13. Attention is drawn in particular to SHTN 02 concerning pipework materials and standards of filtration to be used in Scottish Healthcare Facilities.

8.2.8.14. Cold water system to comply with Hai-Scribe and the Board's infection control requirements.

8.2.8.15. All hand washing facilities to be provided with automatic taps.

8.2.8.16. The Contractor shall carry out a full risk assessment of the complete water systems of the legionella risks and ensure that the system design and equipment selection and installation is carried out to minimise risks.

8.2.8.17. Water shall be provided for fire fighting including sprinklers, wet risers and fire hydrants in accordance with the local authority requirements.

8.2.9. Hot Water Supply

8.2.9.1. Appropriate operational engineering systems for hot water shall be included in the design of The Works.

8.2.9.2. Pipework shall be stainless steel with compatible accessories.

8.2.9.3. Domestic hot water systems shall be designed with plate heat exchangers and buffer vessels to provide adequate flow to satisfy maximum demand whilst minimising stored hot water and energy consumption. The provision of some storage via buffer vessels may be required to minimise the impact of hot water generation on boiler power. (If buffer vessels are required these shall be minimal rating)

8.2.9.4. The adoption of recommended design practices to control of legionella and other bacteria within the systems is critical and is considered mandatory.

8.2.9.5. Type 3 thermostatic mixing valves (TMV's) shall be installed (in accordance with NHS Model Engineering Specification D08) at all HWS outlets to SHTMs and SHGNs except where 60°C water is a particular requirement. Double check valves to be duplicated at TMV's.

8.2.9.6. The Contractor shall carry out a full risk assessment of the complete water systems of the legionella risks and ensure that the system design and equipment selection and installation is carried out to minimise risks.

8.2.9.7. Hot water system to comply with Hai-Scribe and the Board's infection control requirements.

8.2.9.8. Hot water boilers shall be provided in all Staff Rest rooms and Kitchen areas.

8.2.10. Special Water Services

8.2.10.1. The Contractor shall provide all special water services required to support the Employers Requirements, such as but not limited to:-

a) Special supplies such as de-ionised water to specialist Equipment;

b) Special supplies such as de-ionised water to Equipment washers / disinfection Equipment; and

Special supplies for Renal Dialysis (refer to appendix M&E6).

8.2.11. Ventilation & Air Conditioning

8.2.11.1. The heating, ventilation and air conditioning systems shall be logically designed to operate efficiently incorporating heat recovery and provide local control for all areas including single accommodation.

8.2.11.2. The energy and power systems shall be appropriately designed to provide fully integrated designs in terms of the incorporation of engineering services into the building fabric and external spaces.

8.2.11.3. The need to maintain the specified comfort conditions in all areas but particularly in clinical areas is of paramount importance and the Contractor shall develop strategies for achieving the specified environmental conditions with minimum energy consumption.

8.2.11.4. Air Handling Ductwork shall be constructed from galvanised mild steel sheet and not fabricated from any composite board systems. Ductwork shall be manufactured and installed in accordance with DW144.

8.2.11.5. It is essential that the Contractor designs and provides ventilation and air conditioning systems which will ensure occupants comfort. This shall be achieved by use of well tested design principals and suitable plant selection. Air flow problems must be avoided by accurate system balancing, correct selection and location of air diffusers to prevent high air velocities and stratification together with adequate air volumes and accurate temperature control.

8.2.11.6. The Contractor shall comply with the following general criteria for above systems:-

8.2.11.7. Provide natural and mechanical ventilation, comfort cooling, and air conditioning to suit The Works and clinical requirements.

8.2.11.8. Air changes shall be in accordance with CIBSE guides, SHTM's, HTM's and Building Regulations.

8.2.11.9. Provide a climate control facility in clinical and staff areas which are provided with air conditioning (if applicable).

8.2.11.10. Ensure heat gain from all Equipment and personnel is allowed for in sizing and selection of the systems.

8.2.11.11. Demonstrate how their proposals facilitate the control and management of an outbreak and spread of infectious diseases in accordance with SHTM 2025 and SHFN 30 and HAI-SCRIBE. The Contractor demonstration is to cover all aspects of the building, its services, spatial relationships, maintenance regime proposals and incorporate requirements of the Board's Infection Control Team.

8.2.11.12. Ensure that ventilation systems installed in areas classified as hazardous are designed to relevant standards.

8.2.11.13. Where grilles or diffusers are used within rooms the Contractor shall ensure they are:

a) Arranged to avoid draughts;

b) Designed to minimise noise intrusion into the space; and

c) Humidification shall be provided where control of humidity is required for clinical reasons.

8.2.11.14. The Contractor shall provide the resilience requirements of SHPN28 e.g**.** Steam Humidification shall not rely solely on interruptible gas supply.

8.2.11.15. The Contractor shall design the systems set back arrangement in accordance with the requirements of SHPN57 e.g**.** minimum set back temperature in Cardiac CC of 10^{o}C.

8.2.11.16. The Energy Centre shall be adequately ventilated throughout and in compliance with HTM's, SHTN's, CIBSE and Building Regulations current at time of construction.

8.2.11.17. Special consideration shall be given to temperature control and ventilation within transformer rooms, generator rooms, UPS rooms and battery rooms to ensure optimum equipment operation.

Local Exhaust Ventilation Systems

8.2.11.18. The Contractor shall provide all LEV systems including but not limited to that required to support the provision of;

a) Catering;

b) Workshop and maintenance facilities;

c) Plaster rooms;

d) Decontamination suites; and

e) Areas requiring exhaust as noted in SHBN's, SHTN's and SHPN's etc

8.2.12. Fume Cupboard & Micro-biological Safety Cabinets

8.2.12.1. The Contractor shall provide fume cupboard and both CAT II and CAT III microbiological safety cabinet exhaust systems if required to support the Board's Clinical Output Specification, RDS/ADB information. Systems shall comply with NHS Specifications and Guidance documentation which shall include a matched supply system into the room(s) containing fume cupboards and micro-biological safety cabinets. Fume cupboard design and installation shall be to BS 7258. Microbiological Safety Cabinet design and installation shall be to BS 5726.

8.2.13. High Specification Air Conditioning Systems

8.2.13.1. The Contractor shall provide high specification, full function and close control air conditioning systems to support the Board's Clinical Output Specification, such as but not limited to:-

a) Aseptic rooms;

b) Ultra Clean ventilation and / or operating theatres;

c) Pharmacy; and

d) Areas handling radio isotopes or other radiological contaminants.

8.2.13.2. The operating theatre suite within the Adult Acute Hospital shall be provided with five number ultra clean ventilation (UCV) theatres. All other theatres shall be the standard type.

8.2.13.3. This should be verified with the current Architects drawings and Room data Sheets.

8.2.13.4. Each individual operating theatre shall be provided with its own plant, controls and power i.e. One supply and one extract unit, there shall be no sharing of ventilation between the theatre suite.

8.2.13.5. Air conditioning systems installed in the above areas shall be higher specification air conditioning systems with standby motors belted up in accordance with;

a) SHTM 2025;

b) SHTM 2040; and

c) NHS Model Engineering Specification C04.

8.2.14. Ventilation of Isolation Rooms

8.2.14.1. Each 28 bed ward within the Adult Acute Hospital will be provided with a single isolation room.

8.2.14.2. The Children's Hospital will be provided with two isolation rooms per 28 bed ward.

8.2.14.3. This should be verified with the current Architects drawings and Room Data Sheets.

8.2.14.4. The Contractor shall provide air conditioning systems to Isolation Rooms to support;

a) Employers Requirements;

b) Clinical Output Specification; and

c) NHS infection Control standards

With strict positive / negative pressure differentials.

8.2.14.5. A simple to read digital differential pressure gauge shall be provided by the Contractor at the entrance to the isolation suite lobby.

8.2.14.6. Refer to draft SHPN 4 and drawings G1274 M(57)02 & 03.

8.2.14.7. Ventilation and air conditioning systems for these rooms shall be designed and installed in accordance with;

a) SHTM 2025;

b) SHTM 2040;

c) SHPN 4; and

d) NHS Model Engineering Specification C04

8.2.14.8. The Contractor shall demonstrate how their proposals facilitate the control and management of an outbreak and spread of infectious diseases.

8.2.15. ICT Cooling

8.2.15.1. The Contractor shall provide N+1 redundant high specification, full function close control air conditioning systems to support the Board's Technology requirements, such as but not limited to:-

a) Server Rooms;

b) Computer Rooms;

c) Telephone Rooms;

d) CCTV DVR Equipment Rooms; and

e) Entertainment Server Rooms

8.2.15.2. The Contractor shall provide close control cooling systems to support the Board's Technology requirements, such as but not limited to:-

a) ICT Node Rooms;

b) BMS Node rooms (where these are separate from ICT node rooms);

c) Security Node rooms (where these are separate from ICT node rooms); and

d) Entertainment Node rooms (where these are separate from ICT node rooms)

8.2.15.3. No water or condensate generating equipment to be located above racks.

8.2.15.4. All services to be designed to operate on local control from diverse routed automatic change over power supplies to ensure no single point of failure, BMS to monitor plant operation, set points and room environment conditions.

8.2.16. Internal Drainage

8.2.16.1. The Contractor shall provide all necessary drainage to support the Employers Requirements and their aspirations regarding reduced water consumption which shall include but not be limited to:

a) General foul water drainage;

b) General surface water drainage;

c) Kitchen drainage, inclusive of grease traps;

d) Laboratory drainage;

e) Drainage from areas handling radio isotopes, or other contaminants such as silver;

f) Bedpan disposal system; and

g) Harvested rainwater shall not be utilised in clinical areas.

8.2.16.2. The design of the system shall be in accordance with the BS EN 12056 and the Local Authority's Building Inspector's requirements; pipe routing shall be configured to minimize the risk of blockage.

8.2.16.3. Drainage pipework and accessories material shall be selected to suit the appropriate location and type of waste.

8.2.17. Bedhead Services

8.2.17.1. The Contractor shall provide bed head services in line with the ADB sheet requirements together with clinical and operational requirements. The Contractor shall ensure that bedhead services are designed and installed in accordance with SHTM 2015.

8.2.17.2. The units shall be full integrated with the Patient entertainment systems and a dedicated power outlet shall be provided for patient's equipment.

8.2.17.3. The bedhead services shall be provided via high quality proprietary units with integrated lighting and medical gas outlets.

8.2.17.4. Gas Outlets in Children's Hospital to be concealed.

8.2.17.5. The bedhead units at renal locations shall be proprietary type rather than site constructed from standard components provided all in accordance with Appendix M&E6.

8.2.18. CHP Equipment

8.2.18.1. A CHP installation is proposed as part of the low C02 / energy strategy for the new Facilities. The CHP units shall be located within the Energy Centre. The Contractor shall develop the strategy to incorporate the full benefits of tri-generation and select appropriate plant to meet the works requirements.

8.2.18.2. The installation requires to comply with the following general principles;-

a) The system shall be fully integrated with the energy strategy for the new hospital buildings to ensure economical operation;

b) The units shall operate in accordance with the Clean Air Act; and

c) Where biofuels are proposed for the CHP these shall be stored separately from the main fuel storage system and shelf life control regime integrated in the storage facility.

8.2.19. Fire Fighting Systems

8.2.19.1. The Contractor shall provide all fire fighting systems in line with a robust fire strategy for the project as outlined in Volume 2/1 Section 5.11.

8.2.19.2. All elements of the fire fighting systems, such as but not limited to

a) Wet risers;

b) Sprinklers;

c) Gaseous Extinguishants;

d) Fire Hydrants; and

e) Smoke Control Systems etc.

8.2.19.3. The above shall be fully incorporated within the building design at an early date to ensure that all service routes and plant requirements are integrated in the building envelope while maintaining safe, secure access for maintenance and regular system testing of all systems without disturbance to the Clinical operations.

8.2.19.4. Where sprinklers are used special consideration must be given to mitigate infection control issues including risk assessments, water treatment and pre-action systems.

8.2.19.5. All in accordance with (S)HTM 05-01, 05-02 & 05-03.

8.2.19.6. Specialist systems shall be provided by the Contractor for the roof mounted helipad in line with the appropriate standards.

8.2.19.7. Authorised test certificates shall be provided by the Contractor for all life protection systems.

8.2.20. Gas Systems

8.2.20.1. Medical gases

8.2.20.2. The plant shall be rated to accommodate the requirements of the new and retained hospital estate The medical gas pipeline system for the site will require a detailed design package from a specialist consultant including all required co-ordination with existing gas supplies on-site throughout the phasing periods.

8.2.20.3. Contractor to note that detailed design proposals to be discussed and agreed/endorsed with/by Board's Medical Gas Officer.

8.2.20.4. For certification of the works all new developments will require new independent external plant and complete medical gas pipeline systems. The interconnections with the existing and upgraded systems shall be valved off for certification of the main works.

8.2.20.5. The Contractor shall liaise closely with the Boards Supplier who will lease the VIE tanks. The contractor shall carry out all builders work, foundations, bases, blast walls together with all pipe and electrical works

8.2.20.6. The Contractor shall provide all medical gases required to support the Employers Requirements such as but not limited to:-

Oxygen VIE comprising 2 No. Sources (2 fixed manifold rated for the combined load of the new and existing Hospital requirements) (Board provision) Together with connection to existing hospital VIE network and extension of the existing to provide supplies to meet the fall demand requirements of the new works and retained estate;

a) Nitrogen;

b) Nitrous Oxide;

c) Oxygen / Nitrous Oxide mixture;

d) Surgical air 7 bar;

e) Medical air 4 bar;

f) Carbon Dioxide;

g) Helium/Oxygen;

h) Medical Vacuum; and

i) Anaesthetic Gas Scavenging.

8.2.20.7. All medical gas, vacuum, scavenging, and air systems shall be fully maintainable without the requirement to alter other services and a section for each system shall be included in the Contractor's plant replacement strategy detailing the system resilience, redundancy together with the replacement methodology for all vessels, distribution and equipment while maintaining service.

8.2.20.8. All power supplies to medical gas, vacuum, scavenging, and air systems shall be provided from resilient redundant distribution networks with automatic change-overs with

a holistic approach used to minimise disruption to service during electrical testing and maintenance. Isolation and distribution shall be configured to ensure that work on one power stream does not effect other equipment.

8.2.20.9. Medical gas bottles, plant areas and stores shall be accommodated within suitably designed buildings, rooms and enclosures with good access, natural ventilation and satisfactory noise emissions control.

8.2.20.10. All medical gas installations which serve clinical departments shall be connected to essential electrical supplies.

8.2.20.11. The full status of the central medical gas plant shall be monitored by an alarm system with a status signal to an alarm panel located in the FM Control Centre, and local manned office. The panel shall also report the alarm to the BMS.

8.2.20.12. The Contractor shall provide the Medical Gas installation to comply with the following general criteria;

a) Install the piped medical gases in accordance with;

i. SHTM 2022;

ii. (S)HTM 02-01; and

iii. “Model Engineering Specification C11”;

b) Install outlets as required to allow the Clinical operation of each department to be carried out;

c) In accordance with ADB sheets;

d) Within play rooms and recreation rooms all outlets shall be located in lockable area together with masks and flow meters etc;

e) Provide a medical gas distribution system sized to accommodate the demand of The Works as defined in the Room Data Sheets, with the capacity to accommodate an increase in demand (flow and consumption) of no less than 25%;

f) Ensure that the provision of medical gasses to the point of use is continuous. Where the Contractor is providing medical gases via cylinders they shall provide manifold systems with automatic change over from duty to standby to no less than two equal banks of cylinders; and

g) Ensure that adequate points of isolation exist to all medical gas systems in accordance with SHTM 2022, (S)HTM 02-01.

8.2.20.13. The Contractor shall establish duplicate VIE plant compounds within suitable locations to ensure compliance with the Technical Memorandums, Local Approved Person and suppliers requirements. The system shall be rated to accommodate the full site wide requirements and the Contractor shall include for interlinking the new plant with the retained estate systems via valved off interconectors to improve overall site resilience.

8.2.20.14. A ring main will surround the site (NSGH & RHSC) feeding all necessary areas. It will be supplied from primary, secondary and tertiary sources. Compounds shall require an 8m

boundary zone for most activities around the enclosure, going up to 15m for places of assembly and flanges in flammable gas pipes. Allowance should be made for regular large vehicle access for tank refilling.

8.2.21. Medical & Dental Vacuum

8.2.21.1. The Contractor shall provide medical and dental vacuum by duplicate quadruplex vacuum systems each with three pumps and two vessels to provide service as detailed within the relevant ADB Sheets.

8.2.21.2. Medical and dental vacuum plant areas and stores shall be accommodated within suitably designed buildings, rooms and enclosures with good access, natural ventilation and satisfactory noise emissions control.

8.2.21.3. Installations shall be connected to essential electrical supplies.

8.2.21.4. The status of the central medical and dental vacuum plant shall be monitored by an alarm system with a status signal to an alarm panel located in the FM Control Centre, and local manned office. The panel shall also report the alarm to the BMS.

8.2.22. Anaesthetic Gas Scavenging System

8.2.22.1. The Contractor shall provide active AGSS systems in all locations where Nitrous Oxides are used. These shall be duplicate vacuum systems independent of the main vacuum systems.

8.2.22.2. AGSS plant areas and stores shall be accommodated within suitably designed buildings, rooms and enclosures with good access, natural ventilation and satisfactory noise emissions control.

8.2.22.3. The installation shall be connected to essential electrical supplies.

8.2.22.4. The status of the AGSS shall be monitored by an alarm system with a status signal to an alarm panel located in the FM Control Centre, and local manned office. The panel shall also report the alarm to the BMS.

8.2.23. Medical Air

8.2.23.1. Provision of medical air for the New Hospital Buildings would be best provided by duplicate - quadruplex medical air plant, comprising of 4 compressors, 4 dryers and 2 air receivers. It will be located within the Basement plant room area with sufficient air flow for ventilation and cooling of compressors. Each compressor sized for 50% of the design flow – providing the primary and secondary supply. This ensures an N+1 operation allowing full design flow with one compressor out of service. Emergency provision should be an automatic manifold (with cylinders) located within or close to the main building.

8.2.23.2. All supplies will conform to the European Pharmacopoeia standard for controlling air purity, all necessary filters and monitoring systems will be supplied. According to (S)HTM 02, the efficiency of plant, expressed as the volume of air delivered to the pipeline distribution system, a minimum efficiency of 5 m3/kWh at 100% and 10% is required. The power consumption at zero flow should be less than 1% of that at 100% design flow.

8.2.24. Surgical Air

8.2.24.1. The size of the development warrants dedicated duplicate surgical air supply. Surgical air will be provided by a duplex plants, located in each plant room area with sufficient air flow for ventilation and cooling of compressors. An emergency supply from an automatic reserve manifold (with cylinders) will be located in separate accommodation.

8.2.25. Manifold Installations

8.2.25.1. Other gases required throughout the hospital will be supplied by an automatic manifold installation, as in the case of N2O, with an emergency reserve supply connected. Gases used less frequently may be supplied by local cylinders at point of use.

8.2.26. Pneumatic Air Tube Delivery System

8.2.26.1. The Contractor shall provide a pneumatic air tube delivery system as required to the new Facilities to support the Clinical Requirements, as detailed in Appendix M&E7 of the Employers Requirements. The Contractor shall ensure that the pneumatic air transport system shall be designed and installed in accordance with SHTM 2009.

8.2.27. Fuel Storage

8.2.27.1. The Contractor shall provide fuel storage within steel tanks located in the Basement of the Energy Centre. One of the tanks shall be provided early for beneficial use of the Board during the construction works to allow removal of the existing vertical oil tanks. The system shall include, fill points, delivery systems pumps and controls (this facility shall be integrated with the two other tanks to provide a long term fuel management facility for the boards new and retained estate.

8.2.27.2. The following fuels shall be provided by the Contractor and stored:-

a) 35sec Gas Oil - Main Boiler Plant and retained existing estate; and

b) Diesel – Generators.

8.2.27.3. Fill points for the individual fuel types shall be provided by the Contractor at a suitable location on the external wall of the Energy Centre to facilitate automated fuelling from tankers.

8.2.27.4. Supply points shall also be provided by the Contractor for the individual fuel types at a suitable location on the external wall of the Energy Centre to facilitate automated fuel distribution to the site and for tank management.

8.2.27.5. The quantity of oil storage shall be in compliance with the requirements of Appendix M&E2 Paragraph 3.0.

8.2.27.6. All plant and equipment and installations shall be in accordance with the HTM's, SHTM's and National Health Service Model Engineering Specifications with amendments to the Model Engineering Specifications to meet the requirements of the HTM's and SHTM's.

8.2.28. Testing and Commissioning of Mechanical Services

8.2.28.1. All Buildings, Services and Equipment shall be commissioned by The Contractor to ensure that they are all compliant with the quality and performance specifications,

including manufacturer's recommendations, and that all systems operate to the Board's satisfaction.

8.2.28.2. The Contractor shall appoint an independent Commissioning Engineer to manage the Testing and Commissioning as detailed in Appendix M&E3

8.2.28.3. The Contractor shall as a minimum commission the works in accordance with the 'Guidance to Engineering Commissioning' published by The Institute of Hospital Engineers (1995).

8.2.28.4. The Contractor shall be responsible for demonstrating and certifying to the Board the successful completion of all commissioning, testing and compliance with all relevant standards.

8.2.28.5. The Contractor shall provide a comprehensive hard and soft copy sets of Operations and Maintenance Manuals together with the MiCAD as fitted drawings (hard and electronic) for all installed and commissioned Equipment. 3 number off sets of each to be provided.

8.2.29. Connection to Specialist equipment

8.2.29.1. The Contractor shall include for final connection of all specialist clinical equipment including MRI's Xray, Imaging, Theatre, CCU and general equipment as indicated in the Board's Equipment Schedules.

8.2.29.2. The main services shall be terminated within 1m of each piece of equipment with the final connection being carried out in conjunction with the equipment supplier.

8.2.29.3. Energy for all Board equipment shall be supplied from the most efficient source e.g. MTHW for dishwashers etc.

8.2.29.4. All terminations shall be in accordance with the manufacturers written recommendations.

8.2.30. Water Services Leak Detection

8.2.30.1. The Contractor shall provide leak detection to all external water mains and transfer pipework serving the satellite tanks located within the basements of the other buildings by means of pressure switches and interconnecting controls to provide an audible and visual alarm in the event of major leakage and provide alarm signals at the BMS front end within the FM Control Centre.

8.2.30.2. Leak detection shall also be provided by the Contractor at:

a) Perimeter of all ICT Server rooms;

b) Perimeter of all ICT Node rooms;

c) Plant room bunds adjacent to theatres, radiology and critical care areas; and

d) Tunnel sumps.

8.2.30.3. These shall provide an audible and visual alarm in the event of local leakage and provide alarm signals at the BMS front end within the FM Control Centre.

8.2.31. Smoke Control

8.2.31.1. The Contractor shall provide all Smoke Control and Smoke Extract systems and equipment to meet the agreed fire strategy for the hospital developments. All in accordance with (S)HTM 05-01, 05-02 & 05-03.

8.2.32. Stair pressurisation

8.2.32.1. The Contractor shall provide as required Stair Pressurisation systems and equipment to meet the agreed fire strategy for the hospital developments. All in accordance with (S)HTM 05-01, 05-02 & 05-03.

SECTION 8.3 - ELECTRICAL

8.3.1. General

8.3.1.1. The Contractor shall design, supply, install, test, commission and put into service all Electrical Building Services necessary to support the clinical activities of The Works. The following systems are indicative of those anticipated by the Board but are not exhaustive and it shall be the Contractor's sole responsibility to determine that all necessary systems (excluding Medical Equipment) are included.

8.3.1.2. Systems shall be designed, supplied, installed, tested, commissioned and put into service all in accordance with the relevant Regulations and Standards.

8.3.2. Electrical Distribution Systems

8.3.2.1. MV Systems

8.3.2.1.1 A new Primary Sub- Station shall be established within the Southern General Site, discussions have taken place with Scottish Power. The Contractor shall conclude these negotiations and include for all works associated with the Construction of the Primary Sub-Station.

8.3.2.1.2 Refer to Appendix M&E1 for Utility correspondence.

8.3.2.1.3 The new Primary Sub-station shall incorporate a composite Client/Utility Company outgoing 11kV switchboard; the switchboard shall be configured to meet Scottish Power Requirements together with metered outgoing ways to allow:

a) Two ring mains to be provided for the new Hospital system being designed by the Contractor; and

b) Two further ring mains for the Board's future configuration of the retained and future estates requirements.

8.3.2.1.4 Automatic protection shall be provided to route power through the rings to minimise downtime on all unaffected sub-stations after a cable or sub-station fault.

8.3.2.1.5 Distribution in relation to the Works is to consist of separate closed unit protected auto-switching ring mains dedicated to each hospital. Unit protection shall be by pilot cables and time graded relays.

8.3.2.1.6 A full instrumentation and protection system with multi-function meters, over-current and earth fault protection to the primary ring mains shall be provided complete with remote monitoring via the BMS and FM Control Centre.

8.3.2.1.7 Refer to drawing G1274E(60)01 for indicative schematic.

8.3.2.1.8 The new Primary Sub-Station shall be delivered to allow power to be made available in line with the Laboratory Practical Completion date. Refer to Volume 2.2 documentation for details of fall back scenario if this cannot be accommodated.

8.3.2.2. LV Systems

8.3.2.2.1 All wiring systems shall be of a form defined within BS 7671:2008 (IEE Wiring Regulations 17th Edition).

8.3.2.2.2 Main LV switchgear shall comprise metal cubicle pattern switchgear enclosures containing Air Circuit Breakers (ACB) and Moulded Case Circuit Breakers (MCCB) with electronic protection selected to allow short circuit, over-current and time grading for full co-ordination and discrimination.

8.3.2.2.3 Each LV section shall be fitted with automatic power factor correction to correct the local power factor to no less than 0.95, the correction equipment shall be located closed to the corrected load, with hard wired automatic drop out facility during generator run and reset on return to mains.

8.3.2.2.4 All ACB's and main distribution ACCB's shall be fitted with monitoring units to capture and relay switchgear status, energy consumption. harmonic content, operation counter and fault indication via the Central Power Monitoring System

8.3.2.2.5 The Central Power Monitoring System work-station shall be located within the main FM control room with a second work-station located in the Estates Office.

8.3.2.2.6 The Central Power Monitoring System shall provide hierarchical maps indicating active mimic of the complete power and stand-by power distribution systems.

8.3.2.2.7 Each Main Switchboard shall be fitted with a touch screen PC to provide access to the maps and interactive mimic screens.

8.3.2.2.8 A hard copy cellular wall mounted MV Mimic Diagram shall be provided by the Contractor in the Estates Office to allow system status to be recorded manually.

8.3.2.2.9 All main LV switchboards shall be constructed to Form 4 Type 6.

8.3.2.2.10 Sub distribution and final distribution boards shall be constructed to:

a) Form 4 Type 2 for Clinical Risk Categories 1 & 2; and

b) Form 4 Type 6 for Clinical Risk Categories 3, 4 & 5

8.3.2.2.11 Risk Categories determined as (S)HTM 06-01

8.3.2.2.12 For the Works, most of the areas fall into Clinical Risk Categories 3, 4 & 5. Robust electrical supplies shall be provided to serve:

a) General lighting;

b) Standby lighting;

c) General power;

d) Medical power;

e) Medical IPS power;

f) Mechanical services plant (ventilation, medical gases, water, chilled water etc); and

g) ICT Power

8.3.2.2.13 The tower of the Adult Acute hospital contains general ward areas. For the avoidance of doubt the Board require Building Services for the Wards appropriate to Clinical Risk Category 3.

8.3.2.2.14 Due to the adjacencies, dual transformers and switch panels shall be provided to form part of the dual-unified supply philosophy employed in the distribution design. Like the MV distribution, the LV distribution shall be divided into Side A and Side B circuits. Side A and Side B Main LV switch panels adjacent to transformer substations and separate compartments will be linked together via an automatic `*bus-coupler-bus-tie'* cable way and two ACB's.

8.3.2.2.15 A robust arrangement, shall be provided to ensure that a fault or problem on the Side A switch panel does not affect the Side B panel and vice versa.

8.3.2.2.16 The Contractor shall integrate the distributed transformers, main and secondary low voltage switch rooms within the development to suit the final layout while minimising cable losses and providing simple maintenance / replacement access.

8.3.2.2.17 All plant rooms are to be in accordance with (S)HTM 2023 and (S)HTM-06-01 and the contractor shall provide a detailed Plant Replacement Strategy.

8.3.2.2.18 Distribution of LV power within the tower will be by three-phase bus-bar ducting with full size phase, neutral and earth conductors. Multiple tap off units shall be provided at each floor to serve distribution boards for lighting and power together with 25% spare capacity.

8.3.2.2.19 Each tap off unit shall contain a circuit breaker to provide full electronic time graded fault protection. The energy monitoring strategy may incorporate meters within the tap off units however where split distribution boards are proposed multiple meters shall be incorporated in the split distribution boards. All meters shall be linked back to the central system to allow remote load monitoring and energy management.

8.3.2.2.20 Each rising bus-bar pair shall serve each of the 'wings' of the tower. In accordance with the dual-unified distribution, each bus-bar pair shall comprise separate Side A and Side B bus-bars rising through the building in separate risers.

8.3.2.2.21 The final solution shall provide full system resilience and allow the distribution equipment to be maintained with the minimum of disruption to services at ward and departmental level.

8.3.2.2.22 Final circuit distribution boards shall be Type A or B with miniature circuit breaker (MCB) and (RCBO's) boards to BS EN 60439-3 located within risers or dedicated cupboards. All distribution boards are to be lockable with a suited key system with sheet metal doors to prevent unauthorised access. All boards shall be provided with ASTA certified bus-bars (rated to suit the local prospective fault current) neutral and earth terminals for each single phase way, clean earth facilities, extension spreader boxes for incoming cables separate CPC's, RCBO connections and flexible split metering facilities.

8.3.2.2.23 Distribution boards with plastic enclosures must not be used.

8.3.2.2.24 Power for all Mechanical, Public Health and Specialist systems shall be provided with resilience and redundancy to allow maintenance to be carried out on specific plant and distribution paths without the requirement to take other plant out of service.

8.3.2.2.25 All power circuits to be sized in accordance with BS7671.

8.3.2.2.26 Switchgear, Control panels etc, shall be securely located in plant areas and distribution cupboards not able to be accessed by public, patients or non FM staff.

8.3.2.3. Cables and Containment

8.3.2.3.1 Primary LV sub-main distribution is to be by bus-ducts, bus-bars and multi-core XLPE/SWA/LSF (low smoke & fume) cables to BS6724 carried on ladder rack (larger cables) and/or cable tray/basket (smaller cables). Primary LV cabling and containment is to be concealed within dedicated risers, cable trenches and risers throughout the building.

8.3.2.3.2 Side A and Side B cables and containment will be segregated and run by different routes to the final outlet as far as practicable, this requires Side A and Side B final circuit cabling to be run in separate containment up to bed head trunking units.

8.3.3. Lighting and Power

8.3.3.1. Interior Lighting

8.3.3.1.1 The lighting design must be functional for clinical use in accordance with the CIBSE and Society of Light and Lighting guides together with relevant SHTM's, SHBN's etc., the Contractor shall also ensure that the overall lighting concept is co-ordinated with the building structure and the project aesthetic requirements. Particular attention is required within entrance, circulation and non clinical areas where a mixture of LED's, conventional low energy fittings and retail lighting techniques shall be utilised to enhance the internal and external building experience in line with the architectural intent.

8.3.3.1.2 Where high efficient fluorescent lamps are not appropriate e.g. for aesthetics, signage and lighting of art works etc, the use of high output LED units and compact discharge sources shall be selected in lieu of tungsten lamps.

8.3.3.1.3 The Contractor shall provide and install high efficiency luminaires, utilising high frequency electronic control gear to provide occupiers with improved visual comfort while reducing noise levels and running costs.

8.3.3.1.4 Where VDU's are being used, the Contractor shall ensure that the lighting scheme complies with "CIBSE Lighting Guide LG3 and LG7.

8.3.3.1.5 The Contractor shall ensure that corridor lighting is multi circuited to facilitate use of 100% or 50% of the luminaires. Where the corridor is over 15 metres in length interlaced zoned lighting shall be provided. This resilient strategy must be imposed on the lighting control system design to ensure that lighting in each area is partially retained in use during maintenance of the alternate area distribution board and alternate section of the lighting control system.

8.3.3.1.6 Night lighting shall be provided within all corridors either by individual fittings or by selective switching of the general corridor wall/ceiling luminaires. The Contractor shall ensure night lighting in corridors shall not spill into patient bedrooms, or other bedded areas. Night lighting shall be provided at nurse stations, patient bed areas and locations where call systems are installed.

8.3.3.1.7 Ward night lighting override control to be fitted at nurse stations.

8.3.3.1.8 Luminaires shall be located to provide ready access for lamp changing and maintenance, whilst still providing the recommended level and quality of illumination to the area.

8.3.3.1.9 All signage is to be illuminated to ensure ease of legibility without causing glare.

8.3.3.1.10 Where sealed fittings are required e.g. in treatment rooms, isolation suites, theatres etc. the diffusers shall be composite type with easy clean flat surfaces with the optics incorporated within a stable sandwich construction.

8.3.3.1.11 Treatment Room luminaires which provide the general lighting shall be controlled by at least two circuits depending on the arrangement of fluorescent tubes in each fitting. The design of these luminaires must provide ease of access for lamp changing.

8.3.3.1.12 In ward areas the lighting shall be integrated with the bedhead services solution with combination wall mounted dimmer controlled fittings providing patient rest, watch light, reading light and examination facilities.

8.3.3.1.13 Where bed areas are used for intervention and treatment an overhead lighting scheme supplemented by bedhead units providing patient rest, watch light, reading light and examination facilities shall be provided.

8.3.3.1.14 Light fittings shall not be mounted immediately above patient positions.

8.3.3.1.15 All fluorescent lamps used in clinical areas shall have as a minimum a colour rendering capability of ≥ 85 CRI. For practical reasons consideration should be given by the Contractor to using the same luminaire in both Clinical and Non-Clinical spaces within the same ward. A reading light with an on/off switch shall be provided at each bedhead location and at the door. The Contractor shall provide an additional switch on the nurse call handset.

8.3.3.1.16 Where luminaires of the fully recessed type (modular and / or downlighter) are installed within fire rated ceilings, they should be provided with a one hour rated fire canopy. The Contractor shall also ensure that they maintain the integrity of the ceiling and that the canopies are tested to “BS 476 Parts 20 and 23, clause 5. The Contractor shall also ensure that all canopies meet the requirements of “Class O materials”.

8.3.3.1.17 Hazardous areas shall be provided by the Contractor with the appropriate classified luminaries.

8.3.3.1.18 Luminaires with prismatic diffusers installed on fire escape routes shall be fitted with flame retardant diffusers to TP (a) classification, minimum Class 3 surface spread of flame.

8.3.3.1.19 Each high dependency and recovery bed position shall have a wall or bed-head trunking mounted, examination lamp with integral switch.

8.3.3.1.20 Sealed food factory type luminaires shall be provided by the Contractor in areas in which food is prepared, cooked and stored.

8.3.3.1.21 Accessible plant areas, roof void areas, ducts, lift motor rooms, shafts and similar utility areas shall be illuminated utilising suitably IP rated luminaires.

8.3.3.1.22 Over-mirror lights shall be provided by the Contractor in all en-suites, shower rooms bathrooms and in all Male and Female changing rooms.

8.3.3.1.23 Lighting in toilets accessible to the public shall be fitted with blue light effect to minimise unsocial activities.

8.3.3.1.24 Laser and x-ray warning lights shall be provided by the Contractor outside theatres, major treatment rooms and x-ray rooms interfaced with the laser / x-ray machines.

8.3.3.1.25 Lighting levels to be in accordance with CIBSE guides and SHPN's. Theatre Pendants and lights to be selected by Board. Contractor to allow for all services.

8.3.3.2. Lighting Control & Wiring

8.3.3.2.1 The Contractor shall provide automatic control of lighting using natural light level sensing and the BMS scheduling capability for unoccupied periods (with movement sensing override for safety) primarily in circulation areas and large open workspaces.

8.3.3.2.2 In plant rooms additional controls interfaced with the access control system shall be provided at main plant room entrances to override the automatic off signals, allowing staff to carry out inspection and maintenance outwith the normal reach of the presence detection system.

8.3.3.2.3 The Contractor shall ensure that the lighting design incorporates a flexible switching arrangement to allow for varying activities within each room and for cleaning purposes. Switches for all public areas should be positioned by the Contractor so that unauthorised persons cannot switch the lighting.

8.3.3.2.4 Lighting within all WC's, Staff WC's and changing rooms shall be controlled via passive infrared sensors/movement detectors or similar, with adjustable time control facilities.

8.3.3.2.5 Lighting within clinical areas shall incorporate manual override controls

8.3.3.2.6 The Contractor shall arrange the circuiting of luminaires to control groups of fittings in order to provide flexibility of switching arrangements. Such a facility is particularly

important in large spaces where the level of daylight is not uniform and artificial lighting is likely to be needed for long period in areas remote from windows.

8.3.3.2.7 The Contractor shall provide the luminaire isolation requirements of SHPN57 e.g. all luminaires to be provided with means of safe isolation to prevent isolation of adjacent fittings for replacement.

8.3.3.2.8 The Contractor shall provide alternative circuits together with two-way or intermediate switching at all section doors and corridor direction changes for lighting in corridors and circulation areas.

8.3.3.2.9 Where multi-gang lighting control switches are required the Contractor shall provide a label fixed to the grid under the switch plate, indicating the switches are fed from different supplies.

8.3.3.2.10 The Contractor shall provide the Lighting requirements of SHPN57 e.g. all lighting in Critical Care Areas shall be dimmable with local controls. (This is in addition to the general requirement for dimmable lighting which shall be provided throughout for the purpose of energy control and commissioning setting).

8.3.3.2.11 All small power accessories and Isolation devices shall be engraved with the accessory function.

8.3.3.2.12 Circuit designation labels shall be provided at all electrical accessories.

8.3.3.2.13 All power cables shall be provided with circuit references adjacent to terminations, the references shall be co-ordinated with the MiCAD As Fitted drawings and asset register tags.

8.3.3.3. Emergency Lighting

8.3.3.3.1 The Contractor shall connect the emergency lighting to addressable self-monitoring control panels with each luminaire containing an interface unit that shall be monitored and controlled by the control panel which shall report to the BMS system. The Contractor shall demonstrate that the emergency luminaires are automatically tested in accordance with the requirements of the British Standards.

8.3.3.3.2 Local circuit monitoring shall be provided to protect all areas.

8.3.3.3.3 The emergency luminaires may be of either the maintained or non-maintained variety. The Contractor shall ensure that they are powered by a suitable battery supply connected by an auto-changeover switch or utilise self-contained battery packs within luminaires (3-hour rated). The Contractor shall ensure that the emergency luminaires will be automatically energised in the event of a failure to the local lighting circuit.

8.3.3.3.4 The Emergency Lighting shall comply with BS5266 and (S)HTM2011.

Standby Lighting

8.3.3.4.1 The Contractor shall provide 100% standby lighting via the site generation system to enable normal activities to continue during the loss of a normal mains supply.

8.3.3.4.2 The Contractor shall ensure that the quality of standby lighting is equal to that of the normal lighting at the task points.

8.3.3.5. Wiring

8.3.3.5.1 Wiring will be generally be carried out using LSF insulated single cables run in concealed steel conduit and trunking. Connections to all suspended ceiling mounted fluorescent luminaires and non modular lights shall be made via a plug & socket/ lighting control module arrangement and a reasonable length of flexible heat resisting sheathed cable. Flexible cables shall not be trailed across the top of ceiling grids.

8.3.3.5.2 Modular wiring systems may be considered for lighting in non clinical areas, however if these are put forward the components must be sturdy, proven in use with long lifespan.

8.3.3.5.3 Loop In system in metal conduit to be utilised for wiring in areas with fixed ceilings.

8.3.3.6 Small Power

8.3.3.6.1 Where required small power circuits shall be provided in accordance with the MEIGaN.

8.3.3.6.2 Where required small power circuits shall be provided from Insulated Power Supplies.

8.3.3.6.3 Where required small power circuits shall be provided from Uninterruptible Power Supplies (UPS).Final circuits shall be interlaced fed from either side of the dual power distribution systems.

8.3.3.6.4 All clinical circuits shall be wired in metal conduit and containment.

8.3.3.6.5 Power shall be provided at docking stations for recharge of robotic units.

8.3.3.6.6 The Contractor shall provide the small power requirements of SHPN57 e.g. via ceiling mounted medical supply units rather than wall mounted outlets in Critical Care Areas.

8.3.3.6.7 The Contractor shall provide the power requirements of SHPN28 e.g. All Theatres shall be provided with two articulated pendants

8.3.3.7 External Lighting

8.3.3.7.1 The perimeter, including all entrance canopies and pedestrian walkways, to all buildings shall be lit by the use of energy efficient luminaires mounted in canopies, on walls, columns and/or bollards. All on-site access roads, service yards and areas, footpaths and cycle ways shall be lit to levels compatible with the GCC Highway standards. The lighting shall satisfy the requirements of BS 5489. Lighting shall be provided by the Contractor to all direction signs around the Site where these are not adequately illuminated by external lighting.

8.3.3.7.2 The system shall also provide a welcoming atmosphere to the main entrances.

8.3.3.7.3 All access routes to plant areas shall be lit to provide safe access for maintenance.

8.3.3.7.4 All wall mounted luminaries shall be fed by back entry. Cable runs on the outside of buildings shall not be permitted.

8.3.3.7.5 All external columns, bollards etc. shall be provided with fused cut-outs and adequate termination facilities for cabling.

8.3.3.7.6 When selecting luminaires, the Contractor shall give consideration to light pollution, vandalism, security, energy efficiency and local residents. The Contractor shall ensure that the installed scheme meets the requirements of the Civil Airport Authority (CAA).

8.3.3.7.7 The Contractor shall provide warning lighting on the main building and flue in accordance with the CAA requirements.

8.3.3.7.8 The Contractor shall provide helipad lighting in accordance with the CAA requirements and the Hospital Guides.

8.3.3.7.9 The BMS shall control external lighting to minimise energy consumption, by photocell or movement sensor, the lamp type selected must be sympathetic to frequency of switching dictated by the control means.

8.3.3.7.10 The Contractor shall utilise solar powered lighting where this can be shown to be effective on the site over a reasonable time period; these shall be supplemented by conventional luminaires when the output is not available.

8.3.3.7.11 The Contractor shall wire luminaires on multiple circuits to avoid loss of light to whole areas in the event of a maintenance and mains/circuit failure.

8.3.3.7.12 External lighting installations shall be designed to provide safe lighting levels in accordance with CIBSE guides and “Secure by Design” requirements.

8.3.3.7.13 Back-up floodlighting shall be provided from FM building into yard and buildings onto entrances pathways and roads should the ‘Contractors Street Lighting’ fail.

8.3.4 Fire Alarm and Detection Systems

8.3.4.1 The Contractor shall ensure that the fully addressable automatic fire detection system integrated within the BMS for The Works is fully compliant with the performance criteria laid down under (S)HTM05 and BS 5839. Refer to Fire Strategy Volume 2.1 Paragraph 5.11.

8.3.4.2 The systems are to be designed to BS 5839 category L1 and are generally to be analogue addressable with aspirated detection provided in areas including Theatres, X-ray, MRI, and ICT rooms and all other 'specialist suites'.

8.3.4.3 All aspirating air sampling units shall be located away from public areas, either in service cupboards or accessible services risers. All circulation doors shall be installed with integrated electro magnetic door hold open devices with all security door locks interlocked for evacuation in a zoned fire condition. The locks and hold open devices must not reduce the rated fire integrity of the doors.

8.3.4.4 The aspirated systems shall be capable of providing identification of alarms or faults within individual sampling pipes.

8.3.4.5 The system design shall be integrated with the requirements of the clinical requirements.

8.3.4.6 A Fire Control Station shall be set up within the new FM Building providing command and control for the life safety systems including PC Graphics for:

a) Fire Alarm Detection and annunciation;

b) Sprinklers (monitoring);

c) Smoke dampers (monitoring and control);

d) Fire fighting systems (monitoring and control);

e) Stair pressurisation (monitoring and control);

f) Helipad systems (monitoring);

g) Cold smoke extract (monitoring and control); and

h) All systems provided in accordance with the agreed fire strategy.

8.3.4.7 The Contractor shall liaise closely with the following;

a) Board's Fire Officer;

b) Glasgow City Council; and

c) Strathclyde Fire Brigade

and ensure that an agreed fire alarm cause and effect matrix is provided by the Contractor prior to detailed design to ensure that the systems support the overall fire strategy.

8.3.4.8 Control panels are to be provided in the Control Room and at the main entrances (or at the entrances to which the fire service are to attend, if different), with additional indicator panels provided throughout the building to allow staff to respond in accordance with local evacuation procedures, and to guide the fire service to the source of the alarm.

8.3.4.9 The control panels shall be fully networked with resilient connections to the site based PC font end with map facilities and remote graphics monitoring in Hillington via a dedicated link.

8.3.4.10 The system shall be equipped with sufficient sounders to maintain sound outputs in different areas in accordance with (S)HTM 05, and incorporate visual strobe indicators for a fire condition in accordance with the requirements of the Disability Discrimination Act.

8.3.4.11 The Contractor shall ensure that The Works are divided into zones by ward / department / unit area as well as by floors with mimic or repeater panels at each nurse station (or equivalent) and at least one panel per floor located in a central circulation area. In the event of fire The Works shall be capable of individual zone evacuation with all other zones receiving awareness signalling.

8.3.4.12 The Contractor shall ensure that all fire alarm panels are capable of giving details of system status for fire, fault, and alarm conditions including full text descriptions of location at all nodes and staff base positions.

8.3.4.13 All panels shall be capable of data / event logging and report generation.

8.3.4.14 Manual call points must be provided at every exit and staircase with no point in the building being more than 30m travel from a call device.

8.3.4.15 Fire Alarm Evacuation facilities shall be provided at each main node, these shall require a double action e.g. break frangible lid and then break glass unit.

8.3.4.16 Materials and equipment shall be the catalogued products of manufacturers regularly engaged in production and installation of automatic fire detection systems and shall be manufacturer's latest standard design that complies with the relevant Standards and Regulations.

8.3.4.17 The Contractor shall ensure, and provide necessary documentation to confirm that this system will have a documented history of compatibility by design for a minimum of 15 years. Future compatibility shall be supported for no less than 10 years. Compatibility shall be defined as the ability to upgrade existing systems to current level of technology, and extend new field panels on a previously installed network.

8.3.4.18 The Contractor shall take into account the need for maintaining patient security during alarm testing i.e. the testing regime shall not allow for ordinarily secure doors to open as a result of routine testing.

8.3.4.19 The Contractor to provide fire suppression systems in line with the proposed fire strategy, which shall include provision of gaseous systems in ICT rooms and Electrical Sub-stations together with the special requirements for the Helipad.

8.3.4.20 The Contractor shall provide fire hydrants to meet the Glasgow Council’s Building Control Department and Strathclyde Fire Brigade requirements.

8.3.4.21 Progressive horizontal evacuation in patient areas is to be facilitated by each fire resisting sub-compartment being on a separate alarm zone, and by the use of two stage (evacuate/ alert) alarms. To avoid unnecessary disturbance, staff elsewhere in the building who are required to perform particular tasks in the event of a fire are to be automatically alerted by pagers or electronic communications devices to avoid the sounding of the fire alarm.

8.3.4.22 In areas where patients can escape unaided and in non-patient areas the audibility of the fire alarm should be in accordance with BS 5839. However, in other areas an audible alarm may be unacceptable and the use of visual devices is to be provided in areas such as very high dependency patient areas, these include operating theatres, ITU, audiology, plant areas, service yards, imaging and areas with high ambient noise etc.

8.3.4.23 The fire alarm signal is to be transmitted automatically to an alarm receiving centre via a monitored line to supplement the control room operation.

8.3.4.24 The fire alarm system is to contain links to all necessary ancillary services such as;

a) Automatic Door Releases;

b) Door Control Systems;

c) Access Control Systems;

d) Ventilation Systems;

e) Lifts etc; and

f) Robotics

8.3.4.25 All wiring to be MICC with red LSF sheath.

8.3.5 Telephone Distribution Systems

8.3.5.1 The Hospital requires efficient, high quality telecommunications service provided to both its internal and external customers on a 24-hour basis. The Contractor will provide a robust resilient high quality cabling infrastructure, with appropriately selected switches provided by the Hospital.

8.3.5.2 Cable links with existing Telephone equipment throughout the site will be required, with all necessary underground ducts together with copper and blown fibre provided by the Contractor.

8.3.5.3 Mobility will be covered with wireless handsets on the IP network.

8.3.5.4 Analogue line facility to be provided for faxes rather than VoIP.

8.3.5.5 10% fall back lines to be provided by the Contractor throughout the works, present technology is for PABX and analogue phones. (PABX by the Hospital, This may be simplified by technology improvement but allow analogue distribution in the meantime).

8.3.5.6 The Contractor shall supply onsite paging facilities for the works to meet the standards provided by the current service provider Multitone Electronics plc, Unit 33 Geddes House, Kirkton North, Livingston, West Lothian, EH54 6GU. Space to be allocated in node rooms for Multitone paging equipment.

8.3.5.7 New Aerial/s to be provided to ensure full coverage throughout the works.

8.3.5.8 Emergency Voice patching to be colour co-ordinated (grey).

8.3.5.9 Field cabling racks and cabling to be set up for Power over Ethernet to minimise requirement for power plugs at feature phones.

8.3.5.10 Payphones will be provided under the current managed service Premier Telesolutions, 10 Alexandra Way, Ashchurch Business Centre, Tewksbury, Gloucestershire, GL20 8NB. The contractor shall provide telephone outlets and power at required areas and the managed payphone company shall provide the hardware and service. Space to be provided for node cabinet etc.

8.3.5.11 A separate Comms room and Office shall be provided for the patient telephone lease company to accommodate their switch and billing units,

8.3.5.12 The Contractor shall include for Analogue lines to be provided for all remotely monitored systems including: Cardiac, Fire, Lifts, VIE, BMS, etc. and for all systems provided by the Contractor.

8.3.5.13 Lift cars to have two comms connections, one for remote monitoring of performance and one for interlinking to the Hillington Control Centre.

8.3.5.14 GEMS to be provided with dedicated incoming lines for their network and telephone switch equipment.

8.3.5.15 Contractor to include 6 ducts from each main server room to the main hospital boundary for Voice/Data Use to suit the agreed communications vendors.

8.3.5.16 Contractor to include 2 ducts from each main server room to the Laboratories.

8.3.5.17 Contractor to include 2 ducts from each main server room to the Estates Department.

8.3.6 Information Technology (IT) Equipment and Distribution Systems

8.3.6.1 Overall Requirements.

8.3.6.1.1 The Board recognises the importance of information and communication in all aspects of its work; improved communication enables improved efficiency.

8.3.6.1.2 The continued development of technologies provides an increased potential to simplify systems and reduce duplication allowing the Board a more complex management system of greater value to users and the Board itself.

8.3.6.1.3 This specification is intended to co-ordinate the various aspects of communication systems within the Board's operations. The specification does not describe all individual systems and their operation in great detail, but identifies the various communication systems, the Board's current strategies for their development and maintenance, the obligations placed on the Contractor.

8.3.6.2 The Contractor shall design, construct and put into service a comprehensive and robust infrastructure (e.g. containment, cabling, power, A/C, Racks, raised floors, floor grills, comms rooms and server rooms) for The Works in accordance with the requirements of the Board's Requirements.

8.3.6.3 The infrastructure shall be commissioned, labelled and documented prior to handover to the Board.

The Board will install hardware (e.g. servers, comms hardware, PCs, printers, scanners), make the final connections (at the application and in computer rooms) and commission the operational system.

8.3.6.4 The Contractor shall provide only those systems that are fully compatible with the Board's operational Information Technology systems.

8.3.6.5 The Works will be served by an N+1 server room distribution. These shall be provided internally within the new development. The server rooms should have dedicated air conditioning, fire suppression, generator back up with diverse routed power and redundant UPS systems to maintain resilience in the IT network.

8.3.6.6 The 2 main comms rooms will house servers for local distribution whilst providing diverse links with existing comms rooms throughout the Hospital estate and further a field. The Contractor shall design each room to accommodate 6 comms racks, 10 server racks and 10 equipment racks, sufficient racks for the Contractors field cabling together with sufficient racks for the Contractors BMS, CCTV, and Entertainment equipment etc. together with space provision for access round racks and work bench laptop space. All racks to be provided by the Contractor, racks are to be lockable with a suited key system for Voice, Data, combined Voice and Data, CCTV, BMS etc.

8.3.6.7 Within these principal ICT rooms, telephony servers will be provided by the hospital.

8.3.6.8 As above multiple racks shall be provided by the Contractor allowing sufficient space for network expansion. Racks shall be 42U, 800mm x 1000mm (space for 1200mm) suitable for high velocity through ventilation based on hot/cold isle philosophy.

8.3.6.9 Data risers shall be established to interlink the main server and hub rooms, the risers shall be of sufficient size to accommodate 25% network expansion and modification.

8.3.6.10 The Contractor shall provide the requisite number of hubs to suit their proposed building layout to ensure compliance with the cable length restrictions. Hubs shall be sized to accommodate all of the Contractors Equipment together with a 42U rack dedicated for the Board's use.

8.3.6.11 It is envisaged that the Board will be using voice over IP for telephony.

8.3.6.12 It is envisaged that the Board will be using wireless technology (RFID) for public, staff data, patient monitoring, equipment tracking and automated transfer system connections, access points shall be provided by the Contractor throughout the facility to meet these onerous demands. The access points shall be located to meet the various system demands throughout all areas of the works. The Contractor shall provide a robust system with area coverage overlap and resilient interconnection to the network suitable for supporting the full RFID requirements.

8.3.6.13 The Contractor shall ensure that the lighting in all ICT rooms is sufficient to allow for safe working on plant and equipment. No water, steam or waste services shall be located either in or directly above the ICT room due to risk of water damage.

8.3.6.14 Infrastructure provided by the Contractor shall be fully compliant with the requirements of the NHSIA N3 project.

8.3.6.15 The Infrastructure shall provide the Connectivity requirements of SHPN57 e.g. Wide bandwidth service etc.

8.3.6.16 The Infrastructure shall provide the Connectivity requirements of SHPN28 e.g. all theatres to be provided with cabling to theatre lights to allow for camera connection to seminar room and general telemedicine system, refer to section 8.1.34 for Telemedicine details.

8.3.7 ICT Workshop

8.3.7.1 The ICT staff workshop shall be provided adjacent to each server room; the workshop shall have suitable environment and services to allow equipment to be tested.

8.3.8 Wireless Networks

8.3.8.1 The Contractor shall provide a secure wireless network which supports the Board's requirements as set out below:

8.3.9 External Services (WAN)

8.3.9.1 As noted above multiple ducts shall be provided by the Contractor from the network vendors external access points (ducts) to each of the Server rooms. These shall be of a size suitable for external grade fibre cable(s), and copper multi-core cable(s).Further ducts will be required providing links to existing building within the estate. The Contractor shall ensure that the Board is granted free access to these ducts at all times so that it may access communications services from any third party it wishes to nominate.

8.3.10 Cabling

8.3.10.1 Cabling systems shall be installed to the highest ratified specification for IT wiring systems as defined in EN50173 and EN 50173 or equivalent standard.

8.3.10.2 All Fibres are to be single mode blown type, mesh star configuration with minimum of 20 pairs backbone.

8.3.10.3 The Contractor shall demonstrate that the proposed copper structured cable is suitable for the latest available known technology at the time of tender and be as a minimum CAT6 Augmented.

8.3.10.4 The jacket construction of the cable must be suitable for the application and details must be provided in the tender. The installation shall also cater for two outlets at every workstation being able to support a VoIP installation in line with the agreed schedules.

8.3.10.5 All voice cabling installed shall allow for an agreed spare capacity over and above the spare requirements stated in the general section.

8.3.10.6 Cables, which pass through the infrastructure of the buildings, shall be suitably protected against damage. Through walls and floors this shall involve an appropriate type of sleeve, through any form of metalwork or stiff plastic then a rubber grommet shall be used.

8.3.11 Data Patch Panels

8.3.11.1 The Contractor shall take cognisance of the ICT requirements and provide patch panels to meet the outlet requirements. 100% patch leads shall be provided with colours and lengths to be confirmed.

8.3.12 Data Outlets

8.3.12.1 The data and voice outlets will be RJ45, CAT6 augmented type with angled connector.

8.3.13 Public Address Systems

8.3.13.1 The Contractor shall provide a public address system to allow zoned emergency messaging throughout the hospitals, Lifts, Building links, tunnels, FM and Energy Centre together with external mustering areas, supplemented by local background music and zoned PA to allow entrances, receptions, atria, changing rooms and waiting areas to operate in line with the Clinical Requirements.

8.3.13.2 The emergency messaging shall be controlled from two locations and the system shall incorporate pre-recorded coded messages.

8.3.14 Staff Location System

8.3.14.1 Pagers to be integrated in the BMS and Telephone Systems to suit the Board Requirements.

8.3.15 Patients/Nurse Call Systems/Personal Attack Alarm

8.3.15.1 Nurse Call Systems

8.3.15.1.1 The Contractor shall provide a comprehensive Nurse Call System integrated within the BMS networking systems at all bed locations (and en-suites), Nurse Stations, Toilets and Showers, TV Rooms and all other areas frequented by patients. The system must be capable of emitting both audible and visual warnings for the following situations:

a) To summon a nurse (Patient to Nurse); and

b) To highlight a medical emergency (Nurse to Nurse).

8.3.15.1.2 The installation shall have the following functionality;

Ensure that both visual and audible warnings are sited in positions that enable the appropriate staff to respond to the exact location of the call both efficiently and effectively.

Ensure that the warnings, both visible and audible, should be specific to the type of emergency and must be consistent throughout all areas of The Works.

Provide systems that comply fully with the requirements of relevant S/HTMs and S/HBNs. In addition these systems shall enable on-screen alerts at locations to be agreed with the Board.

Ensure that the nurse call button / cord meet the need of the particular patient that may be required to use The Works. Patients may have cognitive problems or have difficulties with mobility.

8.3.15.1.3 A nurse call system is to be part of every bed head service. A patient hand unit with a call button is to link to an indicator panel at the Ward Nurses Station. The system is also to link to call buttons in other areas such as WC's, Bathrooms and Quiet rooms. The system shall include the following facilities:

a) Ensuite protection;

b) Over-door indicator lights;

c) Ability to link calls between adjacent wards; and

d) Cardiac arrest or 'crash' call alarms taken back to a 24 hour manned point to allow the 'crash' team to be paged

8.3.15.1.4 The Contractor shall provide a flexible system which annunciates within the nurse station with route indicators to the activated unit. Each bed system shall be transferable to adjacent and remote nurse stations via a hierarchical password control system to meet the Nursing requirements of the flexible ward configurations.

8.3.15.1.5 The system configuration shall be interlinked with the central PC based bed management system.

8.3.16 Clinical Equipment Alarms

8.3.16.1 Each clinical drug cupboard shall be alarmed as follows;

a) Light externally over door to room

b) Back to Nurses station

c) Back to local office to warn of unauthorised access.

8.3.16.2 The Contractor shall provide a system by which clinical Equipment alarms can be annunciated at a designated location during working hours but out of hours alarms can be directed to a designated member of staff, off-site. The Contractor shall determine all Equipment alarms of this nature.

8.3.17 Call Systems

8.3.17.1 The call systems or speech transfer systems shall be provided by the Contractor where normal speech is impaired by the use of glass security partitions or similar barriers. These shall generally be at public entrances and secure receptions these should contain staff control unit, speakers and microphones.

8.3.18 Induction Loops

8.3.18.1 The design of The Works shall include a comprehensive system of induction loops (fixed or portable) with suitably located dedicated sockets and signage such as to;

a) Reception areas;

b) Bedded bays;

c) Single Rooms;

d) Treatment Rooms;

e) Consulting Rooms;

f) Counselling Rooms; and

g) Interview Rooms.

8.3.18.2 Additionally, the design shall reflect these requirements in areas such as offices where staff may require this facility.

8.3.18.3 The Contractor shall provide induction loop or infrared systems in accordance with DDA requirements. The final provision and locations are to be agreed with the Board, dependent upon the final design solutions.

8.3.18.4 Portable hand held systems for use by visitors shall be made available at Reception. This shall ensure that the parts of The Works not provided with Induction Loops or infrared systems are made accessible to all users.

8.3.18.5 The “ear” symbol denoting the presence of an induction loop shall be prominently displayed. A sign shall explain clearly to people using hearing aids how they can benefit from the Induction Loop.

8.3.18.6 Alternative, proven systems that do not raise issues of patient confidentiality can be proposed by the Contractor to provide facilities wide coverage as appropriate.

8.3.18.7 The Induction Loop system shall be interlinked with the speech transfer system in order to provide a neat and unobtrusive configuration and an aesthetically discreet installation.

8.3.19 Television Installation

8.3.19.1 The contractor shall negotiate with a patient entertainment system supplier and provide the required backbone broadband cabling and wire ways and control room facilities for a leased patient entertainment system, to be installed at all bed heads in the Adult Hospital. Bed Head systems to provide:-

a) Television;

b) Radio;

c) Telephone; and

d) Game and internet services (optional at point of use)

Together with the associated infrastructure to allow these to be charged on a pre-payment basis.

8.3.19.2 Within areas were a conventional bedside screen is not suitable, the Contractor shall provide an alternative solution for location of the screen.

8.3.19.3 The Contractor shall provide a fully operational patient entertainment systems in the Children's Hospital to provide:-

a) Television;

b) Radio;

c) Interactive games;

d) Music;

e) Art; and

Protected Internet services.

8.3.19.4 In addition to facilities at each bed head, in the Children's Hospital, entertainment systems consisting of TV, DVD and games systems will be provided in the main waiting and play areas. These will require a central TV and radio reception and distribution system provided by the Contractor.

8.3.20 TV & Radio Facilities

8.3.20.1 The Contractor shall provide the infrastructure for reception and distribution of television and radio for use by patients, visitors and staff. This shall include external aerials / dishes, containment and cabling / distribution to enable radio (inc local hospital radio), and both digital satellite / terrestrial TV services to be distributed throughout The Works.

8.3.21 Lightning Protection & Earthing

8.3.21.1 The Contractor shall provide a lightning protection system for the protection of the structure, the contents and occupants. The lightning protection installation shall be in accordance with BSEN62305. The lightning protection system shall comprise of air termination network, down conductors, earth termination network, type 1 and type 2 surge arrestors and all required equi-potential bonds.

8.3.21.2 Surface fixed down conductors are not acceptable.

8.3.21.3 The Contractor shall provide a system of earthing comprising earth electrode systems, main and supplementary earth bars, main and supplementary equi-potential bonding, to ensure sufficient and fast operation of protective systems in the case of earth faults.

8.3.21.4 The earthing system shall comply with (S)HTM 06-01, BS7430, and BS7671 and with the Electricity at Work Regulations.

8.3.22 CCTV/Security Systems

8.3.22.1 General

8.3.22.1.1 The systems shall be closely integrated with the BMS to provide an integrated central monitoring and management facility. The Contractor shall provide security systems specifically designed to meet the requirements of each department / unit.

8.3.22.1.2 The systems shall present a secure and reassuring environment for staff, patients and visitors by providing appropriate security measures within the particular restraints imposed by clinical demand and personal freedom.

8.3.22.1.3 The design for all security systems shall be in line with the general principals of the approach recommended by Secured by Design refer also to section 7.

8.3.22.1.4 Local security systems alarm annunciation shall be provided within wards and at the central security facilities with remote monitoring and control off site at the Hillington Control Centre.

8.3.22.1.5 The main receptions shall also incorporate a CCTV monitor positions each with a flexible control facility to allow a combination of monitoring arrangements over two 20” Flat LCD screens.

8.3.23 Panic Alarm Systems

8.3.23.1 The Contractor shall provide panic alarm systems integrated within the BMS. Staff attack alarms will be provided by activation of a fixed discrete push button, hard wired to the underside of reception desks. All principal reception desks and staff bases will be provided with this facility.

8.3.23.2 Staff mobile panic alarms will be provided with link to receptions and security in the following areas:-

a) Accident & Emergency

b) Imaging (out of hours)

c) Pharmacy

d) Emergency Decontamination

e) Out of Hours Service Areas

8.3.23.3 All panic alarms fixed and mobile shall be monitored by the on site FM Control Centre and the remote Hillington Control Centre this shall provide a description of the alarm activation highlighting the precise location of staff members in distress.

8.3.24 Paging, Personal Attack Alarms

8.3.24.1 The Hospitals shall be installed with a radio-frequency network to facilitate the use of paging and personal attack alarms integrated within the BMS. This radio-frequency network shall include location beacons so that the exact location of pagers and attack alarm devices can be determined.

8.3.24.2 The radio-frequency network infrastructure shall be compatible with the Identicom personal security device, which is used widely across the NHS to provide lone-worker protection.

8.3.24.3 Panic buttons linked back to the FM Control Centre, and with a loud alarm at the scene, are to be installed at Reception desks and in Treatment Rooms

Decontamination room to be secured and fitted with Panic Alarm and two way intercom to adjacent area.

8.3.24.4 Treatment space in the Emergency Department to host CatA prisoners required (incl terrorist suspects transferred from 'G' Div HQ at Helen Street). This as well as decontamination room to have discrete entrance (double bank decontamination facility, have lobbies and two areas and may require armed escorts to be present. Provide lobby, seating, WC etc to support together with controlled ingress and egress and airlock type doors.

8.3.24.5 Police room in Emergency Department area to be fitted with panic alarm facilities.

8.3.24.6 The system shall be networked with the central management system and linked with other systems to allow:

The unlocking of doors along all escape routes to assist evacuation in an emergency.
Possible automatic locking of doors within an area if a panic button is pressed.
Activation of a security camera in a particular location when a door is opened to provide a picture of the person entering.

8.3.24.7 All A&E entrances shall have Video Access Control System for use at night time so that security staff can control entry from the desk positions in accordance with the Secured by Design recommendations.

8.3.24.8 General staff panic alarm system shall be integrated within the Wi-Fi network to allow staff to operate two stage affray facility within the hand held electronic PDA type equipment. This shall be configured to triangulate the location of staff members in distress and provide a department location.

8.3.25 Alarms & Intruder Detection System

8.3.25.1 The Contractor shall provide an IDS System within The Works to provide out of hours security cover. This shall be provided by PIR Detectors located within the corridors, rooms with ground floor windows, and rooms internally adjacent to any roof access points. In addition The Contractor shall ensure that restricted areas have door contacts available for monitoring unauthorised entry.

8.3.25.2 The following areas shall be fitted with local intruder alarm systems:

a) Pharmacies (to prevent the theft of controlled drugs)

b) X-ray department areas used for storing silver chemicals

c) Patient record offices

d) Stock rooms

e) Plant rooms

f) FM areas

g) All external doors

8.3.25.3 The intruder alarm systems shall link centrally back to the FM Control Centre.

8.3.25.4 The Contractor shall ensure that the proposed alarm systems for The Works include lifts, refrigeration equipment and all other critical equipment.

8.3.25.5 The Contractor shall ensure that the alarm systems can be securely monitored on Site and also remotely at the Hillington Control Room.

8.3.26 Security Access Control

8.3.26.1 The Contractor shall provide a comprehensive access control system to all external access doors and to internal doors requiring restricted access including access control doors to each ward and departments integrated within the BMS and plant area lighting controls to prevent unauthorised access. Control will be via a hierarchical proximity card system. Some departmental systems may only be activated outside normal working hours.

8.3.26.2 Ward access control doors shall also be fitted with CCTV camera and door access system. The CCTV camera shall be suitable for viewing of visitors in wheel chairs.

8.3.26.3 The Contractor shall provide the Entry requirements of SHPN57 e.g. Entrance to be controlled by use of entry-phone intercom system with CCTV linked to the reception/clerical office and communications base with access control provided across the full Critical Care Accommodation including changing room doors

8.3.26.4 Controlled access shall be provided by the Contractor to the Estates and FM vehicle hard standing and parking facilities for vehicles and pedestrians, traffic management lights and barriers shall be provided to control the yard and the associated slip road.

8.3.26.5 The Contractor shall ensure the system includes all necessary power supplies, card readers, actuators, egress buttons and emergency “break-glass” release units and fire alarm interfaces.

8.3.26.6 The system shall utilise the BMS LAN with separate field cabling and all necessary central controls / network cards provided suitable for future extension.

8.3.26.7 The system shall be interfaced with the robotics system to ensure that controlled access is provided while maintaining system integrity.

8.3.26.8 The system shall be interfaced with the theatre system to ensure that controlled access is provided while maintaining operational integrity.

8.3.26.9 The Contractor shall provide door entry video intercom systems to the designated main entrance doors and the delivery entrances with local control and facility to transfer to the main security room.

8.3.27 External CCTV

8.3.27.1 The Contractor shall provide a comprehensive colour CCTV system integrated within the BMS covering all external access points, car parking and external pedestrian/cycle circulation routes around the full Site including FM, service yards, car parks, walkways, boundary of/entrances to Site, boulevard, service tunnel etc, and the general road network.

8.3.27.2 The design shall also take cognisance of the Board's security requirements as detailed in the Boards operational requirements.

8.3.27.3 The Contractor shall ensure that the system comprises a multi-channel digital recorder with a recording frame per second for each camera which is in accordance with a detailed engineering specification to be agreed with Strathclyde Police.

8.3.27.4 The digital recorders shall also control playback of images onto a CCTV monitor.

8.3.27.5 The cameras shall be fully functional set up with stops to avoid over viewing adjacent properties, the RAID storage shall be 25 frames per second and all equipment shall be selected to provide good quality viewing and reproduction for use in prosecutions.

8.3.27.6 The external PA system shall be linked to cameras so operator can 'speak' to persons in external spaces in emergency or to reprimand/warn.

8.3.27.7 The system shall be fully integrated with the new Laboratories system and shall be configured to allow migration of the retained estate equipment without downtime.

8.3.28 Internal CCTV

8.3.28.1 The Contractor shall provide a comprehensive colour CCTV system integrated within the BMS covering all corridors, reception, lift lobbies and other areas where members of the public gather or areas where access is to be restricted i.e. wards.

8.3.28.2 CCTV cameras shall be installed at the main entrances, waiting and circulation areas of both hospitals where the security and safety of hospital staff and patients is a concern but where free access for the visiting public is allowed. The CCTV systems are also to cover:

a) All Exits and Entrances;

b) Ambulance Parking;

c) Vehicle Bays;

d) Fill points;

e) Cycle sheds;

f) All vehicle and cycle routes within the works;

g) All footpaths within the works;

h) Pharmacy Counters;

i) Ward Entrances;

j) Children's Play Areas;

k) Ambulance Entry Points;

l) A&E Departments;

m) Car Parks, Estates Yards, Public Spaces;

n) Generator Plant rooms;

o) Main Heating Plant rooms;

p) Corridors;

q) Receptions;

r) Lift lobbies; and

s) Other areas where members of the public gather or areas where access is to be restricted.

8.3.28.3 All CCTV cameras will be IP-based. They will be linked back to local hubs by fibre or Cat.6A cabling. Local data hubs will be connected back to a number of CCTV servers adjacent to electrical risers, which will in turn be linked to the main server room via a looped optical fibre network. CCTV servers will include input modules, processors and RAID storage. The system shall record at 25FPS per camera and provide 31 days storage. Each CCTV server will also be provided with an independent broadband connection to provide connectivity in the event of a network failure.

8.3.28.4 All cameras shall be linked back to the FM Control Centre and the off site facility at Hillington with local supplementary monitors in accordance with the Clinical Requirements.

8.3.28.5 The Police room in Emergency Department area to be fitted with CCTV monitors, to receive feeds from the Emergency Department cameras and any other surveillance as provided under the control of the main CCTV monitor position.

8.3.28.6 The CCTV system shall be linked to the intruder alarm and access control systems to provide specific viewing functions, such as presenting a picture on a monitor when an access card is presented to a reader, or when a movement detector activates.

8.3.29 Automatic Barriers

8.3.29.1 The Contractor shall provide all vehicle access barriers including associated power and control wiring. For Vehicle control at the A&E, FM to suit the developed traffic philosophy. Facilities shall be provided for audio visual links to the security desk to provide assistance. The Contractors shall also provide additional ducts and network cabling to strategic areas for future pay stations.

8.3.30 Uninterruptible Power Supplies (UPS)

8.3.30.1 The provision made for interruptible/ uninterruptible power supply (IPS/UPS) solutions to provide electrical safety in the patient environment shall be based on IEC 6034 for Electrical Installations in Medical Locations, (S)HTM-06-01 and the recommendations of Guidance Note 7 to BS7671 Wiring Regulations published by the Institution of Electrical Engineers.

8.3.30.2 UPS solutions shall also be provided by the Contractor to support Grade A standby lighting in Group 1 and Group 2 locations within areas of clinical risk 4 and 5.

8.3.30.3 The Contractor shall provide the UPS requirements of SHPN57 e.g. all patient supplies in Critical Care areas shall be UPS backed, dedicated plug arrangements shall be provided rather than colour coding to differentiate.

Lighting in Critical Care areas to be UPS backed, this element of the requirement may be provided from of series of resilient redundant "lighting off line" battery inverter units rather than from the main series of "on line" UPS sets.

8.3.30.4 UPS units shall be located to suit the load requirements and the Contractor shall allow for UPS resilience, redundancy, automatic by-pass and ensure that the equipment is provided with the appropriate environment to ensure full design life is achieved from all equipment and batteries.

8.3.30.5 Consideration shall be given to UPS island mode operation with measures taken to ensure that the output neutral is referenced to earth at all times e.g. bypass and isolation transformers permanently in circuit with local connection or reconstituting the UPS neutral –earth bond as required.

8.3.30.6 Batteries shall be minimum ten year design life type in accordance with British Standards, these shall be provided in cabinets and battery monitoring and battery isolation devices shall be linked to the central monitoring system.

8.3.30.7 Battery cabinets shall be located in separate plant rooms from all heat generating equipment with appropriate environmental conditions to provide a safe steady state environment for maximum battery life.

8.3.31 Generators

8.3.31.1 The site generation shall be sized to provide stand-by power for The Works and Laboratory with provision for integration of the retained estate.

8.3.31.2 The system shall comply with the distribution requirements of (S)HTM-06 as set out in the schematic drawing ref G1274/E(60)01 and the generators shall have sufficient capacity to pick up the load and meet the minimum frequency and stability requirements for the Emergency System after loss of mains power taking into consideration the site load including Medical equipment, UPS and HVAC variable speed drives.

8.3.31.3 Load management control shall be utilised to ensure that the lighting and small power are reinstated within 15 seconds of power failure. All other loads including Mechanical Services and Lift power shall be re-instated in a controlled manner within 25 seconds of power failure. The Contractor shall include for all load management software and hardware including automated motorised ACB's and MCCB's to ensure that the load management matches the generator status. The Control shall be run over twin redundant PLC's with automatic change over in the event of fault. All control circuits shall be constantly monitored for healthy operation and communication with faults indicted at the Plant rooms with remote indication via the BMS.

8.3.31.4 Active mimics shall be provided via touch screen PC's within each main switchroom to indicate the status of all main electrical plant and emergency systems.

8.3.31.5 All power for controls and monitoring equipment shall be provided from resilient supplies with UPS/ Battery backup, with back up to allow maintenance without system downtime.

8.3.31.6 A full load analysis shall be carried out to ensure that the appropriate generator sets are selected to meet the active power, reactive power and apparent power requirements and that change-overs are bump free with a maximum permissible voltage dip of 2% on load acceptance.

8.3.31.7 The alternators shall be selected to match the inrush current of the transformers which shall be brought on line (with lighting and small power loads connected) when one of the generators in each group is available on the bars. The remaining generators shall synchronise to the first unit in their group and signal to the load management controls when sufficient units are available to take the remaining loads.

8.3.31.8 Generators shall be rated as ISO8528 (2005) Continuous Operating Power COP.

8.3.31.9 Full load management shall be provided by the Contractor to allow isolated island running and parallel utility operation.

8.3.31.10 The engines shall comply with ISO 3046-1 and generators comply with ISO 8528.

8.3.31.11 To improve system resilience the generators shall be located in groups with Fire and Blast Separation.

8.3.31.12 Digital Automatic Voltage Regulations (AVR) shall be provided with optimized transient response to suit site load.

8.3.31.13 A stringent series of “Black Building Tests” shall be developed by the bidder to indicate cause and effect for all of the system fault scenarios, this shall be build up in iterations with simple single system faults escalating to major inter system failures in a matrix.

8.3.31.14 An override facility shall be provided via Castel interlocking to allow a controlled manual engine start up procedure to be available in the event of PLC failure.

8.3.31.15 Once the Matrix is agreed the tests shall be integrated in the overall commissioning strategy.

8.3.31.16 The fuel storage shall be integrated with the standby heating fuel system to provide a modular storage facility as described elsewhere.

8.3.31.17 Each generator shall be provided with a dedicated gravity feed day tank capable of tuning the set at maximum load for 10 hours.

8.3.31.18 A resilient dual piped, multiple pumped supply system shall be provided from the Modular Storage to deliver to the day tanks.

8.3.31.19 All engines should incorporate lean burn technology to minimize NOx, flues shall be run to the energy centre stack and discharged at high level.

8.3.32 Plant Rooms

8.3.32.1 The plant rooms shall be configured to ensure optimum environmental conditions to ensure efficient operation.

8.3.32.2 All walls, ceiling and floors within generator rooms, transformer rooms, MV and LV switchrooms shall be painted to minimize problems associated with dust.

8.3.32.3 All floors and roofs to be of water proof construction with all penetrations formed in bunded up-stands incorporated in the water proof design.

8.3.33 Theatre Panels

8.3.33.1 The Contractor shall provide proprietary theatre panels of touch screen design to meet the Clinical Requirements and provide a centralised control and monitoring position within the Theatre for all Electrical and Environment Systems including Mains power, Generator power, UPS power, fire alarms, temperature, humidity, theatre lights, room lights etc.

8.3.34 Lifts and Escalators

8.3.34.1 The Contractor shall provide bed passenger lifts (suitable for inclusion of at least one hospital bed (orthopaedic bed), goods lifts, service lifts, general passenger lifts, clean goods lifts, dirty goods lifts, FM robotics lifts, dumb waiters and evacuation lifts within the buildings in accordance with (S)HTM 2024 and EN 81. Evacuation lifts for emergency conditions will be considered within the fire strategy and shall be provided if required as part of that agreed strategy. All lifts provided for the movement of patients shall be supplied from the essential services supply in accordance with (S)HTM 2011.

8.3.34.2 The Contractor shall give consideration to the following in the provision of lifts:

a) The lifts shall be vandal / damage resistant but aesthetically pleasing and appropriately sized (lifts designated as passenger bed lifts shall be sized to accept as a minimum a bed and associated equipment);

b) Banks of lifts shall be appropriately controlled to maximize movement;

c) Collective controls of groups of lifts shall be used;

d) All floors including plant levels shall be served;

e) Control rooms shall be easily accessible and designed to minimise the need for artificial cooling;

f) All Lift power shall be via automatic changed over units with power fed from either side of the dual power distribution systems;

g) Emergency hands free telephones in lifts shall be accessible to the blind, partially sighted, deaf and wheelchair users. The Contactor shall link each lift car emergency phone directly to an individual emergency line at the Boards central communications centre, to facilitate emergency clinical support and communication, this shall be in addition to the lift remote fault reporting system provided by the lift suppler;

h) Remote lift operation monitoring shall be provided;

i) Lifts for people and goods shall be separated;

j) Dedicated lifts are required for theatres or swipe controlled staff access override;

k) Key operated Priority Control shall be provided for bed movement and a local controller shall be provided within the helicopter recovery area;

l) Manual Handling shall be reduced with the introduction of Automated transfer Systems which shall be integrated in the vertical transport solution. The Contractor shall clearly set out the number of lifts indicating if these are dedicated to Automated Transfer System or shared with the FM units;

m) All lift car levelling requirements shall be in accordance with the British Standards and also be in accordance with the Automated Transfer System step capabilities if this is less tolerant than the British Standard;

n) Lifts shall be conventional type rather than machine room less type to ensure operation of the Boards passenger evacuation procedures;

o) Escalators to be selected to meet the traffic flow in accordance with the Bidders scheme, units shall be designed and installed in accordance with BS5655;

p) The Bidders shall carry out vertical transport analysis for passenger, bed movement and FM movements and automated material transfer systems based on their proposed scheme and the clinical and operational requirements;

q) Lift and escalator ratings speeds shall be selected to ensure excellent service complete with inbuilt redundancy to allow for unit breakdown and planned maintenance;

8.3.35 Tagging

The Contractor shall provide a full asset tagging system in accordance with the NHS Scotland (HFS) National asset management requirements.

All installed Electrical, Mechanical, Public Health Medical Gases and Specialist systems components shall be asset tagged by the contractor, entered into the PPM system and linked to its full specification and maintenance schedule.

The tagging system shall be capable of simple extension to allow the Bar Coding of Hospital Equipment, and the bidders shall provide technology proposal for Board consideration.

The asset tagging system shall be interfaced with the PDA System to be utilised for Managing Building Handover and Snagging.

8.3.36 Service Tunnels

Full resilient building services shall be provided in the service tunnels including, ventilation, smoke control, heating, small power, lighting, emergency lighting, illuminated signage, fire alarms, leak detection, access control, public address/background music and CCTV etc. to allow the tunnels to continue to operate during sectional maintenance.

The tunnels shall be configured to meet the developed traffic flow requirements, with full consideration of the Automated Material Transfer System operation requirements including power, ventilation, unit recovery, weight, gradient and step limitations.

Special consideration shall be given the risk of single point of failure within the tunnel and the main services shall be separately routed with dedicated maintenance access provided to allow ongoing operation during maintenance.

8.3.37 Laboratory Services

All specialist services e.g. security, access control, CCTV, fire alarms BMS etc within the new hospitals shall be fully compatible with building the services to be provided in the Laboratory Building.

8.3.38 Future Proofing

The Contractor shall ensure that all systems are future proofed and shall provide a compliance matrix indicating measures taken in their supply chain to indicate the level of future proofing included in their bid.

SECTION 8.4 - DRAWINGS (these are located in Appendix M)

Schematics	Number G1274-
Main Power Schematic	E/(60)01
Power Distribution Schematic	E/(60)02
Fire Alarm Schematic	E/(67)01
CCTV/Staff attack & Intruder Schematic	E/(68)01
Nurse Call Schematic	E/(68)02
Data Schematic Diagram	E/(68)03
Typical CWS Distribution Layout	P/(53)01
Wet Riser Distribution Schematic	P/(67)02
Medical Gas Pipeline System Schematic	M/(54)01
Natural Gas Schematic	M/(54)02
Sprinkler Installation Schematic	P/(67)01
Chilled Water Distribution Schematic	M/(55)01
MTHW Distribution Schematic	M/(56)01
Typical LTHW Distribution Schematic within Building	M/(56)02
Isolation Suites, plant room adjacent Ventilation System	M/(57)01
Isolation Suite Vent System plant room above	M/(57)02
Typical Adult Ward Tower Ventilation Schematic	M/(57)03
Operating Theatre Ventilation Outline Plan and Schematic	M/(57)04
Site Layout Drg's	Number G1274-
Water, Gas and electric Site Incoming Services	U(96)01
Indicative MTHW heating distribution route	M/(56)03
Energy Centre	Number G1274-
Proposed Energy Centre Plant room layouts MTHW Solution	ME/(60)01
Indicative Primary Sub Station Layout	ME/(60)02
Detail Drawings	Number G1274-
Indicative layout of Main Services Tunnel	ME/(60)03
Board Drawing	
Existing External Services Site Plan	G1700X G(52)Combined-Site

Section 9.0 Civil & Structural Engineering Requirements

The Contractor shall in carrying out the Works comply with the following non-exhaustive list of civil & structural engineering requirements.

9.1 General Requirements

9.1.1 The Contractor shall ensure that the design and construction of the civil and structural engineering elements of the buildings and external works meets the following criteria:

a) Be designed observing due skill, care and attention to the requirements of the brief;

b) Be fully co-ordinated with the design of the building fabric, finishes, services, facades, internal walls, medical equipment and existing Site features, including buildings / structures;

c) Provide adequate space for the distribution of services, while maintaining the required finished floor levels and the floor to ceiling heights called for in the Room Data Sheets; and elsewhere in the Employers Requirements documents;

d) Maximise the clear zone above the ceilings for services to the degree consistent with overall economy for the Board;

e) Be economically adaptable to meet changing clinical needs; and

f) Require minimum maintenance and be designed to accommodate maintenance requirements for services, equipment and building fabric.

9.2 Minimum Design and Construction Standards

9.2.1 Unless otherwise agreed with the Board the Contractor shall ensure that all structural and civil engineering elements are designed in accordance with current revisions of the following standards and guidance documents:

a) BS6399 - Loading for buildings or Eurocode 1 (incl. Eurocode 0);

b) BS5950 – Structural use of steelwork in building or Eurocode 3;

c) BS8110 - Structural use of concrete or Eurocode 2;

d) BS5628 – Code of practice for the use of masonry or Eurocode 6;

e) BS5268 – Structural use of timber or Eurocode 5;

f) BS8002:1994 – Code of practice for earth retaining structures;

g) BS8004:1986 – Code of practice for foundations;

h) BS8102:1990 – Code of practice for protection of structures against water from the ground;

i) BS8007:1987 – Code of practice for design of concrete structures for retaining aqueous liquids;

j) BRE Special Digest 1:2005: Concrete in Aggressive Ground;

k) BS5606:1990 – Guide to accuracy in building;

l) BS8000 – Workmanship on building sites;

m) BS8500 – Guide to specifying concrete;

n) Glasgow City Council Roads Development Guide;

o) Design Manual for Roads and Bridges;

p) Specification of Highway Works, published by The Stationary Office as Volume 1 of the Manual of Contract Documents for Highway Works;

q) The Traffic Signs Regulations and General Directions 2002;

r) The Traffic Signs Manual;

s) Sewers for Scotland 2nd Edition;

t) BS EN 752:2008 – Drain and Sewer Systems outside buildings;

u) BS EN 12056 – Gravity drainage systems inside buildings;

v) BS EN 1825 – Grease Separators;

w) BS EN 1295 – Structural Design of Buried Pipelines Under Various Conditions of Loading;

x) CIRIA C624: Development and Flood Risk – Guidance for the Construction Industry;

y) CIRIA C635: Design for Exceedance in Urban Drainage – Good Practice: 2006;

z) CIRIA C697: The SUDS Manual: 2007;

aa) CIRIA R168: Culvert Design Guide;

bb) The Water Environment (Controlled Activities) (Scotland) Regulations 2005;

cc) SPP7 – Planning & Flooding;

dd) Glasgow City Council – ENV 3 – Flood Prevention and Land Drainage;

ee) ICE specification for piling and embedded retaining walls, 2nd Edition;

ff) CIRIA 66S: Assessing Risks posed by hazardous ground gases to buildings: 2008; and

gg) WRAS information and Guidance Note No. 9-04-03. The selection of Materials for Water Supply Pipes to be laid in Contaminated Land.

9.2.2 The Contractor shall deliver the Works set out in accordance with BS5606 – Guide to Accuracy in Building Critical dimensions and setting out points shall be clearly marked on drawings.

9.2.3 Construction tolerances, unless otherwise stated by the Board shall be no greater than those specified in Tables 1 and 2 of BS5606. Where the operational constraints of the building require special levels of construction accuracy then The Contractor shall be responsible for establishing and designing for these.

9.2.4 The performance of components shall be in accordance with the appropriate British Standards.

9.2.5 The Contractor shall ensure that building structures are designed to resist imposed, roof and wind loads not less than those required by current revisions of BS6399, Loading for Buildings.

9.2.6 The Contractor shall ensure that building structures are designed to carry the loads of heavy plant or medical equipment (including ceiling mounted tacking hoist systems) in their permanent positions and any loads that will be imposed upon the structures during the installation, removal or replacement of such heavy items. This requirement may involve the design of 'strong routes' through the buildings and/or specially strengthened areas of the roof onto which heavy items can be lifted.

9.2.7 The Contractor shall ensure that any measures considered necessary shall be taken to protect the building from ingress of naturally occurring ground gases e.g. carbon dioxide, carbon monoxide, methane and hydrogen sulphide.

9.2.8 In addition to reference to the above Performance Standards the Contractor shall take cognisance of the comprehensive list of relevant compliance documents as detailed in Section 5.1 of Employers Requirements: Minimum Design & Construction Standards.

9.3 Loadings & Structural Flexibility

9.3.1 The Works shall be designed to cater for the dead loadings associated with the chosen materials for the structure, finishes, partitions and cladding to the buildings. As a minimum, it shall also be designed for the imposed loads as specified in current British Standards. The design shall also take into account the need for specialist measures to allow for the installation, replacement and removal of Special Equipment and associated services. Structural deflections shall be limited as necessary for the proper installation and functioning of specified equipment.

9.3.2 The Contractor shall account for (but not be limited to) the following loading schedule

a) General floor loadings – Dead and Live loads;

b) Point loads for Clinical equipment and Services;

c) Impact loads;

d) Vibration loads;

e) Special plant foundation loads; and

f) Service loads

9.3.3 The Contractor shall take account of concentrated point loads from both mobile and stationary plant and Equipment. The structure should incorporate reasonable measures to accommodate updated versions of such machinery without major disruption. In addition, the Contractor shall ensure that floors and supporting structures have the capacity for retro-fitting lifting devices for all fixed items of plant and Equipment weighing 35kg or more.

9.3.4 The Contractor shall take cognisance of the requirements in designated patient areas for ceiling mounted tracking hoists etc and such measures to allow for the installation of Special Equipment and associated services.

9.3.5 The Contractor shall ensure that specific areas of the Works satisfy particular requirements of the Board's operations or Equipment in those areas. Relevant constraints may include but are not limited to maximum allowable (structural deflections) differential settlement, (vibration) and the meeting of any constraints.

9.3.6 The Contractor shall take account of dynamic loads from general movement of people through to activities such as aerobics, dance or other rhythmic activities that can give rise to harmonic effects in poor design.

9.3.7 Lateral stability bracing systems shall not obstruct or hinder Clinical or Non-Clinical operations and shall not obscure the windows or doors.

9.3.8 The vibration response of the buildings shall comply with the requirements of SHTM 2045 and be compatible with the requirements of the Equipment to be installed.

9.3.9 With respect to the Works, the Contractor shall:

a) Take due account of future flexibility of the Works (in terms of future change of use and/or relocation of equipment);

b) Specifically make allowance for future flexibility of ceiling mounted lifting equipment in designated patient areas, including the requirement for re-configuration, extension and/or retro-fitting of lifting equipment i.e. the whole of the designated area shall be capable of accommodating re-configuration or retro-fitting;

c) Make specific allowance for items of particularly heavy equipment and/or other onerous loading conditions; and

d) Make specific allowance for installation, transfer and/or removal routes for heavy equipment throughout the Facilities.

9.3.10 Parts of the structure potentially subject to damage from trolleys or vehicles shall be designed with adequate protection to prevent such damage from occurring.

9.3.11 Structural deflections shall be limited as necessary for the proper installation and functioning of special mobile, rail mounted, or fixed Equipment.

9.3.12 The Contractor shall include, within their design, provision for removal, replacement and upgrading of installed plant and Equipment. As part of this element of design, a comprehensive replacement strategy shall be prepared for implementation. This strategy shall, wherever possible, consider how these activities can be undertaken whilst minimising disruption to the function of the completed Works.

9.4 Foundations & Sub-Structure

9.4.1 The foundations shall be designed and constructed in accordance with the relevant Codes of Practice, recognising the prevailing ground conditions at the site as identified in the Ground Investigation Report (contained in Appendix N) and historical ground investigation information issued with the tender. Where the Contractor considers there is insufficient ground investigation information within the information issued for tender purposes, he shall identify this and allow for carrying out further investigation as he considers is required.

9.4.2 The Contractor shall take due cognisance of:

a) Recognition of applied loading;

b) Settlement and its effect on new buildings, links to adjacent buildings, existing adjacent foundations and existing services;

c) Dewatering and its effect on new buildings, links to adjacent buildings, existing adjacent foundations and existing services;

d) Earthworks;

e) Basement construction and waterproofing category;

f) Possibility of uncharted services and existing buried structures; and

g) Utilities Diversions.

9.5 **Basements & Tunnels**

9.5.1 The Contractor shall refer to the Masterplan, Acute Adult and Children's Hospital, Laboratory and Energy Building drawings contained in appendices for proposed locations of basements and tunnels. Basements structures in the main hospitals will generally be provided for FM/distribution and plantroom/service areas. Basements areas in the laboratory building are generally for access to the labs and mortuary as well as services distributions. It is intended that significant size tunnels will be provided between and connecting basement areas. The tunnels will provide routes for distribution of services and movement of staff.

9.5.2 Basement and Tunnel structures should be designed in accordance with the recommendations of BS 8102. The Contractor should provide designs appropriate to use of these elements i.e. he is to confirm categories of design A, B or C and identify where each is employed

a) Category A – Technical Protection;

b) Category B – Structural Integral Protection; and

c) Category C – Drained Protection.

9.6 Movement Joints

9.6.1 Structural/movement joints shall not be located through:

a) Kitchen and food preparation areas;

b) Treatment and surgery rooms;

c) Any room that HAI~Scribe prevents a floor joint from being provided in (including Theatres for example);

d) Rooms requiring a sterile environment; and

e) Any room with (now or in the future) tracking hoists or other similar lifting equipment

9.7 Superstructure

9.7.1 The Works primarily comprise the following elements:

a) Acute Adults and Children's Hospital;

b) New Laboratories Building;

c) New Energy Centre; and

d) External works and roadways/infrastructure, including utilities.
(Multi-storey car parks by others).

General

9.7.2 The Contractor shall provide designs appropriate to the type of buildings and in appliance with all SHBN's, SHTN's HBN's and Codes of Practice. The design of each building should demonstrate.

a) Ability to withstand loads and load combinations imposed on the building, vertical, horizontal, dynamic, temporary etc;

b) Compliance with robustness (tieing) requirements of current Codes of Practice and Technical Standards (Scotland) i.e. progressive collapse requirements;

c) Provision of movement must be included in designs, horizontal, vertical, shrinkage, temperature effects etc;

d) Vibration sensitive equipment will be in use throughout the new faculties. Designs should take cognisance of vibration categories;

e) Integration of building services with structure will be a highly important part of the design process. The Contractor shall demonstrate how design coordination will be achieved;

f) All material used in the design of structures shall be compatible with each other and such things as finishes (e.g. Painted); and

g) The Contractor shall prepare and supply an overall Design Philosophy Statement which should include as a minimum, General Project information, The Site, Design Team Parties, Construction Programme, The Structural Scheme, Design Standard and Sources of Reference, Modelling and Analysis and Calculations and Checking.

Acute Adults & Children's Hospital

9.7.3 The building will comprise basements, large area footprint storied structure (podium decks) and ward block multi-storey towers in 4 wings with associated cores. The Contractor shall demonstrate load paths through the building, identifying such things as transfer structures, stability cores, basements, retaining walls and foundations.

9.7.4 It is anticipated that a Helipad will be provided at roof level. The Contractor shall demonstrate a design in compliance with HBN 15-03 Hospital Helipads and identify in particular,

a) Size of helipad;

b) Size of helicopter designed for a loading applied to roof structure;

c) Load transfer of helipad structure to hospital roof structure;

d) Ramp access from/ to pad/ roof; and

e) Integration with emergency services requirements, such as fire fighting systems.

New Energy Centre

9.7.5 The Contractor is required to provide a building structure housing the new equipment that will service the overall hospital development. It is anticipated that large heavy equipment, boilers, generators, CHP plant etc. will be integrated into the design. Large spaced, double storey heights etc. will be required.

New Multi-storey Car Parks (by others)

9.7.6 The Contractor is required to provide a road and drainage and external works design that reflects and takes cognisance of the overall site, including the provision of new multi-storey car parking. Refer to Masterplan Layout for locations and sizes/ capacity of new car parking requirements.

9.8 Fire & Corrosion Protection

9.8.1 The Contractor shall provide fire protection to all elements of structure and ensure fire ratings are in compliance with space used and the more onerous of Building Regulations/the Board's requirements.

9.8.2 The Contractor shall provide a corrosion protection system appropriate to the various structural elements and their location of the buildings.

9.8.3 The corrosion protection system used shall be relevant to type of structure and its structural function and its material and location within the overall building frame. All materials used shall be compatible with each other and with surface finish materials. Reference should be made to the design life of the building structures and finishes, refer Section 5.0.

9.9 Durability & Maintainability

9.9.1 All elements of the structure shall be capable of withstanding potential deterioration due to weather, ground conditions, wear and tear, and accidental damage relevant to their location and environment.

9.9.2 Where the requirement for maintenance is less than the required life expectancy of the element(s) practical and realistic arrangements shall be designed into the construction of the Works to allow for any necessary repairs, replacements and painting etc. to be carried out safely without compromising the operational activities within and around the Works.

9.9.3 Contractor to provide a strategy statement on maintenance and replacement.

9.10 Other Performance Requirements

9.10.1 The Contractor shall ensure that all building elements and retaining structures shall incorporate appropriate means to resist the passage of dampness, both into the building structure and fabric, and into the accommodation, including the resistance to any hydrostatic pressure. The Contractor shall ensure that all such construction shall be in accordance with the requirements of the Building (Scotland) Regulations 2004, BS8102 and Code of Practice CP 102 for Protection of Structures against Water from the Ground.

9.11 Underground Drainage

9.11.1 A 'Drainage Impact Assessment and Strategy Report' has been prepared (see Appendix L) and is prescriptive in outlining the requirements which are to be assessed and met in respect of the foul and surface water drainage from the development. The report covers, *inter alia*:-

a) The proposed surface water drainage strategy and the resulting surface water drainage network design considerations and projected amendments to existing culverted watercourses;

b) The proposed foul water drainage strategy, projected foul flows and the drainage network anticipated. The Contractor is required to confirm by calculation their own assessment of flows for the development;

c) Sustainable Urban Drainage criteria which require to be met for each element of the development. Again, the Contractor is required to review the requirements and develop appropriate methods for implementation of the treatment required;

d) The management and maintenance of the designed drainage systems shall be accompanied by a summary which details the residual requirements for maintenance of each element of the drainage system, including parts of the network prospectively vestable in Scottish Water; and

e) The criteria for assessment of Flood Risk for the designed drainage networks and the development as a whole. The requirements for mitigation of the assessed flood risk and the appropriate finished floor levels for access, egress and buildings are also outlined for the Contractors to address.

9.11.2 In the development of the guidance within the 'Drainage Impact Assessment and Strategy Report', the Contractor shall be responsible for liaison with the relevant stakeholders in agreeing connection requirements to the surrounding public sewers, watercourses and drainage networks. The Contractor is responsible for the design and construction of a drainage solution that meets all the requirements of and satisfies the relevant regulatory authorities including, but not limited to, GCC, SEPA and Scottish Water.

9.11.3 All phases of the development shall treat the disposal of surface water in accordance with the principles of 'The SUDS Manual' Report no C697 published by CIRIA (March 2007)

9.11.4 The Contractor shall provide, where necessary within the on-site drainage network any isolators, retention traps, interceptor tanks and other such devices necessary to prevent the discharge of any potentially dangerous or otherwise contaminative materials to the public sewers.

9.11.5 The Contractor shall design and provide separate foul and surface water drainage systems in accordance with the requirements of the Building (Scotland) Regulations 2004.

9.11.6 All drainage shall be designed to avoid the risk of local flooding and flooding of the system into which they discharge. Flooding of electrical equipment areas and areas where stray current leakage may occur in the presence of water shall be prevented.

9.11.7 Drainage shall be sufficient to ensure that no areas of standing water occur outwith extreme storm events. The drainage systems shall be capable of coping with, as a minimum, the foul loading and the storm event specified by the relevant authority and shall be considered an integral part of

the public sewerage system. This shall include any storage required on the public network to offset the assessed impact of the development.

9.11.8 The drainage system shall be capable of taking such detritus as may normally arise during the operation of the system and during normal and winter maintenance conditions and those within the design criteria of the relevant authority.

9.11.9 The Contractor shall design the drainage system in such a way as to minimise the requirement for internal manholes.

9.12 Roads, Footpaths, Cycle paths and Car Parking

9.12.1 The extent of adoptable and non-adoptable roads is shown on the Exemplar layout drawings.

9.12.2 The Contractor shall provide a network of internal roadways providing;

a) a spine road network through the site between Govan Road and Hardgate Road to facilitate the increased levels of Hospital traffic;

b) a road network through the site between Govan Road and Hardgate Road with designated provision for blue light ambulances, related and relevant to the position of A&E services at all phases of the development;

c) a public transport hub served independently served from (a) or (b) above and in keeping with the requirements of the 'Clyde Fastlink' proposals being promoted by Glasgow City Council;

d) service access to the relevant areas as indicated on the Masterplan, which will be independent of any of the networks in (a) – (c) above;

e) sufficient Ambulance provision at A&E as outlined elsewhere in these requirements, and separate provision for temporary private vehicle layover in the same environs; and

f) a taxi / car drop-off and layover bay at an appropriate location and geometry to effect the efficient and safe pick-up and dropping off of visitors and other users of the hospital facilities.

A maximum of 3,500 car parking spaces, comprising 2400 staff and 1100 visitor / patient spaces are being created on site by others. The Contractor shall require to liaise with the Board and the consultant teams and contractor(s) carrying out this work in order to establish common routes, levels and other relevant co-ordination requirements.

9.12.3 The layout and geometry of the network of internal roads shall be generally in accordance with the Masterplan and exemplar layout provided to the Contractor.

9.12.4 The Contractor will provide details of junction upgrades including priority control measures for blue light ambulances and provision for 'Clyde Fastlink' shall be developed by the Contractor in consultation with Glasgow City Council.

9.12.5 The Contractor shall design the construction of new roads in accordance with the Glasgow City Council 'Roads Development Guide' for a Traffic Distributor Road. Pavements shall provide a residual design life at the year of completion of the works of no less than 40 years.

9.12.6 The Contractor is responsible for all approvals and consents in relation to all on-site and any off-site road, footpath, cycleway or other transport requirement.

9.12.7 The Contractor shall ensure that all roads, delivery and refuse collection areas have sufficient headroom above them to allow for the passage of appropriate emergency, servicing, delivery or refuse collection vehicles and are designed to provide sufficient space to allow efficient manoeuvring of such vehicles without undue difficulty, risk of impact or adverse effect of exhaust fumes on occupants of the buildings.

9.12.8 All structures which support roads / footpaths / cycleway shall be designed in accordance with the relevant provisions of the Design Manual for Roads and Bridges, and assume design loadings equivalent to the maximum permitted vehicle on the public highway.

9.12.9 The Contractor shall ensure that all roads, car parks and other areas that may be used by fire appliances shall have sufficient headroom for such vehicles and are designed to allow their efficient manoeuvring. The Contractor shall agree with the Board the types of delivery vehicles, which require to be considered in the design. Refer to briefing paper, facilities service yard/compound in Appendix L.

9.12.10 New car parks within the Site shall be designed by The Contractor to comply with applicable SHTM, HTM, HBN 45, HFN 20, HFN 21 and the requirements of Glasgow City Council Roads Development Guide.

9.12.11 Details showing the phased construction of all temporary and new car parking facilities constant with the masterplan shall be provided by the Contractor.

9.12.12 Where areas of surface car parks are required to be traversed by vehicles heavier than 2500kg for maintenance or access purposes, the sub-base and surfacing of these areas shall be specifically designed by The Contractor for these heavier loads.

9.12.13 Roads, delivery and refuse collection areas, and car parks, together with their supporting groundworks and structures, shall be designed by The Contractor to provide full and sufficient access for inspection, maintenance and repair of roads, car parks, delivery and refuse collection areas, structures, underground and underground drainage, including existing drainage items such as manhole covers and drains. Where access for maintenance, repair or replacement of underground services is required under the terms of an easement, the design of all elements affecting the exercise of such an easement shall also be in accordance with the requirements of the company that has the right to exercise the easement.

9.12.14 The Contractor shall also comply with the following criteria:

a) To roads, footways, footpaths and cycleways, construction is to be bituminous and in accordance with Glasgow City Council's Roads Development Guide appropriate for a Traffic Distributor Road;

b) Proposals for differential surfacing to pedestrian crossing areas are sought and shall be submitted by the Contractor for approval. Surfaces shall provide 20 years life before replacement form the date of completion of the works;

c) Cycleways shall include green surface finish utilising a recognised surfacing material which will provide 20 years life before replacement form the date of completion of the works;

d) Pedestrian crossings: types, locations, lighting and controls shall be agreed with the Board (controlled crossings to be included, exact locations to be agreed at design development stage);

e) Kerbs: to comply as a minimum standard with BS7263, Part 1: Pre-cast Concrete channels and edgings;

f) Traffic Signs and Markings to be designed to The Traffic Signs Regulations & General Directions 2002 and The Traffic Signs Manual (part of the Design Manual for Roads &

Bridges), and for the Board's approval. Markings and signage shall dimensioned apposite to a road with a design speed equivalent to 30mph;

g) Supplementary signage to support the management of traffic to preserve the provisions in (a) to (g) above shall be submitted for the Boards approval. Furthermore, the Contractor shall design and provide appropriate signage external to the car parking and other facilities to ensure ease of navigation around the Site for intermittent or infrequent users;

h) Gradients outwith carriageways shall comply with the provisions of HBN 45 and the Building (Scotland) Regulations 2004 as applicable. No gradient in excess of 1:20 shall be allowed in parking areas (other than access roadways), and 1:15 on pedestrian staff, patient and visitor access paths from parking areas to the building entrances;

i) Parking bays: comply with the reference documents, HBN 45, HBN 20, HFN 21 and the item on gradients above. The minimum parking standard parking bay shall be 2.5 x 4.8 m. Variation from the standard (to make optimum use of the space for example) may be desirable and allowed subject to agreement with the Board; and

j) Traffic parking restrictions and parking management: to be agreed with the Board.

9.12.15 Designs shall cater for the access and parking needs of pedestrians and the physically disadvantaged. This shall involve catering for visitors and staff using different modes of transport in adapted vehicles and with multiple aids / equipment.

9.12.16 This is to allow tailgate access by disabled people without the need to set ramps or lifts down within the main circulation routes of car parks. The first and last accessible parking bays in a row of 'in line' spaces shall be provided with a minimum clear area of 1.2m to both sides.

9.12.17 Parking for the transport requirements of deliveries and waste disposal, ambulances, fire appliances and other specialist and emergency vehicles shall be segregated from public and staff parking.

9.12.18 Car parking provision shall take into account the following requirements:

a) Dedicated parking for those with disabilities, the elderly and those with small children located close to the clinical areas, especially for those with limited mobility and eyesight;

b) Space for larger vehicles, which may be fitted with wheelchair ramp or carrying specialist mobile equipment from / to the Works (such spaces will be larger than the normal car parking space);

c) Appropriate zoned parking for night staff as near as practical to the controlled night entrance for staff; and

d) Electric car charging facilities in a minimum of 20nr bays.

9.13 Other External Works

9.13.1 The Contractor shall design the external works for ease of navigation and progression around the site by staff, patients and visitors.

9.13.2 The Contractor shall seek advice from the Board to seek to minimise the risk of crime and vandalism on the Works. This advice shall be pro-actively sought by the Contractor as part of the design process.

9.13.3 The Contractor shall seek advice from Strathclyde Police's crime prevention representative on the proposals for external works to minimise the risk of crime and vandalism on the Site and the Works, including compliance with Secure by Design.

9.13.4 The Masterplan and accompanying landscape drawings demonstrate the general arrangements of the external works.

9.14 Hard Landscaping Requirements

9.14.1 The Contractor shall incorporate into the Works all associated hard landscaping for the Site, including but not limited to, the following:

a) Access and hardstanding for emergency and delivery vehicles;

b) Access for building maintenance and window cleaning;

c) Access and circulation for, visitors and patients on foot, bicycles, in cars or on public transport;

d) Parking for vehicles and bicycles including disabled facilities;

e) Drop-off facilities including lay-bys and bus/transport stops;

f) Service areas, as appropriate;

g) Accommodation for building services plant, waste and materials management, as appropriate;

h) Amenity areas for staff, patients and visitors;

i) Suitable pathways and paving;

j) Protection against noise and environmental pollution;

k) Security provisions, as appropriate;

l) Appropriate Site boundary treatment;

m) Walls, fencing, gates / barriers and hedgerows as appropriate along the Site Boundary and at particular locations inside the Site;

n) CCTV surveillance to all car parks, pedestrian routes, cycle paths, therapy gardens and other specified external areas;

o) External lighting;

p) Suitable means of shelter against adverse weather conditions at entrances, bus/transport waiting, and drop-off locations and covered links provided, as appropriate;

q) Automatic vehicle access barriers; and

r) Fire hydrants.

Section 10.0 Sustainability

10.1 Sustainability

10.1.1 The consideration and implementation of sustainable facilities is a key concern and requirement of the Board in all its functions and activities.

10.1.2 The particular low carbon and sustainability considerations and requirements of the Board are provided in Section 8.0 and Appendix M.

10.1.3 The carbon management plan of the Board is contained for reference in Appendix P.

10.1.4 Guidance with regard to the consideration and assessment of BREEAM points are contained in Appendix U for reference.

Section 11.0 Community Engagement

11.1 Community Engagement

11.1.1 The consideration and implementation of Community Engagement (CE) initiatives is of great importance to the Board. The requirements of the Contractor with regard to CE in relation to the Works are contained in Appendix V.

Section 12.0 Bid Return Requirements

12.0 Bid Return Requirements

12.1 The particular bid return requirements of the Board are identified and listed, along with the evaluation process, in Volume 3 of this ITPD.

12.2 It is anticipated that the bid return information will allow the Board to assess the bids and select a private sector partner to contract with.

12.3 The Contractor will then work with the Board through the Stage 3 Design Development period to produce the FBC design requirements as identified in Appendix K.

NHS National Services Scotland

Scottish Health Technical Memorandum 02-01:

Medical gas pipeline systems
Part A: Design, installation, validation and verification

Health Facilities Scotland
Engineering and Environment

June 2012

Contents

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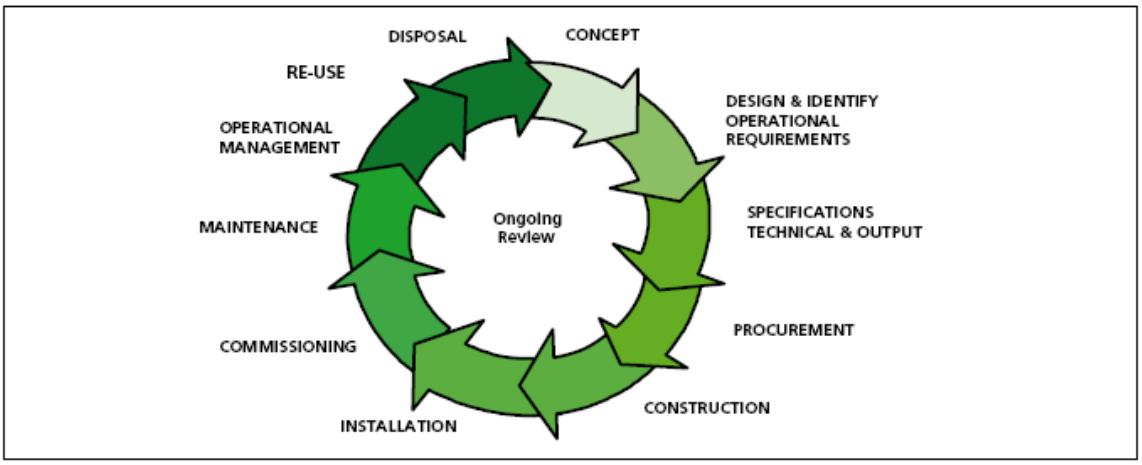
Preface

About Scottish Health Technical Memoranda

Scottish Health Technical Memoranda (SHTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of SHTM guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle:



Healthcare building life-cycle

Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Scottish Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to unnecessarily repeat international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

The new core suite of eight subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- Provides a structured reference for healthcare engineering.

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Structure of the Scottish Health Technical Memorandum suite

The new series of engineering-specific guidance contains a suite of nine core subjects:

Scottish Health Technical Memorandum 00: Policies and principles (applicable to all Scottish Health Technical Memoranda in this series)

Scottish Health Technical Memorandum 01: Disinfection and sterilization

Scottish Health Technical Memorandum 02: Medical gases

Scottish Health Technical Memorandum 03: Ventilation systems

Scottish Health Technical Memorandum 04: Water systems

Scottish Health Technical Memorandum 05: Reserved for future use

Scottish Health Technical Memorandum 06: Electrical services

Scottish Health Technical Memorandum 07: Environment and sustainability

Scottish Health Technical Memorandum 08: Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc. Example: Scottish Health Technical Memorandum 06-02 Part A will represent: Electrical Services – Safety – Low Voltage. In a similar way Scottish Health Technical Memorandum 07-02 will simply represent:

Environment and Sustainability – EnCO_2de.

All Scottish Health Technical Memoranda are supported by the initial document Scottish Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

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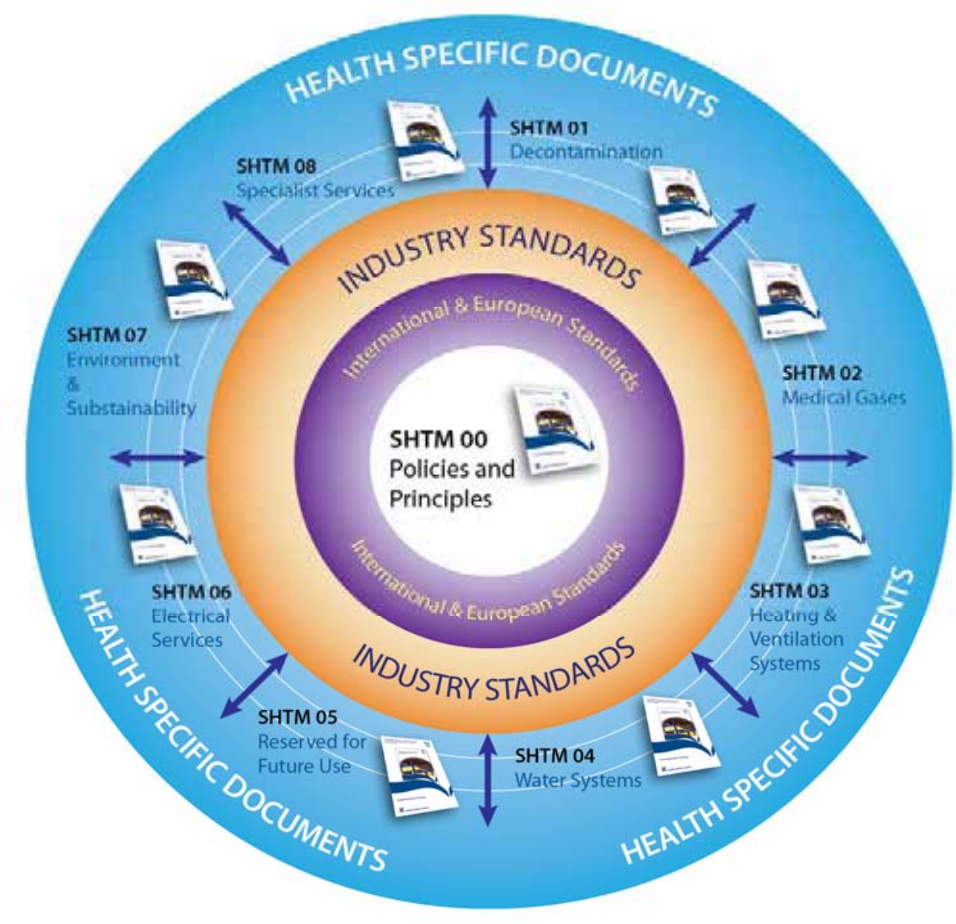

Engineering guidance

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Acknowledgements

Health Facilities Scotland would like to thank the steering group led by the Department of Health for their efforts in producing the HTM 02-01 Part A document.

HTM 02-01 has been updated, expanded and amended by Health Facilities Scotland for use in NHSScotland as SHTM 02-01 Part A. The significant contribution by the following is gratefully acknowledged.

Alex Black Alex Black & Associates Limited

Graeme Dunn Atkins Limited

Ian Sandford Hulley & Kirkwood Consulting Engineers Limited

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Executive summary

Introduction

A medical gas pipeline system (MGPS) is installed to provide a safe, convenient and cost-effective system for the provision of medical gases to the clinical and nursing staff at the point-of-use. It reduces the problems associated with the use of gas cylinders such as safety, porterage, storage and noise.

This Scottish Health Technical Memorandum is divided into two parts. Guidance in this part (Part A) covers piped medical gases, medical and surgical air, and medical vacuum installations: it applies to all medical gas pipeline systems installed in healthcare premises and anaesthetic gas scavenging disposal systems. Specifically, it deals with the issues involved in the design, installation, and validation and verification (testing and commissioning) of an MGPS. Part B covers operational management.

The guidance given in this document should be followed for all new installations and refurbishment or upgrading of existing installations. All new works should be subject to a design review / validation prior to installation by the AP, AE or CSO.

It is not necessary to apply the guidance retrospectively unless patient or staff safety would be compromised. In this case, the guidance given in this document should be followed.

Existing installations should be assessed for compliance with this guidance document. A plan for upgrading the existing system should be prepared, taking account of the priority for patient safety. Managers will need to liaise with medical colleagues and take account of other guidance published by the Scottish Government Health Directorates in order to assess the system for technical shortcomings.

Scottish Health Technical Memorandum 02 supersedes all previous versions of Scottish Health Technical Memorandum 2022. Where SHTM 2022 has been used as the contractual document within current projects, SHTM 2022 would be applicable.

Sources of supply for pipeline installations

Oxygen

Oxygen is generally supplied from:

- a liquid source such as a large vacuum insulated evaporator (VIE);
- liquid cylinders or compressed gas cylinders; or
- a combination of these to provide the necessary stand-by/back-up capacity.

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Oxygen can also be supplied from an oxygen concentrator (pressure-swing adsorber). Such systems are usually installed where liquid or cylinders are expensive, unavailable or impracticable.

Medical air

Medical air is usually supplied from a compressed air plant that includes high-quality drying and filtration equipment. Blending oxygen and nitrogen on-site to provide a high-quality product with minimum maintenance can also provide medical air. Where such systems are installed to provide both oxygen and medical air, nitrogen can be used for the power source for surgical tools.

Other gases

All other gases are supplied from cylinders.(On-site blended oxygen/nitrous oxide mixture is a possibility if bulk liquid supplies of nitrous oxide are available, although this system is unlikely to be adopted in the UK.)

Basic principles of design

Patient safety is paramount in the design, installation, commissioning and operation of medical gas pipeline systems. The basic principles of safety are achieved by ensuring quantity of supply, identity of supply, continuity of supply and quality of supply.

Quantity of supply

This is achieved by ensuring that the design of the pipeline installation and capacity of the supply plant is sufficient to provide the required flows of gases and vacuum for the intended number of patients to be treated at any one time. Adequacy of supply is established during commissioning of the systems.

Identity of supply

This is achieved by ensuring that all points to which the user can connect medical equipment (terminal units) and user-replaceable components are provided with gas-specific connectors. Such connectors are also identified by symbol and often colour. The gas specificity is maintained by comprehensive tests and checks during installation and commissioning, and during any work or maintenance on the systems.

Continuity of supply

This is achieved by installing, as a minimum, duplex components and providing additional means of supply provision in the event of failure of the primary and secondary plant supply system. Systems are also connected to the essential electrical supply.

Quality of supply

Quality of supply is ensured by the use of gaseous or liquid sources that are provided to an appropriate product specification, usually a recognised European

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Pharmacopoeia (Ph. Eur.) monogram. In the case of compressor-based systems, filtration equipment to a known and agreed standard is installed. To ensure that the product is not adulterated in the distribution system, pipeline installations and components are required to meet agreed specifications. There are strict Ph. Eur. requirements for medical gases.

General uses of gas and pipeline installations

- oxygen is one of the most extensively used gases for respiratory therapy and life-support and is additionally used in anaesthetic procedures;
- medical air is mainly used in respiratory therapy as a power source for patient ventilators, and for blending with oxygen; it is also used as the driving gas for nebulised drugs and chemotherapy agents;
- surgical air (of medical air quality) is also used, at a higher pressure, to power a variety of surgical tools and other devices such as tourniquets. (As an alternative, nitrogen can be used for this purpose.);
- nitrous oxide is used for anaesthetic and analgesic purposes, being mixed with air, oxygen, and nebulised agents;
- pipeline systems for a 50% mixture of oxygen and nitrous oxide are widely installed in the UK for analgesic purposes, particularly in maternity departments;
- helium/oxygen mixture is used to treat patients with respiratory or airway obstruction and to relieve symptoms and signs of respiratory distress; guidance on pipeline systems is now included;
- carbon dioxide is used less commonly now as a respiratory stimulant, and for insufflation during surgery. Pipeline systems for respiratory use have not been installed in the UK but they are now being installed for this latter purpose;
- piped vacuum is provided in most clinical areas by means of centrally sited vacuum pumps;
- the control of occupational exposure to waste anaesthetic gas (nitrous oxide) and nebulised agents is a legal requirement under the Control of Substances Hazardous to Health (COSHH) Regulations 2002. Where nitrous oxide is provided for anaesthetic purposes, scavenging systems are installed.

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1. Scope

Guidance in this document

1.1 This Scottish Health Technical Memorandum is divided into two parts. Guidance in this part (Part A) covers piped medical gases, medical and surgical air, and medical vacuum installations; it applies to all medical gas pipeline systems installed in healthcare premises. Anaesthetic gas scavenging disposal systems are also included. Specifically, it deals with the issues involved in the design, installation, and validation and verification (testing and commissioning) of an MGPS. Part B covers operational management.

1.2 The guidance given in this document should be followed for all new installations and refurbishment or upgrading of existing installations.

1.3 It is not necessary to apply the guidance retrospectively unless patient or staff safety would be compromised. In this case, the guidance given in this document should be followed.

1.4 Existing installations should be assessed for compliance with this guidance document. A plan for upgrading the existing system should be prepared, taking account of the priority for patient safety. Managers will need to liaise with medical colleagues and take account of other guidance published by the Scottish Government Health Directorates in order to assess the system for technical shortcomings.

1.5 Throughout this document, “medical gas pipeline system(s)” will be described by the term MGPS.

Other guidance

1.6 Model Engineering Specification C11: ‘Medical gases’ It is anticipated that this publication will be subject to review for compliance with current standards.

1.7 Guidance on the provision of MGPS is given in the Scottish Health Planning Notes (SHPN’s) Health Building Notes that are still applicable in Scotland and other relevant British, European, and International standards.

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2. General principles

Introduction

2.1 An MGPS is designed to provide a safe and effective method of delivering medical gases, medical air and surgical air from the source of supply to the appropriate terminal unit by means of a pipeline distribution system. Medical vacuum is also provided by means of a pipeline system. Anaesthetic gas scavenging disposal systems are provided to control occupational exposure to waste anaesthetic gases and agents.

2.2 It is essential to ensure that there is no possibility of a cross-connection between any system and that all parts of each system to which connections can be made by users are gas-specific.

2.3 Dental compressed air and vacuum systems have differing requirements, and these are covered in Scottish Health Technical Memorandum 2022, Supplement 1: 'Dental compressed air and vacuum systems'. Scottish Health Technical Memorandum 2022 Supplement 2 is concerned with piped medical gases in ambulance vehicles.

2.4 During the installation stage, extensive tests are carried out to verify that there is no cross-connection.

2.5 Medical gas systems may be extended to those departments where respiratory equipment or surgical tools are serviced, such as in electronic and biomedical equipment (EBME) workshops and sterile services departments (SSDs). Specific additional uses of air systems are covered in Sections 7 and 8.

2.6 MGPS should not be used to supply university, pathology and dental laboratories or workshops, steriliser equipment, seals, chamber ballast or controls, washer/disinfection and endoscope drying procedures, air conditioning or other mechanical services. Consideration can be given to the use of MGPS where a university theatre or room teaching medical procedures forms part of the hospital complex.

2.7 Separate installations should be provided for pathology and general laboratories and workshops, although it is recommended that they be constructed to the same specification as MGPS. They should not be provided with medical gas terminal units. Scottish Health Technical Memorandum 08-06 refers.

Note 1: Portable suction devices should be used in infectious disease units.

Quality requirements for medical gases and air

2.8 Medical gases supplied from cylinder or liquid sources comply with the appropriate sections of the current edition of the European Pharmacopoeia (Ph. Eur.). The Ph. Eur. also specifies the approved testing methods to be adopted for gas identity.

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2.9 The quality specification for medical, surgical and synthetic air, and oxygen-enriched air produced from a pressure swing adsorber (PSA) system, is as given in Table 42. The medical air and synthetic air should also comply with the appropriate sections of the current edition of the Ph. Eur. (see Table 43).

2.10 The quality of piped medical compressed air, and the particulate content, dryness and concentration of impurities should comply with the requirements for maximum concentrations given in Table 43. Information on testing procedures is given in Section15 “Validation and verification”.

2.11 Bacteria filters should be included in medical and surgical compressor systems to reduce the risk of delivering spores or other infectious material to vulnerable patients.

2.12 Micro-organisms can penetrate a bacteria filter if the material is wet. Therefore it is essential that the dryness of the medical air supplied to a bacteria filter is checked regularly (at least every three months) at the test point, using the test equipment specified in Section15.

Sources of supply

2.13 Both BS EN 737-3: 2000 and BS EN ISO 7396-1: 2007 + A2: 2010 (which replaced the former standard from 30 April 2009) propose that all medical gas supplies should comprise three sources of supply identified as “primary”, “secondary” and “reserve”, although the latter is more commonly referred to as a third means of supply. The supply system should be designed to achieve continuity of supply to the terminal units in normal condition and in a single fault condition. A single fault condition is where a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present. Loss of supply due to maintenance of a supply source (or a component within it) is not considered a single fault condition. Failure of the pipeline is considered a catastrophic event and is not regarded as a single fault condition.

2.14 With respect to individual banks of a cylinder manifold installation, this Scottish Health Technical Memorandum (SHTM) refers to separate banks of an automatic manifold as primary and secondary supplies as prescribed within BS EN ISO 7396-1: 2007 + A2: 2010. This SHTM will classify an automatic manifold as a single source of supply, when applied to liquid oxygen, medical and surgical air systems.

2.15 Regardless of these classification differences, the choice of central source will be defined by the ability of the source not only to provide a continuous supply of gas over a range of possible flow rates but also to offer security of supply by virtue of adequate capacity.

2.16 For these reasons, types, capacities and locations of primary, secondary and reserve sources of supply will be based on both system design parameters and the need for supply security, identified by a risk assessment during the planning stage. Security of medical air supplies must be given a high priority. Tables 1–9

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describe the various options for gas supply. For each, the primary, secondary and reserve sources are identified.

Primary supply	Secondary supply	Reserve supply (third source of supply
Duty bank of a fully automatic manifold. Number of cylinders based on system design.	Standby bank of a fully automatic manifold.	Manual emergency reserve manifold - to come on line automatically via a non-return valve in the event of a single fault condition and to act as a reserve supply during maintenance / repair works. Type and capacity of supply to be determined by risk assessment.

Table 1: Compressed gas cylinder manifold systems

Primary supply	Secondary supply	Reserve supply (third source of supply)
Simplex VIE (vacuum insulated evaporator) vessel system	Automatic cylinder manifold system. To come on-line in the event of plant failure	Automatic cylinder manifold system. May be sited to support high-dependency areas or whole site OR Locally-based integral valved cylinders with regulators/flowmeters attached.
One vessel of a duplex VIE (vacuum insulated evaporator) vessel system (on same plinth).	Second vessel of a duplex VIE system.	Automatic cylinder manifold system. May be sited to support high-dependency areas or whole site.
One vessel of a duplex VIE vessel system (on separate plinths).	Second vessel of a duplex VIE system (on separate plinths). NB split-site systems are intended primarily for systems where the risk assessment has identified that the site for the primary supply is limited in size or presents too high a risk having both tanks on the same site. These supply systems should be fitted with appropriate non-return valved connections to prevent gas loss in the event of one tank/system failing.	Type and capacity of supply to be determined by risk assessment. May not be required when remote dual supplies are connected to a ring main or to a mains (linked) pipeline distribution system. (Note: a ring main or distribution pipeline is not regarded as a reserve supply (third source of supply)

Table 2: Bulk liquid oxygen VIE systems

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Primary supply	Secondary supply	Reserve supply (Third source of supply)
Liquid cylinder or liquid cylinder manifold system. NB: The latter is NOT a changeover manifold. All cylinders are on-line simultaneously.	Automatic cylinder manifold system. To come on-line in the event of plant failure.	Automatic cylinder manifold system. May be sited to support high-dependency areas or whole site OR Locally-based integral valved cylinders with regulators/flow meters attached.

Table 3: Liquid oxygen cylinder system

Primary supply	Secondary supply	Reserve supply (Third source of supply)
Multiplex compressors and columns (adsorbers). Subject to design.	Automatic cylinder manifold system. To come on-line in the event of plant failure. May be fitted with third party cylinders, or filled from compressor of main plant. Number of cylinders should have sufficient connected capacity to supply the site for at least 4 hours. Locally filled cylinders or gas suppliers' cylinders can be used.	Type and capacity of supply to be determined by risk assessment.

Table 4: PSA plant

Primary supply	Secondary supply	Reserve supply (Third source of supply)
First compressor of a duplex compressor system.	Second compressor of a duplex compressor system.	Automatic cylinder manifold system. To come on-line automatically in the event of plant failure. Type and capacity of supply to be determined by risk assessment.
First compressor of a triplex compressor system.	Second compressor of a triplex compressor system.	Third compressor of a triplex compressor. In addition, an automatic cylinder manifold system to support a dedicated department(s) or whole site.
Two compressors of a quadruplex compressor system.	Other two compressors of a quadruplex compressor system.	Automatic cylinder manifold system to support whole site.

Table 5: Compressor-driven medical air systems

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Primary supply	Secondary supply	Reserve supply (Third source of supply)
Primary oxygen and nitrogen VIE vessels and mixer unit.	Secondary oxygen and nitrogen VIE vessels and mixer unit.	Type and capacity of supply to be determined by risk assessment.

Table 6: Synthetic air plant

Primary supply	Secondary supply	Reserve supply (Third source of supply)
First compressor of a duplex compressor system.	Second compressor of a duplex compressor system.	Two automatic cylinder manifold systems: one dedicated to support medical air (MA4) system. one dedicated to support surgical air (SA7) system. All to come on-line in the event of plant failure. Type and capacity of supply to be determined by risk assessment.
First compressor of a triplex compressor system.	Second compressor of a triplex compressor system.	Third compressor of a triplex compressor system. In addition, an automatic cylinder manifold system to support whole site. SA7 and MA4 with independent ERMs see above for duplex compressors.
Two compressors of a quadruplex compressor system.	Other two compressors of a quadruplex compressor system.	Automatic cylinder manifold system to support whole site. One for MA4 and one for SA7 see above for duplex compressors.

Table 7: Combined medical/surgical air plant

Primary supply	Secondary supply	Reserve supply (Third source of supply)
Simplex compressor unit.	Automatic cylinder manifold system to come on-line in the event of plant failure. Type and capacity of supply to be determined by risk assessment.	Locally based integral valved cylinders with regulators/flow meters attached.
First compressor of a duplex compressor system.	Second compressor of a duplex compressor system.	Automatic cylinder manifold system.

Table 8: Compressor-driven surgical air systems

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Primary supply	Secondary supply	Reserve supply (Third source of supply)
First pump of a triplex pump system.	Second pump of a triplex pump system.	Third pump of a triplex pump system with additional portable suction equipment available.
Two pumps of a quadruplex pump system.	Other two pumps of a quadruplex pump system.	Portable suction equipment.

Table 9: Central medical vacuum systems

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Notes to Tables 1-9: General guidance on vacuum systems is contained in Appendix L. a) Where duplex vacuum plant is currently installed, a risk assessment should be carried out to establish if a third vacuum pump or replacement plant is required to meet the recommendations of this Scottish Health Technical Memorandum;

b) for duplex and triplex compressor systems and triplex vacuum pump systems, each compressor/pump will be sized to provide the system's full design flow;

c) for quadruplex systems, each compressor/pump will be sized to provide half the system design flow;

d) for all compressor systems with a design flow greater than 500 litres/min, two receivers, each able to be isolated individually, should be installed. For compressor systems with a design flow less than 500 litres/min with a single receiver, a valved bypass line should be installed;

e) all plant is to be connected to the essential electricity supply;

f) for vacuum provision during total electricity supply failure, cylinder – or medical-gas-system-powered vacuum generators can be used;

g) the use of venturi-type vacuum generators is recommended only for emergency use, as these units are generally driven from the medical oxygen system and use large amounts of gas. This can lead to oxygen enrichment and present a potential fire hazard and may result in the emission of pathological material;

h) the emergency reserve manifold supporting a fully automatic manifold is usually sited with the manifold system. If a risk assessment indicates that this is not in the interests of supply security, they may be sited remotely from the manifold. In all circumstances, care should be taken to ensure that appropriate backflow protection (or non-return valves) are used to protect the system from failure of either manifold;

i) manifolds supporting medical air, surgical air and PSA systems should be sited remotely from the compressor systems. Appropriate backflow protection should be provided, as above;

j) surgical air plant may be used as an emergency supply to the medical air 4 bar system;

k) a valved by-pass arrangement around compressor and VIE-plant non-return valves should be considered to facilitate valve replacement or servicing of the non-return valve to avoid disruption to the service without plant shutdown;

l) fitting non-return valves one pipe size larger will reduce flow resistance, if this is shown to be a critical factor in system design;

m) all sources of supply should be fitted with a test point consisting of a terminal unit and lockable isolating valve. Where the test point is located externally, this should be located within a weatherproof enclosure.

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Sizing information for gas supply sources

2.17 Table 10, below, provides guidance on suggested maximum sizes for gas sources. Final decisions on plant and manifold capacities will depend on both available accommodation and risks to supply security.

Source	Service	Number of cylinders	Cylinder size	Notes
Automatic manifold	Oxygen	2 x 10	J	Used as a stand-alone manifold or support for cryogenic system / PSA plant
	Medical air	2 x 10	J	Used as a stand-alone manifold or support for compressor plant
	Surgical air	2 x 6	J	For nitrous oxide, a 2 x 2 or 2 x 4 installation may be adequate in some cases – cylinder sizes should be subject to local manual handling operations.
	Oxygen/nitrous oxide mixture	2 x 8	G	
	Nitrous oxide	2 x 6	G	
	Carbon dioxide	2 x 4	VF	
	Helium/oxygen	2 x 4	H	
	Nitrogen	2 x 6	W	
Manual manifold	Oxygen	2 x 2	J	As reserve supply for an automatic manifold system
	Medical air	2 x 2	J	
	Surgical air	2 x 1	J	
	Oxygen/nitrous oxide mixture	2 x 2	G	
	Nitrous oxide	2 x 1	G	
	Carbon dioxide	2 x 1	VF	
	Helium/oxygen	2 x 1	H	
	Nitrogen	2 x 2	W	

Table 10: Suggested sizes for gas sources

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Source	Service	Plant size	Receiver / Reservoir Capacity
Duplex compressor system	Medical air	Each compressor sized at full design flow capacity	Receiver water capacity sized at 50% free air delivery (FAD) in 1 minute
Triplex compressor system	Medical air	Each compressor sized at full design flow capacity	
Quadruplex compressor system	Medical air	Each compressor sized at half design flow capacity	
Simplex compressor system	Surgical air	Compressor sized at 1/3 design flow (when design flow <500 litres/min). For design flows >500 litres/min, refer to Table 33.	Refer to Table 33 (para. 8.9)
Duplex compressor system	Surgical air	Each compressor sized at 1/3 design flow (when design flow <500 litres/min). For design flows >500 litres/min, refer to Table 33.	
Triplex pump system	Medical vacuum	Each pump sized at full design flow capacity	Water capacity of reservoir sized at design flow in 1 minute
Quadruplex pump system	Medical vacuum	Each pump sized at half design flow capacity	

Table 10: (cont'd) Suggested sizes for gas sources

2.18 Sizing of vacuum insulated evaporator (VIE) systems, liquid cylinder storage systems, PSA plant and synthetic air plant should be based on historical consumption data and appropriate risk assessments carried out with the medical gas supplier. Allowance should be made for increases in the use of medical gases and changes to the gas demands caused by local developments and strategic issues. For a completely new site, the proposed gas supplier will need to be consulted so that a review of their historical data can be conducted for similar sites. The graph shown in Appendix M will give an approximate indication of expected annual consumption, based on the number of hospital beds. It should be noted that higher consumption could be expected when, for example, high numbers (>20) of continuous positive airway pressure (CPAP) machines are in frequent use (>40 hours per week).

Note 2: a) Automatic cylinder manifolds are generally expected to hold a minimum of two days' supply on each bank.

b) Sufficient cylinders for changing one complete bank should be stored in the manifold room for all gases except nitrous oxide/oxygen mixture, for which two complete changes should be stored in the manifold room;

c) Sufficient additional cylinders should be held in the medical gas store to ensure continuous supply for one week.

Pipeline distribution system design

2.19 The following general information is required to design an MGPS:

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- schedule of provision of terminal units;
- design flow rates and pressure requirements at each terminal unit;
- diversified flows for each section of the pipeline system;
- total diversified flow.

2.20 Guidance on deriving and calculating the above parameters is given in Sections 3 and 4 of this Part A.

2.21 The definition of “departments”, which may comprise several wards, treatment rooms etc, should be agreed at the project design stage to avoid confusion.

Safety

2.22 The safety of an MGPS is dependent on four basic principles:

- identity;
- adequacy;
- continuity;
- quality of supply.

2.23 **Identity** is assured by the use of gas-specific connections throughout the pipeline system, including terminal units, connectors etc, and by the adherence to strict validation and verification procedures of the system.

2.24 **Adequacy** of supply depends on an accurate assessment of demands and the selection of plant appropriate to the clinical/medical demands on the system.

2.25 **Continuity** of supply is achieved by:

- the specification of a system that (with the exception of liquid oxygen systems which may include a secondary vessel) has duplicate components;
- the provision of a reserve (third means of) supply;
- the provision of alarm systems; and
- connection to the emergency power supply system.

2.26 **Quality** of supply is achieved by the use of gases purchased to the appropriate Ph. Eur. requirements or produced by plant performing to specific standards, by the maintenance of cleanliness throughout the installation of the system, and by the implementation of the various validation and verification procedures.

Installation/supply of equipment/maintenance

2.27 The installation of an MGPS should be carried out only by specialist firms who are either registered to BS EN ISO 9001: 2008 /BS EN ISO 13485: 2003 or who can demonstrate that they are actively working towards registration with the scope of registration appropriately defined.

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Modifications

2.28 Special precautions are required when existing installations are to be modified or extended, to ensure that all sections of the pipeline system remaining in use are not contaminated, and that the supply to patients is not compromised. The section to be modified should be physically isolated from the section in use. Closure of isolating valves is insufficient for this purpose. Where area valve service units (AVSUs) and/or line valve assemblies (LVAs) have been installed, blanking spades should be used. On older installations where the valve design does not include blanking spades, the pipeline must be physically isolated from the valve with the open ends protected to prevent ingress of dust etc.

2.29 Modification of existing systems may be detrimental to the overall performance of the system. In the case of older systems, there may be insufficient capacity to permit the system to operate safely with the flows typically encountered in use today. Any proposal to extend the system should be subject to a design review to ensure the system has sufficient capacity for adequacy of performance.

2.30 Any work involving alteration, extension or maintenance work on an existing system should be subject to the permit-to-work procedure (see Part B, Section 8).

Removal of pipework

2.31 Removal and cutting out of redundant medical gas pipelines and equipment can present as great a hazard to patient safety as any other modification. All such removal (including cutting into existing pipelines, and capping off and removal of redundant pipework and equipment) should be carried out by specialist medical gas contractors only. General demolition contractors should not carry out this work.

Note 3: Removal of vacuum systems may present additional microbiological hazards and should be undertaken in accordance with routine hygiene practices, that is, covering of open wounds and immediate cleansing and dressing of cuts/scratches received while carrying out the work. Immunisation against certain diseases may be required by the Hospital's occupational health department or the employer of tradespeople, therefore, all operatives should ensure that this requirement has been met. Further advice should be sought from the Hospital's Infection Control Team.

Validation and verification

2.32 The objective of validation and verification is to ensure that all the necessary safety and performance requirements of the MGPS will be met. Validation and verification procedures will be required for new installations, additions to existing installations and modifications to existing installations. The scope of work will dictate the specific programme required. This is described in Section15.

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Note 4: The concept of the existing quality assurance BSI scheme schedule QAS 3720. 1/206/A1 is currently under review. Further guidance will be given when appropriate

General fire precautions

General

2.33 The siting and general structural principles for the design of liquid oxygen storage accommodation are given in Section 6, and the requirements for plantrooms and gas manifold rooms in Section14.

2.34 Guidance on cylinder storage and handling is given in Part B.

Fire detection system

2.35 Smoke or heat detector heads should be installed in the plantrooms, medical gases manifold rooms and (when internal) medical gases cylinder stores in any hospital having a fire detection system in accordance with Scottish Health Technical Memorandum SHTM 85: 'Firecode: alarm and detection systems'. External stores may also require fire detection systems.

Electricity supply to medical gas installations

General

2.36 Electrical installations should be carried out in accordance with the current edition of BS7671 wiring regulations and associated guidance documents.

2.37 Provision of electrical supply and distribution should take account of guidance issued in Scottish Health Technical Memorandum 06-01: 'Electrical services: supply and distribution'.

Resilience of supply

2.38 Medical gas pipeline systems, associated equipment and alarms are a critical service within a healthcare establishment. Due consideration should be given to ensure the continuity of service under mains power failure conditions.

2.39 Each item of plant with respect to medical / surgical air and medical vacuum should be supplied from a dedicated, final sub-circuit which is considered "essential" within the electrical distribution strategy. Alternative means of supply should be considered in the event that internal sub-distribution is compromised.

2.40 In the event of power failure or interruption, all systems should continue to function as they did before the interruption occurred. For example, except for automatic cycling compressors, dryers, pumps etc, the same compressor and dryer (or vacuum pump) set should be on-line, and for manifold systems the same bank should be running.

2.41 All electrical systems, including plant control systems, alarm interfaces etc, should be designed in accordance with electromagnetic compatibility (EMC)

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directives. For further details, see the “EMC section” within Scottish Health Technical Memorandum 06-01: ‘Electrical services: supply and distribution’.

2.42 It is important that operational managers and designers are fully aware of stand-by electrical supply arrangements and availability and that plans are available to deal with the total loss of electricity under adverse circumstances.

Electrical installation

2.43 Wiring systems for medical gas installations should be selected in accordance with BS7671 wiring regulations with particular regard to the environment and risk from mechanical damage. In this regard, PVC-insulated MICS (mineral-insulated copper-sheathed) cable for external/ internal locations and heat-rated singles cable in galvanised conduit for plantrooms are considered suitable. For large equipment, fire-rated SWA (steel wire armoured) cable may be appropriate.

2.44 Care should be taken when installing both electrical systems and medical gas pipeline systems to avoid occasional contact between pipework and electrical cables, conduit or trunking. When physical separation is impractical or contact with extraneous metalwork occurs (for example where the pipeline is carried in metal partitions or where terminal units are mounted on metal bed-head units), the pipeline should be effectively bonded to the metalwork in accordance with BS7671 wiring regulations.

2.45 The final connection to any equipment (for example alarm panels or control panels) should be made using a key operated (double pole) fused connection unit should be available to permit work authorised on the equipment.

2.46 Where electrical systems and medical gas pipeline systems are enclosed in a boom, rigid pendant or multi-purpose-type enclosure, care should be taken to ensure that Low Voltage (LV), Extra-Low Voltage (ELV) and communications and data systems are maintained together but separate from pipeline systems. There should be no access to unprotected live parts within the pendant except by the use of a tool. Reference should be made to BS EN ISO 11197: 2009 which gives clear guidance on the requirements for such separation and segregation.

Earthing

2.47 Medical gas pipelines should be bonded together and bonded to the local electrical distribution board in accordance with BS7671 wiring regulations. The pipelines should not in themselves be used for earthing electrical equipment.

2.48 Flexible pipeline connections, wherever used, should be bonded across the fixed points to ensure earth continuity.

2.49 Where a medical gas outlet or pipeline system is present within a group 2 location as defined by IEE Guidance Note 7: ‘Medical locations’, care must be taken to ensure the resistance of the bonding connection is in accordance with the required value.

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3. Provision of terminal units, and the location of AVSUs, area alarm panels and LVAs

General

3.1 Terminal unit provision, location of area valve service units (AVSUs) and area alarm panels are given in Table 11. Medical treatment policy is evolutionary, however, and the project team should review requirements for individual schemes.

Terminal units

3.2 Terminal units should be mounted in positions that result in the shortest practicable routes for flexible connecting assemblies, between the terminal unit and apparatus. Terminal units may be surface or flush-mounted. They may also be incorporated with electrical services, nurse call systems, televisions, radio and audio services, in proprietary fittings such as medical supply units, wall panel systems and pendant fittings etc. When they are installed within such fittings, it is essential to maintain the concentricity of the terminal unit bezel with the fascia plate aperture; if the installation is highly eccentric, the bezel will bind on the fascia plate and the terminal unit will not function properly.

3.3 When planning the installation of operating-room pendant fittings, the location of the operating luminaire and other ceiling-mounted devices should be taken into consideration. When the operating room is provided with an ultra-clean ventilation (UCV) system, it may be more practicable (and cost-effective) to have the services (both medical gas and electrical) incorporated as part of the UCV system partial walls. It is particularly advantageous in the case of surgical air systems as rigid pipework can be used, thus avoiding pressure-loss problems that can occur with flexible assemblies used within pendant fittings.

3.4 The following are not permitted:

- floor-mounted terminal units;
- vacuum systems in which body or other fluids are drawn through a fixed pipeline connecting a terminal unit or other connector to a remote suction jar.

3.5 All terminal units should conform to BS EN ISO 9170-1: 2008. Terminal units intended for wall mounting where directly connected equipment such as flow meters are to be used must include a non-swivel device. Terminal units intended for installation with the socket axis vertical, for example on the under-surface of a pendant and intended for use with indirectly connected equipment by means of a flexible connecting assembly, do not require a non swivel device. Dimensions of probes are given in BS5682: 1998. It is essential that probes be machined from stainless steel.

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3.6 An anaesthetic gas scavenging (AGS) terminal unit should be provided whenever nitrous oxide and anaesthetic agents are available for anaesthetic procedures. In recovery areas, where nitrous oxide is not provided, there is no primary source of anaesthetic gas pollution; thus, no anaesthetic gas scavenging system (AGSS) is required. Guidance on operating departments requires such areas to be mechanically ventilated. Where nitrous oxide mixed with oxygen is provided for analgesic purposes, scavenging is not generally practicable and pollution should therefore be controlled by mechanical ventilation. Details of ventilation requirements are given in Health Building Note 26 (Volume 1): 'Facilities for surgical procedures'. For dental departments, scavenging is possible by means of nasal masks at a reduced flow of 45 litres/min, and reference should be made to Scottish Heath Technical Memorandum 2022 (Supplement 1): 'Dental compressed air and vacuum systems' (see also Section10).

3.7 The terminal unit (AGS) is specified in BS EN ISO 9170-2: 2008. AGSS's are covered in Section10.

Note 5: Reference should be made to the Department of Health's (1996) 'Advice on the implementation of the Health & Safety Commission's occupational exposure standards for anaesthetic agents'. Further guidance is given in the Health & Safety Executive's (1996) 'Anaesthetic agents: controlling exposure under COSHH'.

3.8 Where respiratory equipment or surgical instruments are serviced, such as in EBME workshops, it is normally necessary to install the full range of medical gas terminal units. AGS should be provided as a dedicated system.

3.9 The fixing of terminal units into medical supply systems or to wall surfaces etc. should be such that the following forces can be applied:

- a lateral force of 20 N applied at 50mm from the surface of the terminal unit without dislodgement or breakage;
- an axial force of 500 N without dislodgement or breakage.

3.10 Where an array of terminal units is provided at a location, they should be arranged as follows (see Figure 1):

- for a horizontal array, when viewed from the front, left to right: oxygen, nitrous oxide, nitrous oxide/oxygen mixture (50% v/v), medical air, surgical air, vacuum, anaesthetic gas scavenging, helium/oxygen mixture. If this arrangement is impracticable, a number of rows can be used;
- for a vertical array, with oxygen at the top and in the sequence as for a horizontal array. In many cases a vertical array is impracticable and a more convenient arrangement will comprise a number of rows/columns;
- for a circular array, for example where terminal units are installed on the under-surface of a pendant, with the sequence as for a horizontal array, in a clockwise direction when viewed from below. The AGS terminal unit may occupy the centre of such an array;

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- On occasion, the user may require the configuration of outlets to be out of sequence from that shown in Figure 1 a) to d), however, this should be agreed in line with contractual requirements.

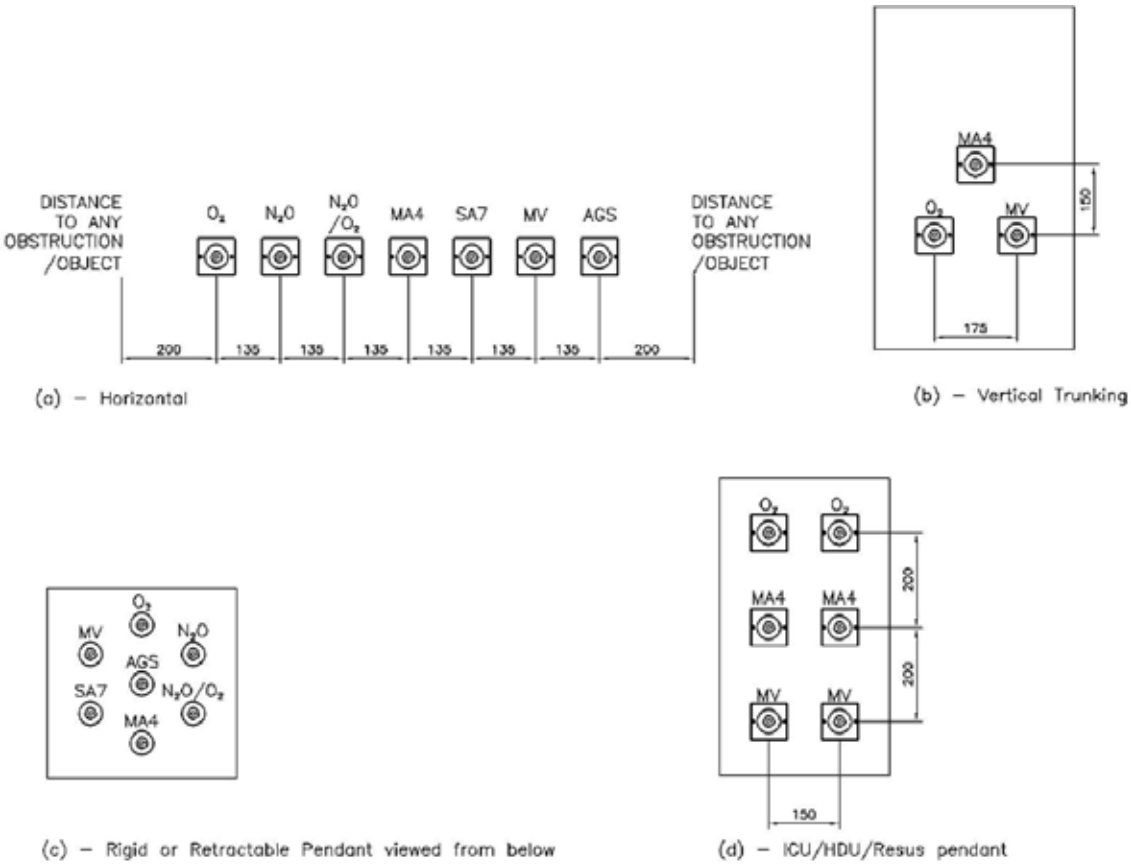

Figure 1: Terminal unit mounting order

3.11 Oxygen/carbon dioxide mixture systems have been installed, but are no longer covered by this Scottish Health Technical Memorandum.

3.12 Helium/oxygen mixtures may be required to be supplied by pipeline in some critical care areas. Systems for these are included in Section 11.

3.13 Mounting heights for terminal units should be between 900mm and 1,600mm above finished floor level (FFL) when installed on walls or similar vertical surfaces – the optimum height for the convenience of users of the medical gas system is 1,400mm (see Figure 2). When terminal units are incorporated within a horizontal bedhead service trunking system, which also provides integrated linear lighting for general room and/or patient reading illumination, it should be of a design that does not compromise the convenience of the medical gas facility. Where there is a desire to mount terminal units below 900mm e.g. below worktops in some dental surgery configurations, prior agreement should be sought from the User.

3.14 When installed in pendants or similar, terminal units should be of a type suitable for mounting within the specified fitting.

3.15 Pressure losses across terminal units should be in accordance with BS EN ISO 9170-1: 2008. The standard does not give pressure loss data for surgical air at 350 litres/min, but this can be ≥150 kPa when connected via a ceiling NIST

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(non-interchangeable screw thread) connector and 5m of hose. This pressure drop could be reduced by removing the non-return valve within the NIST connector and installing a line valve directly upstream of the NIST connector to facilitate future servicing / repair / hose replacement.

3.16 Terminal units that are wall mounted should be located as follows (Figure 2 refers):

- the distance between the centre of the terminal unit and a potential obstruction on either side (for example when installed in a corner) should be a minimum of 200mm on either side;
- distance between centres of adjacent horizontal terminal units should be;
  - 135 ± 2.5mm for three or more terminal units;
  - 150 ± 2.5mm for two terminal units only;
- distance between centres of adjacent horizontal terminal units;
- care should be taken to ensure that connected medical gas equipment and hoses do not foul other nearby equipment and services during use. Particular attention should be given to terminal unit positioning with respect to worktops, electrical sockets, cupboards, equipment rails, ventilation flaps and door openings. A minimum radial clearance of at least 200mm from these items is suggested, but this may have to be increased depending on the nature of connected equipment.

Note 6: To promote a more “domestic” environment, some in-patient accommodation is provided with terminal units installed in recesses behind covers/decorative panels etc. To accommodate this it is necessary to allow an additional 100mm on each side of the outermost terminal units and 200mm from centre to top of recess and 300mm from centre to bottom of recess. The depth of the recess should be 150mm. The surface should be clearly marked with suitable legend denoting medical equipment is installed within.

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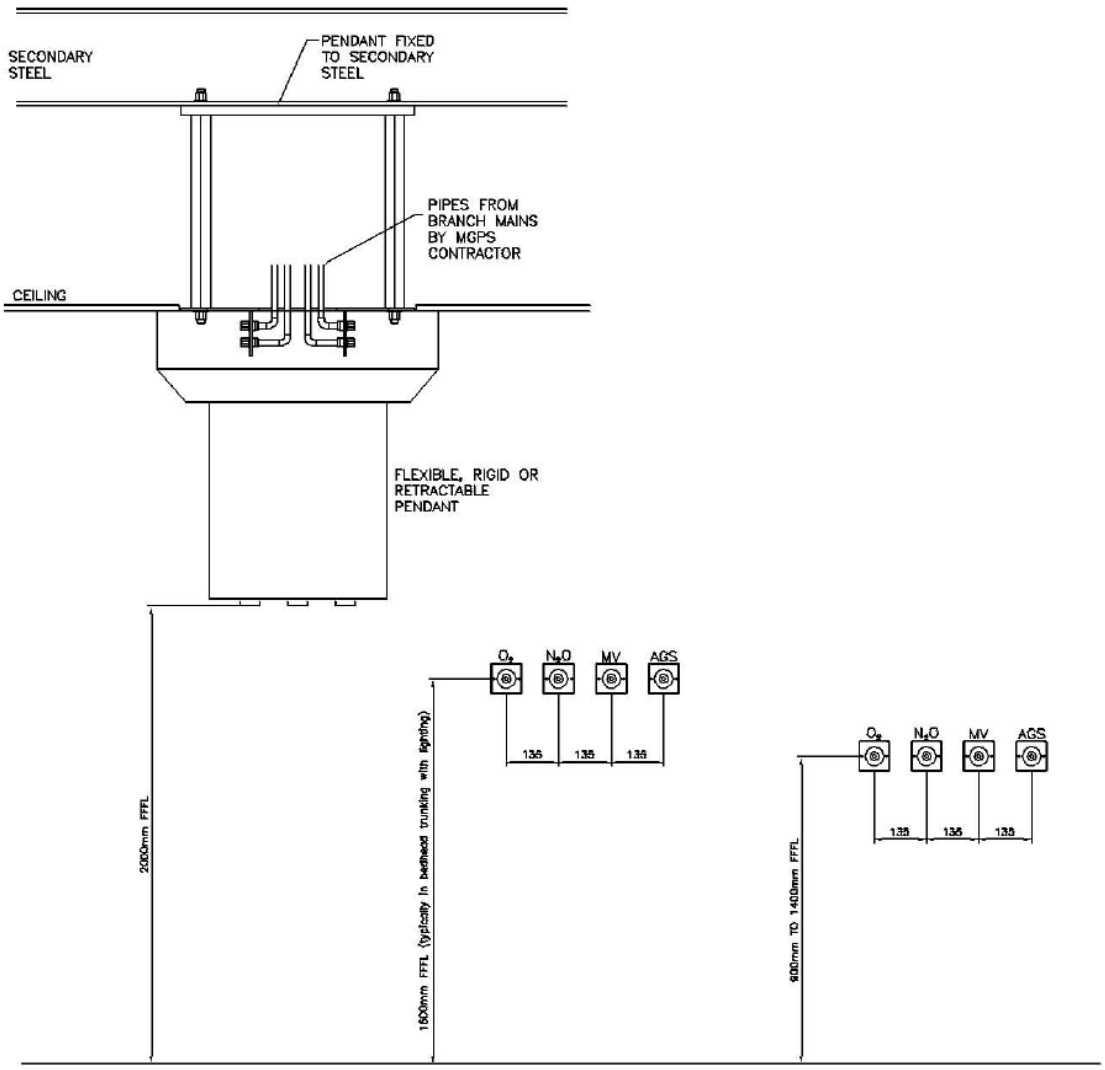

Figure 2: Terminal unit mounting heights

Terminal units for helium/oxygen mixture

3.17 BS EN ISO 9170-1: 2008 does not include a terminal unit for helium/oxygen mixture. They will be included in a new edition of BS5682:1998.

Nitrogen for surgical tools

3.18 BS EN 739:1998 gives details of connectors for nitrogen for driving tools. The body of the NIST connector should form the wall outlet.

Area Valve Service Units (AVSUs)

3.19 AVSUs should be mounted at a convenient height (typically between 1, 000 – 1,800mm) such that they can be operated comfortably by staff without their needing to stoop or overreach (see Figure 3). The order of the location of individual valves in an array should follow that for terminal units, for example: O_2, N_2O and/or N_2O/O_2, MA4, SA7, MV, He/O_2. If the array exceeds 1,000mm in height from top to bottom, it may be preferable to arrange them in two columns. Care must be taken to ensure that AVSUs cannot be obscured by opening doors etc. Details of the design of AVSUs are given in Section13.

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Note 7: The minimum height of 1,000mm is the optimum. In critical care areas where dual circuits are installed, it may be necessary to reduce this to 800mm to avoid an excessive number of columns of AVSUs.

Area alarm indicator panels

3.20 The placing of area alarm indicator panels should be such that they are readily visible by staff. Notices, partitioning, screens, etc. should not obscure them. The mounting height should be such that in the event of an audible alarm sounding, staff can activate the “mute” switch without overreaching, and be a maximum 1,800mm above finished floor level (see Figures 3a and 3b).

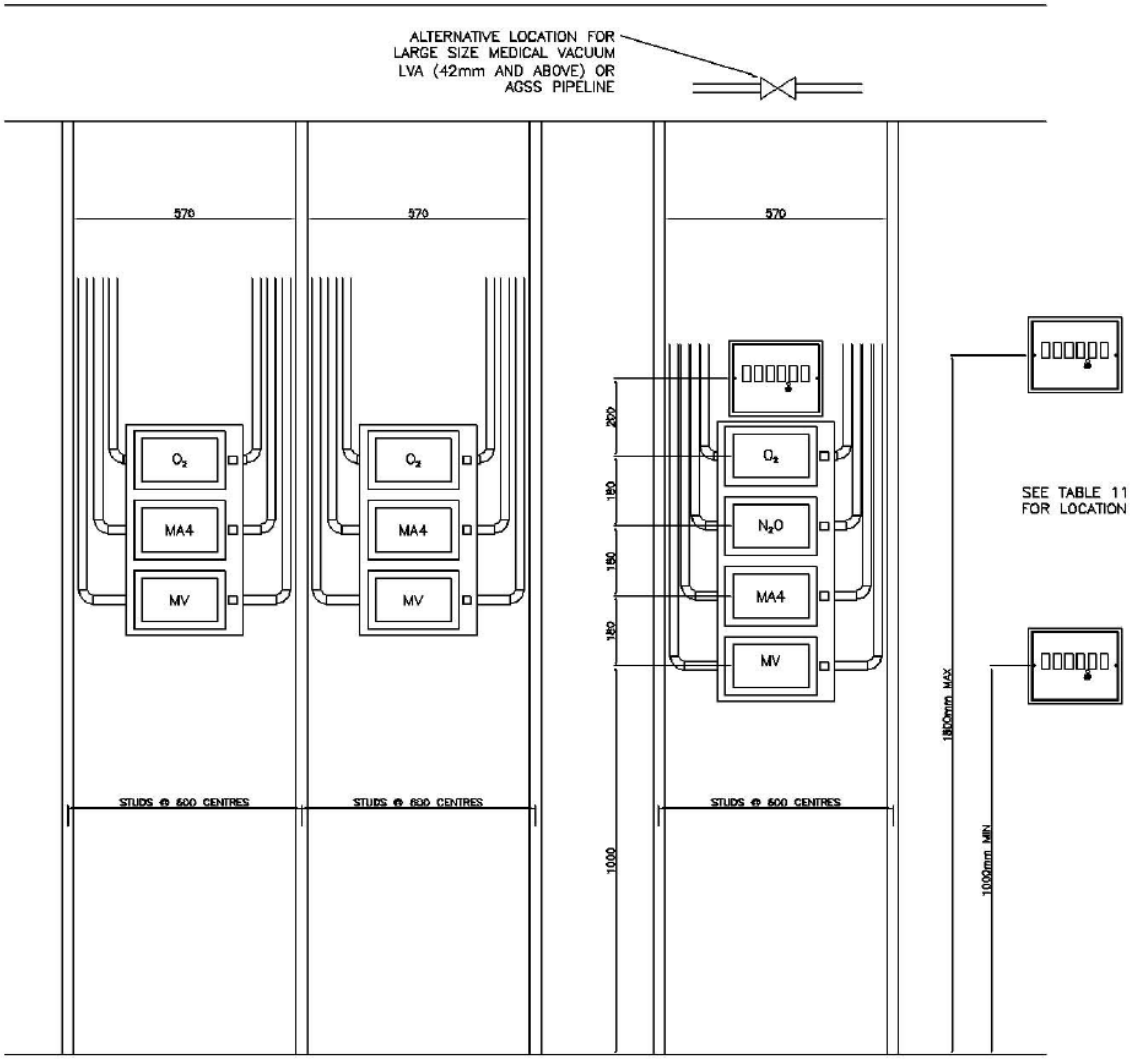

Figure 3a: AVSU and alarm panel mounting heights

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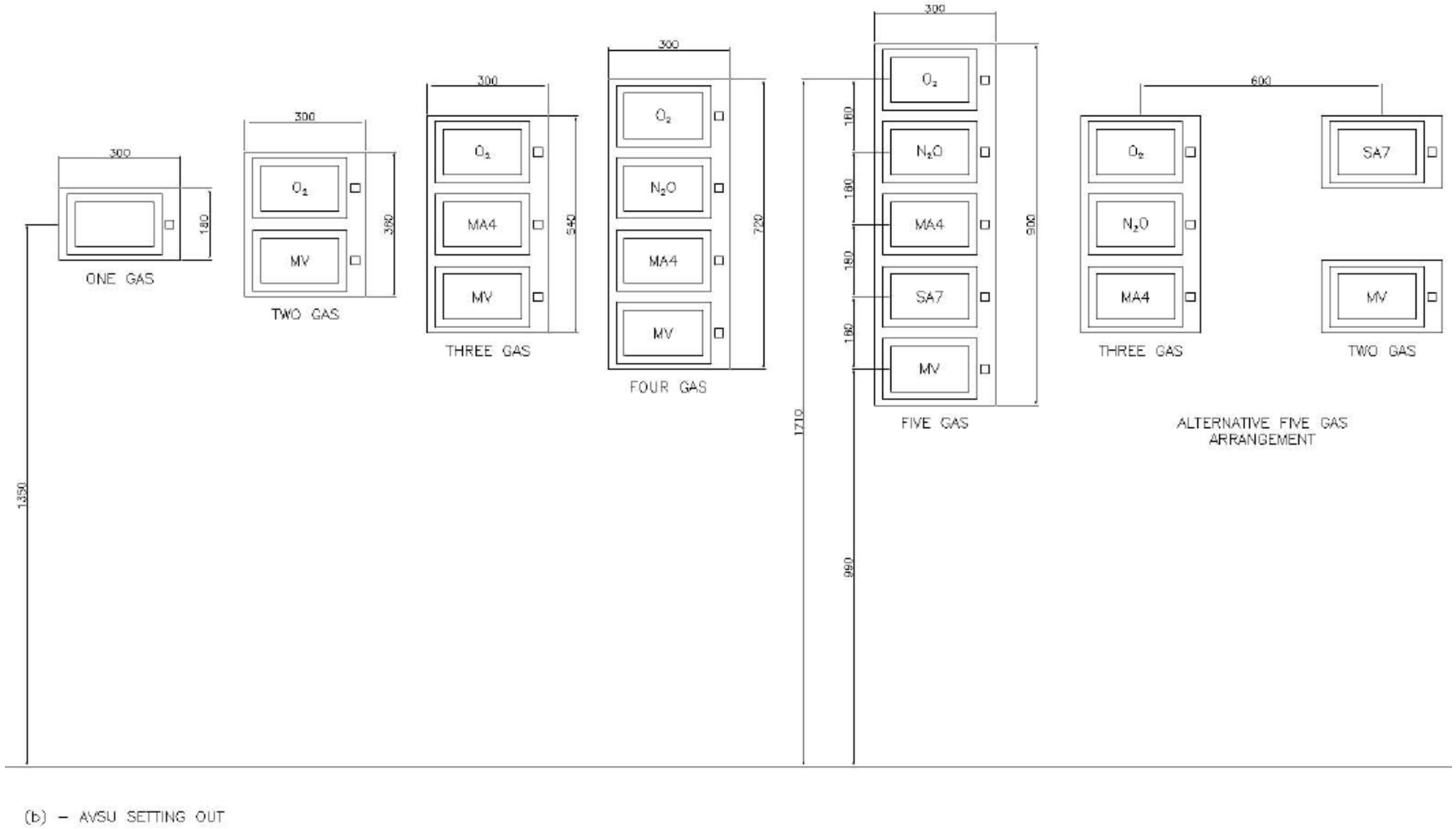

Figure 3b: AVSU and alarm panel mounting heights

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Line valve assemblies (LVAs)

3.21 LVAs should be installed at branches from risers, branches from main runs, and where pipelines pass into or out of a building. Details of the design of LVAs are given in Section13.

Specific labelling requirements

3.22 All AVSUs should be labelled to identify the individual rooms, sets of terminal units, etc. controlled. They should be provided with flow direction arrows.

3.23 In critical care areas where dual circuits and/or subdivision of circuitry occur, terminal units require to be identified as associated with the specific AVSU. Correspondingly, AVSUs should be similarly labelled to identify the terminal units controlled.

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Accident and Emergency									1 set [1]	1 set hp/lp [9]
Resuscitation room, per trolley space **Note:** One set either side of the trolley space, if installed in fixed location, e.g. trunking: or both sets in an articulated supply pendant that can be positioned either side of the bed space.	2	2	-	2	-	2	2	-	2 Sets *	
Major treatment/plaster room per trolley space	1	1	1p	1	1p	1	1	-	1 set per 8 TUs	
Post-anaesthesia recovery per trolley space **Note:** One set either side of the bed space, if installed in fixed location, e.g. trunking: or both sets in an articulated supply pendant that can be positioned either side of the bed space.	2	-	-	2	-	2	-	-	2 sets*	
Fracture Clinic, plaster room	1	1	1 (paed)	1p	1p	1	1	-	1 set [1]	1 set hp/lp [9]
Treatment room/cubicle	1	-	-	-	-	1	-	-	1 set per 8 TUs	

Table 11: Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Operating department									1 set [1]	
Anaesthetic rooms (all)	1	1	-	1	-	1	1	-	With associated theatre suite	
Operating room, orthopaedic:										
Anaesthetist	2	1	-	2	-	2	1	-	1 set per suite [2] [3]	1 set per suite hp/lp [10]
Surgeon	-	-	-	-	4	2	-	-		
Note: Orthopaedic surgery is normally performed in operating rooms provided with ultra-clean systems. Such systems are much more effective in terms of airflow when provided with partial walls. These walls may be effectively used to include terminal units that can be supplied by rigid pipework. Such installations do not suffer from excessive pressure loss when surgical air is required at high flows.										
Operating room, neurosurgery:										
Anaesthetist	2	1	-	2	-	2	1	-	1 set per suite [2] [3]	1 set per suite hp/lp [10]
Surgeon	-	-	-	-	2	2	-	-		
Note: If multi-purpose pendants are used, there may be some loss of performance of surgical tools because of bore restrictions and convolution of the flexible connecting assemblies at the articulated joints.										

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Operating department (cont'd)									1 set [1]	
Operating room, general surgery, etc.:										
Anaesthetist/surgeon (see [14] regarding CO_2)									1 set per suite[2] [3]	1 set per suite hp/lp [10]
Note: Terminal units installed in separate pendants: p = project team option where some orthopaedic overspill surgery may be performed	2	2	-	2	2p	2	2	-		
Post anaesthesia recovery, per bed space									2 sets * [5]	1 alarm for both sets of AVSUs hp/lp [11]
Note: One set either side of the bed space, if installed in fixed location, e.g. trunking: or both sets in an articulated supply pendant that can be positioned either side of the bed space	2	-	-	2	-	2	-	-		
Equipment service room ** per work space	1	1	-	1	1	1	1	-	1 set	1 set hp/lp [12]

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Maternity department									1 set [1]	1 set hp/lp [9]
LDRP room (normal/abnormal):									1 set per 6-8 rooms [5]	
Mother (normal)	1	-	1	-	-	2	-	-		
Mother (abnormal)	1	1	-	-	-	2	1	-		
Baby (per cot space) (allow for 2 cots only)	1	-	-	1	-	1	-	-		
Operating suite:									1 set	1 set hp/lp [10]
Anaesthetist	1	1	-	1	-	1	1	-		
Obstetrician	-	-	-	-	-	2	-	-		
Paediatrician (per cot space) (allow for 2 cots only)	1	-	-	1	-	1	-	-		
Post anaesthesia recovery, per bed space	1	-	-	1	-	1	-	-	1 set per 6-8 spaces [5]	1 set hp/lp [11]
Equipment service room ** per work space	1	1	1	1	1	1	1	-	1 set	1 set hp/lp [12]

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Maternity department (cont'd)									1 set [1]	1 set [9]
Neonatal unit, per cot space **Note:** One set either side of the bed space, if installed in fixed location, e.g. trunking: or both sets in an articulated supply pendant that can be positioned either side of the bed space. It is recommended that the Neonatal unit / SCBU have dedicated departmental AVSUs in addition to those identified for the Maternity department with dual circuits downstream of these AVSUs.	2	-	-	2	-	2	-	-	2 sets [4] [5] *	1 for both sets of AVSUs hp/lp [11]
Equipment service room ** per work space	1	-	-	1	-	1	-	-	1 set	1 set lp [12]
In-patient accommodation:									1 set for ward unit	1 set hp/lp [11]
Single bed room	1	-	-	-	-	1	-	-		
Multi-room, per bed space	1	-	-	-	-	1	-	-		
Nursery, per cot space **Provision for 2 cots only irrespective of number ofcot spaces**	1	-	-	-	-	1	-	-		

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Diagnostics department									1 set [1]	
Special procedures room	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
Anaesthetic room	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
Holding and recovery	1	-	-	1p	-	1	-	-	1 set	1 set hp/lp(n) [11]
Ultrasound	1	-	-	-	-	1	-	-	1 set per group	Part of the department. If remote from main alarm
Fluoroscopy	1	-	-	-	-	1	-	-	1 set per group	
Urography	1	-	-	-	-	1	-	-	1 set per group	1 set per group lp [11]
Tomography	1	-	-	-	-	1	-	-	1 set per group	
Magnetic Resonance Imaging (MRI) suite	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
CT room	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
Angiography	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
Endoscopy	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
Linac bunker	1	1	-	1	-	1	1	-	1 set	1 set hp/lp [10]
General purpose room	1	-	-	-	-	1	-	-	1 set per group	1 set per group lp [11]

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
In-patient accommodation									1 set for the ward unit [1]	1 set hp/lp [11]
Single bed room	1	-	-	1	-	1	-	-		
Multi-bed room, per bed space	1	-	-	1	-	1	-	-		
Infectious Diseases rooms	1	-	-	1	-	Refer to-App L	-	-	1 set [1]	1 set hp/lp [11]
Treatment room (Appropriate for adult acute, children and elderly)	1	-	-	1	-	1	-	-		
Renal department									1 set	1 set hp/lp [11]
Per dialysis station	1	-	-	1	-	1	-	-	1 set per group	1 set hp/lp [11]
Per bed space	1	-	-	1	-	1	-	-	1 set per group	1 set hp/lp [11]

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Critical Care Department									1 set [1]	
Intensive Therapy Unit (ITU)/ Intensive Care Unit (ICU)	4	2p	2p	4	-	4	2p	2p	2 sets * [4][6][7]	1 set for both AVSUs hp/lp [11]
Coronary Care Unit, per bed space	4	-	-	4	-	4	-	-	2 sets * [4][6][7]	1 set for both AVSUs hp/lp [11]
High Dependency Unit, per bed space	4	-	-	4	-	4	-	-	2 sets * [4][6][7]	1 set for both AVSUs hp/lp [11]
Burns Unit	2	2p	2p	2	-	2	2p	-	2 sets * [4][6][7]	1 set for both AVSUs hp/lp [11]
Note: For all the above Critical Care Departments, one set either side of the bed space, if installed in fixed location, e.g. trunking; or both sets in an articulated supply pendant that can be positioned either side of the bed space.										
Equipment service room, per work space	1	1p	1p	1	-	1	1p	-	1 set	1 set hp/lp [12]

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Adult mental illness accommodation									1 set	
Electro-convulsive therapy (ECT) room	1	1	-	1	-	1	1	-	1 set [1]	1 set hp/lp [10]
Post-anaesthesia recovery, per bed space	1	-	-	1	-	1	-	-	1 set per 6-8 rooms [5]	1 set hp/lp [11]
Adult acute day care accommodation									1 set	
Treatment room:										
Anaesthetist	1	1p	-	1p	-	1	1p	-	1 set	1 set hp/lp [10]
Surgeon	-	-	-	-	-	2	-			
Post-anaesthesia recovery, per bed space	1	-	-	1p	-	1	-	-	1 set per 6-8 rooms [5]	1 set hp/lp(p) [11]
Day patient accommodation									1 set [1]	
Single bed room	1	-	-	-	-	1	-	-	1 set [1][13]	1 set hp/lp(p) [11]
Multi-bed room, per bed space	1	-	-	-	-	1	-	-		
Treatment room	1	-	-	1p	-	1	-	-		
Endoscopy room	1	1p	-	1p	-	1	1p	-	1 set [2][13]	1 set hp/lp(p) [10]

Table 11: (cont'd) Provision of terminal units, AVSUs and area alarms

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Department	O_2	N_2O	N_2O/O_2	MA4	SA7	VAC	AGSS	He/O_2	AVSU	Area Alarm
Oral surgery, orthodontic department									1 set [3]	1 set hp/lp [9]
Consulting / treatment room, type 1	1	1p	-	1	Dental air required	†	1p	-	1 set per 4-6 rooms	
Consulting / treatment room, type 2 and 3	1	-	-	1		†	-	-	1 set per 4-6 rooms	
Recovery room, per recovery position	1	-	-	1	-	1	-	-	1 set	
Appliance laboratory, per work space	1	1p	-	1	1	1	1p	-	1 set	1 set hp/lp[11]
Out-patient department										
Treatment room / cubicles	1	-	-	1	-	1	-	-	1 set [1][8]	1 set hp/lp[9]
Sterile services department									1 set [1]	1 set lp [9]
Wash room	-	-	-	1[18]	1[18]	1[18]	-	-		
Inspection, assembly and packing (IAP) room	-	-	-	1[18]	1[18]	-1[18]				
Clinical / surgical training facilities [19]	1p	1p	1p	1p	1p	1p	1p	-	1 set [1]	1 set hp/lp [9]
EBME	1	1	-	1	1	1	1	-	1 set [1]	1 set hp/lp [9]
Other departments (as required by project team)									1 set[1]	1 set[9-12] located as required

Table 11: (concluded) Provision of terminal units, AVSUs and area alarms

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Notes applicable to Table 11:

*	Dual circuits
**	Where the delivery and neonatal units are in close proximity, the equipment service room can be shared.
†	Dental vacuum only
p	Project team option
hp/lp	high-pressure and low-pressure alarms..
lp	low pressure alarm.

Ref: (1)	Departmental AVSUs installed on the hospital street side of fire compartment doors – due consideration should be given to the security of these valves in public areas.
Ref: (2)	Installed immediately outside the room.
Ref: (3)	Where air is used to control movable pendant fittings, it should be taken from the 700 kPa surgical air system. However where surgical air is not available medical air 400 kPa may be used if suitable for the particular pendant manufacturer's requirements.
Ref: (4)	In addition to the dual circuits, additional AVSUs will be required to sub-divide the number of terminal units controlled (typically between 4-8 bed spaces). This subdivision should be based on the layout of the accommodation: for example, if the recovery area is divided into a number of separate room/areas, each would have a separate sub-set (see Figures 4 and 5).
Ref: (5)	This is intended to provide some flexibility and the exact number will depend on the total number of rooms within the department.
Ref: (6)	If a high-dependency unit is included within general in-patient accommodation, a separate set of AVSUs should be provided for the unit. In addition to the departmental valves or the ward as a whole, an additional set will be required to control the single-bed, multi-bed and treatment rooms.
Ref: (7)	Department AVSUs may be required if the units are large and separate from, for example, the critical care area.
Ref: (8)	Additional AVSUs may be required in a large unit: the aim should be to have about 8-12 rooms controlled by a set of AVSUs – discretion is required to arrive at the logical number.
Ref: (9)	Installed in reception area.
Ref: (10)	Installed in the operating room in the "main panel" or within the room, or an ante-room, e.g. control room of an MRI device.
Ref: (11)	Installed at the main staff base (nurses' station).
Ref: (12)	Installed in the room space with the AVSUs.
Ref: (13)	Separate AVSUs will be required if endoscopy room is included.
Ref: (14)	Carbon dioxide is used for insufflation during some surgical procedures. A pipeline installation is a project team option and is covered in Section 11. Two NIST connector bodies units should be installed.
Ref: (15)	Where medical gases are required in Decontamination rooms, such as in A&E, the medical gas should be provided by a dedicated source e.g. gas cylinder or portable vacuum pump.

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Ref: (16)	Where grouping of similar type rooms are possible, e.g. Renal departments, Diagnostics (e.g. ultrasound, general purpose rooms) the grouping should be to have an even number of rooms controlled by a set of AVSUs – discretion is required to arrive at the logical number.
Ref: (17)	Where medical gas terminal units are to be provided in areas such as; en-suite bathrooms/shower rooms, etc. the location of the terminal unit should not be in direct contact with water, or cleaning fluids (soaps, etc.). The designer and User should liaise to establish an acceptable location.
Ref: (18)	Dedicated medical/surgical air and vacuum plant should be provided separately for this department.
Ref: (19)	The medical gases provision and method of supply for dedicated clinical / surgical training facilities should be determined in consultation with the training facility management.

General

Normally, departmental AVSUs would be installed at the hospital street side of the entrance doors to a department and would reflect the method of horizontal evacuation in the event of an emergency. In some large departments, for example an operating department, the clean-service corridor is likely to cross one or more fire compartment walls. Additional AVSUs may therefore be required to reflect the evacuation route.

If a department includes one or more floors, a set of AVSUs should be provided for each floor, which will act as emergency overall fire valves.

AVSUs for zones within critical care areas should be located where they can be seen by staff – not necessarily at the staff base.

Area alarms within critical care areas should be provided for the individual space; that is, if a critical care area of, say, 18 beds is sub-divided into three separate six-bed wards, there should be one alarm only for each space (not one for each of the dual circuits).

Where an anaesthetic room is directly linked to an operating room, the anaesthetic room shall be controlled by the theatre AVSUs. Where the anaesthetic room is remote from a theatre(s) separate AVSUs with area alarm panel should be provided.

When an anaesthetic room forms part of a special procedures suite then one set of AVSUs serving both rooms is permissible. Consideration should be given to the general department layout with regard to the degree of valving required where procedures will not require anaesthetics to be applied.

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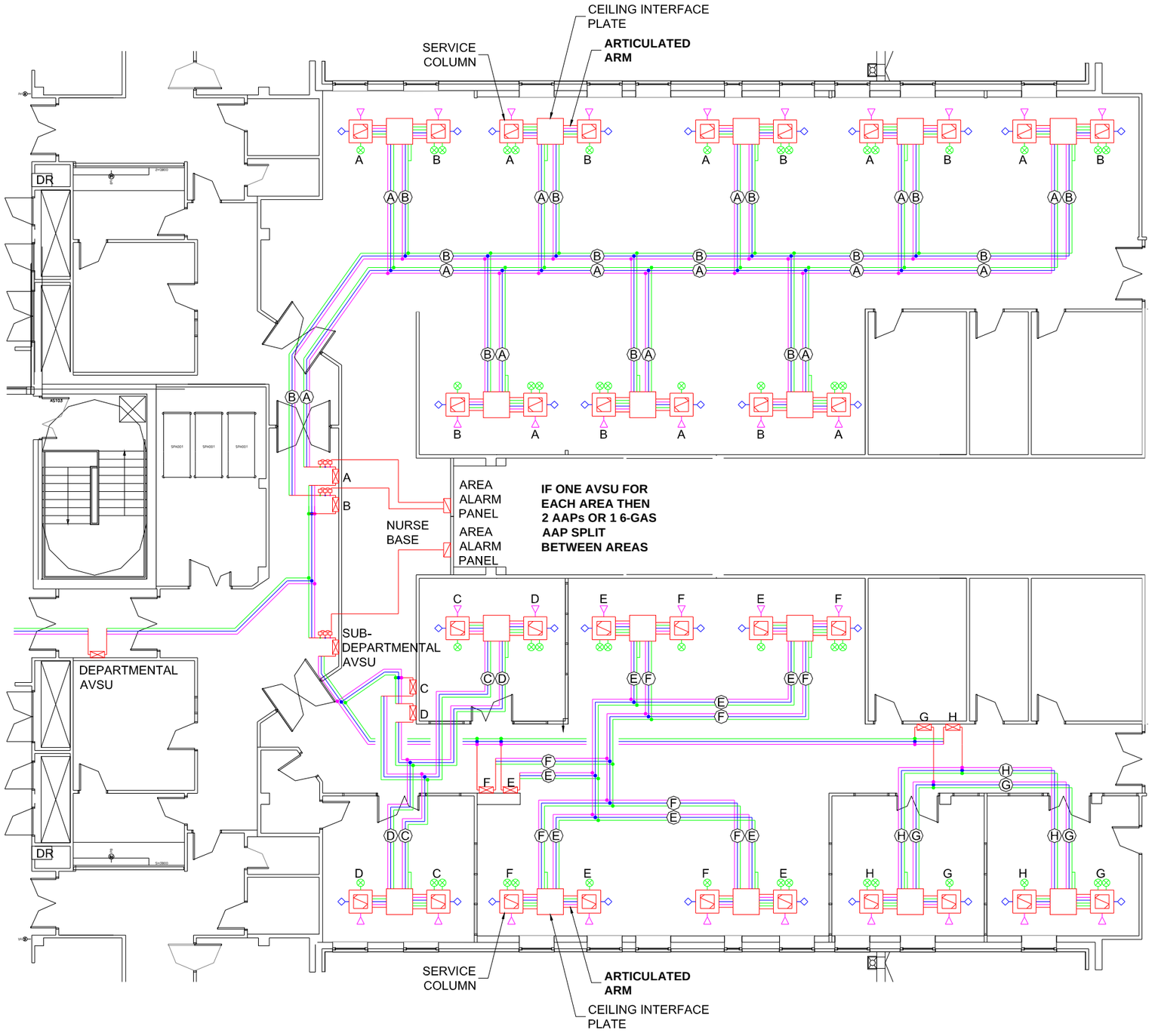

Figure 4: Larger critical care area with open plan and isolation room configuration

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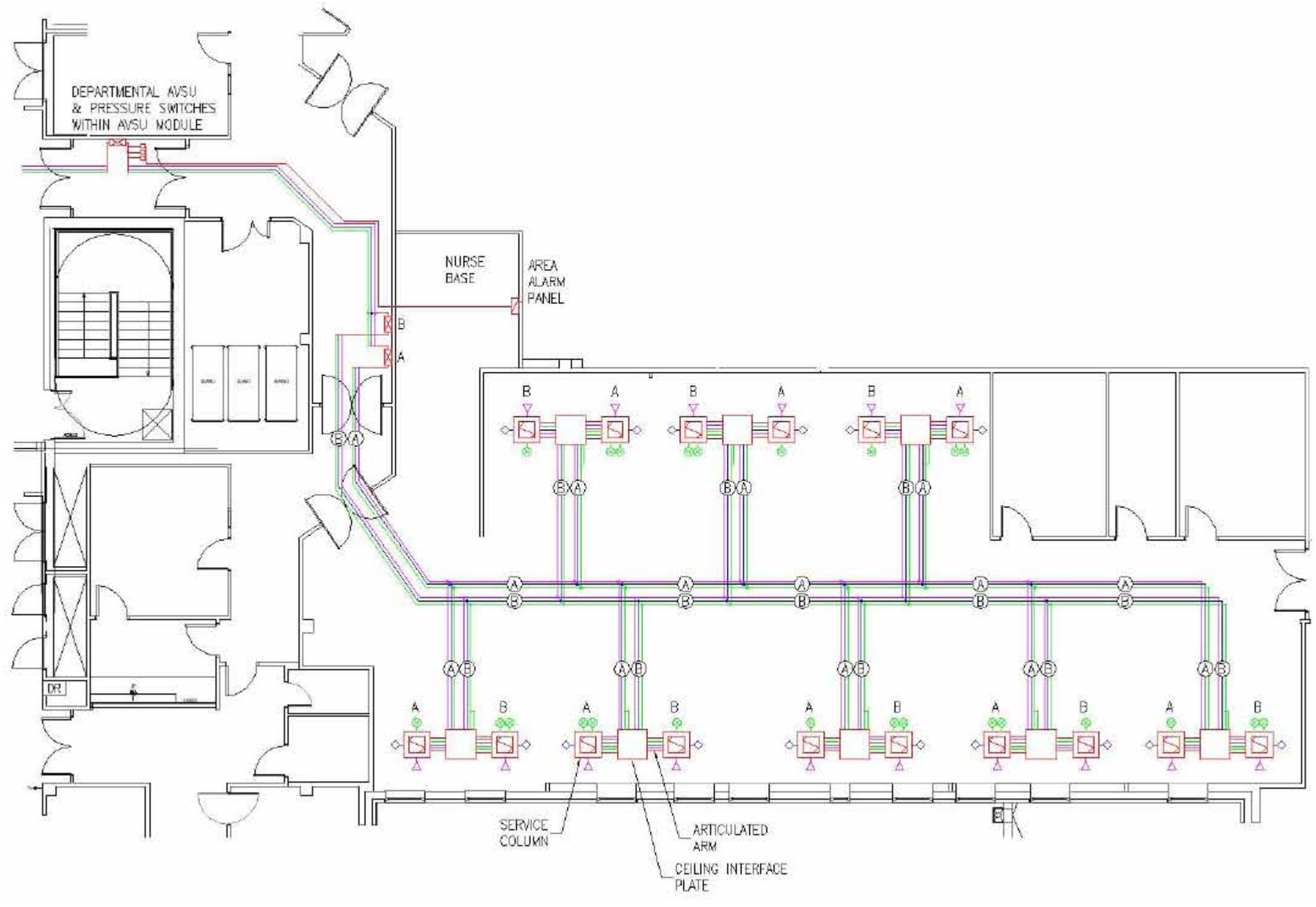

Figure 5: Smaller open plan critical care area

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4. Gas flow

General

4.1 Various layouts of an MGPS are shown throughout this document, and each will need to be designed to take into account the anticipated design flow. Appendix N provides a conversion table for various units of measurement that may be encountered.

4.2 There are several aspects of gas flow to consider when designing the pipeline distribution system:

1. the test flow that is required at each terminal unit for test purposes (this flow is essentially to establish that the terminal unit functions correctly and that there are no obstructions; see Table 12);
2. the typical flow required at each terminal (this is the maximum flow likely to be required at any time in clinical use; see Table 12);
3. the likely numbers of terminal units in use at any time;
4. the flow required in each sub-branch of the distribution;
5. the total flow to the ward/department;
6. the flow in the main branches/risers, that is, the summation of all diversified flows;
7. the flow required at the plant, that is, the sum of all diversified flows to all like departments and wards, plus individual or dissimilar departments.

4.3 The pipeline system should be designed so that the flows given in Table 12 can be achieved at each terminal unit: the flows are expressed in free air. Diversified flows are used for the purposes of pipe size selection.

4.4 The designer should always ensure that due account is taken of the stated use of a particular department.

4.5 There is a limited range of pipe sizes, and where there is any doubt about flow requirements, a larger pipe size should be selected.

Note 8: When calculating diversified flows, it is the number of bed spaces, treatment spaces or rooms in which the clinical procedure is being performed that is used; this is not the individual number of terminal units since, in many cases, more than one is installed. For example, a bed position in a critical care area may have four or more oxygen terminal units.

4.6 The overall pipeline design should be based on a 5% pressure drop from the plant/source of supply to that measured at the rear of the terminal unit outlet at the specified test flows. For multi-movement pendant hoses the 5% pressure drop is only applicable to the pipeline up to the inlet of a NIST connector (refer to Figure 8). For vacuum, this should be 50mmHg pressure loss.

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Terminal unit flows

4.7 At the design stage, the project team should define the individual room/space requirements. Departments usually comprise several ward units, treatment rooms and other spaces. In order to avoid confusion, the nomenclature for each clinical space should be clearly defined so that the appropriate gas flow requirements can be established at the commencement of the design stage.

Pipeline flows

4.8 Precise prediction of pipeline flow is not possible, but there are guidelines that can be used which have been shown to be adequate in practice.

4.9 For vacuum systems, the minimum vacuum should not fall below 300 mmHg at the front of each terminal unit at a design flow of 40 litres/min.

4.10 The design of the pipework system is based on the diversified flows and the permissible pressure loss from the source of supply to the terminal unit excluding the terminal unit pressure loss. The pipe sizes should be selected to ensure that the pressure loss is below 5% of the nominated pipeline pressure. (See Figures 6–9 and Appendix G).

4.11 Pressure requirements for surgical air are based on the requirement that the minimum pressure should be 700 kPa at the terminal unit at a flow of 350 litres/min.

4.12 Details of pressure requirements for all systems are described in paragraphs 4.42–4.49.

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Service	Location	Nominal pressure (kPa)	Design / Test flow (Litres/min)	Typical flow required (Litres/min)
Oxygen	Operating rooms and anaesthetic rooms in which N_2O is provided for anaesthetic purposes	400	100[a]	20
	Continuous positive airway pressure (CPAP)	400	75	30
	All other areas	400	10	6
Nitrous oxide	All areas	400	15	6
Nitrous oxide/Oxygen mixture	LDRP(labour, delivery, recovery, post-partum) rooms	400[b]	275	20
	All other areas	400	20	20
Medical air 400 kPa	Operating rooms	400	40[c]	40
	Critical care high dependency units	400	80[c]	80
	Neonatal	400	40	40
	Other areas	400	20	10[c]
Surgical air/nitrogen	Orthopaedic and neurosurgical operating rooms	700	350[d]	350
	Where multi-movement pendants are installed	900[e]	350	350
	Other areas	700	350	350
Vacuum	All areas	400mmHg – 47 kPa absolute (53 kPa below atmospheric pressure). All further figures will be in 'below atmospheric pressure'	40	40 maximum, further diversities apply
Helium/oxygen mixture	Critical care areas	400	100	40

Table 12: Gas flow – flows required at terminal units

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Notes applicable to Table 12:

(a) During oxygen flush in operating and anaesthetic rooms;

(b) For nitrous oxide / oxygen mixture the pressure at the intermittent patient demand regulator should not be less than 310 kPa;

(c) These flows are for certain types of gas-driven ventilators under specific operating conditions, and nebulisers etc.

(d) Surgical air is also used as a power source for tourniquets;

(e) Surgical air pressure losses across pendant NIST connections, hoses and terminal unit assemblies can be up to 200 kPa (which exceeds the BS EN ISO 9170-1: 2008 requirement) plus regulator and pipeline tolerances. Refer to paragraph 3.15;

(f) Pipeline sizing is designed to meet the total design flow at 5% losses which in practice provides a safety margin over the normal hospital flow demands. For surgical air, some regulator adjustment may be required.

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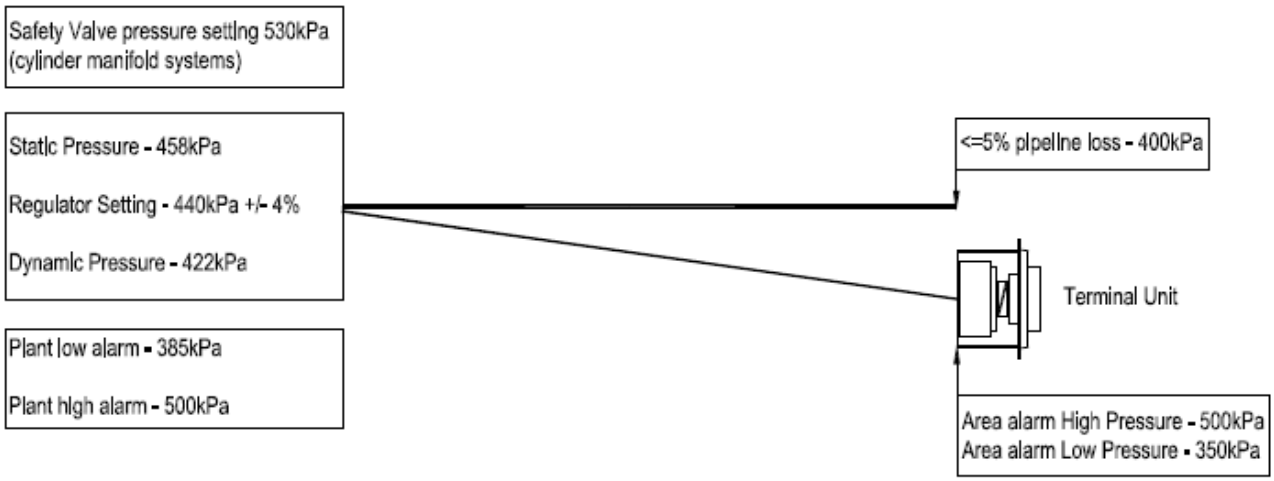

Figure 6: Typical pressures in oxygen/medical air/nitrous oxide/nitrous oxide-oxygen mixture system under design flow conditions

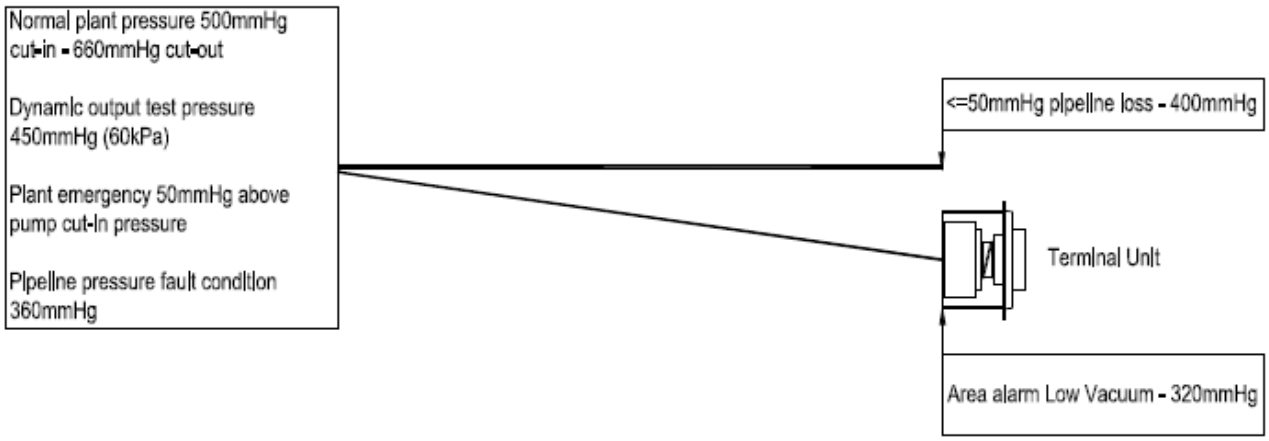

Figure 7: Typical pressures in medical vacuum system under design flow conditions

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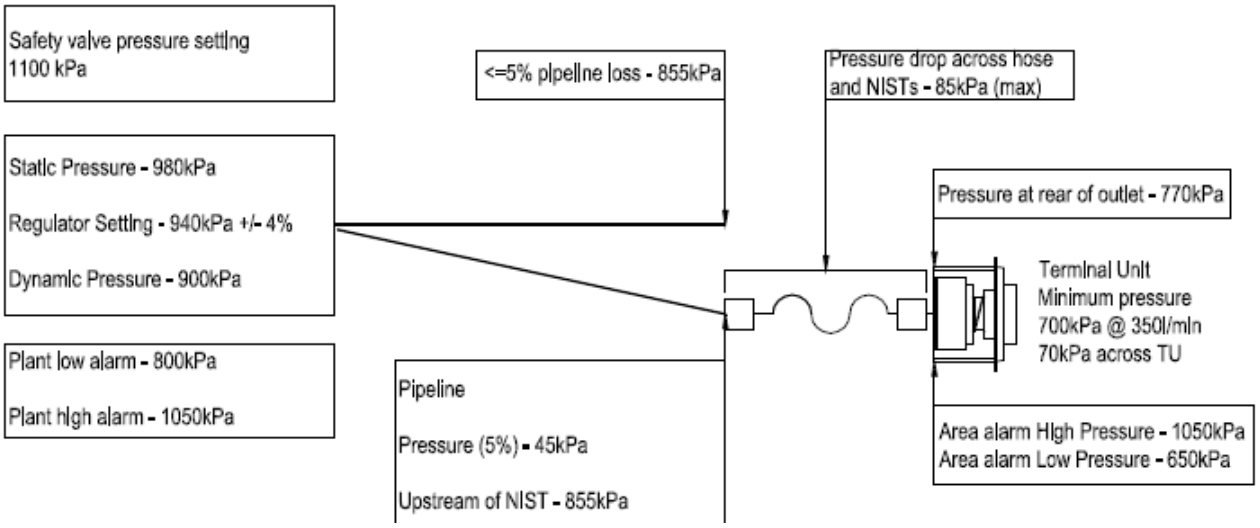

Figure 8: Typical pressures in a single pressure reduction surgical air system under design flow conditions with a multi-movement pendant fitted

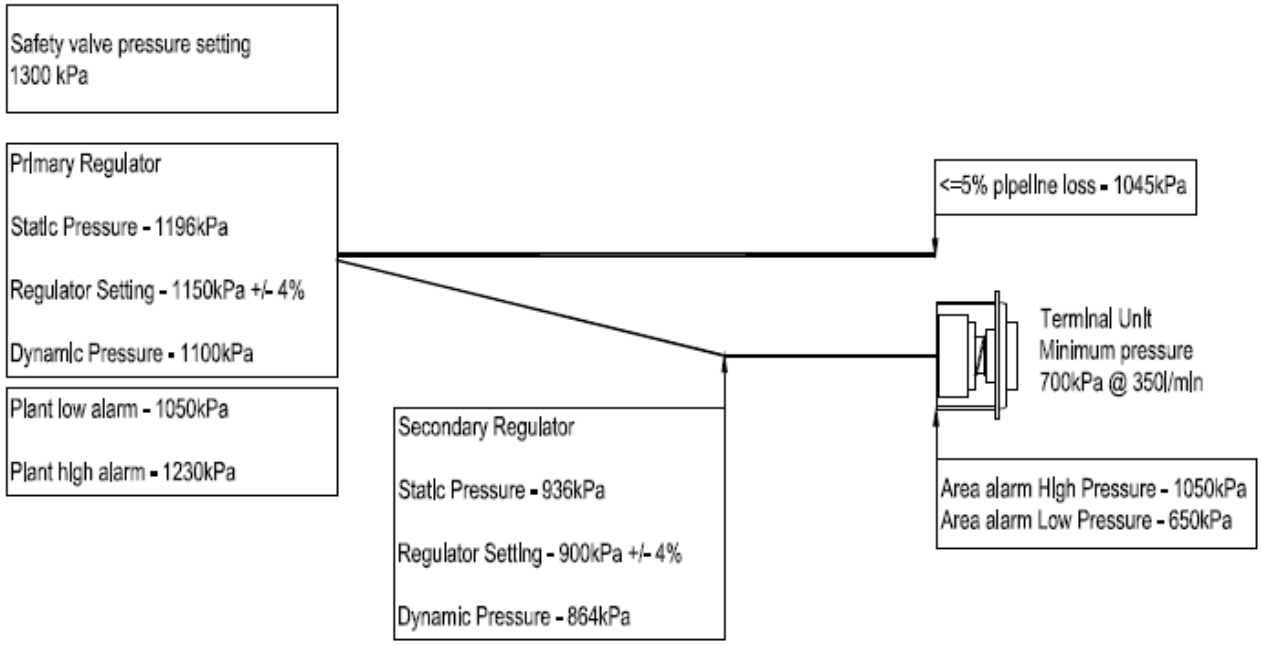

Figure 9: Typical pressures in a double pressure reduction surgical air system under design flow conditions

Oxygen

In-patient accommodation

4.13 Oxygen is used at a typical flow of 5–6 litres/min. Each terminal unit should, however, be capable of passing 10 litres/min (at standard temperature and pressure (STP)) at a supply pressure of 400 kPa (nominal) as shown in Table 12, in case nebulisers or other respiratory equipment are used. Table 13 contains the formula for arriving at diversified flows.

4.14 For a 28-bed ward unit comprising single and four-bed rooms and a treatment room, the diversified flow is calculated on the assumption that one bed space requires 10 litres/min, and one in four of the remainder require 6 litres/min. For the purpose of pipe size selection, the diversified flow at entry to the ward is

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taken as 50 litres/min (strictly 50.5 litres/min).It is assumed that a patient will use oxygen in a ward or in the treatment room but not both.

4.15 A department may comprise several ward units as above. The diversified flow for each department Qd is based on Qw for the first ward unit, plus 50% of the flow for the remaining ward units. For the purposes of this calculation, the first ward unit is taken as the largest within the department.

4.16 If one ward unit is significantly larger than the others, the flows from the ward units should be averaged to obtain a more realistic value.

Operating departments

4.17 The diversified flow for operating departments is based on 100 litres/min required for the oxygen flush. Therefore each oxygen terminal unit in the operating room and anaesthetic room should be able to pass 100 litres/min. It is unlikely that an oxygen flush will be administered simultaneously in several operating rooms. The diversified flow Q is based on 100 litres/min for the first operating room and 10 litres/min for the remainder.

4.18 For anaesthetic rooms, each terminal unit should be capable of passing 100 litres/min (it may be necessary to use oxygen “flush”), but the actual flow likely to be used is 6 litres/min or less. As it is unlikely that a patient would be anaesthetised at the same time that a patient in the associated operating room was continuing to be treated under an anaesthetic (and because the duration of induction is short), no additional flow is included.

4.19 In post-anaesthesia recovery, it is possible that all bed spaces may be in use simultaneously; hence, no diversity is applied.

Critical care, coronary care and high-dependency units

4.20 The flow for these units assumes that all bed spaces may be in use simultaneously, hence no diversity is applied.

4.21 Oxygen should not be used as the driving gas for gas-powered ventilators if they are capable of being powered by medical air. The minimum flow that has been shown to be adequate to drive current types of ventilator is 80 litres/min at 355 kPa.

4.22 If oxygen has to be used to power ventilators and/ or ventilators are operating in CPAP mode, the high flows that may be encountered should be taken into account both when designing the pipeline and when sizing the supply vessel. These ventilators use exceptional amounts of oxygen, particularly if adjusted incorrectly. If incorrectly set, they can use in excess of 120 litres/min, but their therapeutic benefit will be effective at lower flows. To allow for some flexibility, and additional capacity, a diversified flow of 75 litres/min for 75% of beds has been included. If significant numbers of beds are required to treat patients using CPAP ventilation, consideration should be given to running a separate pipeline from the source of supply. Care should be taken when calculating air exchange rates in wards/rooms in which large numbers of CPAP machines may be in use simultaneously and where failure of mechanical ventilation could result in raised

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ambient oxygen concentrations. Consideration should be given to installation of systems to warn of ventilation failure and oxygen concentrations above 23%.

Maternity

4.23 For LDRP (Labour, Delivery, Recovery, and Post-partum) rooms, the diversified flow is based on10 litres/min for the first terminal unit and 6 litres/min for one third of the remaining bed spaces. Two cot spaces may be provided, each with a terminal unit. Only one will be considered to be in use. The diversified flow for cot spaces is based on10 litres/min for the first and 50% of the remainder at 3 litres/min.

4.24 In the event of multiple births, the additional gas usage will have negligible overall effect on the total flow.

4.25 Maternity department operating rooms are designed as a suite; that is, it is presumed that oxygen will be provided either in the anaesthetic room or in the operating room. In post-anaesthesia recovery, it is possible that all bed spaces may be in use simultaneously, hence no diversity is applied.

Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
In-patient accommodation (ward units)		
Single, 4-bed rooms and treatment rooms	10	$Q_w = 10 + [(n - 1)6/4]$
Ward block/department		$Q_d = Q_w[1+ (nW - 1)/2]$
Accident & Emergency Department:		
Resuscitation room	100	$Q = 100 + [(n - 1)10/4]$
Major treatment / operating procedures	100	$Q = 100 + [(n - 1)10]$
Plaster room per trolley space	10	$Q = 10 + [(n - 1)6/4]$
Post-anaesthesia recovery per trolley space	10	$Q = 10 + [(n - 1)6/4]$
Treatment room/cubicle	10	$Q = 10 + [(n - 1)6/6]$
Operating Theatre Department:		
Anaesthetic rooms	100	No additional flow
Operating rooms	100	$Q = 100 + (nT - 1)10$
Post-anaesthesia recovery	10	$Q = 10 + (n - 1)6$
Maternity Department:		
LDRP Rooms:		
Mother	10	$Q = 10 + [(n - 1)6/3]$
Baby	10	$Q = 10 + [(n - 1)3/2]$
Operating Theatre Suite:		
Anaesthetist	100	$Q = 100 + (n - 1)10$
Paediatrician, baby resuscitation	10	$Q = 10 + [(n - 1)6/2]$
Post-anaesthesia recovery	10	$Q = 10 + [(n - 1)6]$

Table 13: Oxygen: design and diversified flows

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Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
In-patient accommodation:		
Single/multi-bed wards	10	Q = 10 + [(*n* – 1)6/4]
Nursery, per cot space	10	Q = 10 + [(*n* – 1)3/2]
Neonatal unit (SCBU)	10	Q = 10 + (*n* – 1)6
Radiological:		
All anaesthetic and procedures rooms with nitrous oxide for anaesthetic purposes	100	Q = 100 + [(*n* – 1)6/3]
Without nitrous oxide	10	Q = 10 + [(*n* – 1)6/3]
Recovery per bed	10	Q = 10 + [(*n* – 1)6/4]
Critical Care Areas: Including Intensive Therapy Unit (ITU), Coronary Care (CCU), High Dependency (HDU), Burns Unit.	10	Q = 10 + [(*n* – 1)6]
CPAP ventilation*	75	Q = 75n x 75%
Renal	10	Q = 10 + [(*n* – 1)6/4]
Adult mental illness accommodation:		
Electro-convulsive therapy (ECT) room	10	Q = 10 + [(*n* – 1)6/4]
Post-anaesthesia recovery per bed space	10	Q = 10 + [(*n* – 1)6/4]
Adult acute day care accommodation:		
Treatment rooms	10	Q = 10 + [(*n* – 1)6/4]
Post-anaesthesia recovery per bed space	10	Q = 10 + [(*n* – 1)6/4]
Day patient accommodation		As “In-patient accommodation”
Oral surgery/orthodontic:		
Consulting rooms, type 1	100	Q = 100 + [(*n* – 1)10/2]
Consulting rooms, types 2&3	10	Q = 10 + [(*n* – 1)6/3]
Recovery room, per bed space	10	Q = 10 + [(*n* – 1)6/6]
Out-patient: Treatment rooms	10	Q = 10 + [(*n* – 1)6/4]
Equipment service rooms, sterile services etc.	100	No additional flow

Table 13 (cont’d): Oxygen: design and diversified flows

Note 9: The main branch line to a department or floor should only allow for 1 oxygen flush of 100 litres/min.

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Legend for Tables 13-21:

Q = diversified flow for the department;

Q_w = diversified flow for the ward;

Q_d = diversified flow for the department (comprising two or more wards);

n = number of beds, treatment spaces or single rooms in which the clinical procedure is being performed, not the individual numbers of terminal units where, in some cases, more than one is installed;

*n*S = number of operating suites within the department (anaesthetic room and operating room);

*n*W = number of wards;

*n*T = number of theatres.

Hyperbaric oxygen chambers

4.26 Hyperbaric oxygen chambers should be supplied from a separate branch from the main riser/ distribution pipe. The pipeline system should be from a liquid supply source. Typical flows for a single patient chamber are as shown in Table 14.

	Max. time for one complete treatment	Total consumption for max. treatment time (litres)	Consumption for each additional minute (litres/min)
O_2 atmosphere and recirculation:			
On open circuit	2 hours	30,000	250
On recirculation	2 hours	7,250	40
O_2 only, no recirculation	2 hours	30,000	250
O_2 delivery by built-in breathing mask and overboard pump	2 hours	1,200	10
O_2 delivery by built-in breathing hood and overboard pump	2 hours	7,250	60

Table 14: Gas flow – hyperbaric chambers

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Notes: a) The flows for a recirculating unit assume the standard method of operation is recirculation throughout the treatment. It is recommended that the pipeline should be designed for open circuit operation to ensure adequate flow under all conditions.

b) Clinical practice may require the inclusion of air during the treatment. It may also be necessary to switch to air in the unlikely event of an oxygen convulsion. Therefore consideration should be given to the provision of medical air from a separate dedicated medical air plant in accordance with Chapter 7.

c) Some hyperbaric chambers use air as a buffer and consequently less oxygen is consumed. The advice of the manufacturer should be sought. Where this is the case, the air should be supplied from a separate supply system complying with the requirements for medical air systems.

Nitrous oxide

4.27 Nitrous oxide is provided for anaesthetic purposes and occasionally for analgesic purposes. In all cases, each terminal unit should be capable of passing 15 litres/min, but in practice the flow is unlikely to exceed 6 litres/min.

4.28 When calculating diversities in a department, 15 litres/min is allowed for the first outlet and 6 litres/min for the remainder, subject to the appropriate diversity factor being applied (see Table 15).

4.29 It is assumed that, for an operating department, nitrous oxide may be in use simultaneously in all operating rooms. As it is unlikely that a patient would be anaesthetised in the anaesthetic room at the same time that a patient in the associated operating room was continuing to be treated under an anaesthetic (and because the duration of induction is short), no additional flow is included.

Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
Accident & Emergency: Resuscitation room, per trolley space	15	Q = 15 + [(*n* – 1)6/4]
Operating rooms	15	Q = 15 + (*n*T – 1)6
Anaesthetic rooms as part of an Operating suite	15	No additional flow included
Maternity: Operating rooms	15	Q = 15 + (*n*T – 1)6
Radiology	15	Q = 15 + [(n – 1)6/4]
Critical care areas	15	Q = 15 + [(*n* – 1)6/4]
Oral surgery/orthodontic: Consulting rooms, type 1	15	Q = 15 + [(*n* – 1)6/4]
Other departments	15	No additional flow included
Equipment service rooms	15	No additional flow included

Table 15: Nitrous oxide: design and diversified flows

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Nitrous oxide/oxygen mixture

4.30 All terminal units should be capable of passing 275 litres/min for a very short period (normally of five seconds' duration) to supply inhalationary "gasps" by the patient, and a continuous flow of 20 litres/min. The actual flow would not normally exceed 20 litres/min.

4.31 The diversified flow in LDRP rooms is based on 275 litres/min for the first bed space and 6 litres/min for each of the remainder, of which only half of the women in labour will be using gas. (The peak inhalationary "gasp" is 275 litres/min, whereas the respirable minute volume will be catered for with a flow of 6 litres/min – it should also be borne in mind that a woman in labour would not continuously breathe the analgesic mixture.) For larger maternity departments with nine or more LDRP rooms, two peak inhalationary "gasps" are included.

4.32 Nitrous oxide/oxygen mixture may be used in other areas for analgesic purposes. The diversified flow is based on 20 litres/min for the first treatment space, and 6 litres/min for a half of the remainder.

4.33 Design and diversified flows for nitrous oxide/ oxygen mixtures are given in Table 16.

Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
Maternity:		
<9 LDRP room(s), mother	275	Q = 275 + [(n – 1)6/2]
≥9 LDRP rooms	275	Q = 275 x 2 + [(n – 1)6/2]
Other areas	20	Q = 20 + [(n – 1)6/2]
Equipment service rooms	275	No additional flow included

Table 16: Nitrous oxide/oxygen mixtures – design and diversified flows

Air

4.34 Air is used to provide power for several types of equipment including surgical tools, ventilators and nebulisers. Oxygen should be avoided as a power source because of fire risk and cost, and should not be used where medical air is available, unless specifically recommended by the device manufacturer.

4.35 Air should be provided at two different pressures but to the same Ph. Eur. Standard:

- a pressure of 400 kPa is required for medical air to drive ventilators and for other respiratory applications;
- a pressure of 700 kPa or higher is required for surgical air to drive surgical tools.

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Medical Air 400 kPa

General

4.36 The use of medical air, particularly for respiratory use and during anaesthesia, has increased markedly in recent years. This service is the most critical of the medical gas services, since air-powered ventilators cease to operate in the event of failure of the supply.

4.37 Medical air is also directly inhaled by patients during ventilation. It may also be used to dilute oxygen before administration because of the potentially toxic effects of pure oxygen.

4.38 The supply system for medical air 400 kPa may be a manifold system, a compressor system or a proportioning system (synthetic air), and normally includes an emergency reserve manifold. A compressor plant, or synthetic air supply, should always be specified where air-powered ventilators are to be used.

4.39 One of the major uses of medical air is for patients' ventilators, which fall into two main categories comprising those used during anaesthesia and those used during critical care. Pneumatically-powered ventilators can use up to 80 litres/min free air continuously. The exact flow requirements will depend on the design of the ventilator. The flow and pressure requirements for some typical ventilators are given in Table 17.

4.40 Current models of anaesthetic ventilator are very similar to critical care models, and may require peak flows of up to 80 litres/min and average flows of 20 litres/min. Almost all such units are pneumatically driven and electronically controlled.

4.41 Medical air 400 kPa is also used for other equipment such as anaesthetic gas mixers, humidifiers and nebulisers. The flow rate normally required would not exceed 10 litres/min, and this flow is always in excess of the actual volume respired.

Pressure requirements

4.42 A minimum pressure required at terminal units for respiratory use is 355 kPa.

4.43 Medical air should not be used to supply mechanical services (see paragraph 7.131).

4.44 Some medical gas pendants use the medical air supply for operating the control/retraction system. This is permitted, provided that:

- a flow limiting device is provided to protect the medical air system in the event of failure of any downstream component;
- a non-return valve is incorporated to protect the system integrity;
- appropriate AVSU arrangements are in place (see Section 3).(The surgical air supply should be used to provide the power source whenever possible.)

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4.45 The flow requirements should be ascertained and taken into account prior to the installation of the equipment.

Flow requirements

4.46 Flow requirements for medical air are given Table 18. In ward areas and treatment rooms, the use of medical air is most likely to be for nebulisers. In these areas they should be capable of passing 20 litres/min, although typically 10 litres/min will be required in in-patient accommodation where air is used for nebulisers.

Ventilator type	Pressure (kPa)	Flow (litres/min)
Anaesthesia, typically gas-driven, electronically controlled	Nominally 400. Max 600(1)	Pneumatically driven ventilators use up to 80 max. 20 continuous
Critical care, electrically controlled, gas-powered	Nominally 400. Max 600(1)	180 peak (2) 80 continuous
Neonatal, gas-driven, electronically controlled	Nominally 400. Max 600(1)	80 peak(2) 40 continuous
Nebulisers	400	10

Table 17: Typical pressure and flow requirements for ventilators and nebulisers

Notes applicable to Table 17:

(1) It is strongly recommended that ventilators are not connected to the 700 kPa system since blenders only work satisfactorily with a tolerance of about 10%: with high differential pressures for air and oxygen an incorrect mixture could be obtained.

(2) These flows can be achieved under certain clinical conditions. The peak flows are usually of very short duration.

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Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
In-patient accommodation (ward units):		
Single / 4-bed and treatment rooms[1]	20	$Q_w = 20 + [(n - 1)10/4]$
Ward block/department		$Q_d = Q_w[1 + (nW - 1)/2]$
Accident & Emergency Department:		
Resuscitation room, per trolley space	80	$Q = 80 + [(n - 1)80/2]$
Major treatment room	40	$Q = 40 + [(n - 1)40/4]$
Plaster room, per trolley space	40	$Q = 40 + [(n - 1)40/4]$
Post-anaesthesia recovery, per trolley space	40	$Q = 40 + [(n - 1)40/4]$
Operating Theatre Department:		
Anaesthetic rooms	40	No additional flow included
Operating rooms	40	$Q = 40 + [(nT - 1)40/4]$
Post-anaesthesia recovery	40	$Q = 40 + [(n - 1)40/4]$
Maternity Department:		
LDRP rooms: Baby[2]	40	$Q = 40 + [(n - 1)40/4]$
Operating suites:		
Anaesthetist	40	$Q = 40 + [(n - 1)40/4]$
Paediatrician (baby resuscitation)	40	$Q = 40 + [(n - 1)40/4]$
Post-anaesthesia recovery	40	$Q = 40 + [(n - 1)40/4]$
In-patient accommodation:		
Ward units	20	As In-patient ward units
Neonatal unit (SCBU)	40	$Q = 40n$
Radiological Department:		
All anaesthetic and procedures rooms	40	$Q = 40 + [(n - 1)40/4]$
Recovery per bed	40	$Q = 40 + [(n - 1)40/4]$
Critical care areas[3] (ITU, ICU, CCU, HDU, Burns)	80	$Q = 80 + [(n - 1)80/2]$
Renal	20	$Q = 20 + [(n - 1)20/4]$
Adult mental illness accommodation:		
Electro-convulsive therapy (ECT) room	40	$Q = 40 + [(n - 1)40/4]$
Post anaesthesia per bed	40	$Q = 40 + [(n - 1)40/4]$
Adult acute day care / day patient accommodation:		
Treatment rooms (optional air requirement)	20	$Q = 20 + [(n - 1)20/8]$
Post anaesthesia recovery per bed (optional air requirement)	40	$Q = 40 + [(n - 1)40/4]$
Endoscopy (optional air requirement)	40	$Q = 40 + [(n - 1)40/4]$
Oral surgery/orthodontic:		
Major dental/oral surgery rooms	40	$Q = 40 + [(n - 1)40/2]$
Recovery	40	$Q = 40 + [(n - 1)40/4]$
All other departments	40	No additional flow allowance to be made
Equipment service rooms (sterile services etc.)	40	No additional flow included

Table 18: Medical Air 400 kPa – design and diversified flows

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Notes applicable to Table 18:

(1). It is assumed that a patient will use oxygen / air in a ward or in the treatment room.

(2). Where two cot spaces have been provided in an LDRP room, assume only one will require medical air.

(3). This diversified flow is also used for helium / oxygen mixture (see paragraph 4.70).

Surgical Air 700 kPa

4.47 The pressure requirements of surgical tools are between 600 and 700 kPa and flows may vary between 200 and 350 litres/min (STP; see Table 19). Most surgical tools are designed to operate within this pressure range. Higher pressures are likely to cause damage to tools. Inadequate tool performance, however, is likely to result from the lack of flow at the specified pressure.

4.48 The introduction of synthetic air (from on-site blending of oxygen and nitrogen) leads to the possibility of using nitrogen as the power source for surgical tools.

4.49 The pipeline systems should be designed to provide a flow of 350 litres/min at 700 kPa at the outlet from the terminal unit. Existing systems may not meet this requirement (but should be capable of delivering 250 litres/min at the terminal unit).

Note 11: Some surgical tools require up to 500 litres/min at up to 1,400 kPa. These will require a separate supply, normally from cylinders.

Dual pressure surgical air systems

4.50 In many instances, particularly where multi-movement pendants have been installed, a 10 bar system is insufficient to overcome the inherent pressure losses within such units in addition to the standard losses which can occur over the desiccant dryer / filtration unit, the tolerances required across the regulator and the pipeline pressure loss. To ensure the flow requirements can be met, the compressed air plant should be capable of 13 bar operation.

4.51 Guidance is given on the pressure requirements of alternative methods of control:

- a single plant pressure reduction system that maintains all control within the plantroom and can be simply adjusted once the actual pressure losses are established following a system performance check;
- removal of the NIST check valve, which can vary in pressure loss per pendant, would assist in standardizing the pressure loss within a single regulated system. In the event that the check valve is removed, permanent labelling will be required at the NIST to indicate this. An additional Line Valve should be provided to allow maintenance;

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- a double pressure reduction system with the second stage pressure regulator locally sited to each operating room or group of rooms. Some thought should be given to the siting of the regulator avoiding the easy option of installing within the ceiling void which is not easily accessible for maintenance or where entry to the void is hygienically unacceptable.

4.52 In each instance some fine adjustment of the regulators may be required to ensure 700 kPa @ 350 litres/min. flow at the terminal unit outlets. This requirement would most certainly be required at the emergency reserve manifold, the degree depending on it's location in the event of a fault condition arising. In both cases, there is a likelihood of static pressure under no flow conditions above 900 kPa at the terminal unit, therefore it is essential that nurse training covers the engagement and removal of probes at point of use.

Diversity

4.53 Surgical air 700 kPa is only required where surgical tools are to be used. This would typically involve orthopaedic and neurosurgery operating rooms, and, possibly, plaster rooms. For flexibility, and to allow for possible overspill, surgical air should be extended to two to four adjacent operating rooms. It is not required in maternity or ophthalmology operating rooms. The diversified flow is based on the assumption of 350 litres/min for the first theatre and a quarter of the remainder when there are more than four operating rooms (see Table 20).

Note 12: Scottish Health Technical Memorandum 2022, Supplement 1: 'Dental compressed air and vacuum systems' allows for the extension of surgical air into dental departments for tool use only.

4.54 Unlike dental departments, the use of surgical tools in an operating procedure takes place for a limited period of time.

Type of tool	Pressure (kPa)	Flow (litres/min)
Small air drill	600-700	200
Medullary reaming machine	600-700	350
Oscillating bone saw	600-700	300
Universal drill	600-700	300
Craniotome	620-750	300

Table 19: Typical pressure and flow requirements for surgical tools

System capacity

4.55 Unlike respirable equipment, surgical tools are used intermittently, typically for a few seconds, up to a maximum of three minutes.

Terminal units intended for equipment testing

4.56 It may be necessary to provide surgical air at 700 kPa in the equipment service workshop for testing purposes. Unless a surgical air 700 kPa pipeline is available nearby, it may be cost-effective to use portable cylinders, with a two-stage regulator.

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4.57 If a pipeline supply is to be provided, each terminal unit should be capable of delivering 350 litres/min. Where several terminal units are provided, it is unlikely that more than one terminal unit will be in use at any time, and therefore the total design flow for the equipment service workshop will be 350 litres/min.

Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
Operating room (orthopaedic and neurosurgical operating rooms only):		
≤4 operating rooms	350	Q = 350 + [(*n* – 1)350/2]
>4 operating rooms	350	Q = 350 + [(*n* – 1)350/4]
Other departments, e.g. equipment workshops, fracture clinic	350	Q = 350
Equipment service rooms	350	No additional flow required

Table 20: Surgical Air 700 kPa – design and diversified flows

Vacuum

General

4.58 In virtually all cases, vacuum is used via a suction control device and fluid is collected in suction jars. On wards these are typically of approximately 1 litre capacity. In operating rooms, two or four 2–3 litre capacity vessels are provided for the suction control regulator.

4.59 Once full, suction jars have to be emptied. Therefore, vacuum cannot be applied continuously.

4.60 The greatest generation of fluid to be aspirated is likely to arise in the operating room, particularly during orthopaedic surgery, where jet lavage to irrigate and cleanse the wound may be in use. The maximum rate of collection is about 4 litres/min, but it is not continuous.

4.61 During induction of anaesthesia, a patient may vomit. Therefore, it is essential that oral and nasal passages can be cleared as quickly as possible. The highest likely amount of fluid to be aspirated in this case will be no more than 0.5 litres.

4.62 In order to aspirate fluid, a suction cannula is normally used, and this will aspirate air as well as the fluid to be removed. The flow required, however, is higher than would be the case if fluid only were to be removed. The ratio of air/fluid aspirated will depend upon the diameter of the cannula.

In-patient accommodation

4.63 For a 28-bed ward unit comprising single rooms, four-bed rooms and a treatment room, the diversified flow is based on 40 litres/min.

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Medical supply units/bedhead trunking systems

4.64 When designing vacuum systems, it is expected that the greatest pipeline pressure losses will occur across the terminal units.

4.65 Care must be taken when sizing vacuum pipework within medical supply units with two or more bed/ treatment spaces, where availability of space will often limit the size of pipe. The largest size of pipe that can be accommodated (typically 22mm) should be used, as this will ensure that excessive pressure losses do not occur within the units. Such losses could necessitate the installation of larger diameter pipework within the rest of the system in order to ensure that the system pressure drops prescribed in this Scottish Health Technical Memorandum are not exceeded.

Operating departments

4.66 Vacuum is provided for the surgical team and anaesthetist in the operating room. It is also provided in the anaesthetic and recovery rooms.

4.67 Since it is possible for both the surgical team and anaesthetist to use vacuum simultaneously, each operating room will require 80 litres/min and each terminal unit should be capable of passing 40 litres/min (see Table 21).

4.68 As it is unlikely that a patient would be anaesthetised at the same time that a patient in the associated operating room was continuing to be treated under an anaesthetic, the need to clear an airway is extremely unlikely and no additional flow is included.

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Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
In-patient accommodation:		
Ward unit (single, 4-bed rooms, treatment room)	40	$Q_W = 40$
Multiple ward units	40	$Qd = Q_W + [(nW - 1)40/2]$
Accident & Emergency Department:		
Resuscitation room, per trolley space	40	$Q = 40 + [(n - 1)40/4]$
Major treatment room	40	$Q = 40 + [(n - 1)40/4]$
Plaster room, per trolley space	40	$Q = 40 + [(n - 1)40/4]$
Post-anaesthesia recovery, per trolley space	40	$Q = 40 + [(n - 1)40/4]$
Treatment room/cubicle	40	$Q = 40 + [(n - 1)40/8]$
Operating Theatre Department:		
Anaesthetic rooms	40	No additional flow included
Operating room:		
Anaesthetist	40	$Q = 40$
Surgeon	40	$Q = 40$
Operating suites	80	$Q_s = 80 + [(nS - 1)80/2]$
Post-anaesthesia recovery	40	$Q = 40 + [(n - 1)40/4]$
Maternity Department:		
LDRP rooms:		
Mother	40	$Q = 40 + [(n - 1)40]/4$
Baby	40	No additional flow included
Operating suites:		
Anaesthetist	40	$Q = 40 + [(n - 1)40/4]$
Obstetrician	40	$Q = 40 + [(n - 1)40/4]$
Paediatrician	40	No additional flow
Post-anaesthesia recovery	40	$Q = 40 + [(n - 1)40/4]$
In-patient accommodation:		
Ward unit (single, 4-bed rooms, treatment room)		
Multi-ward units		$Q = 40$
Nursery, per cot space	40	
Neonatal unit (SCBU)	40	$Q = 40 + [(n - 1)40/2]$
	40	No additional flow
	40	$Q = 40 + [(n - 1)40/4]$
Radiology/diagnostic departments:		
All anaesthetic and procedures rooms	40	$Q = 40 + [(n - 1)40/8]$
Recovery per bed	40	$Q = 40 + [(n - 1)40/4]$
Critical care areas		
(ITU, ICU, CCU, HDU, Burns)	40	$Q = 40 + [(n - 1)40/4]$
Renal		
Day care (out-patients) plus treatment	40	$Q_d = 40 + 40$
Acute services (in-patients)	40	$Q_d = 40 + [(n - 1)40/4]$

Table 21: Vacuum – design and diversified flows

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Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
Adult mental illness accommodation:		
ECT room	40	Q = 40 + [(*n* – 1)40/4]
Post-anaesthesia, per bed space	40	Q = 40 + [(*n* – 1)40/4]
Adult acute day care accommodation:		
Treatment rooms	40	Q = 40 + [(*n* – 1)40/4]
Post-anaesthesia recovery per bed space	40	Q = 40 + [(*n* – 1)40/4]
Stage 1 Recovery	40	Q = 40 + [(*n* – 1)40/8]
Endoscopy	40	Q = 40 + [(*n* – 1)40/4]
Day patient accommodation (as "In-patient accommodation")		As "In-patient accommodation"
Oral surgery/orthodontic:		
Consulting rooms, type 1	300	Dental vacuum only
Consulting rooms, types 2 & 3	300	Dental vacuum only
Recovery room, per bed space	40	Q = 40 + [(*n* – 1)40/8]
Out-patient:		
Treatment rooms	40	Q = 40 + [(*n* – 1)40/8]
All other departments	40	No additional flow
Equipment service rooms	40	No additional flow

Table 21 (cont'd): Vacuum – design and diversified flows

Helium/oxygen mixture

4.69 Helium/oxygen mixture is used by patients with respiratory or airway obstruction and to relieve symptoms and signs associated with respiratory distress. It can be administered by means of a face mask, a demand valve with face mask, a nebuliser, or a ventilator.

4.70 Pipeline supply will be primarily limited to critical care areas, where the gas mixture is used for driving a ventilator. The design and diversified flows should be based on the figures given for medical air (see Table 17).

4.71 Helium/oxygen mixtures administered by means of a face mask and cannula, a demand valve with face mask and cannula attached, or a nebuliser, are normally supplied using cylinders fitted with an integral valve.

Anaesthetic gas scavenging systems

4.72 For anaesthetic gas scavenging systems, it should be assumed that for each operating suite two terminal units could be in use simultaneously, for example in the anaesthetic room and operating room (receiving systems may be left connected when patients are transferred from the anaesthetic room to the operating room). The diversified flows for other departments are as given in Table 22.

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Department	Design flow for each terminal unit (litres/min)	Diversified flow Q (litres/min)
Accident & Emergency resuscitation room (per trolley space)	V(1)	Q = V + [(*n* – 1)V/4]
Operating Theatre departments Operating room and anaesthetic room Recovery rooms	 V(1) V(1)	 Q = 2VnT Q = V + [(*n* – 1)V/4]
Maternity operating suites	V(1)	Q = 2VnT
Radiological (all anaesthetic and procedures room)	V(1)	Q = V + [(*n* – 1)V/4]
Oral surgery/orthodontic consulting rooms (type 1)	V(3)	Q = V + [(*n* – 1)V/4]
Other departments	V(1)	Q = V + [(*n* – 1)V/8]

Table 22: Anaesthetic gas scavenging – design and diversified flows

Notes applicable to Table 22:

(1). For the purpose of sizing the AGS disposal system pump, V is taken as either 130 litres/min or 80 litres/min (see paragraph 10.16).

(2). The AGS flow rate should be advised by the clinicians, in absence of such information, 130 litres/min should be used.

(3). With nasal mask application, flow is 45 litres/min.

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5. Cylinder manifold installations

5.1 A cylinder manifold installation consists of an automatic manifold control system and manual emergency reserve manifold.

Automatic manifold control system

5.2 The primary and secondary supplies are provided by two banks of equal numbers of gas cylinders which are connected to the pipeline via a control panel. The changeover from the “duty” to the “stand-by” bank of cylinders should be automatic. The reserve supply is provided via a manual emergency reserve manifold. All manifolds should be capable of passing the full pipeline flow. The temperature of the gas may fall as low as –30°C as the gas passes through the regulator at maximum capacity, and the equipment should be designed accordingly. In the case of nitrous oxide and nitrous oxide mixtures it is advisable to specify control panel in-line heaters.

5.3 A schematic layout for a typical cylinder manifold system is shown in Figure 10. Total storage is usually provided on the basis of a risk assessment. Each bank of the manifold should have sufficient cylinders for two days’ use. Additional cylinders for one complete bank change should be held in the manifold room; for nitrous oxide/oxygen mixture, sufficient cylinders to change two banks should be held. Each cylinder bank should be capable of isolation of supply without individual cylinder valve closure in order to facilitate periodic testing in accordance with BS EN ISO 7396-1: 2007 + A2: 2010. Each cylinder bank should be capable of independent selection to facilitate maintenance activity, for example, via a control switch.

5.4 The nominal and usable capacities of the cylinders commonly used on manifolds are given in Table 23 (the figures are the equivalents at STP).

5.5 An automatic manifold changeover from duty to stand-by should occur at a cylinder pressure that will ensure the greatest possible utilisation of the contents of the cylinders in the duty bank. If the normal operation of the changeover control depends on an electricity supply, the design should be such that failure of the electricity supply does not disrupt the flow of gas to the distribution system. In some instances, it will be necessary to provide heaters on the manifold, e.g. for nitrous oxide or nitrous oxide/oxygen mixture. The heater should be selected by the manifold manufacturer to match the range of flows for which the manifold is designed to deliver. The heater should be provided in such a location to limit the build-up of ice on the regulator and to operate only during flow conditions.

Note 13: All systems should be designed so that both banks (duty and stand-by) supply gas in the event of a power failure.

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Gas	Nominal capacity (litres) at 137 bar	Usable capacity (litres)[1]
Oxygen J-size	6,800	6,540
Nitrous oxide: J-size G-size	 18,000 9,000	 8,900
Nitrous oxide/oxygen mixture G-size	5,000	4,740
Medical air J-size	6,400	6,220 (400 kPa) 5,550 (700 kPa)
Helium/oxygen mixture K-size	-	7,000 nominal

Table 23: Capacities of medical gas cylinders used on manifolds

Notes applicable to Table 23:

1. The usable figures are for discharge to a gauge pressure of 7 bar. Two sets of figures are provided for air – for 400 kPa systems and 700 kPa systems. The latter is for discharge to 15 bar.

2. Reference should be made to the respective supplier's data charts / sheets for further information.

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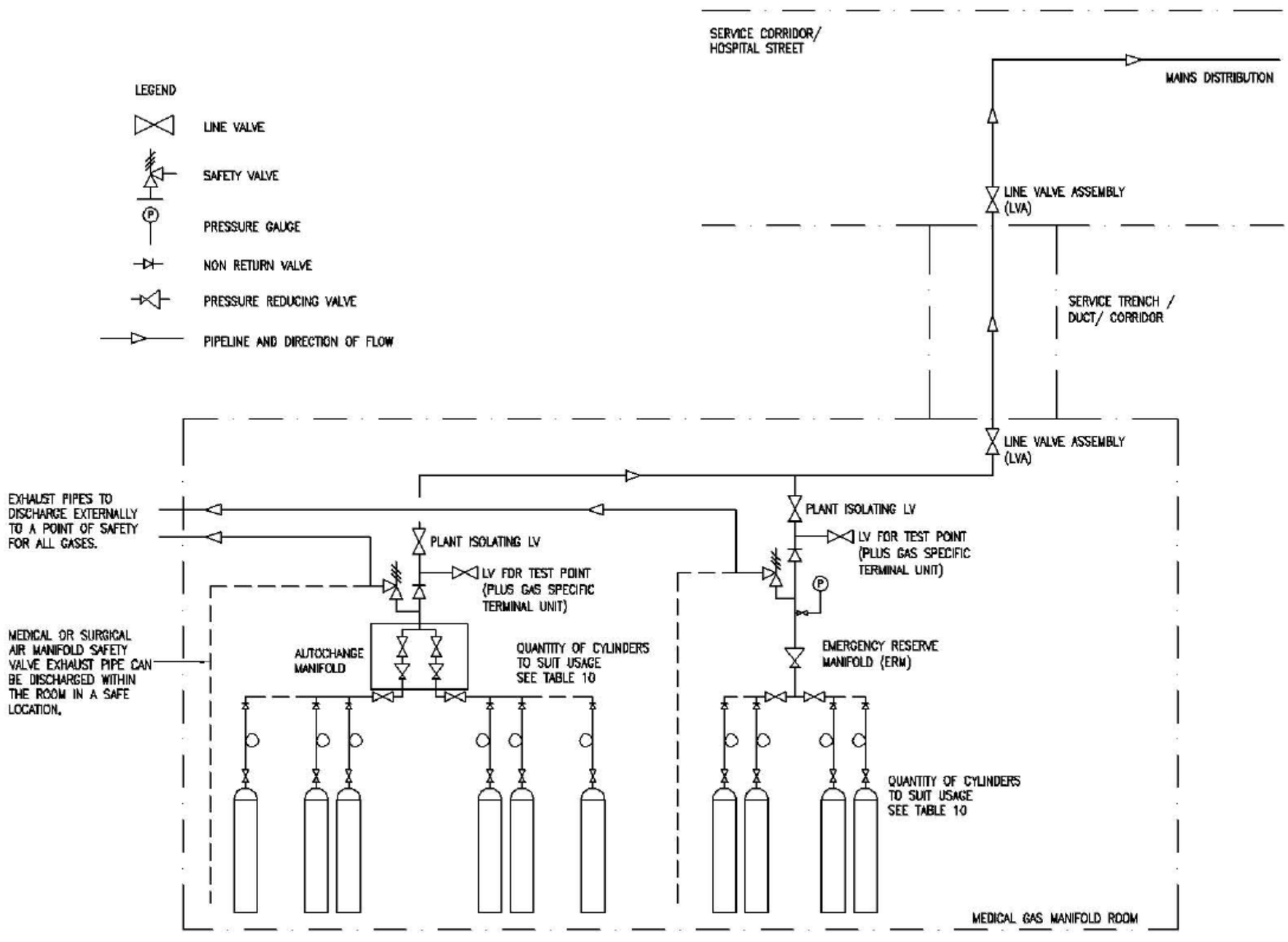

Figure 10: Typical automatic manifold arrangement with manual ERM

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5.6 In the event of power failure, when the power is restored, the original “running bank” should be on-line, that is, the same bank that was the “running bank” prior to interruption of the supply.

Note14: Some manifolds default to a specific bank following a power failure, regardless of which bank was the running bank prior to interruption of the supply. **NB:** Such units will require manual resetting to the original condition.

5.7 Manifolds and control panels should be designed and certificated for use with 230 bar cylinders. The manifold headers should incorporate a renewable non-return valve to prevent the discharge of a complete bank of cylinders in the event of “tail-pipe” rupture.

5.8 The tail-pipe cylinder connector must be a pin-index yoke connector in accordance with BS EN ISO 407: 2004 for oxygen, nitrous oxide/oxygen mixture (50% v/v) and medical air. Non-metallic flexible connectors shall not be used. The connector for nitrous oxide should be a side outlet valve connector in accordance with BS341-3: 2002. The manifold connectors should be in accordance with Table 24:

Thread	Medical gas
M24 x 2	Medical air
M22 x 2	N_2O/O_2
M20 x 2	O_2
M18 x 2	N_2O

Table 24: Cylinder valve thread sizes

Where it is necessary to use non-metallic materials, consideration should be given to the use of non-halogenated polymers in high pressure systems (>3,000 kPa) delivering oxygen or gaseous mixtures with oxygen concentrations greater than that in ambient air. Consideration should also be given to fitting sintered filters upstream of non-metallic materials to minimise the risk of particle collisions and impacts, which are a potential source of ignition. In addition, there are tests that should be conducted to ensure that the risk of ignition is minimised. Attention is drawn to BS EN ISO 15001: 2010.

Note 15: Studies have shown that inadvertent ignition of halogenated polymers can lead to highly toxic by-products being delivered to the gas stream.

5.9 Pressure indication should be provided to indicate pressure in each cylinder bank and in the MGPS.

5.10 The automatic manifold and ERM should be provided with a test point comprising lockable valve and terminal unit. This should be sited within the manifold room and positioned immediately upstream of the distribution pipeline isolating valve.

Pressure control

5.11 The pressure control should maintain the nominal pipeline pressure within the limits given in Section 4. High-pressure regulators should comply with BS EN

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ISO 10524-2: 2006 and be supplied with auto-ignition test results and regulator performance curves for each gas.

5.12 Separate pressure regulating valves should be provided for each cylinder bank. The control system should be designed so that the cylinders of one bank can be changed, or the pressure regulator or any component for one bank can be overhauled, without loss of continuity of the gas supply, refer to Figures 10 and 11 for provision of isolating valves.

5.13 Pressure safety valves should be of the self-closing type and be installed on each distribution pipeline downstream of the manifold line pressure regulator and upstream of the main isolation valve. A pressure safety valve should also be installed between the reserve supply and the pipeline distribution system. It should have a flow capacity at least equal to that of the pressure regulator immediately upstream of it. The discharge pipe should be at least one size larger than the main pipeline and be separate for each safety valve.

5.14 This discharge pipeline should be vented to atmosphere, outside the building, in an area where the discharge of oxygen, nitrous oxide, or nitrous oxide/oxygen mixture will not present a fire hazard or cause injury to personnel. Medical and surgical air may be vented internally normally terminating 50mm above finished floor level. Warning signs should be posted at the discharge positions; access for inspection should be provided.

5.15 Discharge pipelines should terminate at least 3m clear of any door/window that can be opened or other ventilation/air intake. The ends of the discharge pipelines should be turned downwards to prevent the ingress of dirt and moisture, and be placed and protected so that frost cannot form or be collected upon them. Similar safety valve arrangements are required for installations supplied from liquid oxygen cylinders.

Note 16: High pressure cylinders with integral pressure regulation can be used on manifold systems.

Manifold monitoring and indicating system

5.16 The monitoring and indicating system should perform the following functions:

- overall manifold monitoring;
- manifold condition indication;
- overall supply plant indication.

5.17 All functions should be appropriately identified. Indicators should have a design life of at least five years. The system should be capable of automatic reinstatement after restoration of the power supply.

5.18 Manifold monitoring, indicating and alarm systems should be on the essential electrical supply.

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Manifold control unit

5.19 The control unit should include a green “mains supply on” indicator.

Manifold monitoring

5.20 Each automatic manifold should be provided with monitoring to detect:

a) duty bank operating;

b) duty bank empty and stand-by bank operating;

c) stand-by bank below 10% capacity, when the duty bank is empty;

d) each emergency reserve manifold bank below nominal 14 bar (for nitrous oxide) and below 68/100 bar pressure for other gases (typically 50% of cylinder contents);

e) pipeline pressure faults outside the normal range.

Manifold indicator unit

5.21 There should be indicators to show the following conditions:

a) for each automatic manifold;

b) a green “running” indicator for each bank. This should display when the bank is supplying gas, irrespective of the pressure;

c) a yellow “empty” indicator for each bank when the running bank is empty and changeover has occurred;

d) a yellow “low pressure” indicator for each bank to be illuminated after changeover, when the pressure in the bank now running falls to the low pressure setting;

e) for each emergency reserve bank, a yellow indicator to be illuminated when the pressure in the bank falls below 14 bar for nitrous oxide or below 68/100 bar for other gases(typically 50% of cylinder contents)- this will require the use of separate pressure sensors – one for each bank);

f) for the pipeline distribution system, a red “low pressure” and a red “high pressure” indicator to be illuminated when the respective conditions occur.

Alarm signal status unit

5.22 The following indication of manifold conditions should be provided:

a) green “normal”: *normal*;

b) yellow “duty bank empty, stand-by running”: *change cylinders*;

c) yellow “duty bank empty, stand-by low”: *change cylinders immediately*;

d) yellow “emergency reserve bank low”: *reserve low*;

e) red “pipeline (high or low) pressure fault”: *pressure fault*.

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5.23 Conditions (b) to (e) in Paragraph 5.22 should be transmitted to the central alarm system. Where relays are used, they should be normally energised relays, which de-energise under fault conditions, with contacts having a minimum rating of 50 V d.c. and 50 mA. Volt-free, normally closed contacts rated at 50 V d.c. and 50 mA should be provided for transmission of conditions (b) to (e) to the central alarm system.

5.24 The panel can be incorporated into the manifold control unit or be a separate unit within the plantroom. If mounted separately, the cabling should be monitored for open/short circuit. In the event of such a cable fault, a red “system fault” lamp should be illuminated on the alarm signal status unit, together with the appropriate alarm condition.

Manifold management

5.25 Connections should be provided that allow monitoring of manifold alarm conditions (b) to (e) and manifold running for each “bank”. These connections should be Volt-free contacts normally closed for each condition having a minimum rating of 50 V d.c. and 50 mA. The building management system should not be used to control the manifold.

Emergency reserve manifold

5.26 An emergency reserve manifold system should be provided to form a reserve source of supply, for emergency use or to permit servicing or repair.

5.27 The supply should be designed to provide the design flow of the primary system. When such provision would result in more than ten cylinders on each bank, the additional cylinders should be held in the manifold rooms. A non-return valve and isolating valve should be installed immediately upstream of the reserve manifold connection to the pipeline distribution system.

5.28 The requirements for the emergency reserve supply capacity should be set out in the operational policy document; this should take into account the arrangements for the supply of cylinders and the flow that the system is required to provide. The gas supplier should be consulted.

5.29 The specific requirements will depend on the method of primary supply. Where this results in an unrealistic number of cylinders being kept on site, the operational policy should be set out, giving details of procedures to be followed in an emergency to ensure continuity of supply.

5.30 For large installations, it may be impractical to rely on a cylinder manifold system; thus, consideration should be given to either a bulk liquid or liquid cylinder emergency/reserve supply in the case of oxygen and for two or more compressed air plants sited separately for medical / surgical air applications.

5.31 The operational policy document should set out the location of emergency manifolds, cylinders etc and the action to be taken in the event of loss of the primary source of supply.

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Emergency reserve supply for manifold installations

5.32 The reserve supply system for cylinder manifold systems should normally be located in the manifold room adjacent to the automatic manifold. All cylinder valves should be permanently open so that gas is immediately available, but one of the manifold header isolating valves should be closed. A typical system is shown in Figure 10.

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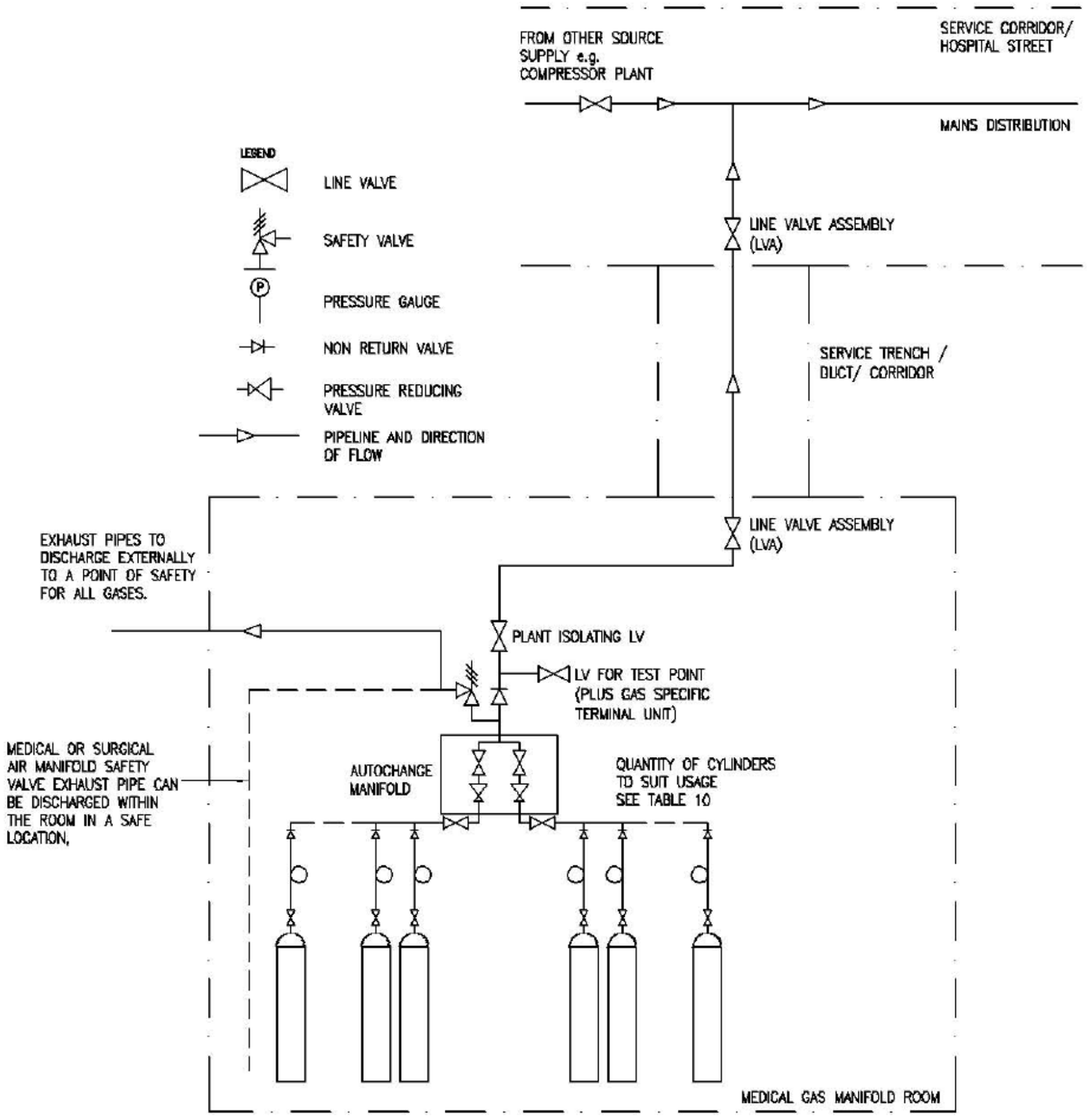

Figure11: Typical automatic changeover emergency reserve manifold for liquid oxygen and medical/surgical air plant

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5.33 The supply system should go into operation automatically via a non-return valve, and the emergency reserve manifold (ERM) isolating valve should remain open.

Reserve supply for air compressors/liquid oxygen/oxygen concentrators (PSA)

5.34 The supply should comprise a two-bank fully-automatic manifold system as described in paragraphs 5.1–5.24 (except for (d) in paragraph 5.20; (e) in paragraph 5.21; and (d) in paragraph 5.22, which do not apply). The manifold system(s) should be installed in an appropriate manifold room(s) separate from the plant. A typical system is shown in Figure 11.

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6. Oxygen systems

Liquid oxygen systems

General

6.1 Over the last ten years, there has been a significant increase in the use of medical oxygen for treating patients in healthcare facilities, with some hospitals seeing annual increases well in excess of 10%. The introduction of the European Standard on medical gas pipeline systems (BS EN 737) has also had implications. Parts 1-4 of BS EN 737 have since been replaced with the standards BS ENISO 9170 and BS EN ISO 7396. Refer to Part B Section 3 for further information.

6.2 The scope of the advice provided by this Section covers the supply of liquid oxygen to healthcare facilities from delivery into bulk storage vessels for the larger hospitals to the supply of liquid oxygen in liquid cylinders to hospitals with lower demands. The guidance given is intended to cover all the aspects of a bulk cryogenic liquid system commonly known as a vacuum insulated evaporator (VIE).

6.3 This chapter also covers the supply of medical oxygen from on-site generation using PSA plant, or in medical cylinders, other than (in the case of the latter) as a means of back-up to the main supply system.

6.4 It does not specifically cover bulk liquid nitrogen installations, but its principles may be applied to hospitals where these gases are used in sufficient quantities to make the use of a VIE cost-effective.

6.5 Significant changes since publication of Scottish Health Technical Memorandum 2022: 2001 include:

- the use of risk assessment as a tool to assist in the development of the medical oxygen installation;
- adoption of the principles outlined in BS EN 737-3: 2000 / BS EN ISO 7396-1: 2007 + A2: 2010;
- new methods of sizing the medical oxygen vessels and back-up manifolds;
- designation of vessel contents as “operational” or “reserve” stock.

A checklist for planning and upgrading an oxygen system is given in Appendix H.

Risk assessment

6.6 Risk assessment is used to assist in the development of the medical oxygen installation to produce a safe and practical design and ensure that a safe supply of oxygen is available for patient use at all times. It is used for all aspects of the process; from the initial concept designs through installation and operation to the routine assessment of the installation, once in service.

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6.7 Advice is given on setting up risk assessment teams and choosing the correct mix of personnel to ensure that all aspects of the associated risks are considered.

6.8 Throughout this section, non-exclusive risk criteria lists are provided to assist these teams in identifying the unacceptable risks and suggesting how they might be addressed. It recommends that annual risk assessments are carried out throughout the life of the system to ensure that a safe system of supply is maintained and any new risks are identified.

6.9 The prime responsibility to ensure that adequate stocks of medical oxygen are available for patient use should remain firmly with the hospital's management team. However, the hospital may agree with its gas supplier or facilities management supplier that they should manage the supplies of medical oxygen and maintain adequate stocks in the vessel. These arrangements should be clearly documented within the MGPS operational policy and procedures document. The effectiveness of these arrangements will need to be assessed as part of the risk assessment review and be validated to ensure that they can be met.

6.10 Consideration should be given to the operational management consequences of using different suppliers to supply medical oxygen to different supply systems on the same pipeline system.

6.11 Any contracts involving different suppliers should clearly state the obligations and limitations of liabilities; and any facilities management agreement between the hospital and the medical gas supplier must define the responsibilities of each party.

6.12 There must be no modification to the design or any part of the medical liquid oxygen system without written authorisation from the gas supplier.

6.13 This guidance adopts the principles outlined in BS EN ISO 7396-1: 2007 + A2: 2010 'Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum' which introduces to the UK the concept of having three sources of supply for medical gas systems. This is covered in Section 2.

New methods of sizing

6.14 New methods of sizing the medical oxygen vessels and back-up manifolds are covered, together with advice on appropriate location of vessels on site using principles of risk assessment. This ensures the provision of a secure source of supply that reflects the degree of risk associated with the hospital's location and its level of dependency on medical oxygen.

Designation of vessel contents as "operational" or "reserve" stock

6.15 The operational stock is the volume of product that the gas supplier uses to manage deliveries to the hospital; when this stock is exhausted, the vessel should be refilled under normal conditions.

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6.16 The reserve stock is the volume of product that is used to provide additional stock to take account of fluctuations in demand or when the supplier fails to make a scheduled delivery.

6.17 Both operational and reserve stock levels are calculated using the risk assessment principles embodied within this document (see Figures 12–17).

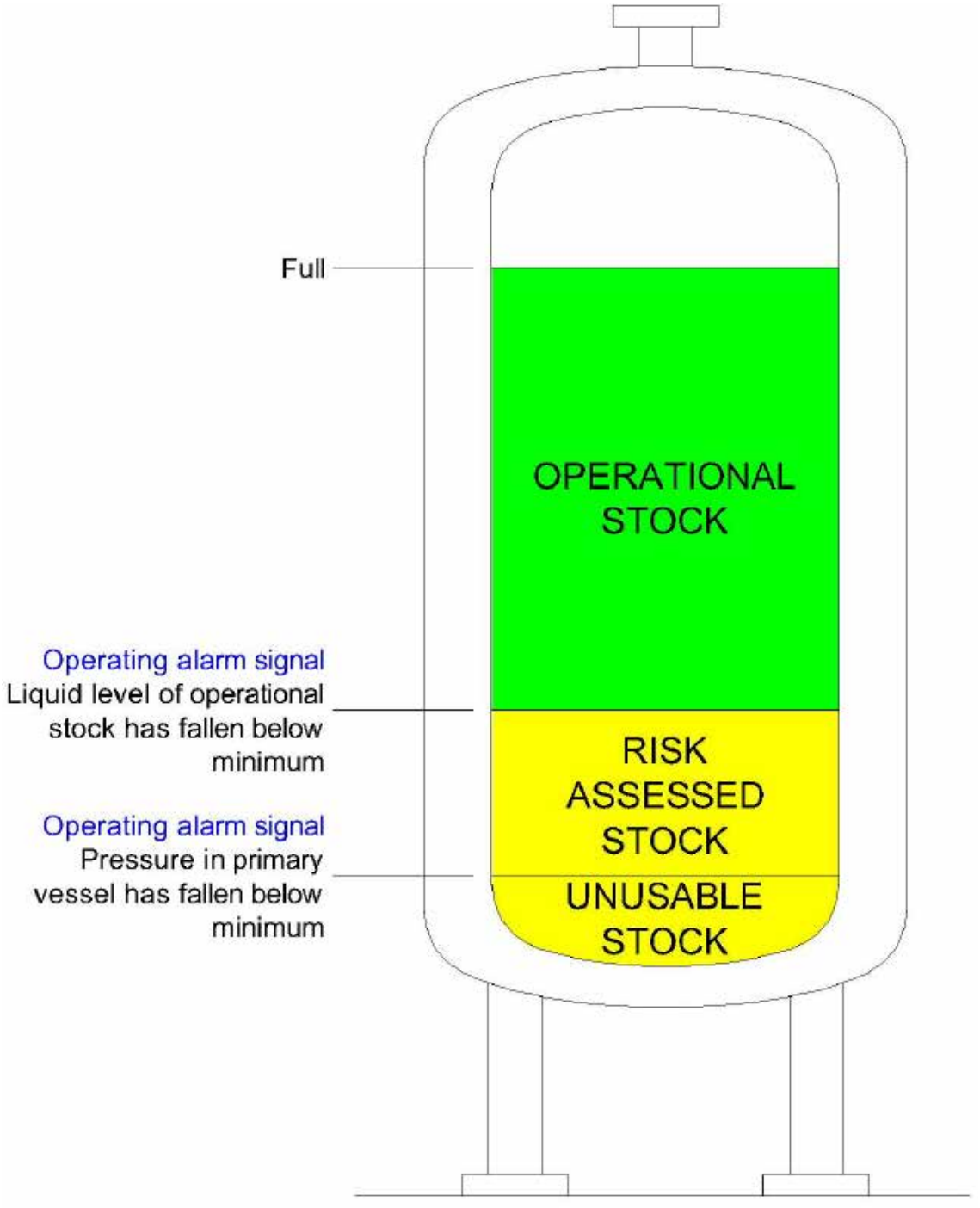

Figure 12: Primary supply (VIE)

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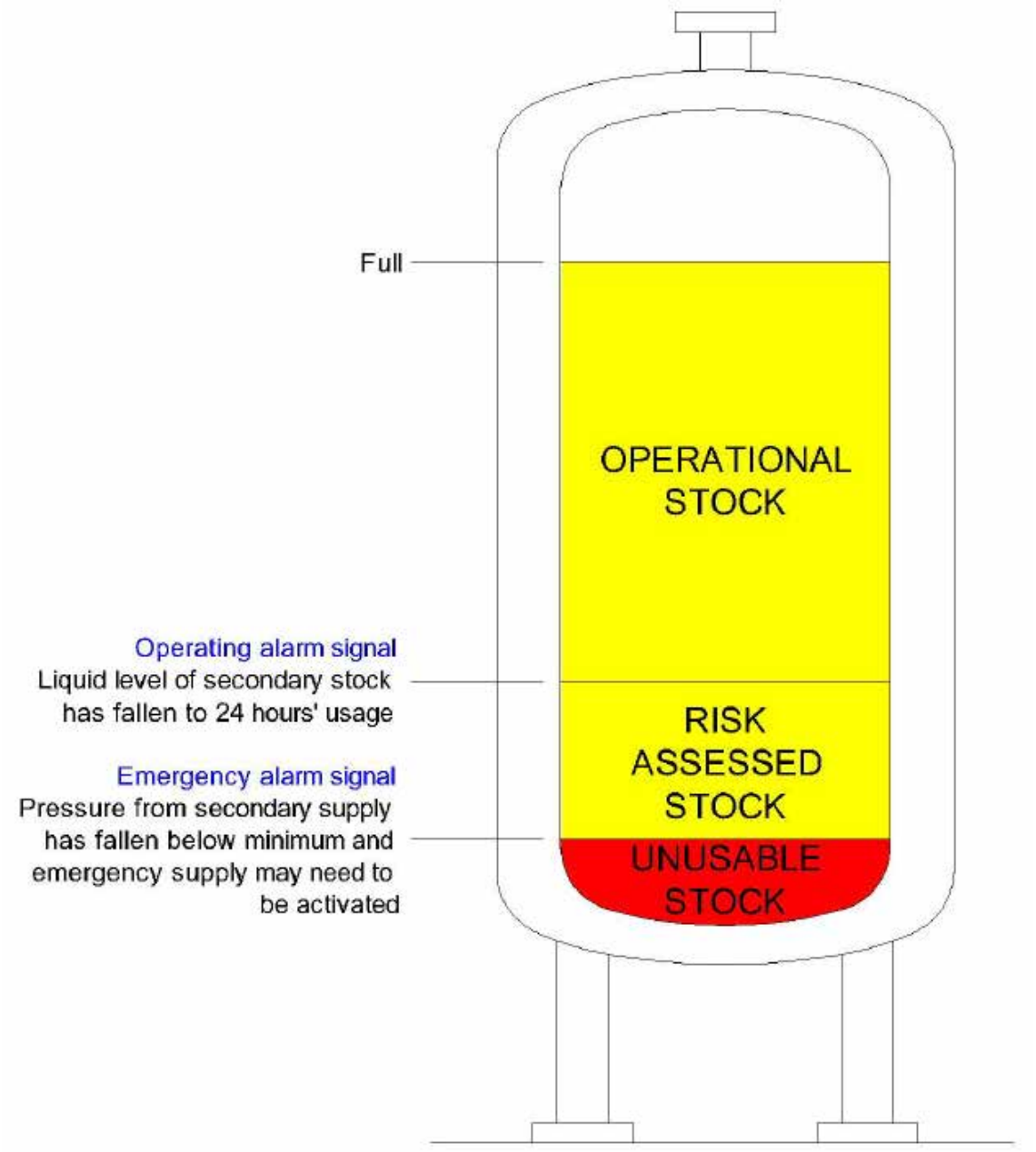

Figure 13: Secondary supply (VIE)

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Figure 14: Primary supply (liquid cylinder)

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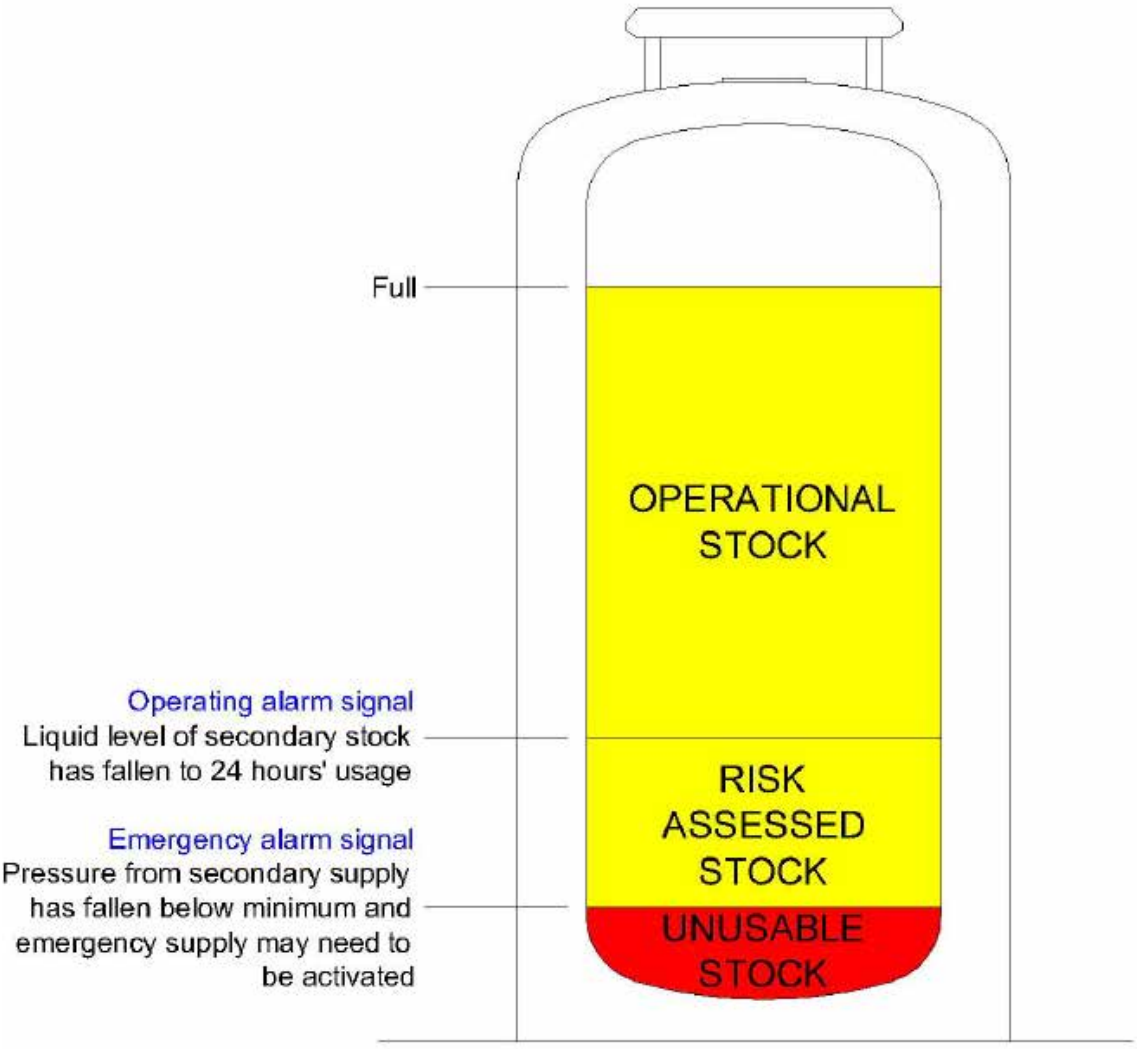

Figure 15: Secondary supply (liquid cylinder)

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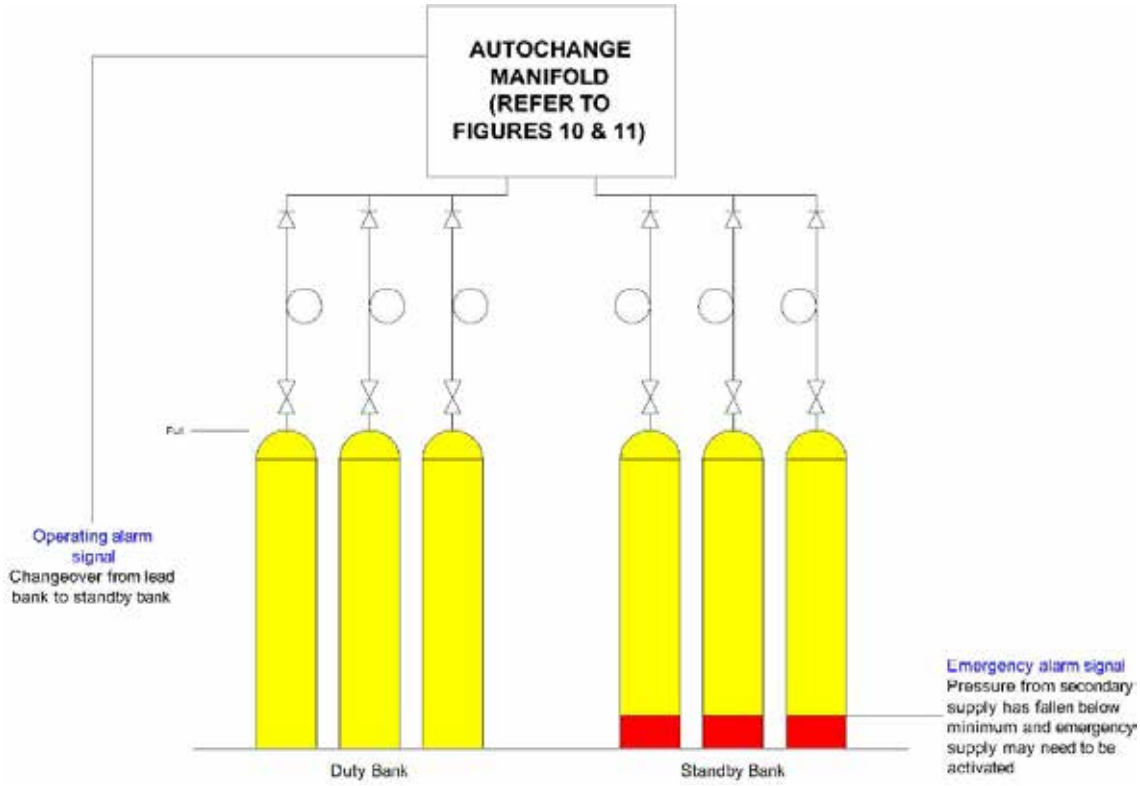

Figure 16: Secondary supply (gaseous cylinder)

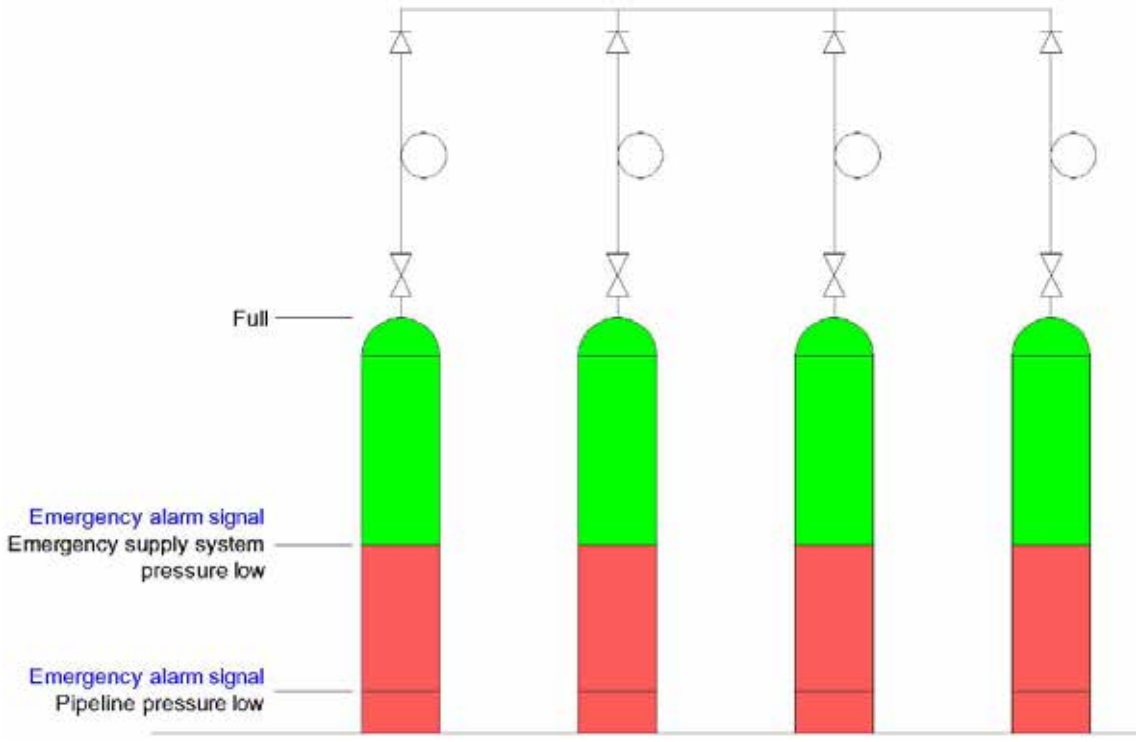

Figure 17: Secondary supply (liquid cylinder manifold)

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Choosing an oxygen supply system

6.18 When designing or reviewing an installation to supply medical oxygen to a hospital, the most appropriate method of supplying the gas will be determined by the potential size and variability of the hospital's medical oxygen demand.

6.19 To determine the most suitable and cost-effective method of supplying medical oxygen and the appropriate size of the installation, comprehensive demand figures should be provided to the designer.

6.20 These demand figures (prepared as a part of the risk assessment) should be based on:

- the current average daily gas usage based on the past twelve months' supplies;
- the maximum potential daily demand volumes based on peak flow conditions, as below;
- any planned extensions to the hospital/pipeline that may affect the demand;
- the expected natural annual growth in the use of medical oxygen.

Portable ultrasonic flowmeters for non-invasive pipeline measurement are a useful tool for arriving at average and peak demand flows.

6.21 The maximum potential daily demand should be based on the peak flow conditions measured between 8.00 am and 6.00 pm, with all operating rooms in use and with maximum demand being provided to pipeline outlets. It should not be based on the theoretical pipeline design flow conditions. Where actual flow monitoring is impracticable, daily cylinder or liquid consumption figures should be used.

Note 17: a) Control panels should be capable of passing the maximum design flow of the oxygen system's pipeline distribution system. This may necessitate installing two control panels in parallel.

b) Plant certification should be issued by the liquid oxygen supply company to demonstrate, on site, the capability of providing the maximum flow as determined as part of the risk assessment process of paragraphs 6.20 and 6.22 within the +/- 4% regulator tolerances required by this Scottish Health Technical Memorandum.

6.22 Additionally, historic consumption records should be reviewed to assess the current usage and the natural growth of the medical oxygen demand. The growth predictions should take into account any planned extensions to the hospital's facilities or pipeline systems and changes in clinical practices in the hospital that could affect the medical oxygen demand. Natural growth in usage of medical oxygen, due to changes in clinical practice, is about 8% to 10% per annum, but individual hospitals will need to establish this growth figure during the risk assessment process. Any planned extensions or estimated natural

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growth forming part of the risk assessment process should incorporate a pipeline distribution system reappraisal.

6.23 For new hospitals, where no historic information is available, the estimated demand should be based on the proposed size and type of the hospital and the usage figures of like facilities.

6.24 It is essential to review periodically the average daily demand with the gas supplier and agree either to revise delivery frequencies to maintain the operational stock levels or increase the size of the storage system on site. Any planned increase in demand due to hospital site developments, pipeline extensions or changes in clinical practice should be notified to the gas supplier to ensure that the changes do not jeopardise security of supply.

6.25 The medical liquid oxygen demand should be reviewed with the gas supplier at least annually (or after a significant extension to the pipeline causing increase in demand) to re-assess the size of the installation.

6.26 As the agreed stocks used for the supply of liquid oxygen are all based on an average daily demand, as the demand grows so the storage volume requirements will increase. With the increased volume requirements for the reserve stock, the volume available for operational stock will reduce. Having reviewed the average daily demand with the gas supplier, it is necessary to agree either revised delivery frequencies to maintain the operational stock levels or to increase the size of the storage system on site.

6.27 The review of the medical liquid oxygen installation should also include a review of the risk assessment to ensure that no other conditions on site have been changed that jeopardise the security of the gas supply.

6.28 For smaller hospitals, where the demand is typically below 3,000m^3 per annum, the most cost-effective method of supplying medical oxygen is from a compressed gas cylinder manifold.

6.29 As the demand increases, it becomes less practicable to use compressed gas cylinders and more cost-effective to use medical liquid oxygen. A cylinder manifold larger than 2 x 10 J cylinders is likely to prove impracticable because of the manual handling difficulties with the number of cylinders involved. Liquid cylinders, which are ideally suited to an annual consumption of between 3,000m^3 and 40,000m^3, can be connected together by a manifold to provide adequate storage capacity and flow rate.

6.30 For hospitals with larger demands, a bulk medical oxygen VIE will generally be used. There is a nominal overlap of annual consumption between 27,500m^3 and 40,000m^3, where either a bulk VIE or a liquid cylinder installation could be considered, either to satisfy a particular requirement, or to accommodate possible site restrictions.

6.31 The main benefit of using gas cylinders is that installation costs of manifold systems are significantly lower than those of a liquid oxygen system. However, the cost of the medical oxygen in compressed gas cylinders is higher than the

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cost of medical liquid oxygen (supplied either into liquid cylinders or into a VIE). As the demand grows, so the lower unit cost of the liquid oxygen offsets the higher installation costs of the liquid oxygen systems.

6.32 Cryogenic liquid systems are normally used where the demand is high enough to make bulk supplies cost-effective and where the demand makes cylinder supplies impracticable. The demand should be greater than the rate of heat loss to avoid pressure build up.

6.33 Liquid oxygen provides a flexible approach to both the size and the choice of installation design. Its provision is determined by factors such as the size of the hospital, the availability of space for both the installation and the delivery vehicle, the proximity of the gas supplier and the size of the demand for medical oxygen.

6.34 There are a number of operational benefits in using a medical liquid oxygen system over compressed gas cylinders, including:

- greater volume of medical oxygen stored on site;
- improved security of supply;
- reduced storage area for the medical gas cylinders;
- reduced manual handling requirements for cylinder handling.

6.35 When determining the cost-effectiveness of specific proposals from suppliers, the total supply costs should be assessed, including costs for the site preparation and vessel installation, vessel rental and liquid supply over the total period of the contract.

System configurations

6.36 In order to comply with the requirements of BS EN ISO 7396-1: 2007 + A2: 2010, it is necessary for all medical oxygen installations to have three independent supply sources capable of feeding medical oxygen to the pipeline.

6.37 These three sources are referred to as:

- **the primary supply** – the main source of medical oxygen on site, providing gas to the pipeline;
- **the secondary supply** – the secondary source of medical oxygen on site, providing gas to the pipeline and capable of providing the total oxygen flow requirement in the event of a primary supply failure;
- **the reserve supply** – the final source of supply to specific sections of the pipeline, capable of meeting the required demand in the event of failure of the primary and secondary supplies, or failure of the upstream distribution pipework. For the larger development or where the existing hospital acts as the emergency supply source to a PFI/PPP project, refer to paragraph 6.41.

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6.38 For smaller hospitals, the primary supply can be fed from compressed gas cylinders but as the demand grows, the most practicable supply source will be either liquid cylinders or a VIE system.

6.39 A fully automatic gas cylinder manifold will normally be used as the secondary supply system for smaller VIEs and liquid cylinder systems. Where it is impracticable to maintain supplies to the hospital using a cylinder manifold, a secondary liquid oxygen system will be necessary.

6.40 Emergency supplies will not normally be fed from a liquid oxygen supply system, as it is not possible to prevent the boil-off of the liquid oxygen over extended periods when the emergency system is not in use.

6.41 In major acute hospitals, the foremost consideration of the assessment process should be to locate the primary and secondary supply systems on separate sites. For the larger developments, this consideration can be extended to installing secondary back-up VIEs to each site. Each site should have independent control, monitoring systems and duplex supply routes into the hospital pipeline distribution system and be valved accordingly to ensure that the systems remain independent outwith an emergency situation. The inherent safety of the present control system of a VIE should not be compromised or rely on minimal distribution pipeline pressure differences to determine the primary site, each site should share the hospital load with emergency valving incorporated in the event of a fault condition arising. Alternatively, consideration can be given to each site serving, at high pressure, a common control panel, the secondary supply incorporating an economy circuit, within the hospital manifold room. Section 13 provides additional guidance on dual supply and ring mains.

6.42 Where it is not feasible to utilise two sites, the risk assessment should evaluate the greater level of risk associated with using a single site and define the appropriate actions that should be established to obviate the higher risks, such as using twin or ring-main pipeline systems, siting of the emergency supply manifold or installing suitable protection for the installation.

6.43 The overall ‘same site’ system should be designed so that the primary supply is used first, with the secondary supply automatically switching in when the primary supply is either empty or fails to supply.

Cryogenic liquid systems / VIE

6.44 These systems, commonly referred to as vacuum insulated evaporators (VIEs), are used to store the medical gas as a liquid at cryogenic temperatures and to vaporise it into a gas at ambient temperature for distribution through the hospital pipeline.

Plant

6.45 The VIE system consists of:

- a vacuum insulated cryogenic storage vessel to store the bulk liquid;

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- one or more ambient-heated vaporisers to convert the cryogenic liquid into a gas for supply to patients via a pipeline;
- control equipment to control the pressure and flow of gas to the pipeline.

6.46 The liquid oxygen is stored at cryogenic temperatures (down to minus 183°C) and converted to a gas at ambient temperature by passing it through an air-heated vaporiser.

6.47 The cryogenic storage vessel is normally constructed from a stainless steel inner pressure vessel that is supported in a mild steel outer shell. The space between the vessels is filled with a high performance insulating material, maintained under a vacuum, to minimise heat transfer to the inner vessel, which reduces the rate of evaporation of the liquid oxygen.

6.48 A pressure-raising regulator that permits the flow of liquid to the pressure-raising vaporiser, as required, automatically controls the pressure in the liquid oxygen system. The vaporised liquid is fed back to the top of the vessel or liquid cylinder to maintain the pressure in the system.

6.49 Under normal operating conditions for a VIE system, the gas supply to the hospital will be maintained by feeding liquid oxygen to the main vaporiser system where it is converted to a gas and warmed towards ambient temperature. There is a tendency for the vaporiser system to “ice up” where hospital demands are high or continuous, or airflow to the vaporisers is restricted. Under these circumstances the options to be considered should include:

- installation of additional vaporisers;
- an auto-changeover system between vaporizers – refer to Note 18;
- hot water/electrically heated vaporisers;
- increasing size of vaporiser;
- repositioning.

Note 18: In the event of power failure, control valves on all vaporisers should fail “open”.

6.50 Where hospital demands are low or very erratic, the natural heat transfer into the vessel causes the liquid oxygen to boil and the vessel pressure to rise. When the vessel pressure rises to a set point, the hospital pipeline can be fed by valve changeover from the top gas to prevent the vessel pressure rising above the safety-valve setting. On safety-valve operation, oxygen must be able to vent safely to atmosphere. All secondary VIEs should incorporate an economiser circuit which will feed into the hospital distribution system on reaching a predetermined VIE pressure level.

6.51 In all cases, the pipeline pressure is controlled using a system of duplex pressure regulators and valves. It is essential that all materials used in the construction of the vessels, control equipment and pipeline are compatible with

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oxygen at the operating temperatures that could be encountered under normal operation with single fault condition. The risk assessment will determine the exact configuration.

6.52 The control panel design should comply with the design requirements specified in BS EN ISO 7396-1: 2007 + A2: 2010 and be sized to provide the system design flow.

Telemetry

6.53 The use of telemetry on the liquid storage system is recommended because it permits both the hospital and the gas supplier to monitor relevant supply conditions continuously, including storage vessel levels and pressure. In addition, it can be used to transmit other operational data from the storage vessel, pipeline and associated equipment for monitoring purposes. It may be beneficial to make this information available to the relevant person(s) in the healthcare organisation. By having continuous monitoring of stock available through the telemetry system, an existing vessel could be retained. This solution is only acceptable provided that an appropriate risk assessment, following the guidance given in this chapter, supports the decision.

Siting

6.54 The Authorised Person (MGPS) will be responsible for agreeing the final location of the liquid oxygen compound(s), taking into consideration any issues raised in the initial risk assessment. It is the supplier's responsibility to assess the space requirements for vehicular access.

6.55 When considering the space requirements for the liquid oxygen compound(s), there may be operational advantages in having two compounds in different areas on the hospital site, rather than one larger site utilising either a single large vessel or multiple tanks. This arrangement may also have benefits with respect to both planning permission and meeting the safety distances specified in the British Compressed Gases Association's (BCGA) Code of Practice 19 (CP19): 'Bulk liquid oxygen storage at users' premises' (henceforth known as BCGA CP19; see Table 25).

6.56 Each supply system should be located in a secure fenced compound, which should be sized to allow adequate access to all of the control equipment.

6.57 The site should essentially be level but designed to have adequate falls to prevent water accumulating beneath equipment.

6.58 The location of drains in the vicinity of the site should comply with the requirements specified in BCGA CP19 (see Table 25).

6.59 Only under extreme conditions should the safety distances specified in BCGA CP19 be reduced. Any relaxation of these safety distances needs to be agreed with the supply company's safety representative and the Authorised Person (MGPS). Both parties must ensure that an equivalent level of safety is achieved, and this should be approved and documented.

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6.60 The layout of the liquid oxygen installation should provide adequate access to all of the relevant components of the system and permit adequate airflow for the ambient vaporisers.

6.61 The plinth should be of concrete construction. The area in front of the vessel(s) (tanker apron) should be non-porous concrete. Under no circumstances should tarmac be used in the vicinity of the liquid oxygen filling point, or areas where liquid oxygen spillage may occur.

6.62 The location of the liquid oxygen compound should permit the supplier to gain safe access with the appropriately sized tanker. It is the supplier's responsibility to assess the space requirements for vehicular access.

6.63 The design of the liquid oxygen installation should take into account the gas supplier's requirements for discharging the liquid oxygen from the cryogenic tanker. The area directly in front of the vessel should be kept clear to provide access for the delivery vehicle at any time. Under no circumstances should unauthorised vehicles be permitted to park in front of the compound.

6.64 The compound should not be used for the storage of other equipment. For ease of maintenance, the liquid oxygen control panel should be housed in an adjacent bricked room or medical gas manifold room particularly where the secondary supply consists of cylinders.

6.65 Where the secondary or emergency supply system is fed from a cylinder manifold, it should be in a manifold room and have adequate space to permit safe cylinder changeover. Spare cylinders should not be held in the VIE compound or liquid cylinder compound but stored in the nearest medical cylinder store.

6.66 A pipework and installation diagram (P&ID) of the plant should be displayed clearly to indicate the appropriate valves that are necessary to operate the plant safely. The medical gases supplier should make the Authorised Person (MGPS), and others in the hospital that may operate the system, aware of its general operating principles. (Typical plant installations are shown in Figures 18–20.)

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Safety distances from exposure to vessel/point where oxygen leakage or spillage can occur	Up to 20 tonnes (metres)	Over 20 tonnes (metres)
Areas where open flames/smoking permitted	5	8
Places of public assembly	10	15
Offices, canteens and areas of occupancy	5	8
Pits, ducts, surface water drains (untrapped)	5	8
Openings to underground systems	5	8
Property boundaries	5	8
Public roads	5	8
Railways	10	15
Vehicle parking areas (other than authorized)	5	8
Large wooden structures	15	15
Small stocks of combustible materials, site huts etc	5	8
Process equipment (not part of installation)	5	8
Continuous sections of flammable gas pipelines	3	3
Flanges in flammable gas pipelines (over 50mm)	15	15
Fuel gas vent pipes	5	8
Compressor/ventilator air intakes	5	8
Fuel gas cylinders (up to $70m^3$)	5	5
LPG storage vessels (up to 4 tonnes)	7.5	7.5
LPG storage vessels (up to 6 tonnes)	15	15
Bulk flammable liquid storage vessels (up to $7.8m^3$)	7.5	7.5
Bulk flammable liquid storage vessels (up to $117m^3$)	15	15
MV or HV electrical sub-stations	5	8

Table 25: Safety distances to comply with BCGA CP19

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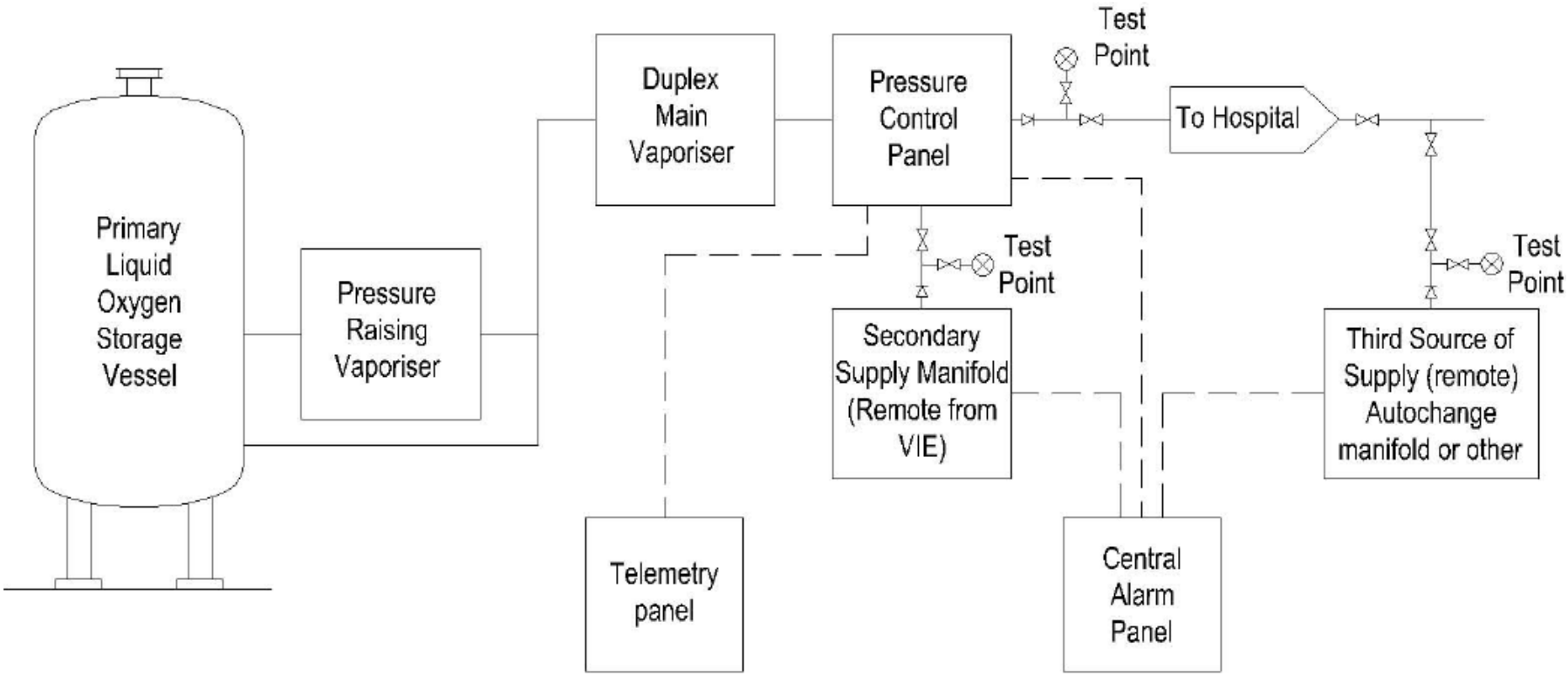

Figure 18: Primary supply VIE system with secondary supply compressed gas cylinder manifold

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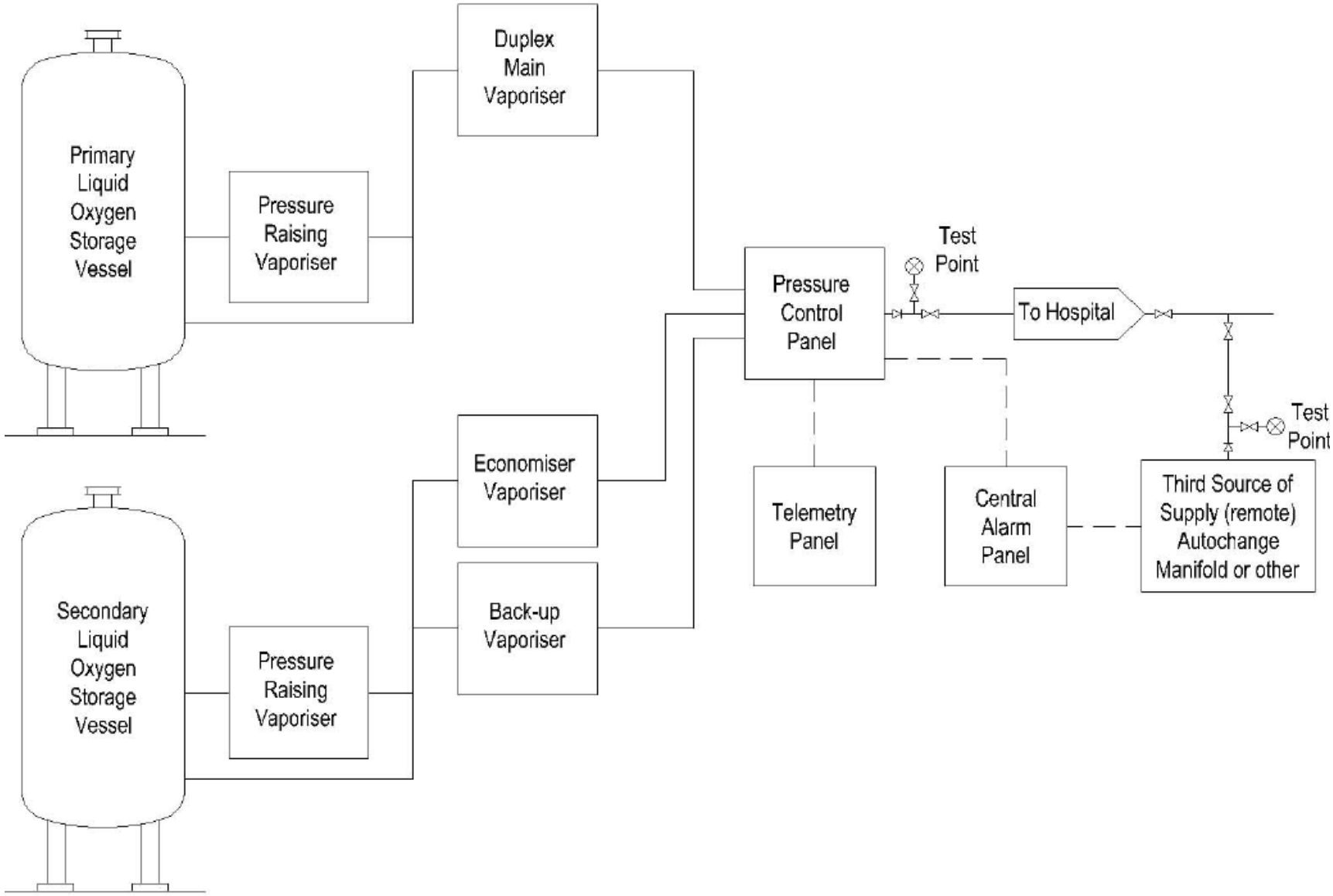

Figure 19: Primary and secondary supply VIE system on single plinth with remote third source supply compressed gas cylinder manifold

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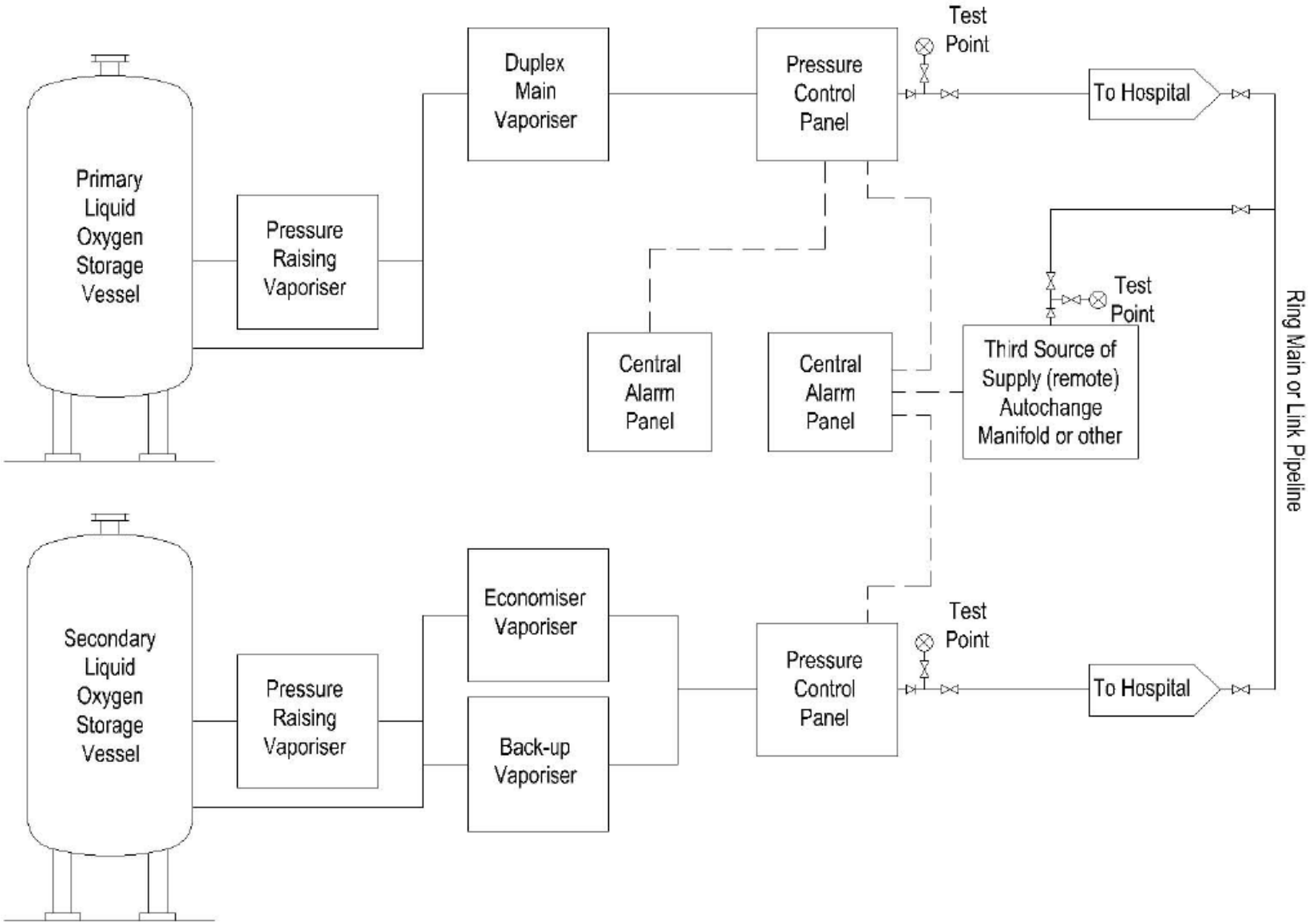

Figure 20: Primary and secondary supply VIE system on separate plinths with remote third source supply compressed gas cylinder manifold

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Liquid cylinder systems

Plant

6.67 Liquid cylinder systems can also be used to store the medical gas as a liquid at cryogenic temperatures and to vaporise it into a gas for patient use. These systems are used where the demand is too high for compressed gas cylinders to be a practicable option but where it is neither economic nor possible to supply bulk medical liquid oxygen in a VIE system.

6.68 Liquid cylinders are constructed in a similar way to vacuum insulated cryogenic storage units, that is, as double-walled vessels. However, unlike the VIE, the liquid cylinder has an internal vaporiser coil to convert the liquid into a gas.

6.69 The size of the liquid cylinder can vary between 200 litres and 1,000 litres water capacity. To obtain sufficient storage capacity and to meet the hospital's flow requirements, a number of liquid cylinders can be connected together via a manifold.

6.70 The liquid cylinder system consists of:

- a number of vacuum insulated liquid cylinders;
- a system to manifold the liquid cylinders together to store sufficient liquid on site to meet the hospital's demand;
- control equipment to regulate the pressure and flow of gas to the pipeline.

6.71 Although liquid cylinders are suitable for transportation when full, they are normally installed as a fixed installation and remotely filled whilst in situ.

6.72 Liquid cylinders are designed and supplied with gas-specific liquid-fill and gas-use connections (including the connection on the remote liquid-fill connection where the liquid cylinders are filled in situ).

6.73 The connections used are:

- liquid fill: CGA 440;
- gas use: ISO 5145.

Siting

6.74 Where there is no alternative, a liquid cylinder manifold may be installed in a building or confined area, but only if the vent header (to which all liquid cylinder vents will be connected) is piped to a safe area via a back-pressure control valve. This valve should be set at a pressure below that of the liquid cylinder relief valve setting, thus ensuring that any excess pressure is safely vented.

6.75 Where installed in buildings, generous ventilation should be provided by means of fully-louvred access doors to the outside. Additional protection of supply and extract ventilation controlled by oxygen monitoring equipment should be

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considered. Further guidance on ventilation requirements is given in BCGA CoP No. 4. The appropriate calculation must be made to ensure adequate ventilation, especially during the filling of the vessels, when they may be venting freely to atmosphere inside the manifold room.

6.76 A P&ID of the plant should be displayed clearly to indicate the appropriate valves necessary to operate the plant safely. The Authorised Person (MGPS) and others in the hospital who may work with the VIE system should be made aware of its general operating principles by the medical gas supplier. (Figure 21 shows a typical liquid cylinder manifold installation with cylinder backup.)

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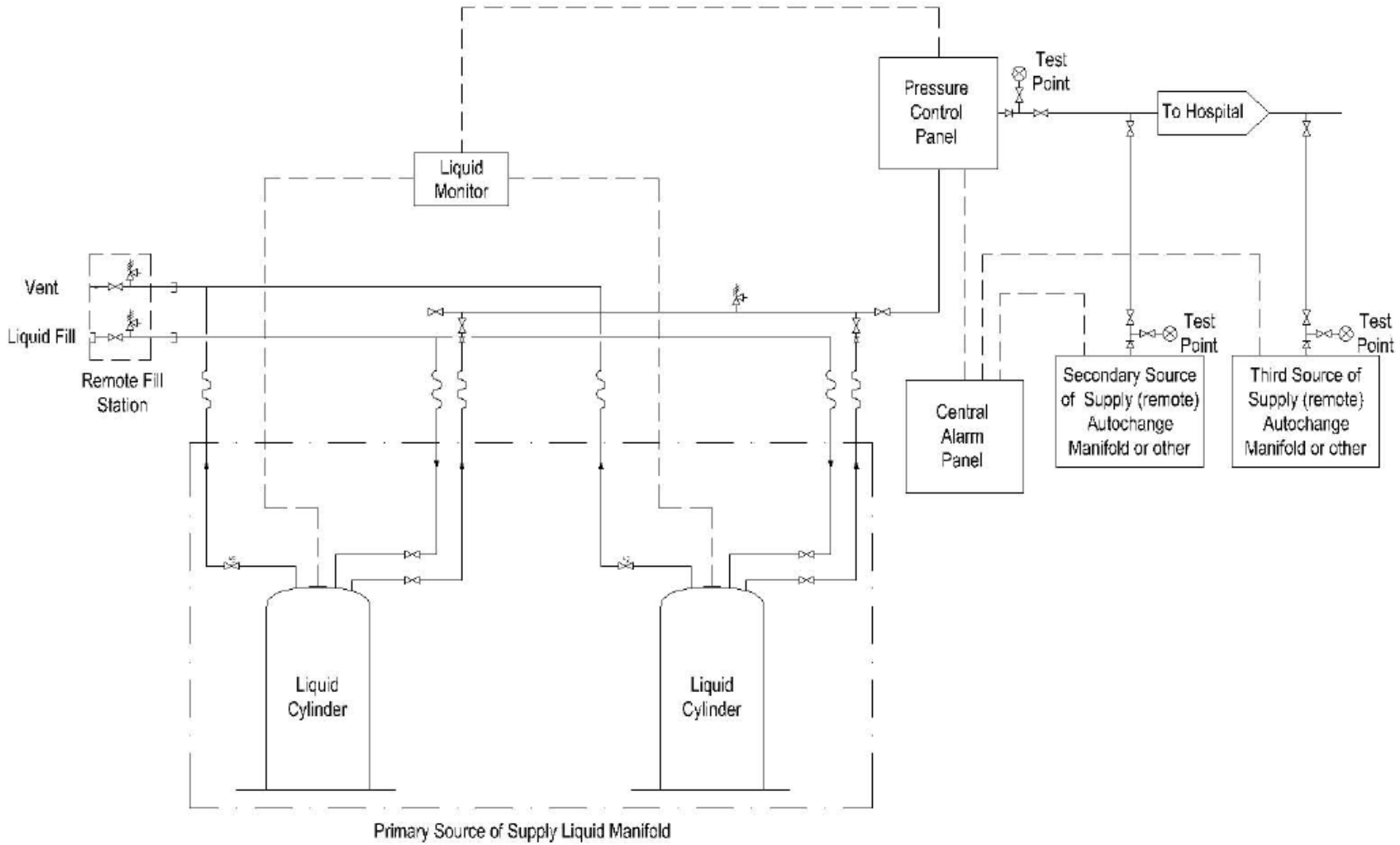

Figure 21: Typical primary liquid cylinder manifold installation with remote secondary supply source compressed gas cylinder manifold and remote third source supply

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Compressed gas cylinder manifolds

6.77 The simplest supply system to provide medical oxygen to a hospital pipeline system utilises compressed gas cylinders, connected together on an auto-changeover manifold. As the demand increases, the number of cylinders fitted to the manifold can be increased to meet the hospital's requirements. The third or reserve supply for this system will usually be a manual changeover compressed gas cylinder manifold, which comes on line automatically (via a non-return valve) in the event of primary manifold failure.

6.78 For a full description of manifold supply systems, see Section 5.

Secondary supply systems

6.79 Where the primary supply system is a VIE, the secondary supply system can be either:

- another VIE; or
- a liquid cylinder manifold; or
- a fully-automatic compressed gas cylinder manifold.

6.80 Where the primary supply system is a liquid cylinder system, the secondary supply system should be a fully automatic changeover gas cylinder manifold that comes into operation automatically.

6.81 There should be a system of backflow prevention to protect either system venting through the other in the event of a single fault in either system.

6.82 Where the secondary supply is fed from compressed gas cylinders, the size of the changeover manifold and the number of cylinders stored on site should be based on the gas supplier's ability to guarantee a delivery service within a defined period.

6.83 Where a liquid oxygen system is used for the secondary supply, the system design should allow any liquid oxygen that has boiled off to be fed to the pipeline system to utilise product.

6.84 Where the feed from the VIE compound to the hospital extends a long distance, or is exposed to potential mechanical damage, particular importance should be given to siting the secondary supply system remotely from the main VIE compound with a separate supply to the hospital pipeline system. In all instances where pipelines cannot be inspected throughout their length, twin pipelines in separate ducts and suitably valved to permit pressure testing whilst maintaining the service should be provided.

6.85 Where the secondary supply is sited remotely, consideration should also be given to the set point of the secondary supply output regulator to ensure that the pipeline dynamic pressure is maintained at a minimum level of 420 kPa. Where a proposal is raised to consider the remote siting of the secondary supply the risk assessment, in consultation with the suppliers, must consider the changes

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from a proved but simple control system that would be required to maintain a control link between primary and secondary panels and the requirement of the secondary supply economiser circuit, unless both primary and secondary VIEs on remote sites are served by a common panel or a back-up service is available on each site.

6.86 When the vessels are located on separate sites, a backflow prevention device must be fitted on each leg feeding into the pipeline system. This will prevent loss of product, either from the other vessel or from the hospital pipeline, in the event of failure of or damage to a VIE unit or its feed into the hospital pipeline. The backflow protection should be sited in a secure location where it is not liable to mechanical damage and be as close to the hospital curtilage as possible.

Emergency supply provision

6.87 In the event of total plant and/or main pipeline failure, an emergency supply of oxygen should be available for patient use.

6.88 The emergency supply system should be activated automatically when the primary and secondary system is empty or fails to supply or when the hospital pipeline pressure falls below 375 kPa. It must have the provision to prevent the automatic backflow of medical oxygen into the remainder of the pipeline system should the pipeline fail upstream of the connection.

6.89 A variety of sources are available for the provision of emergency oxygen, and these are detailed in paragraphs 6.96 – 6.105.

6.90 Under most conditions, compressed gas cylinders are the appropriate method of providing an emergency supply source.

6.91 The size and design of the emergency supply system should allow for cylinders to be changed whilst maintaining the emergency supply.

6.92 Where the emergency supply serves the hospital distribution system, the set point of the regulator should be 375 kPa to ensure that the plant low pressure alarm normally set at 385 kPa is activated thus providing warning of plant failure.

Emergency / maintenance inlet ports

6.93 Emergency / maintenance inlet ports are covered in Section 13. In some instances, installation of a fixed manifold system will obviate the need for fitting an emergency inlet port.

6.94 In smaller installations, fitting an emergency inlet port may be dispensed with if the risk analysis indicates that adequate supplies can be maintained via the NIST connectors of AVSUs supplying critical care areas.

6.95 When planning emergency provision for a complete system, vulnerability of the primary and secondary supplies will be a critical factor in determining both the type and the means of supply.

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Fixed automatic/manual manifold systems

6.96 Where two VIE units on the same plinth are in use, the emergency supply system should comprise a fully automatic cylinder manifold permanently connected to (one of) the main oxygen riser(s) in the hospital, or directly into a ring-main system. It must be able to feed a riser automatically (without back-feeding to any damaged upstream section) on failure of both primary and secondary plant, or the MGPS upstream of the entry into the hospital. Such an arrangement is particularly suited to situations in which the main feed from the VIE installation to the hospital pipeline is vulnerable to mechanical damage, for example when buried under a roadway. The location and size of the manifold should be determined by the risk assessment and according to the dependency of the patients.

6.97 When two separately sited VIE units are used to provide the hospital supply, the need for emergency manifold provision should be assessed against the likelihood of failure of both VIE systems and their respective feeds into the hospital pipeline.

6.98 Where it can be shown through risk assessment that one or both units are fed into the hospital pipeline in a manner such that the probability of disruption of one or both of the feeds is negligible, the option to waive the fitting of further (manifold) supplies can be considered.

Local manifold provision (critical care areas)

6.99 To offer additional protection against the possibility of a pipeline failure within the hospital, further (manual or automatic) manifolds can be permanently connected, via non-return valves, downstream of AVSUs controlling high-dependency areas. Such units should come on line automatically on failure of the main supply to an AVSU. A further non-return valve must also be added upstream of the AVSU to prevent back-feeding into a failed main supply system.

6.100 The positioning of these manifolds is very important to ensure that the critical care/high dependency areas defined in the risk assessment process have adequate stocks of medical oxygen available in the event of a system failure. However, the risk analysis for the complete system may indicate that the probability of use of such a manifold system is negligible, or that the circumstances causing the system failure would in any event require the evacuation of the area.

6.101 Availability of accommodation, staff and manual handling issues would also need to be considered during the risk assessment process. Where space limitations prevent the installation of such manifolds, the implications of providing discrete cylinder/regulator combinations must be considered.

Gas feed via an AVSU (or terminal unit)

6.102 Oxygen supply to the downstream side of an AVSU (with the valve closed) may be achieved using an “emergency supply kit” consisting of two cylinder regulators and associated supply hoses with gas-specific connectors.

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6.103 Such an arrangement may be used to support high-dependency departments, albeit the unit will usually be of limited capacity by comparison to a fixed automatic manifold system.

6.104 Storage, maintenance, testing, security and deployment arrangements for the emergency supply kits must be documented in the MGPS operational policy.

Discrete cylinder supplies

6.105 For non-critical care areas where there are no high-dependency patients, it may be appropriate to use individual cylinders as the reserve source of supply. Cylinders fitted with integral valves and having a product-specific terminal unit outlet are suitable for this purpose. The difficulties associated with storing, testing, maintaining, distributing and connecting large numbers of such equipment must not be underestimated. (Such protocols should be referenced in the MGPS operational policy).

Alarm systems

6.106 Installations of the following type should be fitted with alarm systems to provide visual and audible warnings at the plant (each site) and in a 24 hour manned station with slave panels as required for the following conditions. Variations to supply mode are:

- dual VIE vessels on a common site or separate sites feeding into a single control panel; or
- dual VIE vessels on separate sites each with independent control panels;
- single VIE vessel supported by a liquid cylinder secondary supply; or
- single VIE vessel supported by a fully automatic compressed gas cylinder manifold.

The following displays should be presented at the plant and in a 24-hour-staffed position.

Status/fault condition	Indication	Legend
Normal operation System available for use	Green	Normal
Primary supply system's operational stock empty Primary supply system's reserve stock in use	Yellow	Refill liquid
Primary supply system's reserve stock empty Secondary supply system in use	Yellow	Refill liquid immediately
Secondary supply system empty Emergency system in use	Yellow	Emergency supply in use
Pipeline pressure high or low	Red	Pressure fault

Table 26: Oxygen plant alarm conditions

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6.107 It is not considered advisable that a single VIE in a remote location has no local back-up – refer to paragraph 6.85. Where the third source of supply is a liquid cylinder or fully automatic cylinder manifold serving separate or singular part(s) of the pipeline system the alarm displayed at the liquid cylinder or manifold and the 24 hour manned station will be independent of the primary and secondary sources of supply but similar to the alarm conditions 1, 2 & 4 laid out in paragraph 6.106 and Table 26. Where the assessment process considered that an additional emergency service manifold is advisable in event of maintenance requirements, alarm condition 3 would apply.

At the primary vessel and a 24-hour-manned position		
Status/fault condition	**Indication**	**Legend**
Normal operation System available for use	Green	Normal
Primary supply system's operational stock empty Primary supply system reserve stock in use	Yellow	Refill liquid
Primary supply system's reserve stock empty Secondary supply system in use	Yellow	Refill liquid immediately
Secondary supply system low	Yellow	Secondary stock low
Pipeline pressure high or low	Red	Pressure fault

Table 27: Oxygen central plant alarm conditions (primary supply)

6.108 When the primary system operational stock has been exhausted and the vessel contents reach the reserve stock level, the first alarm condition will be indicated by a yellow alarm and the legend "refill liquid" illuminated.

6.109 When the primary system reserve stock is empty and the secondary supply system is in operation, the second alarm condition will be indicated by a yellow alarm and the legend "refill liquid immediately" illuminated. This alarm condition continues until the primary supply system is refilled.

6.110 When the secondary supply system is low, the third alarm condition will be indicated by a yellow alarm and the legend "secondary stock low" illuminated. This alarm condition continues until the secondary supply system is refilled or the cylinders are replaced.

6.111 Should the primary supply of medical oxygen to the hospital pipeline fail due to lack of contents or mechanical failure of any of the components, or should a serious leak occur, the pipeline pressure will fall. When the plant output pipeline pressure falls below 385 kPa, the condition will be indicated by the "pressure fault" alarm.

6.112 If the regulator controlling the pipeline pressure should fail "open", the pipeline pressure will rise. This condition will be indicated by the "pressure fault" alarm when the pressure rises above 500 kPa.

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At the secondary vessel/liquid cylinder supply/cylinder manifold and a 24-hour-staffed position		
Status/fault condition	**Indication**	**Legend**
Normal operation System available for use	Green	Normal
Secondary supply system's operational stock empty Secondary supply system's reserve stock in use	Yellow	Refill liquid / change cylinders
Secondary supply system's reserve stock empty Emergency supply system in use	Yellow	Emergency supply in use
Pipeline pressure high or low	Red	Pressure fault

Table 28: Oxygen central plant alarm conditions (secondary supply)

6.113 With a correctly installed and commissioned system where the three sources of supply are serving the full hospital distribution system, in the event of a loss of primary and secondary pressure the plant low pressure alarm condition of 385 kPa will be activated with the third source of supply continuing to supply the hospital at 375 kPa. With primary and secondary sources empty, all alarms on both plant and the 24 hour manned station will be activated. In a fault condition the degree of alarm should assist in identifying the problem. The third source should be clearly identified on the alarm panel as the oxygen emergency supply and recognised of having limited capacity. The Operational Policy document emergency procedures should normally ensure corrective action is taken at the first stages of alarm to ensure continuity of supply by arranging a liquid delivery or identify and rectify a fault condition.

6.114 Where the emergency supply is installed on individual zones of the pipeline system, the "emergency supply in use" alarm must be displayed within the pipeline zone area. A separate "emergency supply low" alarm should also be installed on each zone.

6.115 Where more than one VIE is used and the operational and reserve stock is distributed between multiple vessels, a lit "normal" display indicates that the vessel is available for use.

6.116 In the event that the primary (or secondary) vessel should become empty (or suffer from any other fault condition), the "normal" display should be extinguished, indicating that the vessel is not available for use.

6.117 Alarm conditions should be transmitted to the central alarm system.

6.118 Where relays are used, they should be energised relays that de-energise under fault conditions, with contacts having a minimum rating of 50 V d.c. and 50 mA. Alternatively, Volt-free, normally closed contacts rated at 50 V d.c. and 50 mA should be provided for transmission of the conditions to the alarm system.

6.119 Typical alarm trigger points are shown in Figures 12 – 17.

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Determining system size through risk assessment

Introduction

6.120 The 2001 edition of Scottish Health Technical Memorandum 2022 defined a (fixed) VIE primary vessel capacity of 14 days' oxygen supply but did not define capacity for a liquid cylinder system. This section addresses the risk factors associated with the supply of oxygen on a hospital site and, with the aid of defined risk criteria, offers guidance on the sizing of VIE, liquid cylinder and compressed gas cylinder manifold installations for any specified location.

6.121 The risk assessment should take into account all issues concerning the safety and continuity of the medical oxygen supply. It is suggested that identified risk factors and criteria be evaluated using both qualitative and quantitative measures, and that all results be recorded in a logical manner that will support the decisions being made. The record of the risk assessment will also act as a reference document when the system is reviewed.

6.123 Additional local factors and requirements identified by the project team will also need to be considered when carrying out the risk assessment to take account of site-specific issues concerning how the product is stored, distributed and used.

6.124 Any risk control procedures identified by the risk assessment process which are designed to minimise any identified risks must be recorded and incorporated into the relevant hospital standard operating procedures (SOP) or work instructions (WI).

6.125 When sizing the vessels and cylinder manifolds to provide adequate storage of medical oxygen on site, the stock should be distributed between the three sources of supply as defined in BS EN 737-3: 2000 / BS EN 1SO 7396-1: 2007 + A2: 2010; that is, the medical oxygen supply system should normally consist of:

- a primary supply;
- a secondary supply;
- emergency third or reserve supply.

6.126 The capacity of the primary and secondary supply system will consist of:

- operational stock;
- reserve stock.

6.127 The operational stock is the volume of product that the gas supplier uses to manage deliveries to the hospital, and its exhaustion signals the point at which the vessel should be refilled under normal conditions.

6.128 The reserve stock is the volume of product that is used to provide additional stock, to take account of fluctuations in demand, or when the supplier fails to make a scheduled delivery.

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6.129 The system should be designed so that the primary and secondary supply system stocks are kept separate from each other. Under no circumstances can the primary supply system operational stock be stored in the secondary supply system vessel.

6.130 However, where it is not possible to install a single large VIE vessel for the primary supply (such as where planning permission restrictions prevent the use of a single large vessel), it may be appropriate to hold all or some of the primary supply system reserve stock in the secondary supply vessel. Under these circumstances the primary supply vessel should retain a minimum level when changing over to the secondary supply system. The volume retained in the primary supply vessel should equate to the secondary supply system reserve stock. This should provide adequate stock on site to enable the gas supplier to resupply product to the primary vessel in the event of failure of the secondary supply. This level should be determined by the risk assessment process but should be at least one day's usable stock.

Review of risk assessment

6.131 The documented risk assessment should be reviewed after the installation is complete, prior to commissioning, to assess whether any parameters or circumstances have changed since the initial assessment. The risk assessment must also be reviewed at least annually (or when there is any significant change to the medical oxygen supply system or usage pattern) to ensure that the details are current. At this review, all changes should be considered that might have an effect on the safety of the system or the security of supply.

Sizing plant – general

VIE installations

6.132 The operational and reserve stock for each supply system should normally be held in the same vessel. Where planning restrictions prevent the use of a single large vessel on site, it may be appropriate to utilise multiple vessels to provide adequate stocks on site.

6.133 When sizing VIE systems for the primary or secondary supply, the vessel size will be determined by adding the operational and reserve stock together and allowing for the level of unusable stock left in the vessel when the designed flow rate cannot be maintained.

Liquid cylinder installations

6.134 For liquid cylinder installations, the primary system should be made up of a number of liquid cylinders connected together by a manifold. The secondary system will comprise an automatic compressed gas cylinder manifold system.

6.135 Each liquid cylinder will have a maximum design flow rate for continuous use. The number of liquid cylinders required for an installation may be governed by either the maximum storage capacity required on site or the flow rate required to meet the hospital's maximum demand.

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6.136 When determining the number and size of liquid cylinders required for either a primary or a secondary supply to a VIE, an allowance has to be made for the unusable capacity of each cylinder when connected to the manifold system.

Compressed gas cylinder manifold systems

6.137 Where the hospital does not warrant a liquid oxygen system, an automatic cylinder manifold should be considered. This should be sited to facilitate future extension of the manifold banks.

6.138 The reserve supply will normally comprise a manually operated manifold system, connected such that it will come on line automatically (via a non-return valve) in the event of failure of the primary and secondary supply.

6.139 For sizing compressed gas cylinder systems, the size of the manifold will normally be determined by the ability of the hospital to provide adequately trained staff to change over cylinders quickly enough to meet the demand.

The risk assessment process

Risk assessment for management responsibilities

6.140 The risk assessment criteria, when considering management responsibilities for the medical liquid oxygen system, need to include the following:

- the need to document and agree responsibilities for the monitoring of the medical liquid oxygen VIE, and the need to establish a back-up procedure with the gas supplier to ensure that adequate stocks will be maintained in the event of a failure of the fitted telemetry system;
- the hospital should set up procedures to ensure that the VIE system is monitored at regular intervals for any deviation from normal operation (such as safety valves lifting, major leaks, or failure of either the telemetry or alarm system);
- the implications of any decisions to not fit telemetry or to utilise a vessel, or vessels, that do not provide adequate operational and reserve stocks. These decisions should be taken at an appropriate level of management, should be documented, and their implications should be considered as part of the risk assessment;
- consideration of the resources needed to maintain adequate supplies of medical oxygen either under normal, or emergency, conditions. When evaluating these requirements, consideration should be given to the risks that the healthcare organisation would face in the event of supply failure causing disruption of clinical services;
- consideration of the operational management consequences of using different suppliers to supply medical oxygen to different supply systems supporting the same pipeline installation. Any contracts involving different suppliers should clearly state the obligations and limitations of liabilities.

6.141 Where manifolds are used, adequately trained staff should be available, whenever required, to ensure continuity of supply. Consideration also needs to

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be given to the manual handling issues concerned with changing cylinders on the manifold and arrangements to store adequate stocks to meet demands.

6.142 Consideration needs to be given to the type of clinical activities carried out in each area of the hospital and the ability to provide emergency back-up to individual areas used for critical care, or within high dependency units.

Initial risk assessment for siting of plant

6.143 The initial risk assessment should consider the requirements to ensure a continuous supply of medical gas to the patient.

6.144 The initial risk assessment criteria related to the complete installation should include:

- the size and location of each source of supply (for example the volume held as operational and reserve stock for each source of supply, located on one site or two independent sites);
- the associated risks with siting tanks at either the same or separate locations (for example physical space availability, accessibility for delivery and maintenance requirements, accessibility to the pipeline system [to tie-in points etc], alarm systems and cabling, pipeline routing and protection);
- the need to site the reserve sources of supply local to the point of use to protect against pipeline failure where high-dependency patients are located;
- safety requirements for the storage of oxygen on site, including compliance with the safety distances specified in BCGA CP19;
- the location and extent of the medical oxygen pipeline system;
- the vulnerability of the hospital pipeline to mechanical damage and whether underground sections of the pipeline system comply with the requirements of this Scottish Health Technical Memorandum and whether the pipeline is capable of being inspected throughout its entire length or pressure tested (whilst maintaining the supply), or otherwise can be tested;
- the space available for the liquid oxygen installation, or cylinder manifold, and the available access for the delivery vehicle;
- the vulnerability of the site to external damage;
- the possibility of interference with the supply system or other security issues.

Risk assessment for sizing of operational stock

6.145 The risk assessment criteria for the sizing of the operational stock should include:

- the average daily demand at the end of the contract period. Any changes to the predicted growth of demand will need to be considered, and changes made to the vessel size or delivery frequency at the appropriate time within the contract period. It may be beneficial to set a daily demand rate at which changes to vessel size or delivery frequency will be considered;

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- a review of vehicular access to the VIE, timing of the deliveries, any restrictions due to local planning requirements, and the effect of these factors on the delivery frequency;
- an environmental impact assessment.

Risk assessment for sizing of reserve stock

6.146 The risk assessment criteria for the sizing of the reserve stock should include:

- the average daily demand at the end of the contract period. Any changes to the predicted growth of demand will need to be considered, and changes made to the vessel size or delivery frequency at the appropriate time within the contract period. It may be beneficial to set a daily demand rate at which changes to vessel size or delivery frequency will be considered;
- the delivery frequency guaranteed by the gas supplier that can be provided at short notice should the primary supply system fail;
- the minimum response time from when the primary supply system fails to when the delivery vehicle could be on site to refill the secondary supply VIE, or to provide replacement compressed gas cylinders for the manifold.

Risk assessment for the provision of emergency supply systems

6.147 The risk assessment criteria concerning emergency supply systems should include:

- the need for installation of independent emergency supplies to zones on the medical gas pipeline supplying critical care areas or wards or departments that are remote or vulnerable to interruption;
- the positioning of the manifold to ensure ease of changeover of cylinders with respect to access and manual handling issues;
- the storage of cylinders associated with the emergency manifold to ensure compliance with the appropriate codes of practice and local hospital requirements;
- training requirements for both the relevant clinical and operational staff to ensure correct operation of the emergency supply system.

Stock calculations

Calculation of operational stock for primary and secondary supplies

6.148 The capacity of the operational stock of primary and secondary supply systems should be agreed with the gas supplier and based on the following parameters:

- the current average medical oxygen daily demand, plus any natural growth over the contract period;
- any additional planned growth (above any natural growth) in the usage pattern within the contract period;

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- the agreed delivery frequency.

6.149 The current average daily demand can be calculated by dividing the current annual consumption by 365 days.

6.150 The operational stock should be based on an average daily demand predicted for the end of the contract period calculated by:

Average daily demand = Current daily demand + Planned growth + Natural growth.

6.151 The operational stock is calculated as:

Operational stock = Average daily demand x Agreed delivery period.

6.152 If there is significant growth in average daily demand within the contract period, either the vessel should be resized or the agreed delivery frequency should be reviewed to reduce the delivery period and maintain the operational stock level.

6.153 The delivery period for the primary supply will be based on the gas supplier's normal delivery frequency.

6.154 The delivery period for the secondary supply will be based on emergency conditions when the primary supply is not available. Under these circumstances, special delivery response times must be agreed with the gas supplier.

6.155 The supply agreement should commit the supplier to manage the operational stock, based on an agreed delivery frequency and the minimum stock level to be maintained in the vessel.

Calculation of primary reserve stock

6.156 Table 29 provides a matrix for the calculation of primary reserve stock based upon distance from gas supplier and fitting of telemetry.

Kilometres from gas supply depot	No telemetry (no of days' stock)	Telemetry fitted (no of days' stock)
Up to 75	5	3
75-150	6	4
150-300	7	5
Over 300	8	6

Table 29: Requirement for remote indication for stock levels

Calculation of secondary reserve stock

6.157 The minimum level for reserve stock for the secondary supply should allow for circumstances in which the primary supply system is not available for use.

6.158 This secondary supply system reserve stock level will be dependent on:

- the proximity of the supplier's distribution depot;

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- the response time that the gas supplier needs to make a delivery under these conditions;
- the delivery frequency that can be sustained under the conditions when the primary supply is unavailable for use.

Calculation of capacity of emergency supply systems (VIE and cylinder manifolds)

6.159 Where an existing hospital VIE acts as an emergency third source of supply to a new hospital installation, the minimum supply available to both hospitals should be in accordance with the suggested stock levels detailed in Table 29, above. The number of cylinders stored locally to the emergency supply system manifold and the number of connections on the manifold(s) should be determined by risk assessment.

6.160 When determining these requirements, the risk assessment needs to consider:

- the maximum demand from the high dependency patients who may be supplied from the pipeline zone that the emergency supply system protects;
- the maximum duration for which the emergency state is likely to last;
- the proximity of the supplier of the compressed cylinders to the hospital;
- the ability of the hospital to connect cylinders to the manifold.

6.161 Consideration needs to be given to the logistics of storing and handling the number of cylinders needed to provide adequate supplies until the primary/secondary supply systems or the hospital pipeline can be re-established.

Oxygen concentrator installations (PSA plant)

General

6.162 Oxygen concentrators or pressure swing adsorber (PSA) systems may be alternatives to the more traditional supply systems (the terms ‘oxygen concentrator’ and ‘PSA’ are interchangeable). Typical installations where PSA systems should be considered are those sites having no access to reliable liquid supplies, such as remote or off-shore locations, or where the safety criteria for a bulk liquid vessel cannot be met (for example, very restricted sites). Otherwise, PSA systems should only be installed when an investment appraisal shows them to be economical.

6.163 When installed, a PSA system will deliver product gas via the “oxygen” pipeline system.

6.164 Oxygen concentrators operate by adsorbing, under pressure, other gases in the atmosphere onto materials which have specific physico-chemical properties, thus freeing the oxygen which is stored and transmitting it for use. The adsorbents are known as artificial zeolites, more commonly referred to as molecular sieves. The sieve units are arranged in pairs, one adsorbing whilst

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the other regenerates. The waste product, essentially nitrogen, is discharged to atmosphere during regeneration of the adsorbents. In some systems, the use of vacuum to remove the nitrogen increases the efficiency of the regeneration/adsorption process. Regeneration requires the use of a small proportion of the product gas.

6.165 The PSA process has reached a high level of technical sophistication and is capable of producing oxygen with a concentration of about 95%. (For the UK the minimum level, below which the emergency/reserve manifold will come into operation, is 94%.) The remainder is mainly argon with some nitrogen. The highest concentration is not likely to exceed 97/98%, except when the emergency/reserve manifold is in use, when it will be 100% if these are from a gas supplier.

6.166 The major components of a PSA system and their layout are shown in Figure 22. The typical major components of the system are the compressors, receiver(s), dryers, molecular sieves, vacuum pumps, filters and regulators. Other components are identical to those used for medical air and vacuum plant, which are described fully in the appropriate sections. A suitable operating and indicating system is also required, as specified below. Package supply systems, which should be specified to meet the requirements given in this memorandum, are available from manufacturers.

Note 19: Reference should be made to BS7634: 1993 / ISO 10083: 1992 for further guidance.

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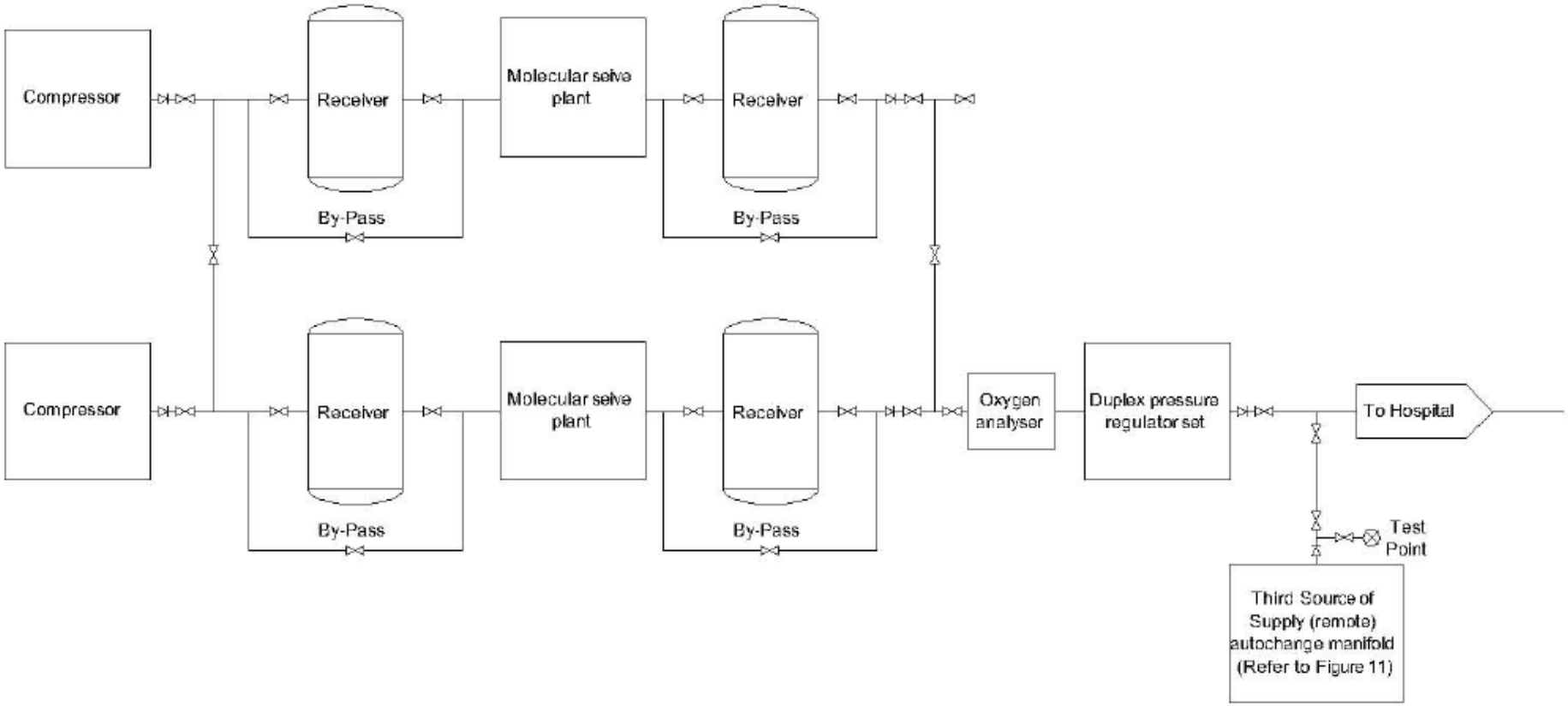

Figure 22: Schematic diagram of a typical PSA installation

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Siting

6.167 The plant should have all-round access for maintenance purposes, and allowance should be made for changing major components.

6.168 The siting of the plant should allow for adequate flows of air for three different purposes:

- air intake to the compressors;
- cooling of the compressed air by the after-coolers;
- cooling of the compressors.

6.169 Each compressor may require ducting to ensure an adequate flow of cool air. The manufacturer should be consulted over the range of operating temperatures for which the system is designed. In extreme circumstances, refrigeration of the cooling air may need to be provided.

6.170 Air-inlet filters should be fitted either to the compressor inlet or at a suitable point in any ductwork. The filters should comply with BS ISO 5011: 2000 and be either dry medium filters or grade CA paper element filters.

Plant configuration

6.171 The plant should comprise:

- a duplex compressor – if more than two compressors are installed, the plant should provide the design flow with one compressor out of service;
- duplexed air treatment/molecular sieve devices, that is, two sets of filters and a pair of molecular sieves (one adsorbing whilst the other regenerates) and one vacuum pump (if required by the manufacturer).

Note 20: All duplexed components should be capable of independent operation.

Compressors and vacuum pumps

6.172 The compressors for the PSA systems may be any of the type recommended for compressed air systems. It is also possible to provide a combined medical air PSA plant. Generally, the compressed air requirement per litre of product gas is of the order 4:1; as a result the compressor plant will be on longer than that typically seen in hospitals.

6.173 A vacuum pump may be required as part of the system. The vacuum pump, if provided, is utilised during the adsorption/regeneration process. Vacuum pumps may be of any type as for the piped medical vacuum system. It will not generally be practicable to use water-sealed pumps or the medical vacuum plant.

Compressor and vacuum pump noise

6.174 The noise level produced by the compressors will increase with the capacity of the supply system. The maximum free-field noise level for un-silenced

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compressed air plant, at 1m from the plant, varies with the type and power of the plant but should not normally exceed the following values:

Reciprocating	Screw	Vane	Power
85 dBA	76 dBA	76 dBA	7.5kW
89 dBA	78 dBA	76 dBA	7.6-15kW
93 dBA	80 dBA	79 dBA	15.1-22kW
97 dBA	92 dBA	90 dBA	22.1-60kW

Table 30: Compressor and vacuum pump noise ratings

6.175 In noise-sensitive areas, an acoustic enclosure should be included in the purchase specification for all compressors. Such an enclosure should produce a reduction of at least 10 dBA in the free-field noise level at 1m.

Molecular sieves

6.176 Duplex molecular sieves should be provided in pairs to permit continuous generation of oxygen. One of the pairs of duplex sieves will be in the adsorbing stage, whilst the other regenerates.

Dryers

6.177 Air dryers of the desiccant type are usually integrated within the molecular sieves and therefore do not regenerate independently. Refrigerant dryers may also be included.

Oxygen monitoring system

6.178 The plant should include a calibrated paramagnetic oxygen monitoring system comprising oxygen analyser, oxygen concentration indicator, oxygen flow monitor and oxygen concentration/flow recorder. Connections for calibration cylinders should also be provided. In the event of the concentration falling below 94%, the monitoring system should isolate the PSA system from the pipeline distribution system so that the emergency/reserve manifold operates. Additionally, an independent monitoring system should be provided to isolate the plant when the concentration falls below 94%. The second system need not be provided with a flow indicator or recorder.

Operating and indicating system

6.179 The operating and indicating system should perform the following functions, as appropriate:

- overall plant control and indication;
- individual compressor starting;
- individual vacuum pump starting (where fitted);
- control of dryers (where installed as a separate component);
- control of molecular sieves;
- plant status monitoring and indication;

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- optional indication of the plant alarm status (this function may be considered to be part of the alarm system).

6.180 Provided that the individual compressor starters are housed in a separate compartment, these functions may be carried out by separate units or may be installed in a common panel and located on the plant or on the plantroom wall.

6.181 Control panels containing pneumatic components should have vents to permit release of pressure in the event of component failure. All functions and indicators should be appropriately identified and should have a design life of at least five years. The operating system should be capable of automatically restarting after reinstatement of the power supply.

6.182 All components of the PSA supply system should be connected to the essential electrical supply. The control system should ensure that compressors restart in sequence to avoid overloading the essential power supply.

Plant control unit

6.183 The plant control unit should have a separate power supply for each compressor and vacuum pump, controlled by a separate sub-circuit. The design should be such that no single component failure in the control unit will result in loss of plant output.

6.184 The unit should allow either manual selection of duty/stand-by for each of the compressors or have an automatic sequence selection with a means for manual override. The unit should ensure that two or more compressors do not start simultaneously when power is applied.

6.185 A warning notice that complies with BS5499-5: 2002 should be affixed which indicates the presence of low voltage.

6.186 A further warning notice indicating that the plant starts automatically should also be affixed near or on the plant.

6.187 Each compressor should have a selector switch which, when turned to the “on” position, allows the maximum and minimum pressure switches on the receiver to control the “on” and “off” loading of that compressor. An alternative “auto” position of the selector switch may allow automatic selection of the compressors.

Plant control indication

6.188 There should be indicators for each compressor as follows:

- green “mains supply on”;
- green “compressor called for”, which indicates that the compressor motor is electrically energised;
- an indicator of the pressure produced by the compressor.

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Compressor and vacuum starter units

6.189 There should be individual starter units for each compressor and vacuum pump, which should include the features recommended for medical air compressor plants and vacuum plants respectively.

Molecular sieve control unit

6.190 The molecular sieve control unit may be mounted on the molecular sieve columns or may be located with the plant control unit. There should be separate power supplies for the “duty” and “stand-by” sieve assemblies, taken from the same phase.

6.191 The vacuum pump, if provided, forms part of the molecular sieve system.

6.192 The molecular sieve control unit should contain the following:

- a duty selector switch;
- an on/auto selector switch;
- individually-fused, separate cycling systems for each sieve pair;
- a system to control regeneration of the sieves in relation to pipeline demand;
- oxygen concentration, dryness and pressure sensors;
- an automatic changeover to the stand-by molecular sieve system, in the event of failure of the duty unit by oxygen concentration, dryness or pressure. This requires:
  - electrical and pneumatic isolation of the “duty” sub-assembly so that it is taken off-stream;
  - electrical and pneumatic energisation of the “stand-by” sub-assembly so that it is brought on-stream;
  - activation of the appropriate fault indicator and associated Volt-free contacts;
  - the sub-assembly to remain in this mode of operation until the fault has been rectified;
- green function indicators for each dryer sub-assembly to indicate:
  - molecular sieve 1 selected;
  - molecular sieve 2 selected;
  - selected molecular sieve – “normal”;
  - selected molecular sieve – “failed” (this fault indicator should remain until manually reset by means of a reset button);
- closure of all inlet, outlet, exhaust and purge valves.

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Plant status monitoring

6.193 A monitoring system must be provided to detect the following faults in the air compressor system:

- plant faults (for each compressor):
  - control circuit failed;
  - overload tripped;
  - after-cooler temperature high;
  - compressor temperature high;
  - compressor run-up time too long;
  - activation of other safety devices supplied by the manufacturers.
- plant faults (for each molecular sieve unit):
  - control circuit failed;
  - “vacuum pump called for”;
  - overload tripped;
  - activation of any of the safety devices supplied by the manufacturer;
  - oxygen concentration failure;
  - pressure fault.
- plant emergency:
  - oxygen concentration failed at below 94% concentration;
  - receiver pressure 0.5 bar (gauge pressure) below the stand-by cut in pressure;
  - dryness above 67 ppm (–46°C at atmospheric pressure).
- pressure fault (cylinder reserve):
  - pressure in either bank below 50% (of normal cylinder pressure).
- pressure fault (pipeline):
  - low pipeline pressure;
  - high pipeline pressure.

Plant status indicator unit

6.194 In addition to the plant control indication, there should be a plant status indicator panel, which may be mounted on the plantroom wall or adjacent to either the compressor starter unit or the plant control unit. It should have a warning notice that complies with BS5499-5: 2002 to indicate the presence of low voltage.

6.195 There should be indicators for each compressor to show the following conditions:

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a) green “mains supply on”;
b) yellow “control circuit failed”;
c) yellow “overload tripped”;
d) yellow “after-cooler temperature high”;
e) yellow “compressor temperature high”;
f) yellow for each individual safety device provided by the manufacturers;
g) yellow “compressor failure”.

6.196 There should be indicators for each molecular sieve dryer system to show the following:

a) green “mains supply on”;
b) yellow “oxygen concentration fault”;
c) yellow “pressure fault”;
d) yellow “dryness fault”.

When the stand-by dryer is in operation, conditions (b) and (c) in paragraph 6.195 should be transmitted as a plant emergency either to the alarm system or to the plant alarm signal status unit.

Alarm signal status unit

6.197 An alarm signal status unit should be provided as part of the control system. It should display the following conditions:

Indication	Legends
a. Green “normal”	Normal conditions
b. Yellow “plant fault”	Conditions (b)-(f) (see paragraph 6.195)
c. Yellow “plant emergency”	Conditions (b) or (c), or see conditions (g) (see paragraph 6.195)
d. Yellow “emergency supply low”	Emergency supply bank(s) low (<50%)
e. Red “pipeline pressure fault”	Pressure fault
f. Red “pipeline concentration below 94% O_2”	Oxygen concentration fault
Conditions (b) to (e) should be transmitted to the central alarm system.	

Table 31: Alarm signal status unit

6.198 Where relays are used, they should be normally energised relays, which de-energise under fault conditions, with contacts having a minimum rating of 50 V d.c. and 50 mA.

6.199 Alternatively, Volt-free, normally closed contacts rated at 5 V d.c. and 50 mA should be provided for transmission of conditions (b) to (e) to the alarm system.

6.200 The panel can be incorporated into the plant indicator unit, or be a separate unit within the plantroom. If mounted separately, the cabling should be monitored for open/short circuit. In the event of such a cabling fault, a red “system fault” lamp

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should be illuminated on the alarm signal status unit, together with the appropriate alarm condition.

6.201 The alarm signal status unit should be supplied from all individual plant control units, or from a separate common supply.

Plant management

6.202 Connections should be provided that allow monitoring (but not control) of the plant operation. For example:

a) compressor – “on”, “off”, “on-load”, “unloaded”;

b) molecular sieves – “on” or “off”.

6.203 These connections should be used to provide input to the hospital building and energy management systems (BEMS).

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7. Medical compressed air systems

General

7.1 Medical compressed air can be derived from compressor systems or by mixing gaseous oxygen and nitrogen from cryogenic liquid supply sources. Air produced by this latter method is referred to as synthetic air.

Compressor systems

7.2 Medical and surgical air can be provided from a single combined system or from separate plants. The choice ultimately depends on the relative consumption.

7.3 In the case of surgical air, consumption is at a high flow at a high pressure (up to 350 litres/min) but for relatively short periods of time (minutes); also, very small numbers of terminal units are in simultaneous use, typically fewer than five. Air for respirable purposes, however, is used at much lower flows (typically less than 80 litres/min) but, particularly in the case of patient ventilation, use can be continuous. Moreover, in the case of medical air there are considerably greater numbers of terminal units in use simultaneously. The installation of separate plants therefore can result in lower running costs. Requirements for separate surgical air systems are given in Section 8.

7.4 Some plant configurations are shown in Figures 23–26: reference should also be made to Tables 5 & 7 in Section 2:

- Figure 23 shows a typical medical air plant with fully automatic emergency reserve manifold;
- Figure 24 shows a combined medical and surgical air plant with emergency reserve manifolds. A combined system would be suitable for a small to medium hospital where separate plant could not be economically justified. In this case, a minimum of three compressors, each capable of supplying the total load should be installed plus automatic air cylinder manifold systems to support both the medical and surgical air;
- Figure 25 shows an option for combined plant with separate dryer and regulator arrangements;
- Figure 26 shows an option for combined plant with common dryer and separate regulator arrangements.

7.5 Other plant configurations are possible depending upon the specific design requirements e.g. for larger hospitals:

- two or three separate plants could be justified each serving a particular area;
- consider surgical air plant acting as an emergency back-up to the medical air plant;

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- with synthetic air, however, careful planning is required to take into account the emergency back-up required, the use of nitrogen for surgical use, safety and cost in comparison to the conventional means of supply.

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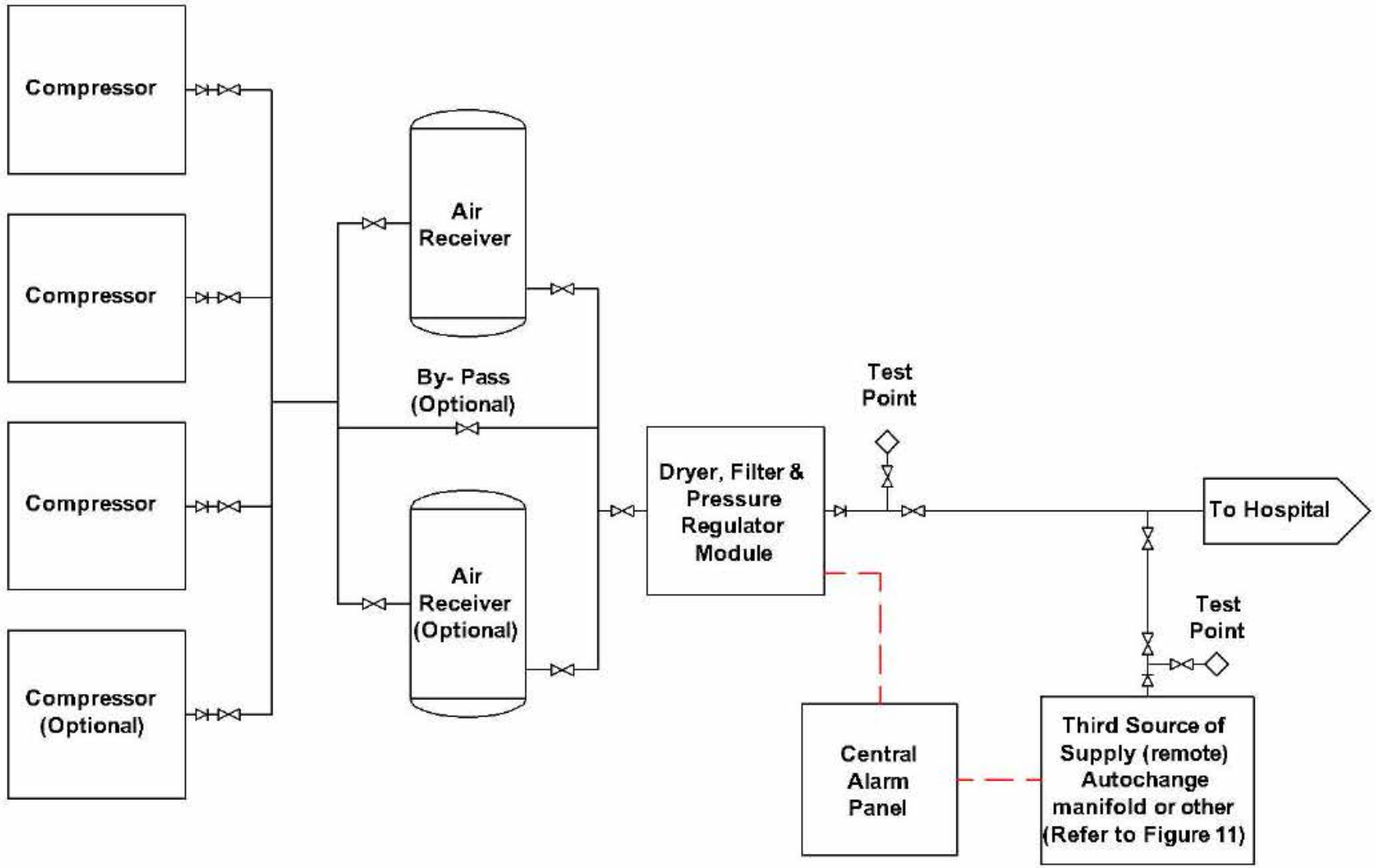

Figure 23: Typical medical air 400 kPa plant and automatic emergency reserve manifold

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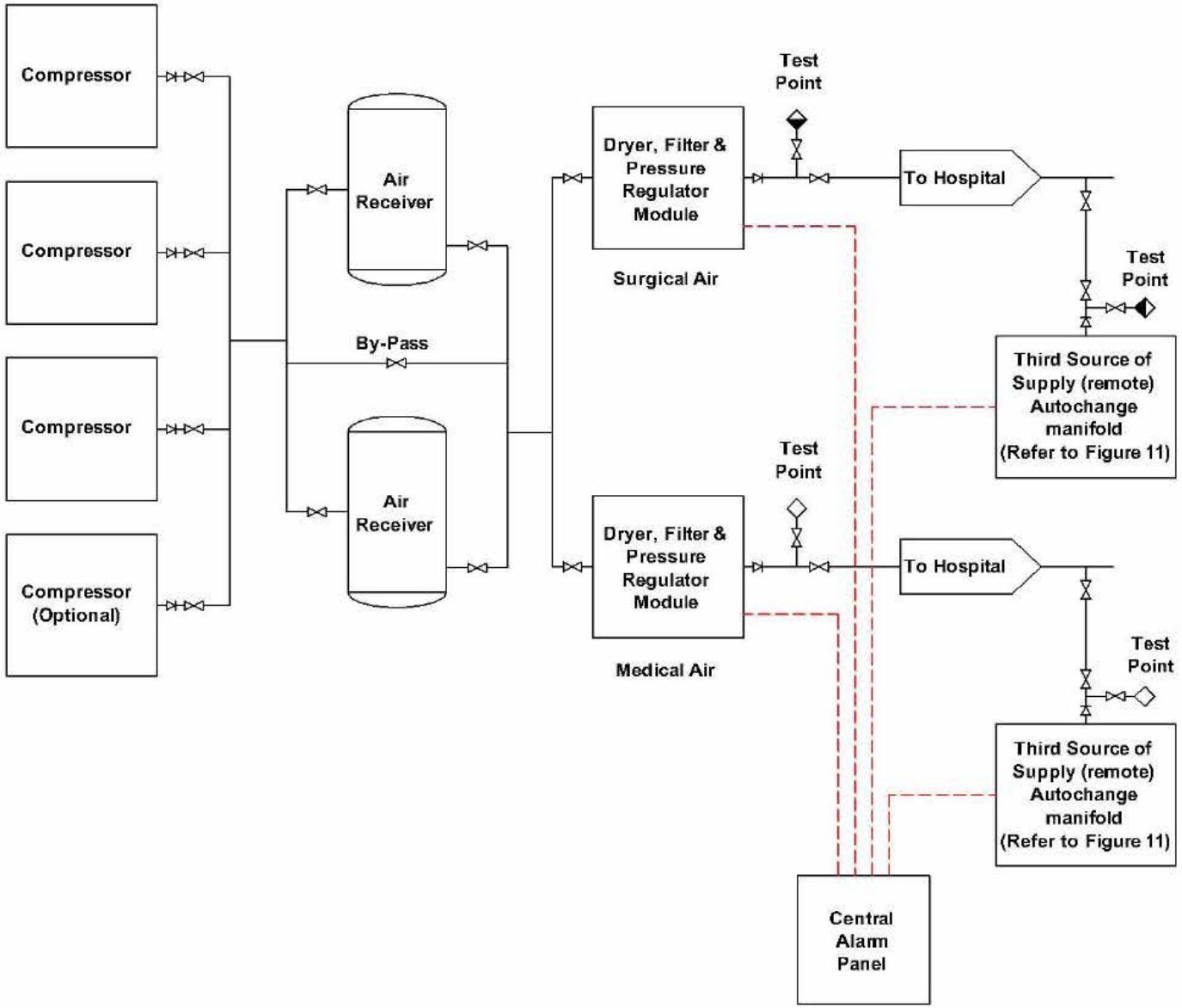

Figure 24: Typical duplex combined medical air 400 kPa and surgical air 700 kPa plant with emergency reserve manifolds

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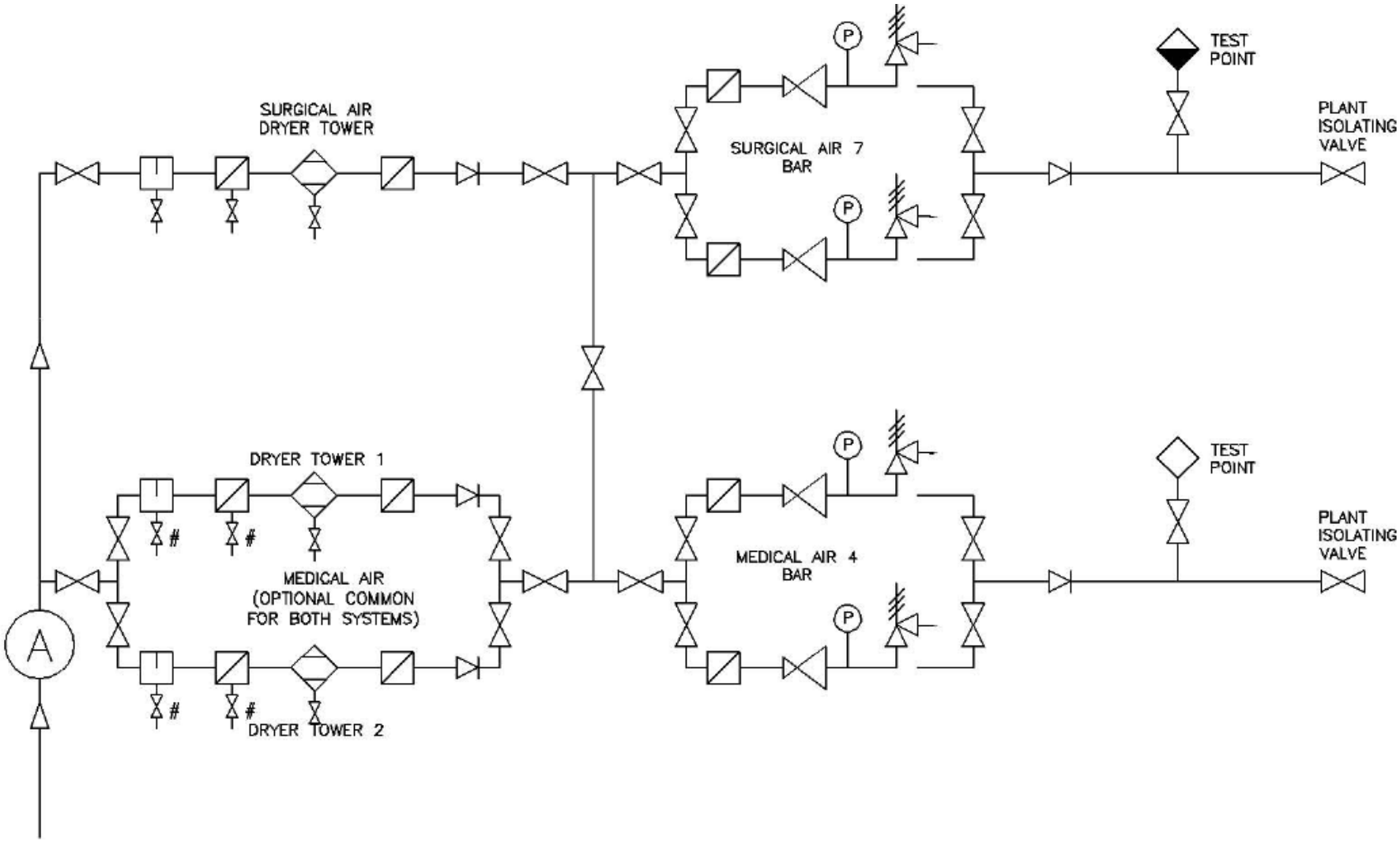

Figure 25: Option 1; medical air 400 kPa and surgical air 700 kPa with separate dryer and regulator arrangements

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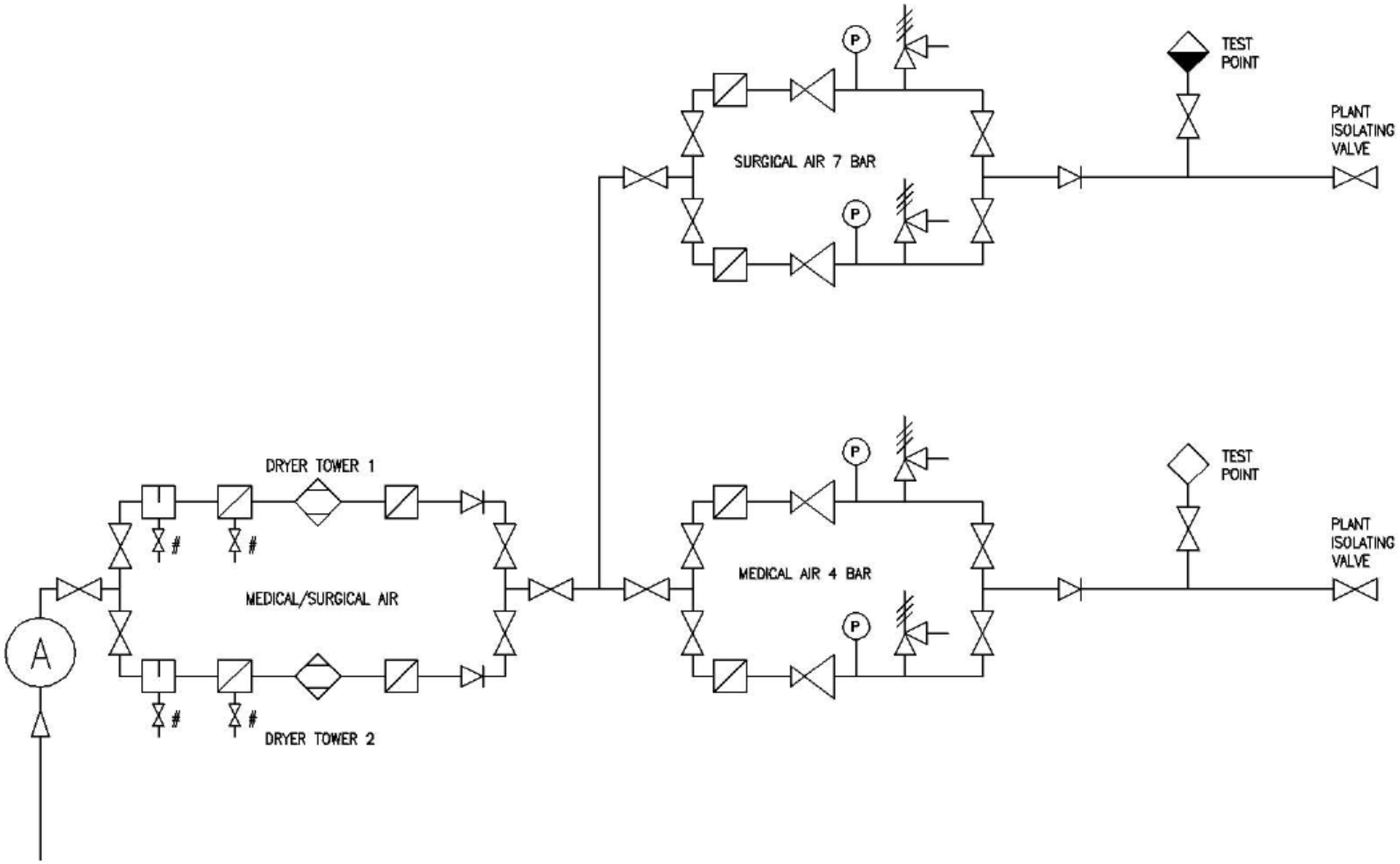

Figure 26: Option 2; medical air 400 kPa and surgical air700 kPa common dryer and separate regulator arrangements

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Quality

7.6 The European Pharmacopoeia (Ph. Eur.) specifies maximum impurity levels for carbon monoxide. It may be necessary to make provision to control the levels of contaminants and to monitor the supply to ensure conformance with the specification. European Commission directive 2001/83/EC specifies that medicinal products should be manufactured to the approved standard.

Siting

7.7 The plant should have all-round access for maintenance purposes, and allowance should be made for changing major components.

7.8 The siting of the plant should allow for adequate flows of air for three different purposes:

- air intake to the compressors;
- cooling of the compressed air by the after-coolers;
- cooling of the compressors.

Compressor noise

7.9 The noise level produced by the compressors will increase with the capacity of the supply system. The maximum free-field noise level for un-silenced compressed air plant, at 1m from the plant, varies with the type and power of the plant but should not normally exceed the following values:

Reciprocating	Screw	Vane	Power
85 dBA	76 dBA	76 dBA	0-7.5kW
89 dBA	78 dBA	76 dBA	7.6-15kW
93 dBA	80 dBA	79 dBA	15.1-22kW
97 dBA	92 dBA	90 dBA	22.1-60kW

Table 32: Compressor noise levels

7.10 In noise-sensitive areas, an acoustic enclosure should be included in the purchase specification for all compressors. Such an enclosure should produce a reduction of at least 10 dBA in the free-field noise level at 1m.

Air intake

7.11 The position of an air intake can have a considerable effect on delivered air quality, particularly with respect to levels of carbon monoxide. The air intake for a compressor should be located to minimise contamination from internal combustion engine exhausts and the discharge from vacuum systems, AGSS and ventilation systems or other sources of contaminants. Air intakes should be ducted where necessary to avoid contamination; a minimum height of 5m above ground level should ensure a reasonable quality of intake air. Where this cannot be achieved, additional filtration and/or air treatment may be necessary. If the siting of the compressor, regardless of the air intake location, is considered

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subject to a risk of aspirating toxic fumes and smoke as a result of a fire, an automatic shutdown system, linked to local smoke detectors, can be installed. If such a system is planned, it is essential that an automatic emergency supply manifold system is sited well away from the fire-risk area and is arranged to come on-line automatically in the event of plant shutdown.

7.12 Care is needed when extending compressor air intakes. Manufacturers' data should be consulted to ensure that intake flow, and hence compressor performance, are not adversely affected by excessive lengths of intake ducting. Choice of intake material is also important. Often, intakes are constructed from solvent-welded PVC. In a fire, toxic materials from the burning intake could be drawn into the air compressor and distributed throughout the system. In addition, there is a risk that inadequate solvent drying time before use of the intake will result in toxic solvent fumes being drawn into the system. Corrosion-resistant ducting (for example stainless-steel flue liner) is a suitable material.

7.13 Air-inlet filters should be fitted immediately upstream of the compressor. In exceptional circumstances, additional screens, filters and silencers may be required. The filters should comply with BS ISO 5011: 2000 and be either dry medium filters or grade CA paper element filters.

Compressor types

7.14 There are many different types of compressor currently available, the most common types being:

- reciprocating piston compressors;
- rotary vane compressors;
- rotary screw compressors.

7.15 The compressors may be of any type, provided they are suitable for continuous running on load and for high frequency start/stop operation. When selecting compressors the opportunity to maximise energy efficiency should be taken e.g. consideration should be given to the variable speed/ inverter drive motors which are increasingly being used in hospitals particularly on heating systems. In medical compressed air applications, this would reduce the stop/start frequency by maintaining a constant pressure within close limits and it is feasible to consider the eventual removal of the receiver. Research is being carried out into the use of variable speed drives with particularly successful applications in AGSS and Dental Vacuum and the removal of the energy wasteful constant volume exhauster. Now that the range of rotary screw compressors has been expanded particularly to the lower kW sizes, they have generally taken over from the reciprocating compressor in medical air applications. If reciprocating compressors are used, they may be either of the single or of the two-stage type, although for a 400 kPa system a single-stage compressor is usually satisfactory.

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Compressor lubrication

7.16 Compressors may be oil-lubricated, provided that suitable arrangements are made to ensure that the air quality specification given in Table 42 is fulfilled (refer to Section 15).

7.17 Rotary screw compressors can be sealed by oil or purified water (reverse osmosis) with cooling by air or water. Water would provide lower operating temperatures with increased efficiency. However, water does introduce another external risk factor to ensuring the service provision. Thus the normal medical application is oil-sealed or air-cooled. Where there is a requirement for ducted intake air, this can be separate from the compressor cooling air. Reciprocating compressors may be oil-lubricated, carbon ring, PTFE ring or diaphragm-sealed type. However, the pulsating frequency of the piston and noise generated would normally require an acoustic enclosure.

7.18 Alternatively, oil-free compressors are available and may be beneficial in reducing filtration requirements.

7.19 Oil-free reciprocating and rotary screw compressors are not necessarily oil-less. Additionally the atmospheric air can carry oil vapours and contaminants and should not necessarily imply a reduction in filtration requirements. Oil-sealed rotary screw compressors have the added advantage of noise reduction, smooth air delivery and are more suited to a variable speed drive.

7.20 There is a danger that PTFE rings and lubricating oils could decompose at high temperatures to form toxic products. It is a requirement of paragraph 7.70 to monitor compressor temperature and to close down the compressor on fault condition. BS EN ISO 15001: 2010 specifies the requirements for selecting materials used in medical supply equipment.

7.21 On start-up, when oil is used as the sealant, moisture condensing at high pressure forms an emulsion with the oil. Once operating temperature is reached, water is readily separated. Because it is impossible to match the varying demand with plant capacity, it may be necessary to include oil heaters to avoid emulsification. If it is intended to omit oil heaters, manufacturers should be asked to confirm the suitability of the compressor for intermittent operation. Oil-lubricated compressors, however, are considered to be satisfactory.

7.22 Where oil-lubricated compressors are used, suitable means of separating oil from condensate is essential.

7.23 Once a compressor installation has been selected:

- the plant should include at least two compressors, but additional compressors may be included in accordance with Table 10;
- the individual compressors should be arranged so that they will supply the system simultaneously if necessary;
- the relative magnitude of the capital and running costs should be evaluated at the time of purchase. Too much emphasis has been placed on low

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capital cost at the expense of reliability and high power costs. The running costs should be calculated at realistic levels of usage;

- the control system for the compressor plant should include an “hours-run” counter and should be constructed in accordance with the guidelines given below;
- the efficiency of plant, expressed as the volume of air delivered to the pipeline distribution system (after losses in the drying system and filtration system) per kilowatt-hour (kWh), should be stated by the supplier of the system. The testing procedure should evaluate this efficiency by testing the power consumption over a suitable period of time at 100%, 10% and 0% of the system design flow. A minimum efficiency of 5 m^3/kWh at 100% and 10% is required. The power consumption at zero flow should be less than 1% of that at 100% design flow.

After-coolers

7.24 After-coolers (and inter-coolers) usually form part of the compressor sub-assembly. After-coolers should be fitted to all medical air compressor systems. These will normally be air-cooled, and may need ducting with forced ventilation to ensure an adequate supply of cooling air.

Receivers

7.25 Air receivers should comply with BS EN 286-1: 1998 + A2: 2005 for all vessels up to 10,000 bar litres, and should be supplied with test certificates. The minimum water capacity of the receivers should be 50% of the compressor output in 1 minute, stated in terms of free air delivered at normal working pressure. Receivers should also be fitted with an automatic drain. Electrically operated automatic drains have been found to be more reliable.

7.26 To facilitate the statutory inspection, there should be either two suitably valved air receivers or, for a single receiver, a by-pass arrangement (for use in manual operating mode only) in order to avoid interruption to the supply. Alternatively the tertiary supply manifold can be used. A by-pass arrangement should only apply if rotary screw compressors are provided. Alternatively the tertiary supply manifold can be used provided an adequate supply of cylinders are available and constant monitoring is applied.

7.27 For systems that have a design flow exceeding 500 litres/min, two receivers should be provided with valve arrangements to permit isolation of one or the other for inspection purposes.

Air treatment and filtration

General

7.28 Contaminants can enter the compressed air system from three sources: the atmosphere, the compressor and the pipeline distribution system. Each potential source must be taken into account when specifying the type and location of air treatment equipment. Filtration equipment may include pre-filters,

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coalescing filters, adsorption equipment, carbon filters, particulate filters, bacterial filters and any other additional filtration equipment necessary to ensure the quality of the product.

Solid contaminants

7.29 Particles in the environment cover a wide range of sizes, but approximately 80% are less than 0.2µm and are therefore not removed by the intake filter to the compressor.

7.30 Although particles smaller than 40µm are unlikely to cause mechanical damage, a 5µm intake filter is preferred to avoid blockage of internal air/oil separators.

7.31 Filters are specified in terms of performance tests – a sodium flame test, a DOP (dispersed oil particulate) test etc.

Water

7.32 Water is always a contaminant in a compressed air system, regardless of the type and location of the compressor plant, since the air drawn into the compressor intake is never completely free of water vapour. The amount can vary from 2.5 g/m^3 to over 40 g/m^3 depending on the climatic conditions. The after-cooler and receiver remove some of this, but about 20 g/m^3 is likely to remain in the compressed air unless removed by dryers.

7.33 A water content not exceeding 67 vpm (parts per million by volume – equivalent to dew-point –46°C at atmospheric pressure) is specified for medical air pipeline systems. Only desiccant dryers can usually achieve this. A variety of desiccant types are available. Silica gel, although a desiccant, can easily fracture and powder and is not used in medical compressed air applications. Activated alumina is the common type employed. Molecular sieve desiccants employing zeolites can also be used, but on occasions it has been found that this material has produced air with an increased oxygen content, in the order of 24%. Refrigerant dryers can perform satisfactorily down to a pressure dew-point of +3°C (atmospheric dew-point –20°C) and are therefore not recommended as the sole form of drying.

Oil

7.34 With oil-lubricated compressors, it is inevitable that the compressed air will contain oil. Even with oil-free compressors (non-lubricated), complete freedom from oil and oil vapour cannot be positively guaranteed, as hydrocarbon vapours may be drawn into the compressor. Oil levels in the air supply must be controlled to 0.1 mg/m^3 with means of monitoring on a routine basis.

7.35 Oil will exist in the system in three forms: bulk liquid, oil aerosol and oil vapour. Provided that the oil lubricant is appropriate and the after-cooler properly designed, the amount of oil present as vapour should be small and is unlikely to exceed 0.5 mg/m^3.

7.36 The amount of oil that is present as bulk liquid and aerosol is more difficult to predict. With modern, well-maintained oil-lubricated compressors, it is unlikely

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to exceed 5 mg/m^3 due to the high-efficiency oil/air separator. A pre-filter/ separator will remove the bulk contaminants which should reduce the remaining oil content to 0.5 mg/m^3, particle removal down to 1 micron and a DOP penetration of less than 0.03%. The coalescing filter should further reduce the remaining oil content to 0.01 mg/m^3, particle removal down to 0.01 micron and a DOP penetration of less than 0.0001%. The preferred practice is to retain the pre and coalescing filter as separate assemblies.

7.37 Oil-contaminated compressor condensate is classified as a trade effluent by virtue of Chapter 14 of the Public Health (Drainage of Trade Premises) Act 1937. An oil condensate separator should therefore be installed.

7.38 Under Scottish environmental legislation, it is illegal to make a discharge of trade effluent to “controlled waters” via a surface water drain without the consent of the Scottish Environment Protection Agency (SEPA).

7.39 Similarly, the Water Authority enforces the limit of oil condensate discharged into the public foul sewer. Prior consent to discharge is mandatory.

7.40 Condensate from oil-free compressors may be discharged to drain.

7.41 Any condensate produced from the compressor/ dryer system must be regarded as trade effluent and is therefore not suitable for discharge to any surface water system draining to any surface water sewer, water-course or soak away; this may not apply if a suitable oil / water separator is installed. Maximum oil content limits range from region to region, from 25 mg/litre up to 500 mg/litre; the water authority should be consulted.

Dryer and filter assembly

7.42 Each dryer and filter assembly should be rated for continuous use at the system demand flow.

Dryer controls

7.43 The dryer control system should ensure that regeneration is operated in proportion to the compressed air usage. The effectiveness of the control system will become apparent when the efficiency of the compressor system is tested at 10% and 0% of the system design flow. Evidence of the reliability and performance of a dryer system should be sought from manufacturers, since these items are critical to the overall performance of the compressor system. The dryer control system should include a dew-point hygrometer and display with a minimum accuracy of ±3°C in a range from –20°C to –60°C atmospheric dew-point, with a set point of –46°C. It should be arranged that in the event of open circuit, a “plant emergency” alarm be initiated.

Dust filters

7.44 There should be a dust filter downstream of the dryers to remove particles down to 1 µm, with a DOP penetration of less than 0.03%, when tested in accordance with BS EN ISO 3549: 2002.

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Activated carbon filter

7.45 Duplex activated carbon filters should be installed upstream of the final bacteria filter for odour removal.

Bacteria filters

7.46 Duplex bacteria filters should be fitted upstream of the final pressure regulator with appropriate isolating valves. The filters should provide particle removal to 0.01 mg/m^3 and a DOP penetration of less than 0.0001%.

Pressure control

7.47 The pressure control should maintain the nominal pipeline pressure within limits given in Section 4. Duplex line pressure regulators should be provided with suitable isolating valves. The regulators should be of the non-relieving type.

Safety valves

7.48 Safety valves should be provided in accordance with the requirements given below. All safety valves should conform to BS EN ISO 4126-1: 2004. A safety valve of the certified discharge capacity stated should be fitted in each of the following positions:

- on the delivery pipe of each compressor and upstream of any isolating valve, non-return valve or after-cooler, capable of discharging the total throughput of the compressor;
- on each air receiver and dryer tower, capable of discharging the sum of the throughput of all the compressors. It is not necessary to provide safety valves on the dryer columns where the system is already protected by a safety valve on the receiver and the downstream equipment, that is, if the dryer column is already sufficiently protected;
- immediately downstream of each pressure regulator, capable of discharging the system demand flow.

7.49 All safety valves should be of the closed-bonnet type and connected to suitably sized pipework to allow safe discharge, not necessarily to the outside.

Traps, valves and non-return valves

Automatic drainage traps

7.50 Electrically or mechanically operated automatic drainage traps should be provided on the after-coolers, receiver, separators and coalescing filters. The discharge from these drainage traps should be piped to a suitable gully via an oil/water separator. Co-ordination with building work is required for this provision. A manual by-pass valve should be fitted to each after-cooler and receiver automatic drainage trap to permit a trap efficiency check. Automatic drainage should be fitted to all pre-filter / separators and coalescing filters. Electrically-operated automatic drains have been found to be more reliable.

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7.51 Drainage and tundishes are usually provided under the building contract. Separators should be provided under the air compressor contract. Provision of oil/water separators should be supplied by the plant manufacturer and matched to suit the combined plant output.

Non-return valves

7.52 Non-return valves are required to prevent backflow of the air supply in certain situations. These valves should be located as follows:

- between the compressor and the receiver, but downstream of any flexible connector;
- downstream of the dust filter on the dryer;
- upstream of the emergency cylinder reserve connection in the pipeline connecting the plant to the pipeline distribution system, to prevent back-feeding this plant;
- upstream of any inlet point that may be used to feed the system in an emergency;
- downstream of the emergency cylinder manifold regulators.

Isolating valves

7.53 Isolating valves should be provided downstream of non-return valves and upstream of, for example, the connection of the emergency reserve manifold. Isolating valves should be provided in order to facilitate maintenance or replacement of plant items.

7.54 Manually-operated ball isolation valves should be located in the positions shown in Figures 23 – 26 to allow isolation of components such as receivers, dryers, automatic drains, pressure regulators and filters. There should also be a valve on the compressed air plant, downstream of the plant non-return valve and the connection of the cylinder manifold supply.

Pressure indicators

7.55 Pressure indicators should comply with BS EN 837-1:1998 or have an equivalent performance if electronic indicators are used. Calibration should be in bar or kPa. All gauges should have a minimum scale length of 90mm, and the working range should not exceed 65% of the full-scale range except on differential pressure gauges. Pressure indicators should be connected by means of gauge cocks.

7.56 Pressure indicators should be located:

- on the plant control unit indicating receiver pressure;
- on each receiver;
- downstream of each pressure regulator;
- on each dryer tower;

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- on the plant pipework, upstream of the plant isolating valve.

7.57 Differential pressure indicators should be provided across each:

- pre-filter / separator;
- coalescing filter;
- dust filter;
- activated carbon odour filter;
- bacteria filter.

7.58 Except for pressure gauges, all control and measuring devices should be connected directly to the pipework via a minimum leak device (to allow removal for servicing) and not isolated by valves.

Operating and indicating system

7.59 The operating and indicating system should perform the following functions:

- overall plant control and indication;
- individual compressor starting;
- control of dryers;
- plant status monitoring.

All pressure switches mounted internally or externally which may require adjustment when 'live' should be designed and operated at extra low voltage.

7.60 Provided that the individual compressor starters are housed in a separate compartment, these functions may be carried out by separate units or may be installed in a common panel and located on the plant or on the plantroom wall. Control panels containing pneumatic components should have vents to permit release of pressure in the event of component failure. All indicators should be appropriately identified and should have a design life of at least five years.

7.61 The operating system of each compressor should be capable of automatically restarting after reinstatement of the power supply.

7.62 All components of the medical air supply system should be connected to the essential electrical supply. The control system should ensure that compressors restart in sequence to avoid overloading the power supply.

Plant control unit

7.63 The plant control unit should have a separate power supply for each compressor, controlled by a separate sub-circuit. Generally, system resilience can be increased through the specification and design of the electrical services by having separate supplies for designated components, for example, two out of four compressors or vacuum pumps being supplied by a separate electrical system / distribution board.

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7.64 The unit should:

- allow either a manual selection of duty/stand-by for each of the compressors or preferably have an automatic sequence selection with a means for manual override;
- incorporate an automatic standby control in the event of a printed circuit board failure;
- be capable of manual operation of the compressors in the event of the main and standby central control panel functions failing;
- ensure that two or more compressors do not start simultaneously when power is supplied;
- for each compressor starter unit or if remote from the compressor, incorporate an independent manual start which will permit the compressor to work under load and fitted with an emergency stop.

7.65 A warning notice that complies with BS5499-5: 2002 should be affixed which indicates the presence of low voltage.

Plant control indication

7.66 There should be indicators for each compressor as follows:

- green “mains supply on”;
- green “compressor called for”, which indicates that the compressor motor is electrically energised;
- an indicator of the pressure produced by the compressor.

Compressor starter units

7.67 There should be individual starter units for each compressor which operate a single designated compressor. The starters should be provided with safety interlocks, as specified by the compressor manufacturers, which should inhibit plant operation until manually reset by means of a button. The starters should allow automatic restart after an interruption to the power supply. Each starter unit should contain the following:

- an isolator interlocked with the covers;
- either HRC (high rupturing capacity) fuses to BS88 or suitable circuit breakers to BS EN 60947-2: 2006 + A1: 2009 and/or BS EN 60898-1: 2003 + A1: 2004;
- an industrial grade ammeter to BS EN 60051-1:1999, IEC 60051-1:1997 (digital ammeters of similar accuracy to those compliant with BS EN 60051-1: 1999, IEC 60051-1: 1997 may be used);
- a “total hours” counter if not included in the plant control unit;
- a green “mains supply on” indicator if mounted separately from the plant control unit.

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Dryer control unit

7.68 The dryer control unit may be mounted on the dryers or may be located with the plant control unit. There should be separate power supplies for the duty and stand-by dryer assemblies taken from the same phase.

7.69 The dryer control unit should contain the following:

- a duty dryer selector switch;
- a service function – to enable selection of continuous/normal running;
- individually fused, separate cycling systems for each dryer;
- a system to control regeneration of the dryers in relation to pipeline demand;
- a hygrometer and display with a minimum accuracy of ±3°C in a range from –20°C to –60°C (set to –46°C atmospheric dew-point) and a pressure sensor;
- an automatic changeover to the stand-by dryer system in the event of failure of the duty unit by either dryness or pressure. This requires:
  - electrical and pneumatic isolation of the duty sub-assembly so that it is taken off- stream;
  - electrical and pneumatic energisation of the stand-by sub-assembly so that it is brought on-stream;
  - activation of the appropriate fault indicator and associated Volt-free contacts;
- the sub-assembly to remain in this mode of operation until the fault has been rectified;
- green function indicators for each dryer sub- assembly to indicate:
  - dryer 1 selected;
  - dryer 2 selected;
  - selected dryer – “normal”;
  - selected dryer – “failed” indicated by an orange or amber light (this fault indicator should remain until manually reset by means of a reset button).With a duty fault condition existing, the standby dryer will function in the normal alternate drying / regeneration mode.
- a fail-safe system which on failure of the power supply causes the following:
  - closure of the exhaust and purge valves;
  - opening of the inlet and outlet valves.

Plant status monitoring

7.70 A monitoring system should be provided to detect the following faults in the air compressor system:

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- plant faults (for each compressor):
  - control circuit failed;
  - motor tripped;
  - after-cooler temperature high;
  - compressor temperature high;
  - compressor failed to go on load.
  - activation of other safety devices supplied by the manufacturers;
- plant faults (for each dryer unit):
  - dryer failure;
  - pressure fault;
- plant emergency:
  - receiver pressure 0.5 bar below the stand- by cut-in pressure;
  - receiver pressure 0.5 bar above cut-out pressure;
  - dryness above –46°C at atmospheric pressure;
- pressure fault (cylinder reserve):
  - as the reserve manifold is a fully automatic cylinder manifold, the full set of standard alarm conditions should apply to the central alarm system.
- pressure fault (pipeline):
  - low pipeline pressure;
  - high pipeline pressure.

Where surgical and medical air are supplied from a standard compressor plant with duplex dryer / filtration unit, each service should be provided with a duplex regulator set. Each set should be fitted in parallel to the other service, each monitored by a high and low line pressure switch. The central alarm panel need only indicate a plant combined line pressure fault, identifying of the service by investigation.

Plant status indicator unit

7.71 In addition to the plant control indication, there should be a plant status indicator panel that may be mounted on the plantroom wall or adjacent to either the compressor starter unit or the plant control unit. It should have a warning notice that complies with BS5499-5: 2002 to indicate the presence of low Voltage.

7.72 There should be indicators for each compressor to show the following conditions:

a) green “mains supply on”;

b) yellow “control circuit failed”;

c) yellow “overload tripped”;

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d) yellow “after-cooler temperature high”;

e) yellow “compressor temperature high”;

f) yellow for each individual safety device provided by the manufacturers;

g) yellow “compressor failure”.

7.73 There should be indicators for each dryer system to show the following:

a) green “mains supply on”;

b) yellow “dryness fault”;

c) yellow “pressure fault”.

Alarm signal status unit

7.74 An alarm signal status unit should be provided as part of the control system. It should display the following conditions:

a) green “normal” (normal);

b) yellow “plant fault” conditions ((b)–(g) in paragraph 7.72);

c) yellow “plant emergency” (low reservoir pressure/high moisture: that is, condition (b) in paragraph 7.72);

d) yellow “reserve low” (emergency/reserve banks low (<50%));

e) red “pipeline pressure fault” (pressure fault).

7.75 Conditions (b) to (e) in paragraph 7.74 should be transmitted to the central alarm system. Where relays are used, they should be normally energised relays that de-energise under fault conditions, with contacts having a minimum rating of 50 V d.c. and 50 mA.

7.76 Volt-free, normally closed contacts rated at 50 V d.c. and 50 mA should be provided for transmission of conditions (b) to (e) in paragraph 7.74 to the alarm system.

7.77 The panel can be incorporated into the plant indicator unit or be a separate unit within the plantroom. If mounted separately, the cabling should be monitored for open/short circuit. In the event of such a cabling fault, a red “system fault” lamp should be illuminated on the alarm signal status unit together with the appropriate alarm condition.

7.78 The alarm signal status unit should be supplied from all individual plant control units or from a separate common supply.

Plant management

7.79 Connections should be provided which allow monitoring of plant alarm conditions (b) to (e) in paragraph 7.74 and pump running for each “compressor”. These connections should be Volt-free contacts normally closed for each

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condition having a minimum rating of 50 V d.c. and 50 mA. The building management system should not be used to control the plant.

Synthetic air

7.80 This section provides technical details of the process and systems required to generate medical air from mixing gaseous oxygen and nitrogen, derived from cryogenic supplies.

7.81 For the purposes of the Medicines Act 1968, it is considered that the synthetic air is manufactured on-site, for use on that site only, in exactly the same way as for medical air derived from compressor plant. The production of synthetic air implies a manufacturing process, and as such, the process should be subjected to the same safety requirements of any pharmaceutical process. This should include, for example, a HAZOP (HAZard and OPerability) analysis and other safety analyses that may be necessary.

7.82 Synthetic air is generated by mixing gaseous oxygen and nitrogen in a blender or mixing panel at pre-set pressures to ensure that the resultant mixture is always correct. Continuous on-line monitoring of oxygen concentration is provided to check the mixture; the system shuts down automatically if the oxygen concentration varies from the specified value.

7.83 If one mixing system shuts down, the pipeline is supplied from the secondary mixing system to ensure continuity of supply.

7.84 The feasibility study should provide more information on the details of the monitoring and alarm systems required, as well as operational information.

7.85 The VIE system supplying the medical oxygen may be used to supply the synthetic air system, depending on the system demands.

7.86 Nitrogen supplied to the synthetic air system may also be used to provide the power source for surgical tools instead of surgical air at 700 kPa.

7.87 An electrical power supply is required in order, for example, to operate solenoid valves and monitoring instrumentation. Therefore the system should be connected to the essential power supply and via an uninterruptible power supply (UPS) with at least four hours' capacity; this should ensure continuity of supply in the event of power failure.

System description

7.88 The gaseous oxygen and nitrogen are derived from bulk liquid supplies contained in a VIE – asset out in the "Liquid oxygen systems" text within Section 6.

7.89 The oxygen for synthetic air may be taken from the VIE supplying the medical oxygen system or it may be from a dedicated VIE. It would normally be more cost-effective for the oxygen to be taken from the main VIE, although this would obviously depend on the existing VIE capacity, the demand, space constraints etc. The feasibility study should provide more detailed information on whether it

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is likely to be more cost-effective to provide a totally separate VIE system or to use the existing medical oxygen VIE. The feasibility study should include a cost comparison against other methods of supply. Unlike the renting of liquid vessels, there can be a high capital cost for the ancillary mixing equipment which may not come under the rental agreement.

7.90 For both the oxygen and nitrogen it is necessary to have a secondary supply system to ensure continuity of supply; the system demands are such that this should be derived from a second – normally smaller – VIE.

7.91 This secondary oxygen supply can also serve the hospital's medical oxygen system.

7.92 Since four VIEs will be required, the space requirements will need special consideration when planning the installation of a synthetic air system.

7.93 The system comprises:

- storage vessels – one main vessel and one secondary supply vessel for both oxygen and nitrogen;
- vaporisers for both oxygen and nitrogen;
- medical oxygen flow control – where used to supply medical oxygen systems;
- surgical nitrogen flow control – where required;
- a control panel for the nitrogen and oxygen supplies to the mixing panels;
- duplicate air mixing panels;
- buffer vessels – each mixer has a buffer vessel to smooth fluctuations in demand;
- a warning and alarm system;
- duplicate oxygen analysers on each mixer.

7.94 A typical system is shown in Figure 27 overleaf which supplies synthetic air with a third source of supply for medical air (remote), surgical nitrogen and oxygen with a third source of supply for oxygen (remote).

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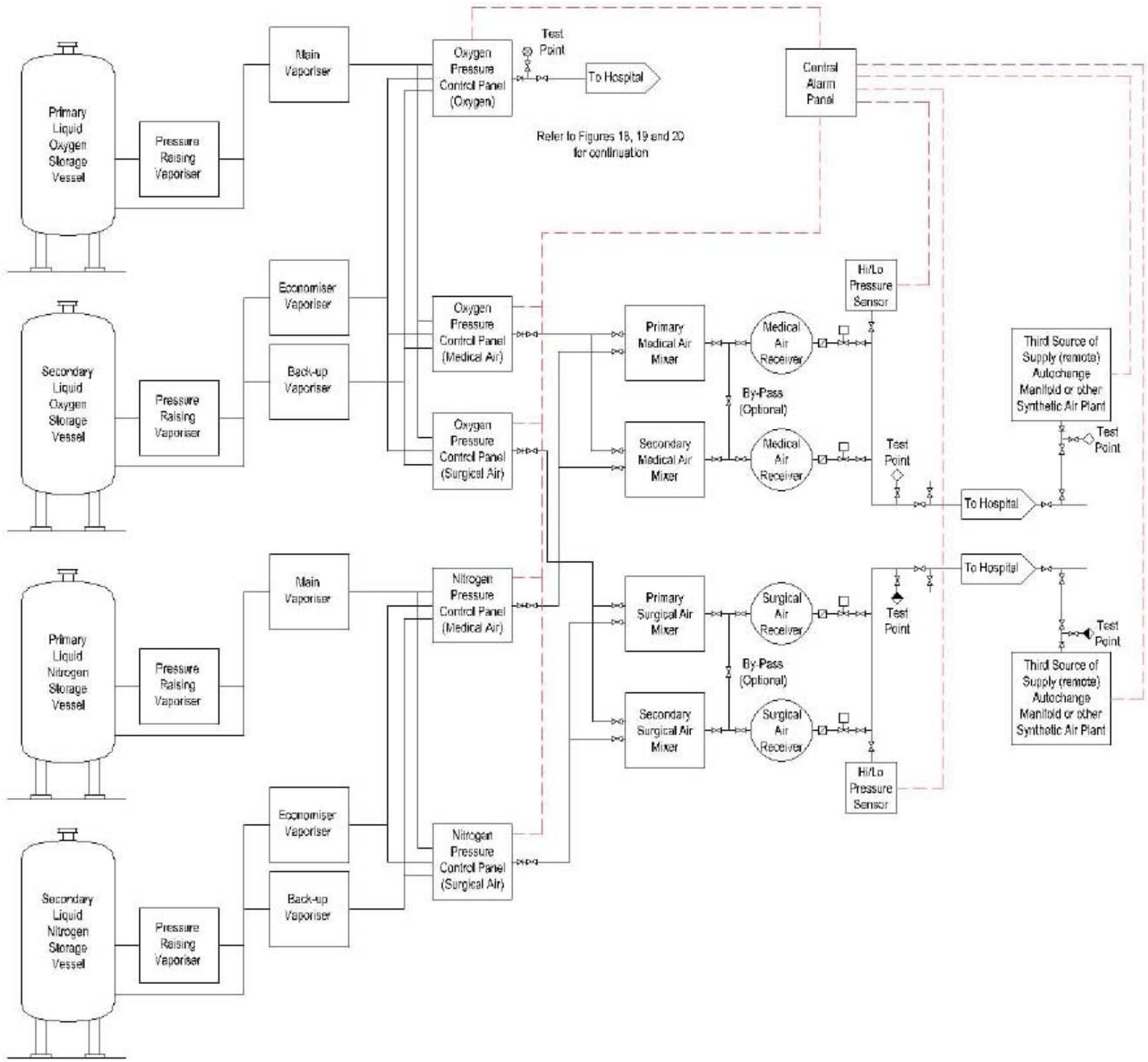

Figure 27: Synthetic air plant

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Storage vessels

Vessel summary

7.95 The following vessels are required:

- one main oxygen vessel;
- one secondary oxygen vessel with at least 24 hours' capacity;
- one main nitrogen vessel;
- one secondary nitrogen vessel with at least 24 hours' capacity.

Vessel operating pressure

7.96 The following operating pressures are required:

- main vessels: 12.5 bar;
- back-up vessels: 12.5–14 bar.

Main vessel capacity

7.97 The main vessel should normally be sized on the basis of two weeks' supply. This should be calculated as 14 x the average daily usage. This should provide adequate storage and a cost-effective vessel-filling regime. The gas supplier should, however, be consulted as there may be other factors, such as geographical location, space etc, which need to be taken into account when sizing the main vessels.

Back-up vessel capacity

7.98 The stand-by vessel should have 24 hours' capacity at any time; that is, it should be sized on the basis of twice the average daily usage. This will ensure that there is always 24 hours' supply available.

7.99 In addition to the normal instrumentation as set out in the "Liquid oxygen systems" text within Section 6, the vessels should be fitted with a telemetry system to monitor continuously the vessel contents.

7.100 This information should be transmitted direct to the gas supplier and also the hospital. The exact details of how much information, and where it should be received, will depend on each hospital site.

7.101 The main vessel low level alarm is activated at 25% full; the back-up low level alarm is activated at 50% full.

7.102 The safety relief valves and bursting discs should be sized in accordance with BCGA CP19.

7.103 The liquid from the vessels should be supplied to the process at a nominal pressure of 12.5 bar.

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Vaporisation

7.104 The main and stand-by vessels should have dedicated vaporisers designed for continuous capacity and 24-hour capacity respectively at 1.5 x the required flows to ensure that the vaporisers are not overdrawn.

7.105 This may be achieved in each case by either a single set of vaporisers or by vaporisers operated on timed or manual changeover.

7.106 It is preferable for the vaporisers to operate on a timed changeover as this avoids the need for hospital staff to manually operate the changeover valves.

7.107 The timed changeover will require a 110 V or 240 V supply; this should be on the emergency supply and a UPS should also be provided, with at least 4 hours' capacity.

7.108 Each vaporiser or set of vaporisers must have a safety relief valve.

Medical oxygen flow control

7.109 A control panel (similar in principle to a C11 panel) should be provided – the only difference is that the secondary supply is taken from a low-pressure liquid source.

Surgical nitrogen flow control

7.110 A control panel to regulate the gaseous nitrogen to between 7.5 and 9.5 bar, depending on the system design, should be provided.

7.111 The pipeline distribution system should be designed in exactly the same way as for surgical air 700 kPa systems, as described in Section 8.

Control panel for the nitrogen and oxygen supplies to the mixing panels

7.112 The control panel should be sized to provide pressure-regulated flows as appropriate for the mixing system; this would typically be up to 200 Nm^3/hr (normal cubic metres per hour).

7.113 The stand-by supply regulation cuts in when the main line pressure falls to 11 bar; there is no regulation on the main supply line.

7.114 A non-return valve should be installed in both the nitrogen and oxygen supply lines within the mixer to prevent cross-contamination.

7.115 A non-return valve should also be installed on both the main oxygen supply and the stand-by oxygen supply to the mixer to prevent the medical oxygen line becoming contaminated with nitrogen.

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Air mixing panels

7.116 A range of sizes of mixing panels is available with, typically, nominal capacities of 50, 100 and 200 Nm^3/hr.

7.117 A regulated supply of nitrogen and oxygen is blended in a mixing valve. The differential pressure at the inlet to the mixing panel is critical and should not exceed 0.5 bar. A pressure-switch-operated solenoid valve opens and shuts on a 0.5 bar differential.

7.118 The main mixer solenoid valve opens when the line pressure falls to 4.2 bar; the stand-by mixer solenoid valve will open if the line pressure continues to fall to 4.0 bar.

7.119 Two independent paramagnetic oxygen analysers are provided on each mixer to give continuous on-line measurements.

7.120 If the oxygen concentration falls outside 20–22% as measured by either analyser, the mixer solenoid valve is held closed and the mixer is shut down. In addition, a signal is relayed downstream to close the solenoid valve on the buffer vessel associated with that mixer.

Buffer vessels

7.121 Each mixer has associated with it a buffer vessel to smooth fluctuations in demand.

7.122 In the event that the oxygen concentration differs from the specification (that is, 20–22%), the solenoid valve downstream of the buffer vessel will also close, preventing air from the buffer vessel from entering the distribution system.

7.123 The buffer vessel, together with appropriate means of safety relief, should be sized to match each mixing panel to provide stable operation.

Alarm signal status unit

7.124 The same alarm conditions for liquid oxygen should also be transmitted and displayed for the liquid nitrogen system. The following conditions should be displayed for the mixing panels:

a) green “normal” (normal);

b) yellow “plant fault” (low gas pressure to any mixer);

c) yellow “plant emergency” (analysis out of specification on any mixer);

d) yellow “reserve low” (operating on final mixing panel/buffer vessel only);

e) red “pressure fault” (pressure fault).

7.125 Conditions (b) to (e) of paragraph 7.124 should be transmitted to the central alarm system. Where relays are used, they should be normally energised relays that de-energise under fault conditions, with contacts having a minimum rating of 50 V d.c. and 50 mA.

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7.126 Volt-free, normally closed contacts rated at 50 V d.c. and 50 mA should be provided for transmission of conditions (b) to (e) of paragraph 7.124 to the alarm system.

7.127 The panel can be incorporated into the mixing panel control unit or be a separate unit within the plantroom. If mounted separately, the cabling should be monitored for open/short circuit. If such a cabling fault occurs, a red “system fault” lamp should be illuminated on the alarm signal status unit together with the appropriate alarm condition.

Emergency supply provision

7.128 A risk assessment should be carried out to establish the vulnerability of the main supply system of both oxygen and nitrogen. Further information is given in Section 2 on sources of supply and in Section 6.

Additional use of medical air systems

7.129 It is possible to use medical/surgical air as a power source for pendant control and braking systems.

7.130 These additions must not compromise either the medical air system or operation of connected equipment. They must be connected via a non-return valve and flow-limiting device, and be capable of isolation by means of an AVSU labelled to identify the equipment controlled.

7.131 Medical air systems must not be used for applications referred to in paragraph 2.6.

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8. Surgical air systems

General

8.1 Surgical air at 700 kPa is only used as the power source for surgical tools. These tools typically require high flows – up to 350 litres/min – at 700 kPa at the point of use. Where nitrogen is available on site, it may be used as an alternative source of supply.

8.2 Supply systems for surgical compressed air may be a cylinder manifold system, a dedicated 700 kPa compressor system or a compressor system capable of supplying both the 700 kPa and the 400 kPa supplies. In practice, the decision about which compressor system to install needs careful consideration because of the flow rates required and total usage (see Section 7).

8.3 A compressor system will be required for large operating department complexes specialising in orthopaedic and/or neurosurgery that require the use of pneumatically-powered surgical tools. An automatic reserve manifold located in separate accommodation should be provided. A typical system is shown in Figure 28 overleaf.

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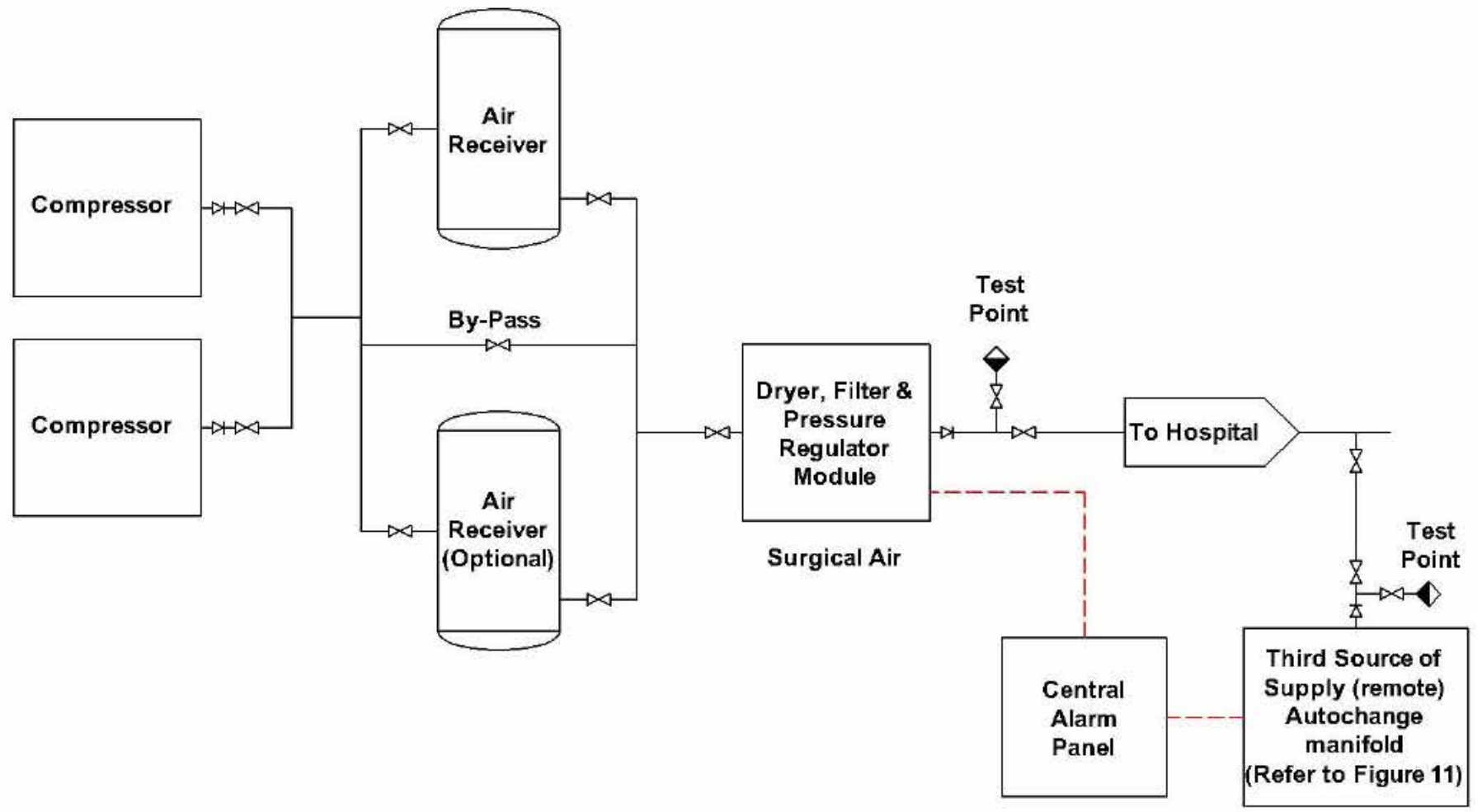

Figure 28: Typical surgical air plant and automatic emergency reserve manifold

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8.4 It is possible to use nitrogen instead of air as the power source for surgical tools. This may be derived from either a liquid source or cylinders. In either case, the terminal units must be different from the existing medical air 700 kPa terminal units. A NIST connector is already specified for nitrogen and should be used.

8.5 The pressure control equipment should comprise duplex regulating valves with upstream and downstream isolating valves, pressure gauges and pressure relief valves.

8.6 Whatever supply system is installed, the overall system should be designed to provide a minimum of 700 kPa at the front of each terminal unit at a flow of 350 litres/min.

Note 21: Systems designed to meet requirements of earlier editions of Scottish Health Technical Memorandum 2022 may not provide 350 litres/min at 700 kPa. Information on upgrading surgical air systems in given in Appendix J.

8.7 The maximum pressure at the terminal unit under “no flow” conditions should not exceed 980 kPa.

8.8 Cylinders of medical air or nitrogen stored locally should always be available for use in an emergency.

8.9 Vessels should be selected as follows:

Design flow (Litres/min)	Vessel size	Compressor output (litres/min)
< 500	1 x 200% design flow	0.33 x design flow
500 - 2000	2 x 66.6% design flow	0.66 x design flow
2001 - 3500	2 x 50% design flow	0.66 x design flow
> 3500	3 x 33.3% design flow	0.50 x design flow

Table 33: Air receiver vessel selection

Extension of surgical air systems into dental departments

8.10 The preferred option for dental surgeries is a dedicated compressor system often purchased as Group 3 equipment. However, some surgical air systems, where pipelines are reasonably located, have been extended into the surgeries. When such extensions are made, a duplex regulator set incorporating upstream and downstream isolating valves, safety relief valves, pressure gauges and flow restrictor to provide 50/60 litres/min per chair per regulator should be fitted, located in a suitable plantroom secure from unauthorised access with gauges visible to the eye. Monitoring of low and high pressure by an area alarm panel should be in place. There should be no need to include a non-return valve or back feed protection. The following must be taken into account:

- the extra demand on the existing system must not compromise patient safety or operation of either the existing system or its extension. In

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particular, the ability of an existing emergency supply system to cope with potentially very high demands must be carefully assessed;

- the Authorised Person (MGPS) with responsibility for the existing surgical air system will automatically assume responsibility for the whole of the dental compressed air and vacuum system. Both the Authorised Person (MGPS) and Quality Controller (MGPS) must appreciate that extending a surgical air system into a dental unit for dental instrument use will introduce “non-standard” pipework terminations, for example crimped or compression-fitted connectors, in addition to non-degreased components. Failure of these “non-standard” components could lead to a serious de-pressurisation of the existing surgical air system and, if provided from the same source, the associated medical air system. Under no circumstances should the surgical air system at original or reduced pressure be extended into a dental laboratory;
- a test point should be available at each chair;
- if the medical air is derived from a plant that supplies surgical air, the medical air supply should have a separate manifold reserve supply when space and system design makes this practicable.

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9. Medical vacuum systems

General

9.1 The medical vacuum pipeline system provides immediate and reliable suction for medical needs, particularly in surgical accommodation.

9.2 The medical vacuum pipeline system consists of the vacuum supply system, the distribution pipework and terminal units. The performance of the pipeline system is dependent on the correct specification and installation of its component parts. This chapter describes the requirements of the vacuum supply system.

9.3 The medical vacuum pipeline system should be designed to maintain a vacuum of at least 300 mmHg (40 kPa) at each terminal unit during the system design flow tests.

9.4 To ensure continuity of supply, the vacuum plant should be connected to the essential electrical power supply.

9.5 The capacity of the vacuum supply system should be calculated in accordance with the design and diversified flow data provided in Table 21.

9.6 With the exception of the vacuum discharge to atmosphere, the pipeline distribution system for vacuum has traditionally been constructed of copper. PVC pipework can be considered where cost-effective. Pressure testing of PVC pipework should be carried out at 150 kPa. Pressure testing of copper pipework should be carried out at 500 kPa.

9.7 The major components of a medical vacuum system and their layout are shown in Figure 29 overleaf. A suitable operating and indicating system with alarms is also required. The location of the components should allow adequate space for access for maintenance. Packaged supply systems are available from manufacturers that should be specified to meet the requirements given in this memorandum.

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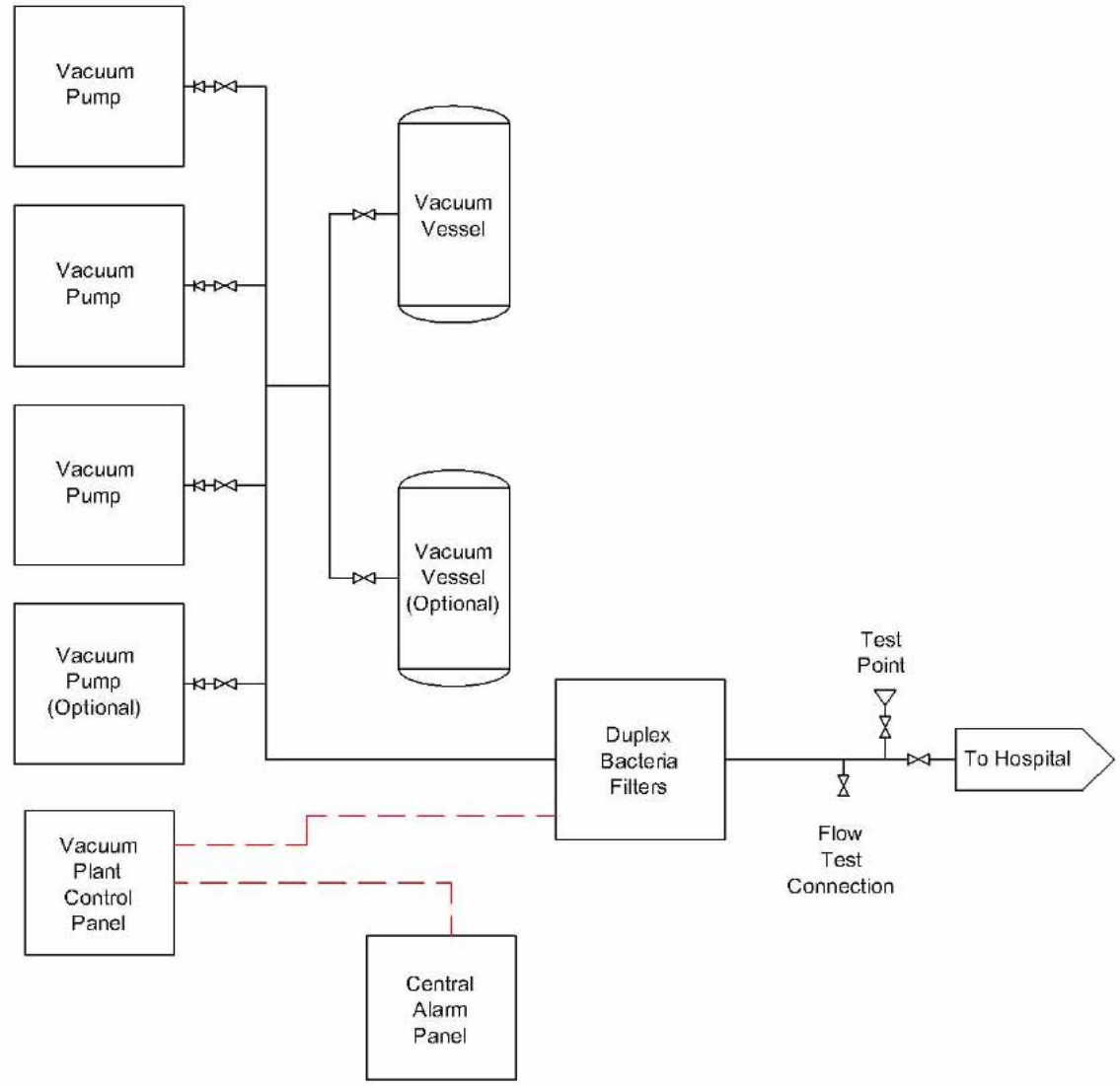

Figure 29: Typical medical vacuum plant

9.8 The plant should consist of at least three identical pumps, a vacuum reservoir(vessel) with by-pass facilities, duplex bacteria filters with drainage traps, appropriate non-return valves, isolating valves, gauges and pressure switches, an operating and indicating system, an exhaust system and a flow test connection. For capacities in excess of 500 litres/min, two vessels that can be independently isolated should be installed.

Note 22: The third means of supply for a vacuum installation will comprise of portable suction equipment and/or the third vacuum pump of a triplex pump system.

Siting

9.9 The plant should have all-round access for maintenance purposes, and allowance should be made for changing major components.

9.10 The siting of the plant should allow for adequate flows of air to cool the pumps. The manufacturers should be consulted over the range of operating

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temperatures for which the supply system is designed. In extreme cases, refrigerator cooling may be required.

Pump noise

9.11 The noise level produced by the pumps will increase with the capacity of the supply system. For larger systems this can result in an unacceptable noise level at the pump. The maximum free-field noise level at 1m from the un-silenced pump should not exceed the following values for individual pumps:

Power (kW)	Noise level (dBA)
5	75
5.1 -15	82
15	89

Table 34: Vacuum pump noise levels

9.12 A suitable acoustic enclosure may be required in the purchase specification for all pumps with a free-field noise level at 1m of 80 dBA or over. An enclosure should produce a reduction of at least 10 dBA in the free-field noise level at 1m. Vacuum pumps should be mounted on anti-vibration mounts, where necessary, to minimise transfer of noise and vibration to the building structure.

Vacuum plant exhaust

9.13 The position of the termination point should be carefully chosen to be clear of windows, ventilation intakes and the intake of air compressors and other equipment, since for oil-lubricated pumps the vacuum exhaust is likely to be polluted with oil fumes.

9.14 Noise from the exhaust should be considered and a silencer fitted if necessary.

9.15 The construction should conform to the following criteria:

- the exhaust should be sized to give a back pressure at system design flow which is matched to the pump performance;
- the termination point should be turned down and provided with protection to reduce the effect of wind pressure and prevent the ingress of rain, snow, insects or animals;
- weatherproof notices should be fixed at the discharge point(s) with the legend “medical vacuum discharge point – do not obstruct”;
- the exhaust pipe should be provided with a drainage valve and transparent collection jar at its lowest point;
- a silencer should be fitted in the exhaust pipe from each pump. This may be integral with the pump unit.

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Efficiency

9.16 The pump should be capable of producing a higher vacuum than that required in the pipeline, so that the resistance of the bacteria filter and back pressure in the exhaust system can be overcome.

9.17 The capacity of the vacuum pump should be specified in terms of the free air aspirated (FAA) in litres/min when the pump is operating at a vacuum of 475 mmHg (63 kPa) and at 450 mmHg (60 kPa) at the plant pipeline connection.

Vacuum pumps

9.18 Any type of pump apart from water-sealed pumps can be used.

9.19 Pumps should normally be oil-lubricated. Vapours from the lubricating oil are unlikely to be a significant component of the exhaust gases if correctly maintained. “Dry running” rotary vane pumps are available at increased capital cost and with lower efficiency than oil-lubricated pumps of comparable performance.

9.20 At least three pumps should be provided. The actual number is at the discretion of the plant manufacturer to ensure optimum cost benefit of the system. All pumps should be designed for high frequency stop/start or continuous operation. The opportunity to maximise energy conservation should be taken into consideration. Variable speed / frequency inverter drive motors are being increasingly used in industry with consumption being electronically controlled to give rapid response to any output change and avoiding the energy wasteful start/stop frequency within the present wider pressure change corridor. Dental centralised systems and AGSS are obvious applications for such systems but could equally apply to medical vacuum systems with the larger capacity pipe sizing in many instances avoiding the need for a reservoir.

9.21 All systems should comprise pumps and motors of identical type that are suitable for continuous running and stop/start operation.

9.22 Pump motors should comply with the Model Engineering Specification C51 – ‘Electrical requirements for specified equipment’ with the addition of Class F insulation and Class B temperature rise.

Vacuum reservoirs

9.23 In conventional pump control a vacuum reservoir should be provided so that the duty pump does not run continuously for low loads. The reservoir should be manufactured in accordance with BS EN 286-1:1998 + A2: 2005, with test certificates provided to the user. The minimum test pressure should be 400 kPa / 4 bar. For variable speed applications seek advice from the manufacturer.

9.24 The water capacity of the reservoir should be equal to the plant design flow at 450 mmHg (60 kPa) in terms of free air aspirated in one minute with the pump operating at 475 mmHg(63 kPa).

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9.25 Provision should be made for draining the reservoir under vacuum conditions. By-pass facilities should be provided so that the reservoir can be drained and inspected without interruption to the vacuum supply. The reservoir should be fitted with suitable lifting lugs and feet.

9.26 If multiple reservoirs are provided, they should be arranged in parallel.

Bacteria filters

9.27 The bacteria filters and drainage trap should comprise two identical sub-assemblies with manually-operated isolating valves, arranged to allow either sub-assembly to be on stream. Each sub-assembly should contain a bacteria filter rated at the plant capacity.

9.28 The bacteria filter should be marked with the legend “bio-hazard”, together with a description of a safe procedure for changing and disposing of the filters and emptying the drainage trap. Refer to Part B of this SHTM – Appendix D.

9.29 The bacteria filters should have a filter efficiency, when tested by the sodium flame test in accordance with BS3928:1969, of greater than 99.995% at the system design flow.

9.30 The pressure drop across a clean filter at the system design flow should not exceed 25 mmHg (3 kPa) at a vacuum of 475 mmHg (63 kPa).

9.31 The drainage trap may be integral with the bacteria filter and should be fitted with a transparent bowl to collect liquid. The bowl should be suitable for steam sterilization at 134°C.

9.32 Although there is no firm evidence that has demonstrated the need for bacteria filters, it is recommended that such devices are included as precautionary measures.

Pressure control

9.33 The cut-in setting for the vacuum pumps should be adjusted to allow for the pressure drop across the pipeline distribution system and the bacteria filters. The cut-in may be expected at about 500 mmHg (67 kPa).

9.34 The cut-out setting should be at an appropriate point on the performance curve of the pump, which minimises stop/start operation but is at a vacuum which is economically attained by the pump. This cut-out setting may be expected at about 650 mmHg (87 kPa).

Valves

9.35 Non-return valves should be fitted, when necessary, at the inlet and outlet of each pump to prevent backflow when a common discharge pipe is used. (Some vacuum pumps include integral non-return valves).

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9.36 Manually operated valves should be arranged in the positions shown in Figure 29 to allow isolation of components such as pumps, reservoirs, by-pass pipework, drainage traps and bacteria filters.

Pressure regulation of vacuum system

9.37 A minimum vacuum level of 300 mmHg (40 kPa) is required at the connection point of each terminal unit with a flow of 40 litres/min whilst the system is operating at system design flow.

9.38 This performance is tested by the procedures carried out in accordance with Section15.

9.39 A maximum pressure drop of 100 mmHg (13 kPa) is allowed across the terminal unit at a free air flow of 40 litres/min to provide a minimum pressure of 300 mmHg at a pipeline pressure of 400 mmHg. At lower negative pressures, the volumetric flow would increase by expansion and be represented by a larger pressure drop across the terminal unit. Such tests must be qualified by the pipeline pressure at the time of test. The minimum pressure permitted at the front of the furthest terminal unit on each branch line should be 300 mmHg (40 kPa) at a flow of 40 litres/min. When the system is subjected to the total design flow, the minimum dynamic pipeline pressure from the plant should be 450 mmHg (60 kPa).

Vacuum indicators

9.40 Vacuum indicators should comply with BS EN 837-1:1998 or have an equivalent performance if electronic indicators are used. Calibration should be 0–760 mmHg (0–101 kPa). All gauges should be a minimum scale length of 90mm.

9.41 Vacuum indicators should be located on:

- the plant control unit indicating the vacuum in the pipeline (that is, on the pipeline side of the bacteria filter);
- each reservoir.

9.42 A differential vacuum indicator (to indicate filter blockage rather than quantitative pressure drop) should be located across the bacteria filter and have a service isolation valve.

Electrical supply

9.43 The electrical supply to the medical vacuum plant should be connected to the essential electrical supply. The control system should ensure that pumps restart in sequence to avoid overloading the power supply.

Pump operating and indicating system

General description

9.44 The operating and indicating system should perform the following functions:

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- overall plant control and indication;
- individual pump starting;
- plant status monitoring and indication;
- alarm signal status unit.

9.45 Provided that the individual pump starters are housed in a separate compartment, the operating and indicating system may be housed in separate units or may be installed in a common panel and located on the plant or on the plantroom wall.

9.46 Pneumatic components should have ventilation. All functions should be appropriately identified. Indicators should have a design life of at least five years. The operating system should be capable of automatically restarting after reinstatement of the power supply.

Plant control unit

9.47 The control unit should have a separate power supply for each pump controlled by a separate sub-circuit. It should be manufactured and installed in accordance with IEE regulations, and the design should be such that no single component failure in the control unit will result in loss of plant output.

9.48 The unit should allow either manual selection of duty/stand-by for each of the pumps or have an automatic sequence selection with a means for manual override. The control unit should ensure that two or more pumps do not start simultaneously when power is applied.

9.49 A warning notice which complies with BS5499-5: 2002 should be affixed which indicates the presence of low voltage.

9.50 For testing purposes, each pump should have a selector switch which when turned to the “on” position allows the pump to run continuously.

Plant control indication

9.51 There should be indicators for each pump as follows:

- green “mains supply on”;
- green “pump operating”, which indicates that the pump motor is electrically energised;
- green “pump operating”, which indicates that the pump is drawing vacuum;
- an analogue or digital gauge registering the vacuum level within the pipeline.

Pump starter units

9.52 There should be individual starter units, each one operating a single designated pump. The starters should be provided with safety interlocks as specified by the

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pump manufacturers, which should inhibit plant operation until manually reset by means of a button. The starters should allow automatic restart after an interruption to the power supply. Each starter unit should contain the following:

- an isolator interlocked with the covers;
- an emergency stop;
- either HRC fuses to BS88 or suitable circuit breakers to BS EN 60947-2: 2006 + A1: 2009 and/or BS EN 60898-1: 2003 + A1: 2004;
- starter;
- an industrial grade ammeter to BS EN 60051-1: 1999, IEC 60051-1:1997 or an electronic digital instrument of comparable, or higher, standard;
- a total hours run counter, if not included in the plant control unit;
- a green “mains supply on” indicator, if mounted separately from the plant control unit.

Plant status monitoring

9.53 A monitoring system must be provided to detect the following faults in the vacuum supply system:

- plant faults for each pump:
  - control circuit failed;
  - motor tripped;
  - pump failed to go on load;
  - activation of other safety devices supplied by the manufacturers;
- plant emergency – receiver vacuum has fallen, for example, by 50 mmHg below the cut-in setting for the pump;
- pressure fault (pipeline) – pipeline vacuum less than 360 mmHg.

Plant status indicator unit

9.54 In addition to the plant control indication, there should be a plant status indicator panel that may be mounted on the plantroom wall or adjacent to either the pump starter unit or the plant control unit. It should have a warning notice that complies with BS5499-1: 2002 to indicate the presence of low voltage.

9.55 There should be indicators for each pump to show the following conditions:

a) green “mains supply on”;
b) yellow “control circuit failed”;
c) yellow “motor tripped”;
d) yellow for each individual safety device provided by the manufacturers;
e) yellow “pump failure”.

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Alarm signal status unit

9.56 The following indication of plant conditions should be provided:

a) green “normal” (indicator normal);

b) yellow “plant fault” conditions (b)–(d); see paragraph 9.55;

c) yellow “plant emergency” condition (e); see paragraph 9.55;

d) red “pipeline pressure fault” (pressure fault).

9.57 Conditions (b) to (d) of paragraph 9.56 should be transmitted to the central alarm system. Where relays are used, they should be normally energised relays, which de-energise under fault conditions, with contacts having a minimum rating of 50 V d.c. and 50 mA.

9.58 Volt-free, normally closed contacts rated at 50 V d.c. and 50 mA should be provided for transmission of conditions (b) to (d) of paragraph 9.56 to the alarm system.

9.59 The panel can be incorporated into the plant status indicator unit or be a separate unit within the plantroom. If mounted separately, the cabling should be monitored for open/short circuit. In the event of such a cabling fault, a red “system fault” lamp should be illuminated on the alarm system status unit together with the appropriate alarm condition.

Plant management

9.60 Connections should be provided which allow monitoring (but not control) of plant alarm conditions (b) to (d) of paragraph 9.56 and pump running for each vacuum pump. These connections should be normally closed, volt-free contacts for each condition having a minimum rating of 50 V d.c. and 50 mA.

9.61 Plant should be operated in accordance with the manufacturer’s instructions and be covered by a sound, effective planned preventative maintenance (PPM) policy.

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10. Anaesthetic gas scavenging disposal systems

Terminology

10.1 An active system, as specified in either BS6834: 1987 or BS EN ISO 7396-2: 2007 is one in which a high air flow generated by an electrically driven pump is used to exhaust air through the system's fixed pipework. This in turn entrains waste gases from the patient, or patient ventilator, via a transfer hose and receiving system.

10.2 The transfer and receiving system form part of the anaesthetic/breathing system.

10.3 The receiving system is designed to match the variable flow in the breathing system to the constant flow of the disposal system and ensure that very low induced flows are imposed (0.5 litres/min in the case of BS6834:1987 and 0.05 litres/min in the case of BS EN ISO 7396-2: 2007).

10.4 In the UK, only systems complying with the BS or EN Standards above are considered appropriate for scavenging waste anaesthetic gases from accommodation in which general anaesthesia is taking place.

10.5 Active scavenging for dental installations is an entirely different concept. An active system is one in which there is a flow generated through the patient's nasal mask and this carries away the waste gases exhaled by the patient. This flow is in the order of 45 litres/min and is achieved by connection of the mask (via a suitable flow-limiting adaptor or terminal screw adjustment) to an active scavenging system (BS/EN) wall terminal unit. Alternatively, a Group 3 local active unit is available designed for dental purposes. Consideration should be given to providing additional room ventilation i.e. high level supply and low level extract.

General

10.6 Anaesthetic gases are considered to be substances hazardous to health for the purposes of the Control of Substances Hazardous to Health Regulations 2002 (COSHH), except where they are administered to a patient in the course of medical treatment.

10.7 Detailed guidance on compliance with COSHH is given in the Department of Health's (1996) 'Advice on the implementation of the Health & Safety Commission's occupational exposure standards for anaesthetic agents'. Further guidance is given in by the Health & Safety Executive's (1996) 'Anaesthetic agents: controlling exposure under COSHH'.

10.8 The COSHH regulations set out very specific duties that apply to anaesthetic gases, and employers have a legal obligation to ensure that these duties are discharged. It is therefore the responsibility of the general manager or chief

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executive to implement the requirements of the COSHH regulations with respect to anaesthetic gases. This subject is covered in Part B.

10.9 For new installations, an assessment should be made of the transfer and receiving equipment currently in use and intended for use with the new installation. Where the transfer and receiving equipment has been designed to BS6834:1987, the disposal system design should be to BS6834:1987. Where the transfer and receiving equipment in use has been designed to BS EN 740:1999, the disposal system should be designed to BS EN ISO 7396-2: 2007. Where a mixture of equipment is in use, the system should be designed to BS6834:1987. Where both types of equipment are required to be used on the same disposal system, a restrictor should be provided for the BS EN 740:1999 equipment to restrict the flow to its design flow rate. The system should be installed in all operating departments and other areas, as required, in accordance with the levels of provision given in Table 11.

Note 23: BS6834: 1987 covered all aspects of the anaesthetic gas scavenging systems. BS EN 737-2: 1998 and BS EN 737-4: 1998have now been replaced with BS EN ISO 7396-2: 2007 and BS EN ISO 9170-2: 2008 respectively.

10.10 A typical system schematic is illustrated in Figure 30a and 30b and shows the terminology used.

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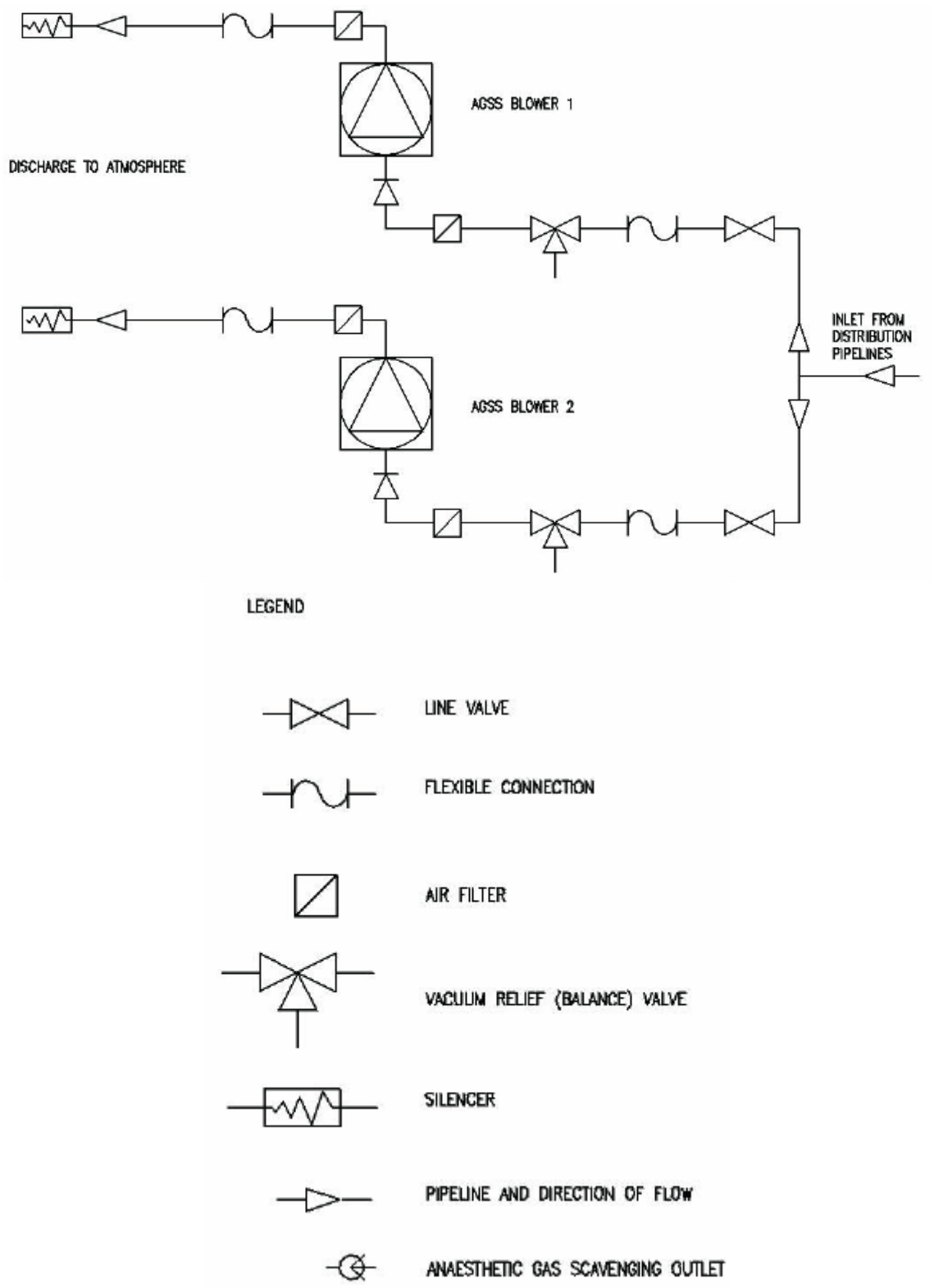

Figure 30a: AGSS Plant schematic (duplex blowers shown)

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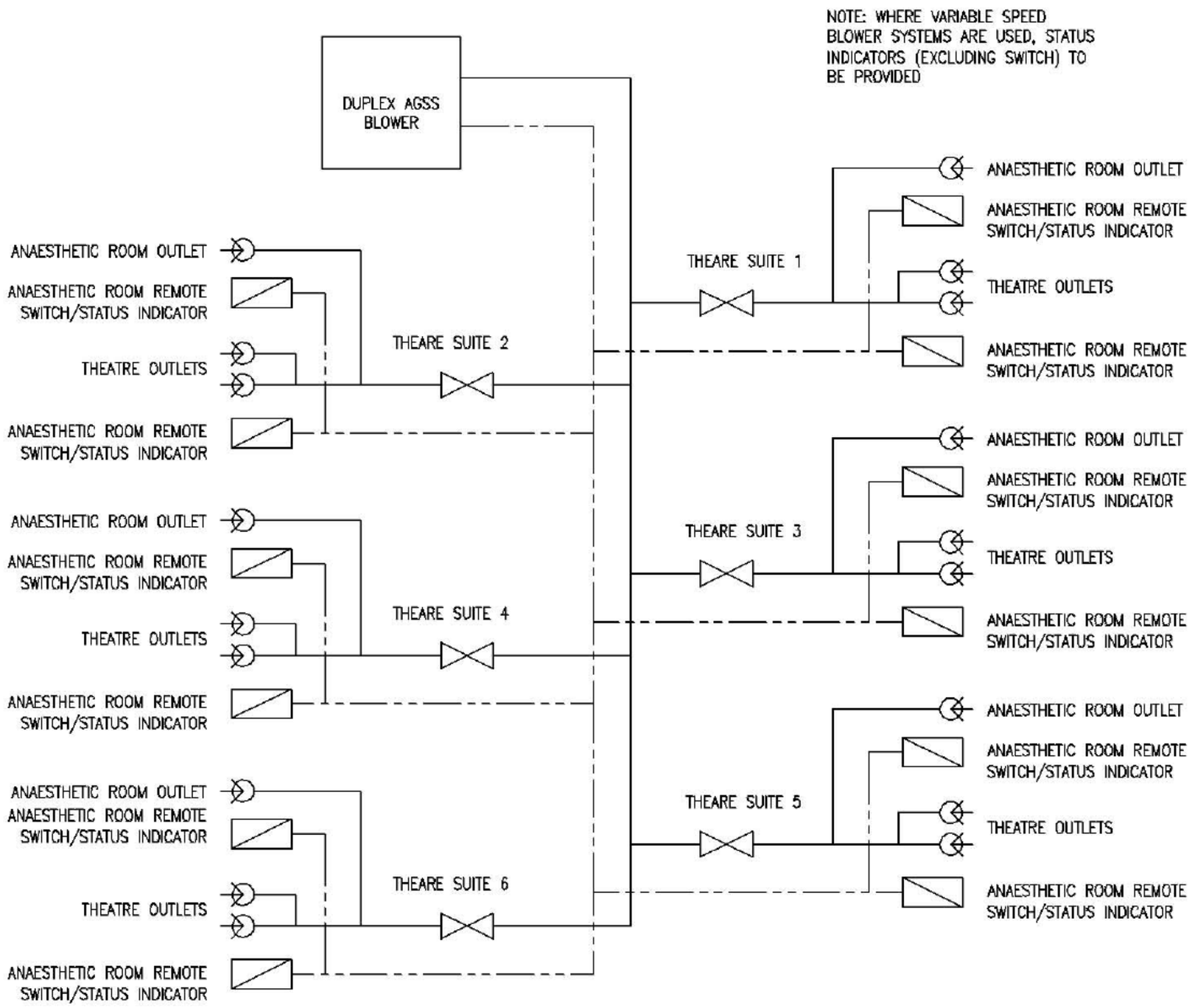

Figure 30b: Pipeline schematic, including remote AGSS switching

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10.11 The internal components and pipework of AGS disposal systems are in contact with a patient's expired breath. Even though there is considerable dilution by virtue of the receiving system that forms part of the anaesthetic equipment, there is, however, potential for bacteriological contamination. The materials should be reasonably resistant to corrosion and should withstand cleaning, disinfection or sterilization as appropriate.

10.12 The fixed pipework may be of copper or other suitable material such as PVC. Where copper pipework is installed at the same time as the MGPS, it is desirable to use degreased pipework to the same specification as that used for the MGPS (see Section13) in order to avoid confusion. Pipeline pressure testing and loss allowances should be in accordance with the requirements for medical vacuum pipeline pressure tests.

10.13 Where PVC pipes larger than 38mm diameter pass through a fire compartment, they should be protected with metal sleeves extending for 1m either side of the compartment in accordance with the Building (Scotland) Amendment Regulations 2006. The recommendations of Firecode and Scottish Health Technical Memorandum 81 should be followed.

Selecting the number of disposal system pumps

10.14 The number of disposal system pumps selected for operating theatre suites should be determined through consideration of a number of factors including: the number of theatres concerned; the layout of the department; the degree of difficulty associated with the pipework installation; a cost comparison between systems; together with an evaluation of the impact and level of disruption likely to be realised in the event of a fault condition occurring which could result in the loss or partial loss of the system. The following selections could be considered:

- An individual pump per theatre suite will not maintain the system under a fault condition. Spare pumps can be carried in store, however, the disruption factor and outage time must be taken into consideration.
- A duplex pump set will ensure continuity of supply in the event of a single fault condition. When applied in conjunction with other control measures, such as the mechanical ventilation system providing the specified number of air changes for the room, the exposure to anaesthetic agents should be maintained below the prescribed occupational exposure standards in compliance with the COSHH requirements being achieved.
- When specifying a simplex or duplex pump set providing AGS to a number of areas, consideration must be given to future maintenance requirements which will require all rooms with an AGS outlet on the system to be accessed almost simultaneously for the purposes of carrying out a system performance test either as a ppm activity or following modification of the system.

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Note 24: Anaesthetic gas scavenging systems when installed, commissioned and operated should maintain the service in normal use and on a single fault condition. To ensure continued service under a fault condition as required by European Standards, a minimum of a duplex pump plant assembly would be required. The single pump arrangement with a replacement pump in store would not meet the requirement for maintaining the service under a single fault condition. The impact and level of disruption to service in the event of simplex plant failure should be carefully evaluated when finalizing the plant selection.

10.15 Historically a fixed volume exhauster was installed which generated noise, at times unacceptable depending on location and was not energy efficient. With respect to patient safety, the air admittance valve imposed a further risk factor and in most instances staff failed to switch off the system when not in use, resulting in 24/7 exhauster operation and premature replacement of plant. In order to avoid such problems, variable speed/ frequency inverter vacuum pumps should be considered as a first option. As described in other sections of SHTM 02–01 the electronic control will give optimum efficiency with virtual instantaneous response to any output demand. If required the controller will automatically engage the standby pump within preset parameters, however, normally the duty pump would be sized for the design flow taking account of the appropriate diversity factors.

10.16 With variable speed control, tight pipeline pressure loss tolerances, pipe sizing and a terminal unit with variable screw adjustment, the system can be designed to meet the performance requirements of both BS6834: 1987 and BS EN ISO 7396-2: 2007. Protection of the system should include a safety relief valve set to suit system requirements.

10.17 The number of operating theatres and departments served by any one system should be estimated by plant location to departments. Eventually separate switching at each terminal unit should not be a requirement, however, it remains a requirement of BS6834, therefore switching should remain for the present even though the variable speed motor will adjust or automatically closedown at no demand. Further consideration should be given to the location of the plant control indication which rather than individually located at each plant control switch, can be incorporated within the area alarm panel.

Flow and diversity

10.18 Although more than one AGS terminal unit may be installed in an operating room or anaesthetic room for convenience, it may be assumed that only one terminal unit in each room will be in use at any given time. The AGS terminal unit in the anaesthetic room and operating room, however, may on rare occasions be in use simultaneously; therefore, the plant is sized for two AGS terminal units for each operating suite.

10.19 The performance criteria for the disposal system are specified in the relevant British, European and International Standards in terms of the extract flows at specified resistance. The disposal system should meet the requirements set out in the table

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	Disposal system standard			
	Pressure drop		Flow rate	
	BS6834: 1987	BS EN ISO 7396-2: 2007	BS6834: 1987	BS EN ISO 7396-2: 2007
Maximum	1 kPa	1 kPa	130 Litres/min	80 Litres/min
Minimum	4 kPa	2 kPa	80 Litres/min	50 Litres/min
Maximum static pressure	20 kPa(-ve)	15 kPa(-ve)		

Table 35: Disposal system pressure and flow rates

Notes applicable to Table 35: a) Since the preparation of BS6834:1987, developments in anaesthesiology have resulted in reduced flows being used. Depending on local circumstances, it may be possible to commission systems for different flows in accordance with BS EN ISO 7396-2: 2007.

b) Details of the test flows should be recorded in the commissioning documentation.

c) The pump inlet should include a vacuum indicator for commissioning and servicing purposes.

Discharge outlet

10.20 Careful consideration should be given to the siting of the discharge from the disposal system. It should preferably be sited at roof level, well away from ventilation inlets, opening windows and other apertures, to prevent pollution re-entering the building. Signage should be provided in accordance with Appendix K.

Plant control indication

10.21 There should be indicators to show the following conditions:

- green “mains on”;
- green “air flow” normal;
- yellow “duty pump failed” (plant fault) – applies to duplex plant only;
- red “system failed” (plant emergency).

10.22 Indicator panels should be installed in operating rooms and at other locations where gas scavenging is available.

10.23 The “air flow normal” indication should be initiated by either a pressure switch or air flow detection device at the pump when vacuum is established within the pipeline.

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11. Other medical gas pipeline installations

General

11.1 It is possible to extend medical gas system design concepts to other gases used from cylinders and still maintain the elements of gas specificity that are essential requirements together with all other relevant safety considerations.

Helium/oxygen mixture

11.2 Helium/oxygen mixture is used by patients with respiratory or airway obstruction and to relieve symptoms and signs associated with respiratory distress. It can be administered by means of face mask and cannula, a demand valve with face-mask with cannula attached, a nebuliser, or by a ventilator.

11.3 Its main use will be in Accident & Emergency (A&E), supplied from portable cylinders with integral control valve and regulator, and in critical care areas.

11.4 When provided by means of a pipeline installation, all the elements of a manifold supply system for other medical gases should be installed.

11.5 The manifolds will be designed to operate at low pressure (10 bar), and connection to K-size cylinders will be made by means of a low-pressure flexible assembly to a terminal unit integral with the cylinder regulating valve. The connection to the manifold will be by means of a NIST connector.

11.6 The individual cylinders will include pressure transducers to monitor the pressure upstream of the integral control valve. (Cylinders do not necessarily discharge simultaneously.)

11.7 The manifold should be located close to the facility that it supplies.

Compressed Gas Cylinder Manifold Systems		
Primary supply	**Secondary supply**	**Tertiary supply (third source of supply)**
Duty bank of a fully automatic manifold. Number of cylinders based on system design.	Standby bank of a fully automatic manifold.	Manual emergency reserve manifold - to come on-line automatically via a non-return valve in the event of a single fault condition and to act as a reserve supply during maintenance / repair works Type and capacity of supply to be determined by risk assessment.

Table 36: Compressed gas cylinder manifold systems

Oxygen/carbon dioxide mixture

11.8 Oxygen/carbon dioxide mixture has been supplied by pipeline in at least one installation in the UK for anaesthetic purposes in cardiothoracic procedures.

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11.9 There has been little interest shown in installing others and, therefore, this medical gas is no longer included within the scope of this Scottish Health Technical Memorandum.

Carbon dioxide

11.10 Carbon dioxide is now not generally used as a respiratory stimulant post-operatively. Pipelines have not been installed in the UK for respiratory applications. Its main use today is for insufflation during surgery, and to date there have been some installations in the UK.

11.11 When pipeline systems are installed for such purposes, the general requirements for other medical gas pipelines should be followed. The terminal unit should comprise a NIST connector with integral check valve contained in the surgeon's pendant. The level of provision of AVSUs should be provided as for other medical gas pipelines.

11.12 A semi-automatic manifold will normally be satisfactory and it should be installed "locally". A 2x4 VF-size manifold will provide adequate capacity. The safety valve discharge should be taken outside the department. The warning and alarm system indicator will normally be installed in the operating room control panel.

Nitric oxide

11.13 Treatment using nitric oxide is subject to specific Ph. Eur. requirements. Distribution of the gas by pipeline systems is not considered appropriate.

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12. Warning and alarm systems

General

12.1 The provision of a warning and alarm system is essential to monitor the safe and efficient operation of an MGPS. There are three reasons for this monitoring:

- to indicate normal function of the pipeline system by means of visual indicators;
- to warn by visual and audible indication that routine replacement of cylinders or other engineering action is required;
- to inform the user by visual and audible emergency alarms that abnormal conditions have occurred which may require urgent action by the user. This alarm condition will require a rapid response by the various departmental staff.

12.2 To date, practice has been to have a “dedicated” medical gas warning and alarm system and this approach will remain in many situations. With the development of computer-based integrated patient/ management systems, nurse call and other alarm systems, however, there is considerable scope for including medical gas system information including text action prompts etc. Additionally, building management IT-based systems will play an increasing role in the operation and management of an MGPS.

Dedicated systems

12.3 The requirements of “dedicated” warning and alarm systems are covered in paragraphs 12.3 to 12.62 and a schematic diagram of a typical central system layout is shown in Figure 31. Warning and alarm systems are required for all medical gas and vacuum systems. A simplified system is required for AGSS, with the warning/indication panel located in the operating room or other area where AGSS is used.

12.4 Warning and alarm systems comprise pressure sensors, a central system providing information on all monitored functions, with repeater panels located where information is required to ensure the necessary action is taken. Area alarms should be provided to give warning to users downstream of the designated departmental AVSU (see Section 3).

12.5 Pressure sensors should be connected to the pipeline by means of a minimum leak device. Whenever possible, pressure sensors should be installed outwith the ceiling space e.g. within wall mounted AVSU panels, within individual AVSUs or within a dedicated panel or box. Where this cannot be achieved, ventilation of the space will be required.

12.6 All MGPS warning and alarm indicating panels should comply with the requirements of this Scottish Health Technical Memorandum, including all operating room panels.

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Panel location

Central indicator panel

12.7 Warning and alarm conditions for all medical gas supply systems should be displayed on a central panel located in a position where there is continuous 24-hour occupation, such as the telephone switchboard room or the porters' lodge.

Repeater indicator panel

12.8 Repeater panels should be provided in other locations to display all or some of the information on the central alarm so that appropriate action can be taken to ensure the continuing operation of the system. Some warning system information may be appropriate for display in specific departments, for example cylinder manifold status information in a porters' room, and oxygen concentration in the pharmacy department when a PSA plant supplies the hospital pipeline installation. The inclusion of a repeater alarm panel within critical care areas (ITU, CCU, HDU, SCBU etc.) should be considered to advise staff of high / low pressure fault conditions and whether the emergency supply is in use.

Area warning and alarm panel

12.9 Area panels to display "high" and/or "low" gas pressure should be installed in the locations given in Section 3. The sensors for these panels should be located downstream of the designated AVSUs, normally the departmental AVSUs. It should not be possible to isolate the sensor with a separate shut-off valve and they should be connected to the pipeline by means of a minimum leak device.

System components

12.10 Warning and alarm systems include the following functional elements:

- interfaces/transmitters that convert the signal from the plant or manifold Volt-free alarm contacts into a form which can be transmitted via multiplexed cable (for example using pulse-width modulation). The transmitter may be a separate unit or may be incorporated:
  - in plant or into a manifold control panel;
  - into an indicator panel. Line-fault monitoring devices should be included in both cases;
- indicator panels which display the transmitted signals;
- interconnecting multiplex wiring which connects all interfaces/transmitters to all indicator panels.

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System layout

Central plant alarm system

12.11 A typical system layout is shown in Figure 31, which shows initiating devices at remote locations such as the VIE compound, medical air and vacuum plantrooms, manifold rooms and emergency/reserve manifold rooms. The transmitters are normally located close to the initiating devices. Central / repeater alarm panels are typically located at the telephone exchange, the security room, the porters' room and the engineer's office to provide information requiring action by engineering and other support staff.

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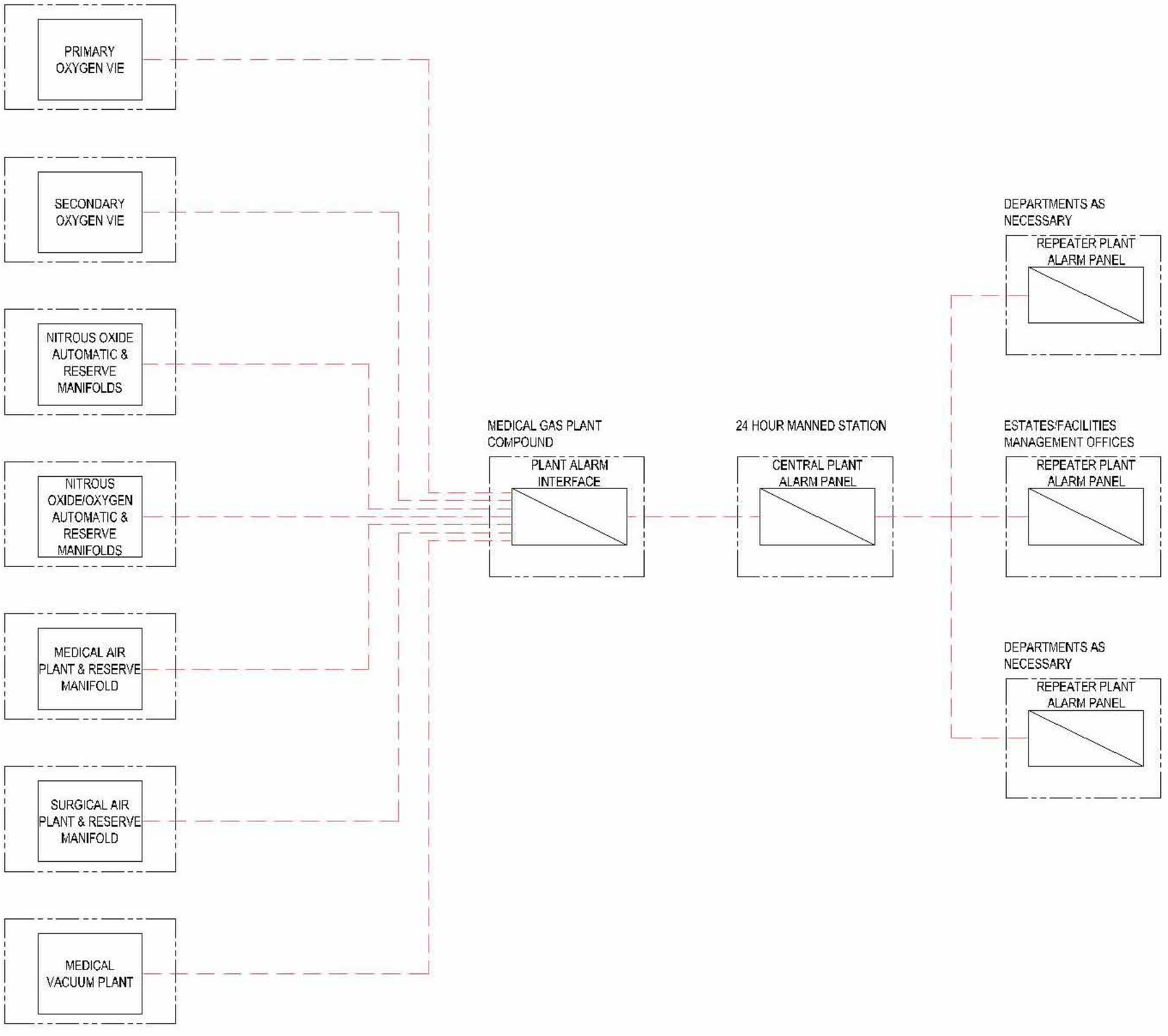

Figure 31: Central plant alarm

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Area alarm systems

12.12 A typical layout of an area alarm system is shown in Figure 32 for illustration purposes. For each gas service there should be local pressure switches for low pressure; high pressure switches are also required when there is any combination of oxygen, nitrous oxide and medical / surgical air installed together. These conditions should be indicated on a locally-mounted indicator panel, with the facility to provide a common alarm condition for connection to other repeater alarm panels. In situations where the staff base is not in close proximity to the AVSU module / pressure switches, the area alarm panel should be located where it will be both audible and visible from the staff base. Area panels carry no indication of the warnings for cylinder replacement and plant functions that are given on central indicator panels.

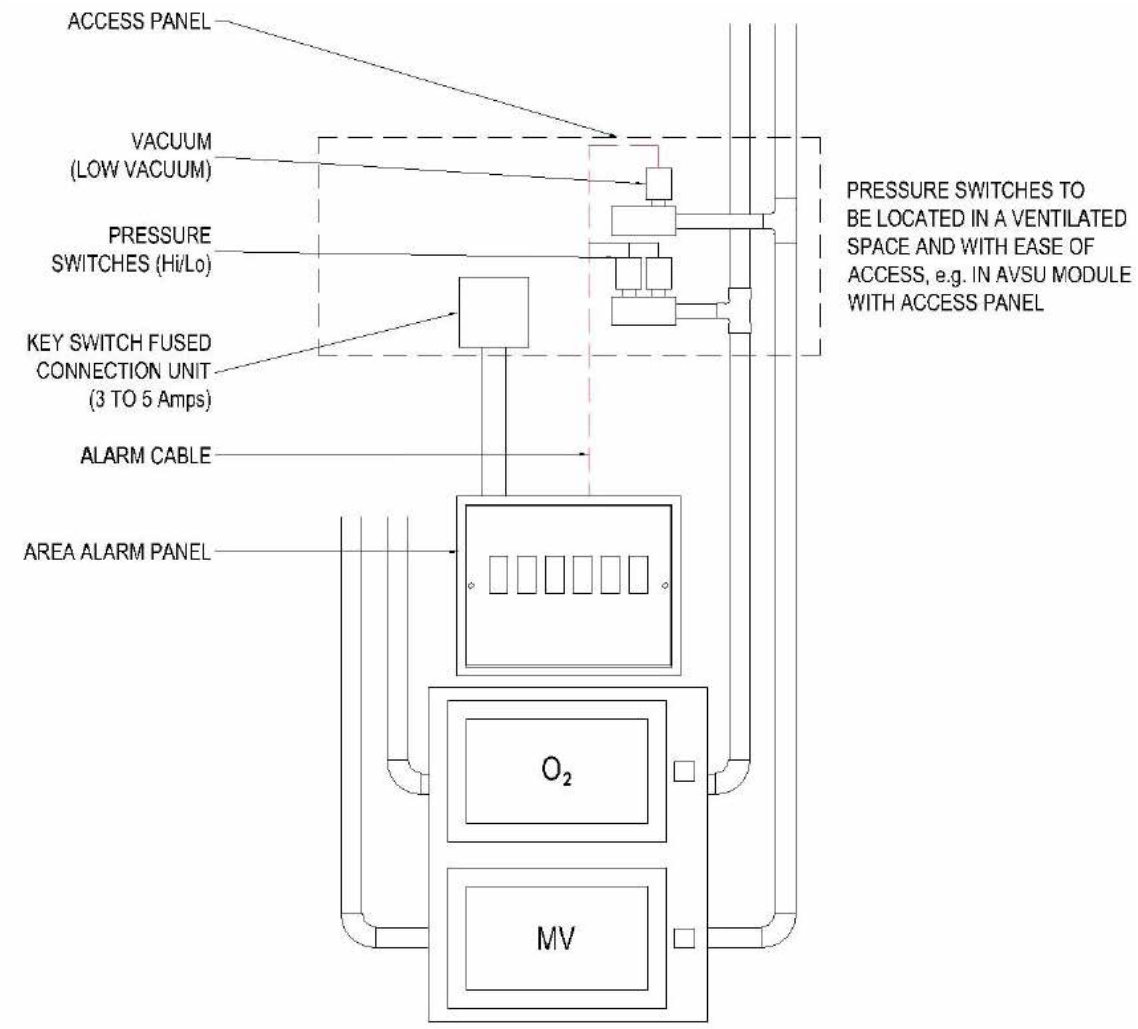

Figure 32: Area alarm panel arrangement (2-gas service shown)

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General requirements

Labelling

12.13 All visual signal panels should be permanently labelled according to their function, including clear identification of the areas, rooms or departments served.

Visual signals

12.14 Flashing visual signals should have alternate “on” and “off” periods, each of equal duration between 0.25 and 0.50 seconds.

12.15 There should be two separately energised light sources for each signal, arranged so that the failure of one source does not affect the other.

12.16 The light sources should have a design life of at least five years of continuous operation.

Audible signals

12.17 All audible signal tones should be modulated equally at a rate of 4 Hz ±10% between two tones of 440 Hz ±10% and 880 Hz ±10%.

Automatic resetting

12.18 When a warning or alarm signal occurs and the system condition subsequently reverts to normal, the corresponding visual and audible signals should automatically reset to normal.

Temporary muting

12.19 Means must be provided on each panel for the user to mute the audible signal. The signal must re-sound after a nominal 15-minute period if the fault condition still exists. The process of muting and reinstatement of the signal should be repeated until the fault condition has been rectified. Operation of the mute on the central panel should be accompanied by change from flashing to steady illumination of the corresponding visual indicator irrespective of the number of alarm conditions displayed on the central and any repeater panels. Operation of the mute on area alarm or repeater panels should not be accompanied by a change from flashing to steady illumination.

Continuous muting

12.20 An internally-mounted switch should be provided to allow continuous muting during periods of maintenance. When the system condition returns to normal, the continuous muting should automatically reset to normal operation. When the continuous muting is in operation on any alarm condition, it should not prevent the operation of the audible signal on other alarm conditions when a fault condition arises.

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Electrical wiring

12.21 All electrical wiring should be in accordance with IEE Regulations.

System integrity

12.22 If extra low voltage (ELV), maximum 50 V, is superimposed on the signal or communication circuit (for example by cross-connection), the system design should ensure that any damage to the system is limited to replaceable panel components and that such damage is indicated as a system fault.

12.23 The performance of the system should not be compromised by the use of multi-core cabling that carries ELV and communication signals in adjacent cores.

12.24 The system should be designed to reject spurious radio frequency (RF) or mains noise typically arising in hospitals, examples being diathermy equipment and current spikes caused by plant start-up etc.

Relay conditions

12.25 If relays are used to transmit alarm signals, the relays should be energised in their normally closed condition.

Mains power supply

12.26 The mains electricity supply should be derived from the essential power supply (that is, it must be on the emergency system).

Safety extra low voltage/functional extra low voltage power supply

12.27 The panel power may be designed either as a safety extra low voltage (SELV) system or as a functional extra low voltage (FELV) system, as defined in Part 4 of the IEE Wiring Regulations.

12.28 The ELV power supply may be housed either in the alarm panels or in a separate metal enclosure.

12.29 The power supply should be rated for the full load of the panel, with visual and auditory signals on all normal and alarm conditions.

Test facility

12.30 Each panel should be provided with a means to test all visual and audible signals on that panel. The power supply should be capable of sustaining all indicators and audible signals.

Warning and alarm system faults

General

12.31 A flashing red visual indicator and an audible signal should operate on all panels when any of the following conditions occur:

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- line fault from the initiating device;
- communication fault or other wiring fault;
- mains power failure.

Line fault

12.32 The system should monitor the integrity of the lines between the initiating devices and the panel or transmitter units. The “alarm system fault” condition should be indicated on loss of integrity, for example open or short circuits, together with the visual alarm indicator(s) associated with the faulty wiring.

Communication/wiring fault

12.33 The system should indicate an alarm system fault in the event of loss of data transmission between panels and transmitters.

Mains power failure

12.34 Failure of mains power should be shown by a flashing red indicator and an audible signal, which should be powered from an internal battery. The audible signal may be muted and not automatically reinstate as required under normal power supply (see paragraph 12.19), but the visual indicator should continue to flash until either the fault has been rectified or the battery has discharged.

Stand-by battery

12.35 A battery should be provided with sufficient capacity to power the visual and audible “alarm system fault” signal for a minimum period of four hours. The battery should be sealed and exchangeable, and should automatically recharge within 72 hours.

Legend

12.36 The legend on this indicator should be “alarm system fault”.

Indicator panel requirements for all systems

Indicators

12.37 Panels should be provided with all indicators for the gas services in local use.

12.38 The visual indicators should be arranged vertically in priority order, with the normal indicators at the top. The sequence of gas services should be, from left to right:

- medical oxygen (cryogenic and cylinders/ pressure swing adsorber (PSA) systems);
- nitrous oxide;
- nitrous oxide/oxygen mixture;

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- medical air 400 kPa (compressor plant, cylinders and synthetic air);
- surgical air 700 kPa;
- medical vacuum plant;
- helium/oxygen mixture.

12.39 In addition to the gas service signal indicators, each panel must include:

- a green “power on” indicator without an audible signal;
- a red “alarm system fault” indicator with an audible signal.

Labelling

12.40 Panels should be labelled as follows:

- medical gas alarm;
- with the identification of the medical gas services indicated, and the areas and departments served.

Construction

12.41 The fascia panel should be removable to allow access to the rear of the fascia or to the panel for maintenance purposes.

12.42 Access to the interior of the panel should be tamper-proof.

12.43 It should be possible to replace the source of illumination without removing the legend.

12.44 Panels should have electrical sections with protection at least equal to IP4X as defined by BS EN 60529:1992.

12.45 Panels and their housings should be of adequate strength for their purposes and be manufactured from corrosion-resistant materials.

12.46 If gas services are brought into the panel, they should be housed in separate, enclosed compartments, which are vented to the outside.

12.47 There should be gas-tight seals where electrical services pass through any gas compartment.

Remote audible sounder

12.48 All panels should have provision for connection to a remote audible sounder.

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Central indicator panel requirements

Displays

12.49 The central panel should display all signals for all MGPS which are generated by the warning and alarm system, as described in paragraphs 12.50–12.53, below.

Normal

12.50 The normal condition for all piped MGPS should be displayed as a steady green visual signal. The “normal” indicator should extinguish in warning and alarm conditions.

Warnings

12.51 Warning conditions appropriate to each MGPS should be displayed as a flashing yellow visual signal that may be accompanied by a mutable audible signal (see Table 37).

Emergency alarms

12.52 Emergency alarms are generated by loss of pipeline pressure or vacuum and are indicated by flashing red visual signals accompanied by mutable audible signals.

Alarm system fault

12.53 The “alarm system fault” condition should be displayed as a flashing red visual signal accompanied by a mutable audible signal.

Mute functions

12.54 The temporary mute should cancel the audible signal for about 15 minutes and change the visual indicators from flashing to continuous on all central and repeater panels.

12.55 Operation of the continuous mute should inhibit the 15-minute reinstatement of the audible alarm.

12.56 Operation of the mute should not inhibit the visual or audible indication of any subsequent alarm conditions.

Panel legend and display

12.57 Panel legend and display should be as shown in Table 37.

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Repeater indicator panel requirements

Displays

12.58 The repeater indicator panel should always display “normal”, “emergency alarm” and “alarm system fault” conditions as given above. The repeater panel should display some or all of the warning conditions that are displayed on the central indicator panel. The extent of the display of warnings should be varied to suit local clinical requirements.

Mute functions

12.59 The temporary mute should cancel the audible signal for about 15 minutes whilst the visual indicator continues to flash. Operation of the temporary mute (on the central panel) should change the visual indicator to continuous illumination on the central and any repeater panels.

12.60 Operation of the continuous mute must inhibit the 15 minute reinstatement of the audible alarm.

12.61 Operation of the mute should not inhibit the visual or audible indication of any subsequent alarm conditions.

Panel legend and display

12.62 The panel legend and display should be as shown in Table 37.

Area alarm panel

Panel displays and legend

12.63 Area alarm panels should display the conditions listed in Table 38.

Mute functions

12.64 The temporary mute should cancel the audible signal for about 15 minutes whilst the visual indicator continues to flash.

12.65 Operation of the mute should not inhibit the visual or audible indication of any subsequent alarm conditions.

Integrated systems

12.66 The introduction of computer-based systems for a range of functions such as patient information, nurse call and other alarm conditions provides an opportunity to further include certain provisions of medical gas pipeline warning and alarm conditions. This concept is totally new and, at this stage, the applications have not been thoroughly evaluated or analysed. One of the advantages of the concept is that text prompts can be displayed on the computer display when changes in the status of the pipeline occur, and these prompts can advise staff of the need to take specific action.

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12.67 The advantage of a computer-based system is that the advice given in the text message can be varied to take account of specific circumstances, changes in operating procedures and functional changes within individual departments. Such systems are likely to be of most use in in-patient ward accommodation; it may not be appropriate for central warning and alarm conditions or in individual operating rooms and other accommodation in which anaesthetic procedures are taking place.

12.68 It will be necessary to change the perception of users in that with this approach the “normal” conditions of the pipeline systems that are continuously displayed on alarm indicator panels will not exist – audible emissions and displayed messages generated by the computer-based system will be in response to changes from the “normal” situation. To ensure the long-term viability of the system, any supplier or installer of such a system must supply sufficient information about the system to allow modification, expansion or replacement of sections of the system by a third party. This must include source code for any software, passwords and details of any other security device, and details of any communication protocols. This information must be handed to the end-user before the system is accepted by the end-user.

Note 25: No further information can be given at this stage until further development and consultation takes place.

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Supply system [1]	Alarm conditions	Legend	Colour	Audible system	Location [2]
Automatic manifold as primary and secondary source of supply	1. Duty bank empty: stand-by bank running	Change cylinders	Yellow	Yes	A B
	2. Stand-by bank below 10% capacity	Change cylinders immediately	Yellow	Yes	A B
Automatic manifold as reserve supply for liquid oxygen and compressed air plant	Manifold to be monitored. Refer to para. 5.15	Reserve low	Yellow	Yes	A B
Compressed cylinders on reserve manifold serving an automatic manifold	Reserve pressure below 68 bar (<14 bar for N_2O)	Reserve low	Yellow	Optional	A B
Medical air compressor and surgical air compressor	1. Plant fault	Plant fault	Yellow	Yes	A B
	2. Plant emergency	Plant emergency	Yellow	Yes	A B
Medical vacuum plant	1. Plant fault	Plant fault	Yellow	Yes	A B
	2. Plant emergency	Plant emergency	Yellow	Yes	A B
Oxygen concentrator	1. Plant fault	Plant fault	Yellow	Yes	A B
	2. Plant emergency	Plant emergency	Yellow	Yes	A B
Pressure fault (pipeline) high or low and oxygen concentration fault for PSA plant	For each gas service to indicate that the pressure in the distribution system has risen/fallen from the “normal” working pressure given in Section 4 and, for PSA plant, that O_2 concentration <94%	Pressure fault	Red	Yes	A B
Vacuum pressure (pipeline)	To indicate that vacuum in the pipeline distribution system has risen above the normal working pressure given in Section 4	Pressure fault	Red	Yes	A B

Table 37: Signals and displays for central alarm panels and repeater panels

Notes applicable to Table 37: 1. For liquid supply systems, see Section 6.

2. A = Central alarm panel – telephone room and/or porters’ room, ie. with 24-hour occupancy.

   B = Facilities Management office reception.

3. Locations should include Critical Care Areas, (ITU, CCU, HDU, SCBU, A&E Resuscitation, etc.) can be considered as appropriate.

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Alarm function	Legend	Colour	Auditory signal
For oxygen, nitrous oxide and medical air(1) to indicate that the pressure in the pipeline serving the department has risen above the normal value given in Section 4	High pressure	Red	Yes
For each gas service to indicate that the pressure in the pipeline serving the department has fallen below the normal value given in Section 4	Low pressure	Red	Yes
For vacuum to indicate that the pressure in the pipeline serving the department has risen above the normal value given in Section 4	Vacuum fault	Red	Yes

Table 38: Area alarm panel legend and display

Note 26: A high pressure alarm is only required when oxygen, nitrous oxide and medical air are installed together. Refer to Table 11 for location of area panels.

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13. Pipeline installation

General

13.1 Generally, MGPS should be kept away from areas where they may be subject to any of the following:

- mechanical damage;
- chemical damage;
- excessive heat;
- splashing, dripping or permanent contact with oil, grease or bituminous compounds, electrical sparks etc.

13.2 Service ducts, ceiling spaces or voids containing pipelines that include valves etc. should have adequate ventilation to prevent gas build-up in the event of any leakage. Where piped medical gas services are installed of all welded, brazed or joint-free construction, it is generally not necessary to provide ventilation in service ducts, ceiling spaces or voids provided the piped systems are subjected to the rigorous testing imposed by this SHTM. Service ducts, ceiling spaces or voids containing mechanically connected valves or pressure switches will require ventilation in line with the requirements of BS8313:1997.

13.3 Exposed pipelines should not be installed in lift shafts, kitchens, laundries, boilerhouses, generator rooms, incinerator rooms, storage rooms designed to house combustible materials, or in any other fire-risk areas. Additionally, medical gas pipelines should not be installed in fire escape compartments (e.g. stair wells, fire exit lobbies). Where pipelines in hazardous areas are unavoidable, they should be enclosed in non-combustible, non-corrosive materials that have no electrolytic reaction with copper in order to prevent the possibility of the liberation of gases into the room in the event of pipeline failure. Medical gas pipelines should not be run in the same duct as flammable substances, oils, cryogenic or hot services such as steam, condensate, high or medium temperature hot water. Allowance may be made for steam and hot water services where they can be regularly inspected and are routed clear of the medical gas pipelines. Corrosion of copper pipe through chloride deposits from steam pipe leakage could result in the loss of the supply.

13.4 External pipe runs should be avoided when possible. Where external runs are necessary, they should be protected as follows:

- **on external vertical surfaces up to the maximum height of exposure to possible damage (for example vehicular movement):** by means of galvanised, profile-section steel of sufficient thickness to afford adequate protection. The protection should cover the entire space taken up by the pipeline(s), but stand off the surface such that the pipes can be inspected visually. The armour should be readily detachable to permit more detailed inspection;

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- **when crossing horizontal surfaces, roofs etc:** similar protection as detailed previously should be provided to withstand “stepping” damage using profiled section.

13.5 Pipework should be protected from lightning strikes by ensuring that they are run within a 60º cone beneath the lightning conductor, for example when run along parapet walls, or when penetrating parapet walls. When run across roof surfaces, a copper lightning conductor should be run on the top surface of the pipework cover providing physical protection, and should be bonded to it.

13.6 Internal pipelines should be suitably protected where there is a possibility of physical damage, for example from the passage of trolleys, tugs etc.

13.7 Wherever practicable, a clearance of at least 25mm should be maintained between each service and 150mm should be the separation distance between the medical gas pipeline and the outer surface of insulation of heating pipes, hot water service and steam pipelines to prevent heat transfer. Where pipelines cross over services and a clearance of 25mm cannot be maintained, they should be electrically bonded and wrap-insulated, in accordance with IEE Regulations. They should be bonded to the main earth at building entry and exit. Care is required when selecting pipeline routes to prevent the pipes coming into contact with electric cables and wiring, and to minimise the risk of electric shock in the event of a fault on adjacent cables (see Section 2).

13.8 Underground pipelines should be run in properly drained ducts not less than 450mm x 450mm which have removable covers to facilitate installation and subsequent inspection. Where it is not possible to provide removable covers, two pipes should be run in separate ducts / trenches with valves provided in a convenient location at either end. The valves should comprise LVAs with NIST connectors for the purposes of pressure and other tests. The separation distance between the two trenches should be not less than 2m where practicable (see Figure 33). The two pipes should each be sized for the design flow. One or more different gas pipelines can be run in each duct / trench. The route of the pipeline should be identified on the surface and should be clearly shown on site layout drawings. The possibility of installing a “ring-main” (see Figure 34) or double-end supply should also be considered for both air and oxygen within the curtilage of the building.

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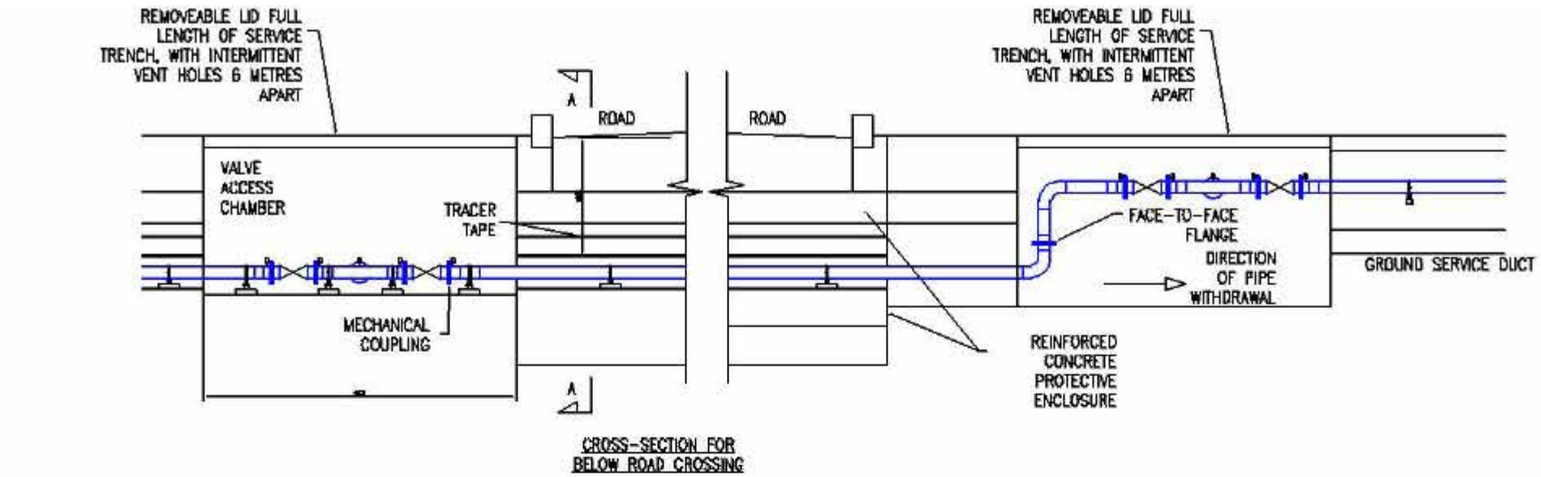

Figure 33: Miscellaneous pipe routing and protection arrangements

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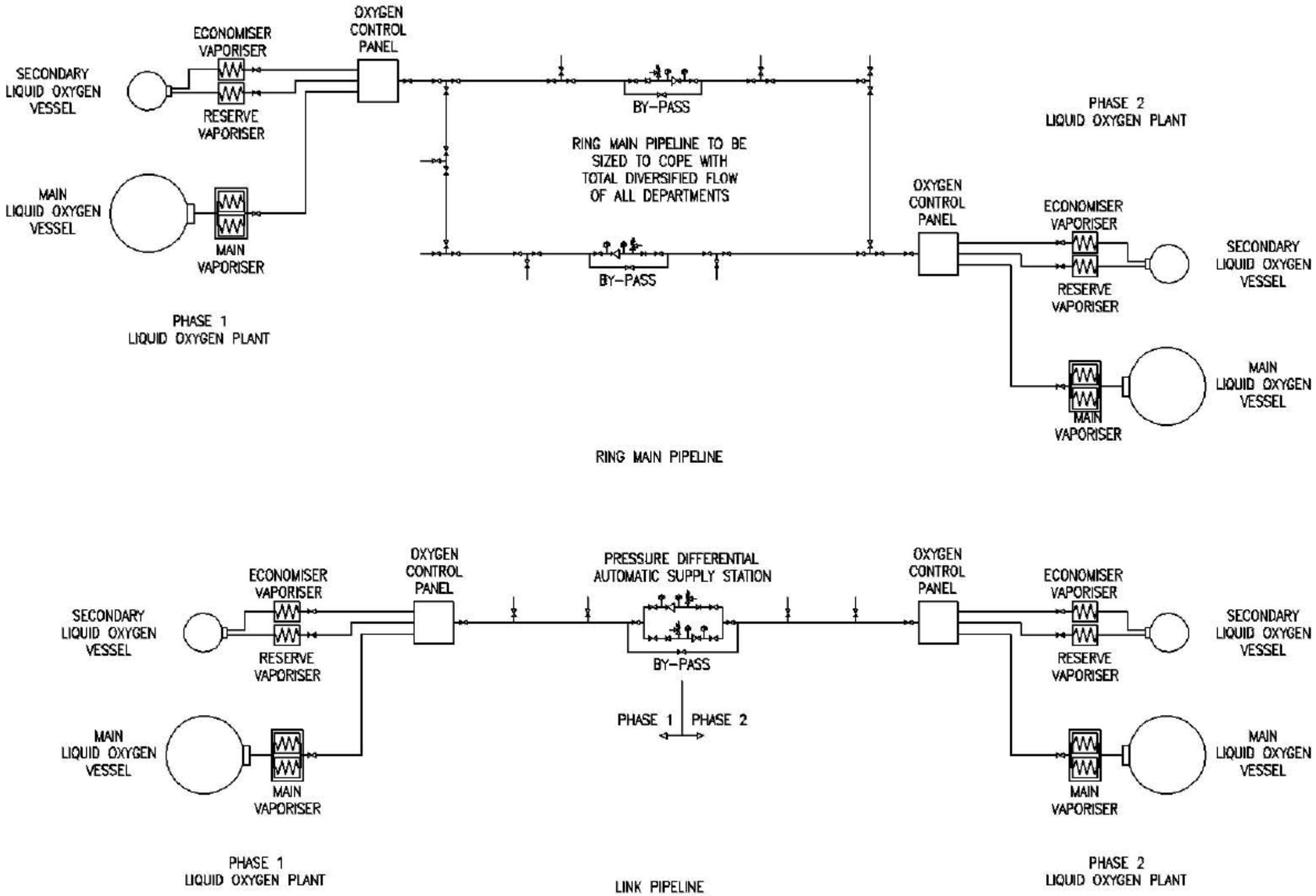

Figure 34: Typical ring main and link pipeline arrangement

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13.9 Pipelines concealed within walls should have their route clearly shown on “as-fitted” drawings. Pipelines should not be encapsulated in floors, and any joints should be kept to the minimum practicable. Pipelines in stud or plasterboard walls or partitions are acceptable, but the pipeline should be protected from corrosion. If the enclosure of pipelines within plaster wall finishes is unavoidable, they should be wrapped in protective grease-free tape.

13.10 Pipelines need further protection in certain circumstances as follows:

- where pipes pass through walls, partitions or floors, they should be provided with sleeves of copper pipe (with fire stopping), which should extend at least 50mm from the surface of the wall, partition or floor. Since it is normal for other trades to seal the pipe sleeves at the penetration the medical gas contractor should ensure that the pipe sleeves are secured temporarily in place during the construction phase, e.g. by adhesive tape;
- where penetrations are exposed to general view, be provided with appropriate wall or ceiling plates;
- in radio-diagnostic procedure rooms etc., radio frequency (RF) screening wave guides may be required (the advice of the equipment manufacturer should be sought);
- corrosion of pipes can occur where they are in contact with timber that has been treated with fire-resistant or flame-retardant compounds, for example some timber used for roof trusses and floor joists.

13.11 This contact should be avoided by the use of impermeable non-metallic materials in the area where contact may occur. PVC spacers or adhesive PVC tape may be used for this purpose. If spacers are used they should not be liable to drop out due to shrinkage or subsequent movement of the pipe or timber.

13.12 Such precautions are not required where untreated timber is used or where the treated timber is effectively sealed with paint or varnish before the pipes are fixed to it.

Pipeline materials

Quality

13.13 The manufacturer should comply with BS EN ISO 9001: 2008 for pipes and for all materials including fittings, terminal units etc.

13.14 Where materials are obtained from suppliers from other countries, the suppliers should be registered in accordance with BS EN ISO 9001:2008.

Pipes

13.15 Material for pipes should be manufactured from phosphorus deoxidised, non-arsenical copper to BS EN 1412:1996 grade CW024A (Cu-DHP) in metric outside diameters and to:

- BS EN 13348: 2008 – R250 (half hard) for sizes up to 54mm; or

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- BS EN 13348: 2008 – R220 (annealed) for larger sizes.

Pipe jointing fittings

13.16 In addition to the above, pipe jointing fittings should be end-feed capillary fittings to BS EN 1254-1:1998.

Other fittings

13.17 Other fittings (oxygen compatible) for connection to copper pipes (for example valve and control panel fittings) may be of copper, brass, gun-metal, bronze or stainless steel.

Cleaning

Pipes

13.18 All pipes must be cleaned and degreased for oxygen service and be free of particulate matter and toxic residues in accordance with BS EN 13348: 2008. They must be individually capped at both ends and delivered to site identified as medical gas pipes.

Pipe jointing fittings

13.19 All pipe jointing fittings and sub-assemblies of fittings for connection to pipes must be cleaned and degreased for oxygen service and be free of particulate matter and toxic residues. They must be individually sealed in bags or boxes and delivered to site identified as medical gas fittings.

13.20 Although it is not essential to use degreased pipelines and components for vacuum and AGSS installations, these are frequently installed by the contractor simultaneously with the medical gas pipelines. Degreased pipe and fittings should therefore be used for the vacuum and AGSS installations to avoid confusion. PVC pipework may also be used for vacuum and AGSS but is unlikely to be of benefit other than for exhaust discharges.

Note 27: Pipes should only be cut with wheel pipe cutters, not hacksaws, to prevent the ingress of copper particles.

Pipeline jointing

General

13.21 Except for mechanical joints, only copper-to-copper joints will be permitted on site, made with brazing filler rods that can be used without flux.

Note 28: Brazing is performed at a higher temperature than in the case of silver soldering with capillary fittings; the exterior of the pipe will therefore have considerably darker oxide deposits.

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13.22 Copper joints to brass or gun-metal fittings will require the use of flux, with subsequent cleaning to remove the flux residues and oxide deposits.

13.23 Heating of the joint for brazing should be carried out with oxygen/acetylene, liquid petroleum gas/oxygen torches. Additional heating may be required for larger pipe sizes / fittings, for example, by means of a second torch.

Note 29: Oxygen / acetylene has an excellent safety record when used on site by the specialist MGPS contractor. This fuel-gas provides a narrow controlled flame with the higher flame temperature providing rapid heat transfer to the pipe and is generally the most suitable method for brazing pipelines in close proximity to other services and building fabric. In view of the unstable nature of the fuel-gas, brazing equipment must be in excellent condition with all component parts checked daily and subject to the correct lighting procedure prior to going on site. The control of cylinders on site should be governed by specific site procedures. The cylinders should be removed from site at the end of the working day. Oxygen / propane has a lower flame temperature and a wider spread of flame making it unsuitable for work in enclosed spaces or close to other unprotected services or building fabric. Small hand-held gas canisters, although limited in terms of their contents, can be useful for 15 / 22mm diameter pipe on a small project or break-in.

13.24 The techniques recommended cover all copper-to-copper joints and all copper-to-brass/gun-metal/ bronze joints in an MGPS, and are explained in more detail below.

13.25 The brazing technique should be used on all medical gas pipeline services.

Pipe preparation

13.26 Pipe ends should be cut square with the pipe axis, using sharp wheel cutters whenever possible, and be cleaned to get rid of any cuttings or burrs. Where a pipe shows a deformation or the pipe ‘cut’ shows a significant ragged burr, that pipe section and the pipe wheel cutters should be replaced. On no account should de-burring be attempted unless the burr is at the lower end of the pipe when in a vertical position, the likelihood by doing so when horizontal could leave deposits within the pipeline. All installation teams should carry spare wheel cutters.

13.27 Evidence of such burrs during examination of selected cut-out connections would be classed similarly to oxidation of pipelines and would result in additional joint removal for inspection until satisfied that a quality standard was being achieved. The use of a hacksaw for copper pipe should mean instant degrading of any certificate of competency of the individual and removal from site.

13.28 When brazing copper-to-copper joints:

- the brazed joints should be made using a silver-copper-phosphorus brazing alloy CP104 to BS EN ISO 17672: 2010. No flux should be used;
- ensure adequate protection of adjacent pipe runs and other services.

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Note30: Brazing copper to brass/gun-metal/bronze is not performed on site. Manufacturers use copper-silver-zinc brazing alloy AG203 to BS EN ISO: 17672: 2010 with an appropriate flux. The flux residues created by the process are chemically removed and, if necessary, the complete assembly is cleaned and degreased for oxygen service. Where brass/gun-metal/bronze fittings are required to be installed they should be supplied complete with copper "tails" of adequate length to ensure that the brazing process does not damage the components.

Use of N_2 internal inert gas shield

13.29 Brazing should be carried out using oxygen-free nitrogen (OFN) as an internal inert gas shield to prevent the formation of oxides on the inside of the pipes and fittings. This method leaves a bright, clean bore. Some slight burnishing may occasionally be observed on sectioned joints. Purging is still required to remove the internal shield gas and the other particulate matter not associated with the brazing operation.

13.30 Oxygen-free nitrogen (OFN) should be supplied to the inside of the pre-assembled, unbrazed pipework through a pressure regulator and flow controller or flow-regulating device.

Application

13.31 OFN should be used as an internal inert gas shield for all positive pressure gases, vacuum and AGSS pipelines.

Note 31: During the first-fix (carcass) stage of pipeline installation, particularly when installing in confined locations such as medical supply units or running pipework within partitions, etc. to individual terminal unit drops, it is possible to inadvertently crossover a pipeline. This is usually discovered at an early stage and, so that the pipe section can be re-assigned and the fault can be corrected, it is essential to use the shield gas to maintain the cleanliness of the internal bore.

13.32 By agreement between the health facility management and the medical gas contractor, the use of a purge gas may be waived on joints such as break-ins to old pipeline systems, where pipe joints will not have been made in accordance with this technique.

13.33 It is recommended that the pipeline to be brazed should first be subject to a high flow of oxygen free nitrogen (OFN) to remove air, followed by a period of 'pickling' at a low flow prior to brazing whilst maintaining the flow.

13.34 Cleanliness of the pre-brazed joint is important. Prepared joints will pick up surface tarnish or moderate oxidation if left and can influence the quality of braze particularly when the permitted depth of braze is 3mm. Failure to braze within the day can be accepted, however any delay should not extend beyond the third day. The nitrogen purge must be maintained during the cool-down of the joint. Adjacent pipes should preferably be subjected to an OFN purge for the duration of the work and cooling period. If it is not possible to introduce OFN

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into an adjacent pipe, e.g. pipeline with a live working gas, a heat resistant blanket(s) wrapped round the adjacent pipe(s) should be made available in proximity to the pipeline being brazed.

13.35 Pipe ends may be capped if desired to direct the flow of nitrogen into sections of the pipe or pipes to be brazed. Particular attention should be given to the gas shielding of T-joint fittings. It is essential that there is a leak-free connection between the pipework to be brazed and the OFN supply.

13.36 On completion, all pipes should be maintained under pressure following tests. The pressure to be maintained to ensure internal cleanliness should be agreed on site, however, 1 bar (max) (100 kPa) has been recognised as an accepted pressure.

13.37 Internal oxidation of pipes could mean replacement of pipe thus careful preparation is normally repaid. Purging on completion will remove dust particles or possibly the odd copper particle. It is not intended to remove oxides developed during the brazing stage.

Safety

13.38 If working for prolonged periods in very confined spaces, precautions must be taken to avoid excessive build-up of nitrogen by ventilating the space or by piping the shield gas safely out of the space. The oxygen content of the ambient air should be monitored when brazing in a confined space.

Control of cylinders

13.39 The contractor and the site engineer must keep a record of nitrogen cylinders held on a site. Nitrogen cylinders should be accounted for and removed from the site at the end of the contract, and must not become mixed up with medical gas cylinders.

Inspection of joints

13.40 Inspection of joints should be carried as a “rolling” procedure on a monthly basis as work progresses for each team performing the installation in accordance with the following procedure:

- the Contract Supervising Officer (CSO) or Authorised Person (AP), whoever is responsible for the inspections and validation, should identify a number of fittings to be cut out for examination in order to establish the quality of the finished joint. The exact number to be cut out will vary with the size of the installation: as a guide, a ratio of one fitting per 200 should be cut out; a minimum of ten for all systems should be cut out for examination (it is preferable to perform these checks before pressure-testing sections of pipeline). The actual removal of the joints should be witnessed by the CSO or AP (MGPS). It is generally not necessary to request cut-outs from vacuum and AGSS pipelines;

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- the fittings cut out should be cut open (quartered longitudinally) and examined. If unacceptable joints are found, adjacent fittings should be cut out until the extent of any faulty workmanship has been established. This may require extensive removal of sections of the installation;
- In order to maintain a record of the inspected joints, consideration should be given to photographing the joint, recording the pipeline section the joint was removed from, the Competent Person (MGPS) who made and cut out the inspection joint and finally comments by the CSO or AP on their findings, e.g Passed or Failed and reasons for failure. This method of recording is more viable now with the availability of digital photography and electronic file storage systems, particularly on larger projects. The above will also act as a means to assess the competence of the individual Competent Person (MGPS) and act as a tool for the CPs employer to validate the CPs competency under the company's quality management system.

Internal cleanliness

13.41 The tube and fitting should be internally clean and free from oxides and particulate matter. Some heat burnishing may be apparent and is acceptable.

Penetration

13.42 Penetration of brazing alloy:

- due to tolerances of the capillary space on these pipes and fittings, full penetration of the brazing alloy may not occur and is not necessary;
- the minimum penetration at any point on the joint must be three times the wall thickness of the tube or 3mm, whichever is greater;
- the pipe should be fully inserted up to the shoulder of the fitting.

Note 32: These tests can be carried out on a sectional basis.

Jointing methods (mechanical)

13.43 It is not envisaged that mechanical joints, with the exception of NIST connections, will be required for new works. In exceptional situations, such as when brazing could impose an unacceptable risk or in situations when patients cannot be transferred to alternative accommodation, should mechanical connections be used. They may also be used for connecting pre-piped bedhead trunking and wall units to the pipeline distribution system. In which case they should be of the permanent swaged type, not contain elastomeric materials, and if located within ceiling voids, that void should be subject to adequate ventilation to prevent any gas accumulation in the event of any leakage.

13.44 Mechanical joints in keeping with paragraph 13.43 should only be viewed as a non-permanent emergency connection, with each connection number tagged and marked up on the record drawings with all remaining work fitted with brazed copper end caps. The installation should be made good as soon as possible in

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accordance with paragraphs 13.29 – 13.35.Mechanical joints will in all instances be subject to, prior to fitting, approval by the Authorised Person and be located readily accessible for periodic inspection.

13.45 PTFE tape is not an acceptable sealing material on oxygen systems or elsewhere downstream of final filters on supply plants.

Note 33: PTFE tape, if applied, can enter the gas system and fragments can block terminal units and present a fire hazard with high-pressure oxygen. Also, when applied by hand, traces of oil and grease can contaminate the inside of the pipeline.

13.46 Liquid or gel-sealing media should be used only if they have been tested and proven safe when subjected to the tests specified in BS EN ISO 15001: 2010.

Capping

13.47 Sections of pipeline should be capped and pressurised with medical air as soon as they are completed so as to prevent the ingress of debris.

Pipeline supports

13.48 The pipeline should be adequately supported at sufficient intervals in accordance with Table 39, below, to prevent sagging or distortion. Supports for surface-mounted pipework should provide clearance to permit painting of the surface. Where it is essential for pipes to cross electric cables or conduit, they should be supported at intervals on either side of the crossing to prevent them from touching the cables or conduit. Supports should be of suitable metallic, non-ferrous material or suitably treated to minimise corrosion and prevent electrolytic reaction between pipes and supports. Supports for vertical drops to terminal units within medical supply units can be of a suitable non-metallic material.

Pipeline outside diameter (mm)	Maximum interval between supports (m)
Up to 15	1.5
22-28	2.0
35-54	2.5
>54	3.0

Table 39: Intervals between copper pipe supports (horizontal and vertical)

Note 34: Consideration should be given to additional supports near LVAs, elbows, etc. where the potential effects of inadvertently applied torque can result in severe pipeline distortion or fracture.

13.49 In situations where medical gas pipelines are required to span building movement joints, consideration should be given to the method by which pipelines are supported to prevent mechanical damage.

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13.50 Pipelines need not be laid with falls. In the case of vacuum, the sub-atmospheric pressure will result in the evaporation of any moisture entering the system.

13.51 The connection of individual, or a number of vacuum terminal units into branches, should be taken into the top of the pipeline to avoid flooding other vertical pipe drops should liquid carry-over occur. Within trunking systems and medical supply units etc, vacuum pipes should connect into the underside of terminal units.

13.52 Each vacuum main riser should be provided with a drain leg consisting of a single full bore flanged valve up to pipe diameters of 42mm - pipe diameters in excess of 42mm can reduce to accommodate a 42mm valve followed by a pipe extension of similar bore to valve off a minimum length 0.5m extension terminating in a capped screwed connection. The extension should have a clear sight glass throughout its length or alternatively be fully transparent. Robust flexible hosing, providing it is of sufficient clarity and capable of withstanding 150 kPa positive pressure and 100 kPa negative pressure is a further alternative and has the advantage of being easily replaced. A double valve arrangement increases cost and has no advantage. It is not recommended that such a drain leg be cleaned in situ. This should be bagged and taken to a safe environment for cleaning, disinfection, sterilization or disposal as appropriate in accordance with the Hospitals' infection control / clinical waste procedures.

13.53 Competent persons carrying out work on vacuum or AGSS systems should be suitably clothed and protected in accordance with SHTM 02-01 Part B, Appendix D or as directed by the Infection Control Officer.

Identification of pipelines

13.54 Pipelines should be identified in accordance with BS EN 1710: 2005 + A1: 2008, and colour banding for the pipelines should be used. Colour band identification (see Figure 35) should be applied adjacent to valves and on either side of walls, obstructions such as ventilation ducted services when they obscure pipe run, junctions and change of direction. A label applied every 3m and bearing 6mm size letters should identify each gas. Self-adhesive plastic labels of approved manufacture may be used for this purpose. A band 150mm wide is usually adequate. All colour-coded tapes applied by the pipe manufacturers should be removed before the systems are identified, in accordance with this paragraph.

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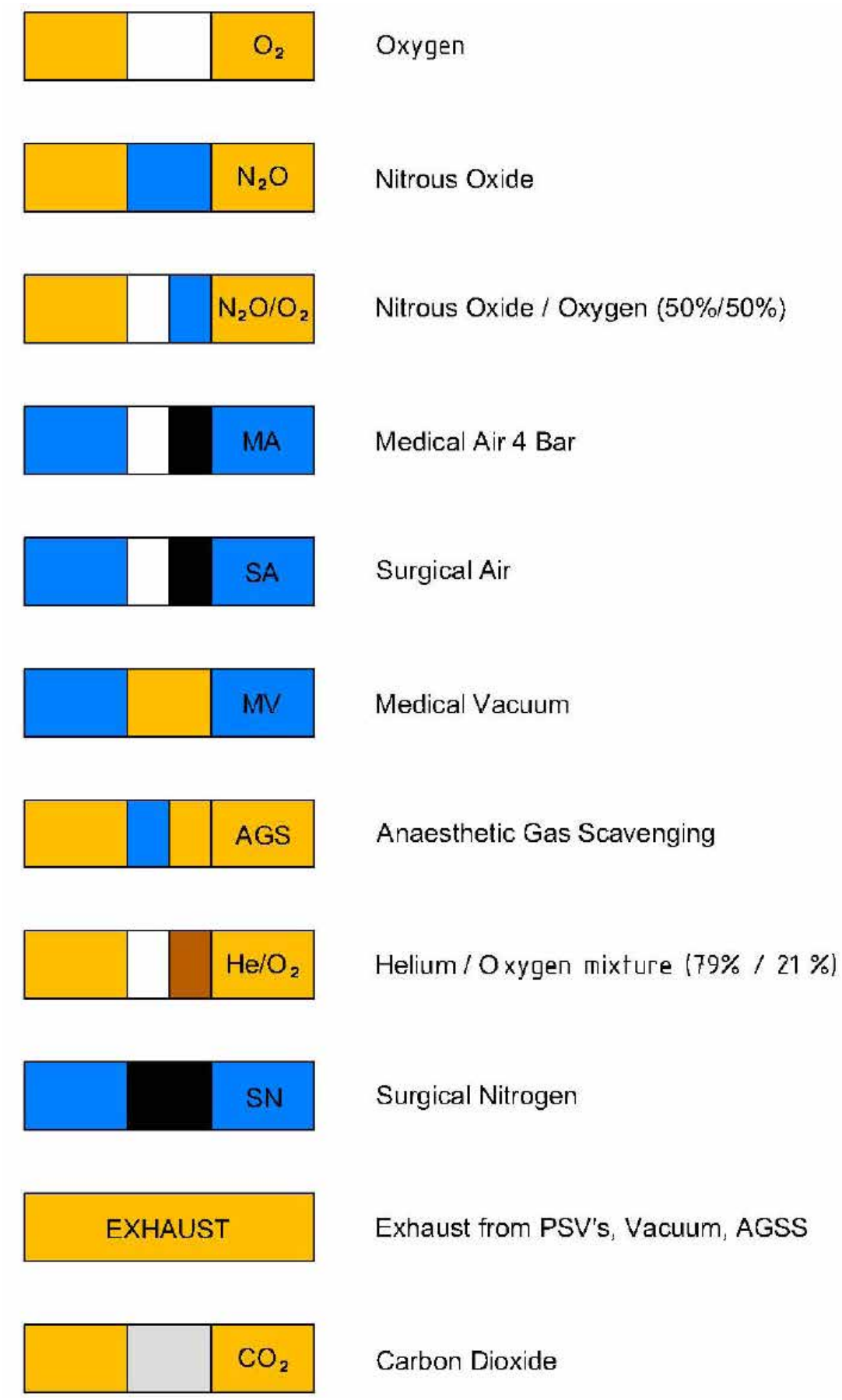

Figure 35: Pipeline identification colours

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13.55 Care should be taken to maintain pipeline identification when periodical re-painting is undertaken. The direction of flow should be indicated. Where a pipeline is used as a link between two systems or is part of a ring main, direction flow arrows should indicate bi-directional flow. Alternatively, the pipeline can be labelled to indicate the purpose of the pipe, e.g. Ring Main or Link Pipeline.

Pipeline components

13.56 Pipeline components, which may be attached to an MGPS, include various types of terminal unit, AVSUs and other components such as emergency inlet ports and pressure control equipment.

Medical supply units

13.57 These should comply with BS EN ISO 11197: 2009. The construction should provide segregation of FELV electrical services by means of partitions or flexible conduit as appropriate. Access to “live” components should be via panels that are removable by means of tools only.

13.58 All rigid medical supply units should be piped in copper, which will avoid the higher pressure losses, leakage, probable volatile contaminants, regular inspections and replacement associated with flexible hoses. Exceptions will be motorised and multi-movement pendants which should be constructed in such a manner to ensure that the flexible hoses are not subjected to kinking or twisting.

13.59 The flexible hoses should be free from volatile or organic compounds and certificated to that effect by the pendant manufacturers or suppliers by QC tests conducted at manufacturers’ premises prior to pendant assembly.

13.60 Where the pendants incorporate flexible hose assemblies, the hoses should only be of sufficient length to provide connection to the fixed pipeline and terminal unit by means of the appropriate NIST connection in accordance with BS EN ISO 9170-1: 2008

13.61 Excess hose length is a contributory factor in surgical air system pressure drops across the pendant which may exceed this Scottish Health Technical Memorandum 02-01 and BS EN ISO 9170-1: 2008. Where Ultra-clean canopy systems are in place, consideration should be given for surgical air to be piped in copper within a custom built support utilising the canopy structure.

13.62 All equipment incorporating gases suspended from the ceiling structure or wall mounted should provide sufficient venting to allow the escape of gas to the room in the event of leakage/rupture of one or all of the medical gas services.

13.63 The recommended height for rigid pendants is 2,000mm above FFL. The maximum height for pendants capable of vertical movement should be 2,000 mm above FFL in the fully retracted position.

13.64 The use of medical air for pneumatically actuated pendants is covered in Section 3 Table 11, note 3.

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Note 35: In cases where medical or surgical air terminal units are not required to be included in these pendants, an AVSU will still be required "locally" for emergency isolation and servicing of the air-braking mechanisms of some units.

The pendant manufacturer should advise the designer of the requirements for the particular pendant, i.e. the pressure required.

Flexible pendant fittings

13.65 These should comply with the requirements of BS EN ISO 9170-1: 2008 and BS EN 739: 1998. In particular, all loose assemblies should be provided with appropriate NIST connectors.

Bed-head trunking/walling systems

13.66 These fittings should generally be in accordance with BS EN ISO 11197: 2009. Separate compartments should be provided for electrical services, nurse call/radio, etc. and medical gas pipelines.

13.67 The medical gas compartment should be provided with ventilation by means of louvres, slots, etc. to prevent the accumulation of any gas in the event of leakage of the medical gas pipeline services. Unit construction should prevent the accumulation of gas in event of leakage from any of the medical gas system components. Ventilation by any other means, such as natural gaps in trunking sections, are not acceptable as such gaps are dependent on the quality of manufacture and/or fitting and can therefore not be relied upon to adequately vent off leaked gas.

13.68 In some departments, to engender a more domestic environment, medical gas and other bedhead services are installed within concealed recesses (or behind decorative panels, paintings etc). In such cases, adequate provision must be made for ventilation, and the required space to permit connection and disconnection of equipment should be considered. The covers should be clearly labelled to indicate that medical gas equipment is installed within/behind.

13.69 There are three possible installation procedures:

- the introduction of prefabricated units carrying services will require a technical specification, co-ordination of services and procedures. As a minimum to ensure the cleanliness and integrity of the medical gas pipeline systems is retained, brazed copper end-caps or temporary mechanical connections should be a requirement for all pipe terminations;
- providing the bedhead trunking or wall panel is accompanied by a test certificate, the joints can be subjected to a completed installation (2nd fix) pressure test;
- any temporary emergency connection should be removed at the earliest date when a permanent brazed connection should be made.

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Note 36: After any such disconnection and reconnection, it will be necessary to carry out the full range of anti-confusion tests.

LVAs and AVSUs

13.70 All valves should be of the lever-ball type, having flanged O-ring seal connections which open and close with a 90º rotation: the handle should be in line with the pipeline when open.

LVAs

13.71 LVAs should be capable of being locked with the valve in the open or closed position. Means of physically isolating and blanking the pipeline both upstream and downstream of the valve should be provided. The means of isolation should be in the form of a spade that can be readily deployed. It should blank both the pipeline and the valve port and be visible when deployed. Each valve should be provided with a set of “through” and “blanking” spades; they should be coloured white and red respectively. The valve flange should include the thread, and the bolts should be of sufficient length to permit loosening to allow removal/replacement of the spades without loss of structural integrity of the connection. Union-type connections with O-rings are permissible, but the securing nut must also have sufficient thread length to permit venting while maintaining the structural integrity of the connection. A single key for each service is considered to provide sufficient security.

13.72 In the event of leakage of the through or blanking spade, gas must be capable of venting to atmosphere and must not be able to enter either the valve port or the pipeline section blanked.

13.73 The appropriate NIST connector bodies with self-sealing check valves and lockable blanking nuts should be provided upstream and downstream of the flanges. Gas identity and flow direction arrows should be provided for each valve.

Note 37: A single NIST connector will suffice in ring-main branch connections between the three closely spaced valves.

13.74 LVAs should be provided as follows:

- at the connection of the pipeline to any source of supply;
- at the emergency inlet port (that is, it forms the emergency inlet point);
- at the pipeline entry to a building;
- at the pipeline exit from a building;
- at the connection of branches to the main pipeline run;
- at the connection to risers;
- at branches from risers to serve a number of similar departments;
- upstream, downstream and in the branch connection to a ring-main.

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Note 38: a) Good practice with respect to patient safety should ensure that the oxidising medical gases, each capable of vigorously supporting combustion, in each department, ward area and floor can be speedily shutdown in an emergency fire situation.

b) Where departments on a floor are functionally very different, for example wards and diagnostic areas, each area when branching off the main floor pipeline should have a fire valve (AVSU) installed together with AVSUs within the area as detailed in Section 3.

c) Where a risk assessment has evaluated that the installation of an AVSU located at the riser would give cause for concern from tampering by unauthorised persons, an LVA can be installed in the riser at an accessible height.

d) Individual pipelines radiating from the riser to functionally different departments is not seen as a benefit towards higher fire safety practices.

e) Restrictions are placed on permitting mechanical connections for oxidising gases in ceiling spaces or voids, with or without elastomeric o-rings or materials, in the event of a leak resulting in an accumulation of gas. Where this possibility exists, mechanical ventilation would be required.

f) Installation of line valves, LVAs, pressure switches, etc. in risers can be considered if there is adequate movement of air within riser compartments.

AVSUs

13.75 AVSUs are provided for user access in an emergency (or for maintenance purposes). They should be in accordance with the requirements above for LVAs except that security is achieved by installing them in an enclosure with a lockable door designed such that it can be closed with the valve either in the “open” or “closed” position.

Note 39: The views of the building operator should be sought as to the level of security that will be required and hence the range of keys. The medical gas operator, e.g. Estates Department or Facilities Management provider’s views should be sought in determining the number of MGPS keys required per building:

a) One key and duplicate per service;

b) One key and duplicate per valve;

In either case, a key cabinet and valve schedule should be provided. The schedule should provide information of gas service, key and valve numbers and department and/or terminal units controlled by the valve.

Crossover pipelines above AVSUs should be avoided wherever possible.

13.76 In an emergency, the user must be able to gain access in order to operate the isolating valves quickly and simply without the need for a key. There are several

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methods of providing such emergency access, for example break-glass panels and plastic push/pull-out inserts. Whichever method is used must be safe and secure and must clearly act as a deterrent to tampering without introducing undue risk of injury to the user. Float glass must not be used. The method of emergency access must be obvious and clearly labelled, and its use must be evident.

13.77 AVSUs may be designed for a single pipeline service for each gas type or combined within a multi-service module. Single AVSU covers should be gas specific, while multi-service AVSU module covers should only require a door for each valve, the covers need not be gas specific. However, access to each valve in a single AVSU or multi-service AVSU module should be by a unique lock and key. In the instance where a hose is to be connected to a NIST, for example to back feed a gas service during a system closure or for emergency supply to a department/room, the protocol for such a requirement would be for the connected cylinder to be permanently supervised by a suitably qualified person. In this case, the door would remain open during the temporary cylinder connection, thereby negating the need for hose access slots.

13.78 The enclosure should have adequate ventilation to prevent the accumulation of gas in the event of a leak. Pipe entries and other penetrations should be sealed to prevent gas escape by routes other than the vents or openings into the user space. The enclosure should be designed to facilitate sealing of these entries on site. Gas identity and flow direction arrows should be provided for each valve.

13.79 Provision and location of AVSUs is covered in Section 3.

Note 40: AVSUs should not be installed in positions where they can be obscured or damaged, for example within the “swing” of a department door or behind partitions.

Specific labelling requirements

13.80 All AVSUs should be labelled to identify the individual rooms, sets of terminal units etc controlled. The upstream and downstream NIST connectors should be clearly identified by a permanent label, securely fixed.

13.81 In critical care areas, where dual circuits and/or subdivisions of circuits occur, terminal units need to be correspondingly identified with the specific AVSUs (see Figures 4 and 5).

13.82 In the case of pneumatically-powered pendant fittings where, typically, medical air or preferably surgical air should be used for the power source that controls the pneumatically-powered devices, the appropriate controlling AVSU should be identified.

Pressure control equipment

13.83 Medical gases may be distributed at a higher pressure than the eventual nominal pipeline distribution pressure at terminal units. Where this is the case,

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the maximum pressure should not exceed 980 kPa, and the local pressure "control" equipment should be installed in an area that has good ventilation and be housed in a clear-fronted lockable cabinet, fully identified for service and area served. It should be in a position where it is readily accessible for maintenance/service.

13.84 The pressure control equipment should include duplex pressure-regulating valves, each with upstream and downstream isolating valves, safety valves, up and downstream pressure gauges and NIST connectors. The safety valve discharges should be run to the exterior of the building; medical air and surgical air may be discharged within a plant space, for example a plantroom above an operating department, provided it is terminated in a safe position.

Pressure sensors

13.85 Pressure sensors to provide the alarm function will need to be fitted to pipeline distribution systems. In all cases they should be installed in a location which is adequately ventilated and having access for maintenance. They may be incorporated downstream of AVSUs. Where not incorporated into an AVSU, the pressure sensor should be close to the AVSU so that it is accessible for maintenance. Pressure sensors should be factory-set and be a replacement item. They should be connected to the pipeline by means of a minimum leak connector. Suppliers, contractors and training course providers must be fully aware of the difference in settings between HTM 02-01 and this Code of Practice.

Pressure switches can be installed within:

- AVSUs valve boxes;
- AVSU modular wall panels;
- individual wall box;
- pressure switches need not be installed close to an alarm panel, but appropriately located pressure switches can aid setting alarm conditions visually.

Pressure gauges

13.86 Pressure gauges are not usually required outside the MGPS source plantroom unless they form part of a remote regulating set. If provided, however, they should similarly be installed in an adequately ventilated location. They may be incorporated within AVSUs, operating room supply fittings etc. They should be installed with isolation cocks.

Test points

13.87 Each supply plant, that is, liquid facility, manifold (main and ERM), compressor plant, PSA and blending plant, should be provided with a test point comprising lockable valve and terminal unit. This should be within the plantroom or

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enclosure, and be sited immediately upstream of the distribution pipeline isolating valve.

Emergency / maintenance inlet port

13.88 Medical oxygen and 400 kPa medical air systems should be provided with an emergency inlet port to the pipeline distribution system. This should be located downstream from the main source of supply line valve isolation point, in a remote location to permit connection of a temporary supply plant. The emergency inlet should comprise a 28mm dia. LVA, an additional non-return valve on the emergency inlet side and a connection that can be blanked, to which the emergency inlet can be made.

13.89 An emergency inlet port is not required for 700 kPa surgical air systems.

Line pressure alarms and safety valves

13.90 The purpose of the line pressure alarm is to warn users that the nominal line operating pressure is out of limits and that gas mixtures, whether supplied by a blender/mixer, an anaesthetic machine or patient ventilator, may deviate from the clinically desired proportion. Local action can then be taken to adjust the mixture, or when an anaesthetic machine is in use the reserve cylinders can be brought into use. The low-pressure alarm for nitrous oxide/oxygen mixture supply pipelines will warn of possible demand valve regulator failure so that a portable cylinder can be made available. The high/low pressure limits have been set to accommodate the design of most types of anaesthetic equipment where differential pressure or low pressure may affect performance.

13.91 The line pressure safety valve provides limited safety from differential pressure effects since the pressure at which maximum discharge occurs will result in a differential much greater than that for which the anaesthetic equipment has been designed. They are therefore strictly system protection devices. All safety valves should have a separate discharge pipe that is run to a safe position which – except for air – should be external.

13.92 The commissioning of medical gas pipeline line pressure regulators, warning and alarm systems, and pressure settings is crucial to the performance of anaesthetic equipment and patient safety; once commissioned, medical gas pipelines are subject to strict permit-to-work procedures. Decommissioning a complete system is highly disruptive to patient care and introduces considerable risk.

13.93 The Pressure Systems Safety Regulations 2000 require pressure safety devices to be tested periodically. It is not appropriate to test an MGPS by either raising the line pressure regulator setting or manually unseating the relief valve. Such action could result in failure of anaesthetic equipment and – if the safety valve fails to reseat – it could result in considerable gas loss and further hazard. Medical gas pipeline distribution systems should be provided with a pressure relief device downstream of the line pressure regulator connected by means of a three-way cock so that the safety device can be exchanged for a “certificated” replacement in accordance with the frequency required by the Regulations.

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14. Design and construction of plant and manifold rooms

Location of manifold rooms

14.1 Cylinder gas/liquid supply systems should not be located in the same room as medical air compressors, PSA systems or vacuum plants.

14.2 Manifold rooms, emergency/reserve manifold rooms for PSA systems, VIE installations and medical compressed air systems should be located to take account of the risk assessment, but should also take account of the location of the medical gas cylinder storage area.

14.3 All manifolds, including the emergency reserve manifolds, may be located within the same room. Manifold rooms should be located on an external wall(s) to facilitate ventilation, which will be required at high and low level. Internally sited manifold rooms for gases other than medical air and cylinder stores may require mechanical ventilation.

14.4 The emergency/reserve manifold for liquid oxygen systems has traditionally been located within the VIE compound, but it is preferable to site the manifold separately. For new installations, these emergency/reserve manifolds should be located separately.

14.5 In the case of surgical air the volume of gas used is relatively small even though the instantaneous flow rates are high. Therefore, it may be more convenient to include the manifold within the operating department.

14.6 Where a surgical air 700 kPa manifold room is provided it may be used as the ready-use store for a small number of spare cylinders to be used on anaesthetic machines.

Note 41: It is permissible to accommodate medical compressed air plant, vacuum plant and AGS disposal system pumps within general plant areas accommodating such equipment as air handling units, water service systems etc. They should not, however, be located with heating or hot water service equipment or equipment likely to produce any fumes or odour.

Access

14.7 Access to manifold rooms should be from the open air, not from corridors or other rooms.

14.8 Normal commercial lorry access is suitable for gas cylinder delivery vehicles, but consideration should be given to the provision of a raised level loading bay to reduce cylinder handling hazards.

14.9 Two doors should preferably be provided in a manifold room. One should be large enough to facilitate cylinder handling and must be in an outside wall. Exits

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must be free of all obstructions. Doors must open outwards. All doors must normally be locked to prevent unauthorised access, but should be provided with means of entry and exit in an emergency (for example by a push-bar arrangement on the inside).

14.10 Internal walls and ceilings, including any internal doors of the manifold room, should be of a suitable non-combustible two-hour fire-resistant material as defined in BS476-4:1970 and BS476 Parts 20–23 (1987). Internal doors should be avoided where practicable. Smoke detectors should be provided. The provision of automatic fire suppression / gas leak detection should be considered as part of a risk assessment which reflects local conditions.

Construction and layout of manifold rooms

14.11 The manifold room will contain the manifolds as well as cylinder racks holding sufficient spare cylinders to replace one bank of each manifold and the emergency/reserve manifold. (For nitrous oxide/oxygen manifolds, sufficient spare capacity for two banks of cylinders should be provided.) Further replacement cylinders should be supplied from the medical gas cylinder store. The size of the manifold room should therefore be determined by risk assessment. Adequate space should also be allowed for cylinder handling.

14.12 A typical automatic manifold with two duty and two stand-by cylinders is approx. 1,800mm long and 600mm deep. One extra cylinder on each bank adds approximately 500mm to the overall length, so that a 2 x 6 manifold is approximately 4,500mm long.

14.13 All medical gas manifolds may be installed in the same room. Additional floor area should be provided to accommodate separate storage racks for each gas. The racks should be designed along the lines of those on the manifolds, but the stored cylinders may be closer together. Racks should conform to ISO 32:1977. With the exception of small cylinders of N_2O/O_2 mixtures, under no circumstances should rooms contain gas cylinders other than those appropriate to their manifolds.

Heating and ventilation

14.14 Ventilation louvres should be provided at both high and low level for all manifold rooms, to allow circulation of air. A risk assessment should be carried out to assess the potential risk of staff being exposed to leaking gas within manifold rooms. BCGA Code of Practice 4 provides methods to calculate either oxygen depletion or enrichment and appropriate ventilation rates. Further consideration could require the inclusion of gas leak detection systems. However, these systems would only be required if the risk is high or the organisation responsible for accessing the manifold room deems it necessary.

14.15 Air intakes for compressor inlets should, if possible, be located externally. However, they should not be installed as an alternative to the provision of adequate ventilation for cooling purposes.

14.16 All ventilation louvres should be vermin/bird-proof.

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14.17 PSA and medical air compressors liberate, under maximum flow conditions, considerable heat. Moreover, these plants aspirate air for breathing purposes. Generous natural ventilation should be provided, and where this is not possible if the plantroom is deep-plan, mechanical ventilation should be provided. The ambient temperature of manifold rooms and plantrooms should be maintained within the range of 10–40°C. The ventilation rates should ensure that the plantroom temperature does not exceed ambient temperature by more than 10°C.

14.18 Manifold rooms may be used to store small numbers of nitrous oxide/oxygen cylinders intended for portable use; these are taken from the main cylinder store for the purpose of temperature equilibration, before being delivered to wards etc.

14.19 To achieve temperature equilibration, additional heating may be required; the natural ventilation must not be reduced. Where such heating is provided, it should be by indirect means, for example steam, hot water or warm air. Naked flames and exposed electric elements should not be used, and excessive surface temperature should be avoided. If necessary, cylinders should be protected from excessive heat. Any primary heat source should be located in a safe position, preferably remote from the manifold room.

14.20 Cylinder recognition charts, supplied by the medical gas supplier, should be prominently displayed as appropriate.

Lighting

14.21 Manifold rooms and medical gas plantrooms should be provided with lighting to an illumination level of 200 lux by means of lighting fittings to BS EN 60529: 1992.

Noise control

14.22 Plantrooms should be designed and constructed to ensure the satisfactory control of noise emission. The effect of two vacuum pumps or compressors running together, in the case of duplex installations, and three or more in the case of multiplex installations, will be to increase the free-field noise level outside the plantroom by 5 dB(A) for each additional pump or compressor operation over and above the specified limits. Consideration should be given to providing acoustic enclosures to reduce the free-field noise levels in noise-sensitive areas adjacent to plantrooms.

14.23 Acoustic enclosure and/or plantroom design must not inhibit normal cooling functions or maintenance activities.

14.24 Free-field noise levels should be given to the architect to assist in acoustic design of the plantrooms.

14.25 The discharge from some vacuum pumps may require silencing.

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14.26 Compressors and pumps should be mounted on properly-selected anti-vibration mounting, where necessary, to minimise transfer of noise and vibration to the structure of the building.

14.27 All pipework and electrical conduits connected to the plant should be fitted with flexible connectors where necessary to prevent the transmission of noise and vibration along the pipelines and conduits. Electrical bonding will be required.

Labelling/signage

14.28 Labelling for medical gas systems, equipment and accommodation should be in accordance with Appendix K.

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15. Validation and verification

General

15.1 This chapter covers the validation and verification and filling for use of MGPS. Validation and Verification is required to determine that the designer and MGPS contractor have fulfilled all the necessary conditions by confirming and verifying the initial design data and substantiating that the contractor has installed the medical gas pipeline systems in accordance with the specification and to an acceptable standard. For this purpose the designer will supply the specification, drawings, isometrics and pipeline design calculations at an early stage of the contract. This ensures any design discrepancy can be rectified, preferably prior to installation work commencing.

15.2 This chapter describes the tests required and the test methods. The contractor should provide instrumentation for the engineering tests. The Quality Controller (MGPS) normally provides instrumentation for the gas quality and identity tests. Calibration certificates should be available for all instrumentation. Tests are listed in Appendix A with the associated forms.

15.3 The objective of testing and commissioning is to ensure that all the necessary safety and performance requirements of the MGPS will be met. Testing and commissioning procedures will be required for new installations, additions to existing installations and modifications to existing installations. The scope of work will dictate the specific test programme required. This is described in more detail in paragraphs 15.12 – 15.14.

15.4 For modifications and extensions (except for the final connection), all work should be performed with an inert gas shield; thus, it is essential that a physical break is employed between the pipeline being modified/extended and the system in use. This will usually be by deploying “spades” in AVSUs and LVAs, or by cutting and capping the pipe. Prohibition labels should be affixed to all terminal units of the system affected in occupied areas.

15.5 For small extensions comprising fewer than 20 brazed joints per gas service, all the tests may be performed with the working gas – the carcass pressure tests being replaced by a system leakage test of the complete extension. An extension comprising more connections would, however, be deemed to be a small installation, requiring all the appropriate tests to be carried out, up to the final connection; the final connection would be tested at pipeline distribution pressure. For the purpose of ascertaining the number of joints, a straight coupling comprises two joints and a “T” comprises three joints. On a minor modification, from which existing terminal units would not be removed, the carcass pressure test can also be omitted. All other tests would be required, including a working pressure test.

15.6 The programme of tests is divided into the following phases:

- validation of design

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- tests and checks on the pipeline carcass;
- engineering testing, commissioning and purity of the medical and surgical air plant and the testing and commissioning of the vacuum plant;
- tests and commissioning of the complete pipeline system (with terminal units installed) for safety, performance and particulate contamination using test gas;
- filling of the systems with specific gases for the purposes of identity and quality tests of the specific gases prior to use for patient care;
- gas identity and quality tests.

Note 42: a) Systems that are not to be taken immediately into use should be filled with medical air and maintained at operating pressure. Systems other than medical, surgical or dental air supplied from compressors should be filled with medical air from cylinders.

b) Commissioning of liquid supply systems prior to handover should be avoided. (Under “no flow” conditions, liquid will evaporate and oxygen will blow off to atmosphere.)

15.7 The personnel and test equipment needed for these tests are listed together with the test requirements in Table 40. The particulate contamination test for all pipeline systems may be checked using medical air to establish that the pipeline has been constructed correctly and is not contaminated. Successful completion of the commissioning tests normally indicates the end of the installation contract. The systems may then be left under pressure, filled with medical air, for an indefinite period. Responsibility for the system during this period needs to be clearly defined in the contract; the Authorised Person (MGPS) under a conventional build hospital ultimately responsible for the day-to-day management of the MGPS after handover should be permitted access during contract work. This should be included in the contract agreement. For PFI/PPP projects, to ensure there cannot be a conflict of interest, the Contract Supervising Officer preferably from an independent organisation, can be appointed in accordance with Scottish Health Technical Memorandum 00, Scottish Health Technical Memorandum 02-01 Part B and be acceptable to all parties.

Note 43: In some circumstances an MGPS may not be taken into use immediately after construction and will be left filled with medical air. In these circumstances, the particulate contamination and odour/taste tests may be carried out before purging and filling with the working gas (see paragraphs 15.95 – 15.101).

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Paragraph	Test	Personnel	Equipment
15.1	Validation of design prior to installation	CSO or AP	
15.11	Labelling and marking	CSO or AP and CR	Visual
	Sleeving and supports	CSO or AP and CR	Visual and tape
	Leakage	CSO or AP and CR	Pressure-measuring device
	Cross-connection	CSO or AP and CR	Pressure-measuring device
15.12	Functional tests of all supply systems	CSO or AP and CR	Flow meter / Dew-point meter/ electrical test equipment
	Leakage	CSO or AP and CR	Pressure-measuring device
	Closure of AVSUs and LVAs	CSO or AP and CR	Pressure-measuring device
	Zoning of AVSUs and terminal unit identification	CSO or AP and CR	Open probes or special test device
	Cross-connection	CSO or AP and CR	Open probes or special test device
	Flow and pressure drop at individual terminal units, mechanical function and correct installation	CSO or AP and CR	Special test device, certified probes
	NIST connectors	CSO or AP and CR	Full bore NIST probes and nut
	System performance	CSO or AP and CR	Metered leaks and special test device
	Supply systems	CSO or AP and CR	Visual
	Pressure safety valves	CSO or AP and CR	Visual
	Warning and alarm systems	CSO or AP and CR	Visual
	As-fitted drawings	CSO or AP	Visual
	Purging and filling	CSO or AP and CR	Gas source and delivery equipment
	a) Other supply system functional tests b) Particulate contamination (see note after paragraph 15.8)	CSO or AP and CR	Particulate matter test device (PMTD)
	AGS disposal systems	CSO or AP and CR	Metered leaks and AGS test device
15.13	Gas quality	CSO or AP, CR and QC (MGPS)	PMTD, oil, moisture, CO, CO_2, SO_2 and N_2 oxides measuring devices, O_2 and N_2O analysers
	Gas identification	CSO or AP, CR and QC (MGPS)	O_2 analyser and N_2O meter

Table 40: Personnel and test equipment requirements

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Note 44: Refer to Scottish Health Technical Memorandum 02-01 Part B for description of the duties and responsibilities of the various parties included in Table 40.

15.8 All supply systems and their major components should have certificates (as specified in Model Engineering Specification C11 – 'Medical gases') which show that they meet the design requirements of the pipeline system.

15.9 Only contractors who are registered to BS EN ISO 9001: 2008/BS EN ISO 13485: 2003 with their scope of registration defined to include commissioning should undertake engineering validation and verification. Contractors who may not be registered as such, but who can actively demonstrate that they are working towards registration may also be considered for this work.

Note 45: BS EN ISO 9001: 2008 registration is also recommended for independent medical gas testing agencies but is not necessary for appropriately trained and appointed hospital-based QCs (MGPS).

15.10 All relevant tests should be carried out by the persons listed in Table 40 and witnessed by the appropriate persons, who must record the results of the tests in writing for the hospital authority.

Summary of tests

Tests and checks on the pipeline carcass

15.11 The following tests must be carried out after installation of the pipeline carcass but before concealment:

- visual check of pipeline labelling, marking, sleeving and supports;
- leakage test;
- tests for cross-connection;
- valve tests for closure, zoning and leakage. (These tests will be repeated as part of the pipeline system tests and the contractor may wish to defer closure and leakage, but may choose to carry out a zoning check.)

Tests on the pipeline system

15.12 The following tests and checks must be carried out after complete installation of the pipeline system:

- tests for leakage on each MGPS;
- tests of AVSUs for closure, correct service and control of the terminal units in the zone: checks for correct labelling of AVSUs for zone reference and identity of terminal units controlled and flow direction indication;
- tests of LVAs for closure and identification;
- tests for cross-connection, flow, pressure drop, mechanical function and correct identity of the terminal units: checks for correct labelling and

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association with AVSUs (this is only required when, within a specific area, there are separate circuits for the same service, for example dual/ split circuits);

- tests for mechanical function and identity of NIST connectors;
- performance tests of the pipeline system;
- functional tests of all supply systems;
- checks of safety valve certification;
- tests of warning systems;
- tests for particulate contamination should be carried out by the contractor and the AP or CSO during the course of the engineering tests. Where it is shown that a high degree of oxide particles were present within the piped system (this would indicate a deficiency in the initial oxygen free nitrogen purging) the AP or CSO would decide whether to continue with the medical air purging or reject the system. At this stage the Quality Controller (MGPS) would not be required. If the AP or CSO is satisfied with the cleanliness and depending on the contract programme handover date, the QC (MGPS) could be invited to carry out particulate contamination, odour and taste tests using the working gases. An advantage in programming these tests at this stage is the use of the medical air which avoids the high usage of the working gases and risk factor to site staff. The CSO particulate test does not negate in any way the role and responsibility of the QC to repeat the test;
- tests for anaesthetic gas scavenging disposal systems.

Note 46: Nitrous oxide and nitrous oxide/oxygen mixture are not tested for odour.

Tests before use

15.13 The following tests must be carried out after purging and filling with the working gas:

- tests for particulate contamination (see para 15.94 and 15.131 to 15.137);
- tests for gas identity;
- tests for gas quality.

General requirements for testing

15.14 The tests described in this document are generally carried out, in the order given, for new installations. It may be necessary to amend the test programme for modifications or extensions to existing systems. Care must be taken, however, to ensure that the basic principles are followed. Para 15.33 to 15.46 give details of the tests required for modifications/extensions to existing systems.

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15.15 In all cases involving plant, the medical air and vacuum plant should be tested during or immediately following carcass tests. This test will include the QC certification of the medical / surgical air plant.

15.16 On major projects the availability of the following plant is essential to progress the commissioning programme:

- vacuum plant to allow vacuum leakage and flow tests to be carried out on the completed system.
- medical air plant certificated by CSO or AP and QC to enable its use during the testing of all gas systems. Cylinder supply will not typically provide sufficient capacity when testing large MGPS installations.

Note 47: When tests and/or purging are/is carried out on systems fed by sources serving an operational hospital, it is essential to ensure that the flows generated during any tests do not result in interruption of continuity or impairment of adequacy of supply within the operational areas.

15.17 Testing for leakage is normally carried out in two stages: the first to the pipeline carcass, the second to the completed distribution system, which will include terminal units and medical supply units as appropriate.

15.18 Purging and testing must be carried out with clean, oil-free, dry air or nitrogen, except for those tests where medical air or the specific working gas is prescribed. All test gases must meet the particulate contamination requirements set out in paragraphs 15.131 – 15.137. The shield gas may be used for the tests on the pipeline carcass described in paragraphs 15.50 – 15.57. Cylinders of medical air will normally be used as the source of test gas for oxygen, nitrous oxide, nitrous oxide/oxygen mixture and helium/oxygen systems in order to prevent the possibility of contamination with oil.

15.19 However, in the case of a large oxygen system, for example a new-build, the use of cylinders will be impracticable for the total system performance test. As it may be undesirable to commission the liquid supply system, the total system performance test can be carried out by using the medical compressed air plant, provided that the quality tests have been satisfactorily carried out to demonstrate that the criteria set out in Table 43 have been met and that the air supply plant is continuously monitored for moisture during the test.

15.20 The medical compressed air plant can also be used for the single point performance tests etc and for initial purging and particulate testing of these systems. Once tests have been completed, the system should be maintained under pressure by means of air supplied from medical gas cylinders until filled with the working gas, when full QC checks will be carried out.

Note 48: The use of portable, non-medical air compressors is not appropriate. Not only should a Quality Controller (MGPS) check all compressors before use, but also QC checks during use are important. Preferably, an on-line dew-point meter should be fitted to the plant or pipeline system.

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15.21 When employing medical compressed air plant for this type of test, it is important that the system demand should not exceed the maximum flow capacity of the dryers, otherwise wet air will result. It is suggested that the total flow required by the system under test should not be more than 75% of the flow capacity of the dryers.

15.22 It is also important not to introduce such a compressor after identity checks have taken place.

15.23 Special care will be required when carrying out QC checks, as some synthetic oils cannot be detected using portable equipment.

15.24 Special connectors will be needed to introduce test gas into different pipeline systems. These must be of distinctive construction and permanently labelled with their function and the contractor's name. The location of special connectors on the site must be recorded and should be subject to routine inspection under a planned preventive maintenance (PPM) system. They should be removed from site when work is complete and the contractor should record their removal.

15.25 New terminal units are supplied with "Do not use" labels. These labels should remain in place until the final identity and quality tests have been completed. They are then removed by the Authorised Person (MGPS).

15.26 In the case of existing systems, "Do not use" labels should be affixed to all terminal units within the section being modified.

15.27 The results of all tests must form part of the permanent records of the hospital and should show details of the services and areas tested. Examples of the appropriate forms are given in Appendix A. All signatories are entitled to copies of the test forms. The procedure for filing and retaining these forms should be included in the local MGPS operational policy.

15.28 For total system pressure tests on oxygen, nitrous oxide and nitrous oxide/oxygen mixture, the system under test must be physically isolated from the source of supply (for example by the use of spades). In the case of compressed air and vacuum systems, the pressure at the plant must be respectively below and above pipeline distribution pressure.

15.29 All errors found during testing must be rectified, and the relevant systems must be retested as appropriate before the records are signed.

15.30 The contractor (MGPS) must provide all engineering forms, labour, materials, instruments and equipment required to carry out the tests described in this chapter. In the case of engineering tests, this must include all cylinders of test gas together with "open" bore NIST connector probes, pressure-measuring equipment and gas specificity/ flow pressure testing device(s), metered leaks and AGS disposal system test equipment. The Quality Controller (MGPS) will be responsible for supplying all QC forms, unless otherwise requested by the Hospital Authority, calibrated test equipment, connections etc.

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Note 49: If there is to be a delay between completion of the MGPS and when it is taken into use, it will be necessary to carry out the particulate and odour test prior to purging and filling with specific gases. In such cases the contractor must also provide labour, materials and equipment to carry out these tests.

15.31 The Quality Controller (MGPS) should provide the test equipment specified in Appendices D, E and F. The Quality Controller (MGPS) should provide all equipment for gas quality and identity testing. It should be regularly serviced and calibrated to an appropriate standard and the Quality Controller (MGPS) should maintain calibration records. On-site pre and post-testing calibration of equipment against an appropriate standard will be performed at the discretion of the Quality Controller (MGPS).

15.32 In a completely new installation, flow meters, anaesthetic trolleys etc should not be moved into rooms until validation and verification tests have been satisfactorily completed.

Note 50: In existing installations, particular care must be taken to ensure that medical gas equipment left in areas where work or testing is taking place is, and remains, disconnected from the system. Medical and nursing staff should be made aware of this situation by the posting of appropriate exclusion notices and terminal unit “Do not use” labels.

Modifications, extensions or repairs to existing systems

15.33 Where modifications, extensions or repairs to existing systems are carried out, the tests and the sequence of tests summarised in paragraphs 15.12 – 15.14 should be followed as far as possible.

15.34 The permit-to-work system should always be followed whenever any work is carried out on an existing system. The Authorised Person (MGPS) should act on behalf of the management and therefore would not normally be a member of the installation contractor’s staff.

15.35 Whenever modifications or extensions are carried out, it may be advisable but not always possible to test both the existing system and the new system separately before the break-in is made. Existing systems should, if possible, be tested to determine their performance and to identify any potential limitations that may arise as a result of modifications.

15.36 Where there is any doubt as to the cleanliness, it is in the interest of both the contractor and management for particulate tests to be carried out on the existing system prior to any break-in, and it is the responsibility of the hospital authority to ensure that these tests are carried out prior to the design phase of any modifications or extensions.

15.37 It is the responsibility of the hospital’s management to ensure that any required remedial work is carried out on an existing system before extensions are added.

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15.38 No system should be modified during the process of testing. It is important that any modifications are documented and that any additional testing required, as a consequence of those modifications, is performed.

15.39 A permit-to-work (or another form of appropriate document) must be issued if additional works are to be carried out during the commissioning process, even though a permit will not have been issued for the original commissioning.

15.40 The tests for particulate contamination of any extension or modification may be carried out with medical air, prior to connection and handover to the Quality Controller (MGPS), although in extensions comprising fewer than 20 joints, the working gas will generally be used to perform all tests.

15.41 The Quality Controller (MGPS) will normally carry out all checks, including a repeat of the particulate matter test, using the working gas.

15.42 The exact tests to be carried out will depend on the nature of the modification/extension. A specification should be prepared for the performance of the completed system. This specification should be as close as possible to that given in Table 41.

15.43 Some older compressed air systems will have been designed to provide 250 litres/min at the terminal unit in accordance with Health Technical Memorandum 22 (1978). It may not be possible for such systems to provide 350 litres/min, as specified in Table 19, and there may be circumstances where this would be acceptable. This should be clearly stated in the specification for the performance of the completed system. However, every effort should be made to comply with the performance and quality specifications given here, although particular care must be taken to avoid degradation of air quality arising from dryer units working at flow rates above their design specification.

15.44 It may be necessary to repeat some of the system performance tests (such as flow and pressure drop) at selected terminal units on the completed system to demonstrate satisfactory performance (see paragraph 15.78). To ensure a valid result from such a test, it should be performed when flows in the system are representative of typical maximum demands.

15.45 The break-in to the existing system should be carried out with an inert gas shield where possible, for example where AVSUs have been installed, and a downstream blanking spade has been deployed. A leak test must be carried out using a suitable leak detection fluid on this final joint at working pressure, and the joint purged with the working gas.

15.46 Connection of the upstream side of the AVSU into the existing system will usually be made without use of the shield gas. This joint can be purged with the working gas (exiting via the AVSU upstream NIST).

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Note 51: In some articulated pendant fittings, it is not always possible to achieve the specified pressure requirements for surgical air and vacuum. In the case of surgical air, it is most likely to be a potential problem in orthopaedic operating rooms. As these normally include an ultra-clean system into which can be incorporated surgical air (and other terminal units), supplied by rigid pipework, there may not be a problem in practice. If the static pressure exceeds the nominal pressure during flow by more than 25%, the possibility of installing hoses with a greater bore should be considered. In the case of vacuum, the flows required during surgery are less than those used during testing.

Medical gas	Plant Regulator Setting +/- 4% (kPa)	Distribution pressure (kPa)	Allowable pipeline losses to rear of terminal unit 5% (kPa)	Test flow (litres/min) (measured at terminal unit outlet)	Minimum pressure at design flow (kPa)
O_2	440	420	400	40*	380
N_2O	440	420	400	40*	380
O_2/N_2O mixtures	440	420	400	275 (LDRP) 40* (others)	310(2) 380
Medical air (400 kPa)	440	420	400	80 (critical care) 40* (others)	380
Surgical air (700 kPa) Wall outlet	860	825	784	350*	700
Surgical air (700 kPa) Pendant	940	900	854	350*	700
He/O_2	440	420	400	80 (critical care)	380
Vacuum	67 – 88 (500-660 mmHg)	60 kPa (450 mmHg)	55.3 kPa (400 mmHg)	40	40 kPa (300 mmHg)

Table 41: Validation and verification: pressure during pipeline system tests

Requirements for pipeline carcass tests

15.47 If sectional testing is performed, it is essential that as-fitted drawings are available so that the extent of the system(s) under test can be identified. For the purpose of the leakage test, all pressure gas systems may be interlinked, provided that the test can be performed at the highest pressure required. This also has the advantage that the pipeline carcass could be assigned to a different service.

Note 52: In the event of a leak, it will be necessary to test each system separately. It is advantageous to perform the tests with nitrogen, since – in the event of a leak or cross-connection – remedial action can be taken immediately. When connecting systems together, vacuum systems should not be included, as particulates from an un-purged vacuum system may be drawn into any part of any pressure gas system by venturi effects.

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Labelling and marking

15.48 A visual check must be made on each pipeline system to ensure that the pipelines are labelled in accordance with the contract specification, and that the terminal unit base blocks are marked in accordance with. BS EN ISO 9170-1: 2008. The results of the checks are recorded on Form A2.

Sleeving and supports

15.49 A visual check must be made on each pipeline system to ensure that the pipelines are sleeved, where required, and supported in accordance with Table 39. The results of the checks are recorded on Form A2.

Leakage

15.50 The aim of the test is to establish that there is no leakage from the piped medical gas systems. This is demonstrated by the use of electronic pressure measuring equipment with a minimum resolution of 0.2 kPa in 1,000 kPa and 0.5 kPa in 2,000 kPa. If the performance of the measuring equipment is in doubt, recourse can be made to a test period extension of between 2 - 24 hours.

Note 53: With suitable equipment, it is possible to carry out this test during a relatively short period to minimise the effect of temperature change. To ensure fairness of the test, it is essential that temperature measurements are taken and recorded at the start and finish of the test irrespective of the period of the test. Over a one hour period with an allowance of 0.2 kPa, a small temperature change may be sufficient to fail the test. Appendix B provides information on the method of calculation. Temperature measurements should be taken throughout the area of test at the beginning of the test and the average temperature should be calculated. Temperature measurements should be taken at the end of the test at the same measurement points. The resulting temperature difference can be used to establish if a pressure loss/increase is acceptable.

15.51 During a test period of one hour, the maximum pressure loss should be ≤ 0.2 kPa for 400 kPa systems, plastic or copper vacuum and ≤0.5kPa for 700 kPa systems. Systems should be tested at a working pressure of

- For medical compressed air systems for surgical use - 18.0 bar (1,800 kPa);
- For all other compressed medical gas systems - 10.0 bar (1000 kPa);
- For vacuum systems constructed in copper 5.0 bar (500 kPa);
- For vacuum systems constructed in plastic 1.5 bar (150 kPa):
- Leakage tests for AGSS systems, the pressure should be set at 70 kPa (± 10%) with a pressure loss of no more than 10 kPa over a period of 15 minutes.

15.52 This test should be carried out with AVSUs, LVAs and other service valves open; any safety valves and pressure-sensing devices installed may be

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removed and the connections blanked off. The results of the test may be recorded on Form A2.

Cross-connection

15.53 Before performing these tests, any links between systems should be removed and all pipelines should be at atmospheric pressure with all AVSUs etc open.

15.54 A single pressure source should be applied to the inlet of the system to be tested and at least one terminal unit base block on all other systems should be fully open.

15.55 Each terminal unit base block on the pipeline under test should be opened in turn, checked for flow and then re-blanked. (To permit refitting of blanking caps, it is necessary to partially open at least one base unit – but it is still necessary to achieve a detectable flow.) When the test on one pipeline has been completed, the pressure source should be removed and the pipeline should be left open to atmospheric pressure by removing at least one base block blanking plate.

15.56 The test is repeated for other systems, one at a time.

15.57 The results may be recorded on Form A2.

Requirements for pipeline system tests

15.58 There must be no links between the pipeline systems. Engineering (pressure) tests should be carried out with electronic pressure-measuring equipment with a minimum resolution of 0.2 kPa in 1,000 kPa, and 0.5 kPa in 2,000 kPa.

15.59 The scope of the system and scale of provision of terminal units, AVSUs, LVAs and warning and alarm system panel indicators should be checked for compliance with Table 11 and any deficiencies noted.

Leakage from total compressed medical gas systems

15.60 This test must be carried out on the completed system at working pressure with all terminal units, AVSUs, pressure safety valves and pressure transducers fitted. Once the test pressure has been applied, the system should be physically isolated from the plant. For the purpose of this test, the supply system extends from the last valve(s) nearest to the plant detailed on the appropriate schematic drawing. This point should be identified on the contract drawings. The test is performed at pipeline distribution pressure.

15.61 During a test period of one hour, the maximum pressure loss should be

- ≤ 0.2kPa for 400 kPa systems;
- ≤ 0.5kPa for 700/900 kPa systems.

The test results may be recorded on Form A3.

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Leakage into total vacuum systems

15.62 Prior to testing, the vacuum plant should be operated to allow any moisture in the system to evaporate. With the system at pipeline distribution pressure and with the source isolated, the pressure increase in the pipeline must not exceed 1 kPa (7.5 mmHg) after one hour. There is no additional allowance for temperature correction in this test.

15.63 The test results may be recorded on Form A3.

Closure of area valve service units and line valve assemblies

15.64 For pressurised systems, the system upstream of the closed AVSU under test must be maintained at pipeline distribution pressure and the downstream line pressure should be reduced to about 100 kPa. The downstream pressure must be recorded, and there should be no change in pressure over a period of 15 minutes.

15.65 For vacuum systems, the systems on the supply plant side of the closed valve must be maintained at pipeline distribution pressure and the terminal unit side should be at about 15 kPa (115 mmHg). The upstream (terminal unit side) pressure must be recorded, and there should be no change in vacuum over a period of 15 minutes.

15.66 For LVAs, a similar test procedure is adopted. There is no change in the time for vacuum.

Note 54: The reduced residual pressure is intended to take into account any potential terminal unit leakage on the assumption that it is unlikely any such leakage would equate to that of the valve under test; there would be less certainty if the pressures were reduced to zero.

15.67 The test results may be recorded on Forms A4 and A5.

Zoning of AVSUs and terminal unit identification

15.68 This test is performed to ensure that each AVSU in the pipeline controls only those terminal units intended by the design. Each terminal unit must be checked to ensure that it is for the correct service and that it is in accordance with BS EN ISO 9170-1: 2008; unambiguous cross-referenced labelling of AVSUs and terminal units controlled by them, is essential. It is particularly important to establish correct identification where dual or separate circuits have been installed; often it is not obvious by the spatial relationship of AVSUs and terminal units which of the AVSUs controls which terminal unit arrays.

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Note 55: a) The contractor may wish to carry out this test as part of the carcass tests before any section of the pipeline is "enclosed".

b) Terminal-unit first-fix back blocks inadvertently fitted upside-down will result in inverted second-fix components, unless gas-specific components are deliberately removed. Therefore, a selection of terminal unit second-fixes, for example one per ward area, should be removed and examined to ensure that no gas-specific components have been removed.

15.69 The test is performed by turning off an individual AVSU and venting the zone to atmospheric pressure. A check is then made to establish that only those terminal units controlled by the AVSU are at atmospheric pressure. All other terminal units, including those for other gas services, should be at the operating pressure. Once a zone has been vented, it is not necessary to re-pressurise. The other AVSUs are then tested successively.

Note 56: a) These tests can be performed at the same time as the cross-connection/terminal unit pressure drop tests.

b) Where pneumatically activated pendant fittings are installed, a check should be made to ensure that the source of air has been taken from the correct AVSU zone.

15.70 The test results may be recorded on Forms A4 and A5.

Cross-connection

15.71 All systems must be checked to ensure that there is no cross-connection between pipelines for different gases and vacuum. The tests should not commence until all installations are complete and plant operational. The tests can be performed using "test" gas or "working" gas.

Note 57: Oxygen and vacuum can be tested simultaneously, followed by medical air and surgical air simultaneously, followed by the other gases, that is, nitrous oxide and nitrous oxide/oxygen mixture. Helium/oxygen mixture usage is increasing, and pipeline systems may be encountered. Also, carbon dioxide pipelines are being installed.

15.72 The sequence of the test is, first, to open all valves on all systems (for example AVSUs, LVAs and any other valves). For oxygen and vacuum systems, the main plant isolation valves should be opened (the main plant isolation valves on other systems remain closed). A check must be made to ensure that there is a flow at every oxygen terminal unit and suction at every vacuum terminal unit, and that the systems are at the correct operating pressure; there must be no flow at any other terminal unit for the other gases.

15.73 For the next stage, the main isolation valves for medical air and surgical air, if present, are opened. (It is not necessary to return the oxygen and vacuum systems to atmospheric pressure.) A check is made to ensure that there is a flow at every medical air terminal unit and every surgical air terminal unit and

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that the operating pressure is correct; there must be no flow from the nitrous oxide and/or nitrous oxide/oxygen mixture terminal units, if present, and helium/oxygen, if present.

15.74 The process is then repeated for nitrous oxide – again there is no necessity to return any of the previously tested systems to atmospheric pressure. A check is made to ensure that there is flow at every nitrous oxide terminal unit and that the operating pressure is correct; there must be no flow from the nitrous oxide/oxygen terminal units and helium/oxygen terminal units (if present).

15.75 The process is then repeated for nitrous oxide/oxygen mixture, and finally helium/oxygen mixture. If other medical gases are encountered, for example carbon dioxide, the sequential testing methodology will continue. As before, there is no necessity to return any of the previously tested systems to atmospheric pressure. Checks are made to ensure that there is no flow from any system that is still isolated at the plant.

Note 58: The tests can be carried out on a total system basis, departmental basis or sub-departmental basis, having previously checked for cross-connection up to the appropriate AVSUs. When carrying out the tests on a sectional basis, it is essential that as-fitted drawings are available such that the extent of the system(s) can be established.

15.76 This test must be repeated in full if any subsequent modifications are made to the pipeline system.

15.77 The test results may be recorded on Form A7/1.

Flow and pressure drop at individual terminal units, mechanical function and correct installation

15.78 These tests can be carried out as part of the cross-connection tests above using appropriate test devices as described in Appendix C with the correct probes inserted for the pipeline(s) under test. The pressure must achieve the values given in Table 41 at the specified flows.

Note 59: When performing these tests as part of the cross-connection tests, there is the possibility that the 400 kPa and vacuum test devices could be connected to the incorrect service, particularly a vacuum and oxygen reversal. The instruments used, therefore, should include appropriate directional check valves. (There is a possibility of damaging the gauges. Alternatively an open probe can be used to determine pressure or vacuum.)

15.79 It must be demonstrated for each terminal unit that the appropriate gas-specific probe can be inserted, captured and released, and it should be visually confirmed that an anti-swivel pin is present, or absent, in terminal units with a horizontal or vertical axis, respectively. Terminal units should be challenged by the test probes of all other gases within the department or ward to ensure non-interchangeability.

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Note 60: a) Terminal units to BS EN ISO 9170-1: 2008 need not be challenged with the full complement of BS 5682:1998 test probes.

b) The terminal unit should be fitted complete with bezel plates etc. The clearance hole should be reasonably concentric with the terminal unit rim – it must not be in contact.

c) By connecting a flowmeter to the terminal unit, the terminal unit should be standard throughout by being proud of the wall, slightly greater than the movement necessary for the release action and sit parallel to the wall on a vertical axis.

15.80 The results of the tests may be recorded on Form A8.

15.81 All NIST connectors, including those provided on AVSUs, LVAs and pendants / flexible hoses, must be checked to ensure that gas flow is achieved when the correct NIST probe is inserted and mechanical connection made. The correct identification of gas flow direction should be confirmed for AVSUs (that is, which are the upstream and downstream NIST connectors). NIST connectors can be checked when performing other tests on AVSUs and LVAs.

Note 61: a) In certain circumstances factory-assembled units are dismantled for installation purposes and can be subsequently incorrectly re-assembled. In the case of LVAs (whether or not CE marked), disassembly and subsequent incorrect re-assembly or, indeed, insertion into an incorrect line, is also possible. The primary purpose of the test is to ensure that whenever it is necessary to make a connection, the appropriate connectors will be to hand; the test is a further safety aid, although it is assumed that personnel making connections to NIST fittings are appropriately qualified and authorised to do so.

b) All NIST connectors should have the manufacturer's certificate of test provided for fitted terminal units within pendants.

15.82 It must be demonstrated (except for vacuum) for each NIST connector that the self-sealing device substantially reduces the flow of gas when the connector is removed without hazard to personnel or reduction in pipeline pressure. This will not apply where the surgical air pendant hose self-sealing device of the NIST has been removed and replaced by an in-line valve.

Note 62: Personnel should take care not to stand in front of the NIST connector when performing this test.

15.83 The results may be recorded on Form A8.

Performance tests on the pipeline system

15.84 The performance of individual pipeline systems is measured by introducing a sufficient number of calibrated metered leaks (with orifice sizes providing different flows that replicate the range of medical devices for which the pipeline is designed; see Table 12) to represent the total "diversified" system design flow, less the flow generated by the test device. Thereafter, a representative

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number of terminal units (see note below) are tested for pressure and flow: the diversified flows should be derived from the data in Tables 13, 15, 16, 18, 20 and 21.

Note 63: a) In a 28 bed ward module, metered leaks equal to the total design flow of the ward should be distributed through the ward. A pressure reading should be taken at the furthest located terminal unit and nearest to the entrance to give the pressure loss across the unit. No noticeable loss should occur with ward gases

b) This procedure is applied systematically for a total system design flow by applying metered leaks equal to the hospital diversified design flow. Pressure readings can be taken throughout the system from source to furthest terminal units from source. Normally an index run is selected based on the heaviest diversified flow demand concentration rather than distance from source.

c) In a ring main distribution system the total flow is designed by measurement in turn in each direction from the source. Requirement for sectional or phased testing to be included.

15.85 The metered leaks should be stamped or similarly be identified to show the flow (air equivalent) at, for example, 10, 20, 100, and 275 litres/min for 400 kPa systems, and 350 litres/min for 700 kPa systems.

Note 64: In principle it is permissible, although unlikely to be practicable for large installations, to test all systems simultaneously, particularly oxygen and vacuum, where terminal units are installed in pairs and where they require different metered leaks (this includes vacuum when testing oxygen will not significantly increase the time needed).

Functional tests of supply systems

15.86 All supply systems must be tested for normal and emergency operation, according to the manufacturers' manuals and contract specifications. For the purpose of the tests, the systems must be connected to both the normal and stand-by power supplies. The results of these tests should be recorded on Forms A9 - A13 and A17.

Pressure safety devices

15.87 Pressure safety valves are not tested. They should be examined to ensure that they are correctly rated for the pipeline system and are in accordance with the contract specification. Each should be provided with a test certificate confirming the certificated discharge pressure. Records of safety valve details should be noted on Forms A9 to A12 inclusive.

15.88 Check that the specified pressure safety valves have been fitted.

15.89 Verify that the pressure safety valves are certified to operate in accordance with the contract specification and conform to BS EN ISO 4126-1: 2004.

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Warning and alarm systems

15.90 The operation of warning and alarm systems should be tested in all normal operating and emergency modes. Particular attention should be paid to the following:

- that all systems operate within the specified tolerance limits at all operating parameters and fault conditions, and can be seen and heard as specified in Tables 37 and 38;
- that systems react correctly following return to normal status;
- that all indicator panels and switches are correctly marked;
- that all functions on all indicator panels operate correctly;
- that the system will operate from the essential supply stand-by power source;
- that all indicator panels are labelled to show the areas they serve, or as detailed in the contract specifications.

15.91 The following tests should also be carried out:

- for central indicator panels, check that the operation of the mute switch cancels the audible alarm and converts the flashing signals to steady, for all systems and conditions;
- for repeater indicator panels, check that the mute switch cancels the audible alarm and that the flashing signals are converted to steady only on the central alarm panel, for all systems and conditions;
- for area alarm panels, check that the operation of the mute switch cancels the audible only, for all systems and conditions;
- check power failure operates red “system fault” indicator and the audible alarm;
- check that a contact line fault operates the “system fault” indicator, the main alarm displays and the audible alarm;
- check audible reinstatement for each alarm panel;
- check that the audible signal can be continuously muted via operation of the internal push-button for gas service alarm conditions only;
- check for correct identification of each gas service on alarm panels and “departmental” or plant specifying labels;
- check that each alarm panel emits the correct (two-tone) audible alarm. (Some manufacturers supply panels set for a single tone – in use, staff may confuse this sound with that emitted by some models of patient monitoring equipment.)

15.92 The results of the tests are recorded on Form A14.

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Verification of as-fitted drawings

15.93 The as-fitted drawings should be checked to ensure that all variations from the contract drawings have been recorded and the results may be recorded on Form A18.

Filling with medical air

15.94 An indefinite time may elapse after completion of the MGPS before the system is taken into use. The installation contract may be written in the expectation that this will happen. In such circumstances the contract should require that the particulate contamination and odour tests, specified in para 15.131 to 15.137 are carried out as an interim measure, using medical air as the test gas. Satisfactory completion of these particulate contamination and odour tests may then signify the completion of the construction contract.

15.95 It is the responsibility of the contractor to ensure that proper provision is made in a specific contract for the maintenance of the systems, their integrity, and any special connectors that may be required during this interim period.

15.96 All MGPS should be left filled with medical air at pipeline distribution pressure until they are filled with the specific working gas shortly before use. The medical vacuum pipeline need not be maintained under vacuum.

15.97 Provision should be made for regular running and maintenance of all supply plant during such an interim period.

15.98 Details of the work carried out, as well as records of the system pressures, should be recorded. This information is required in order to demonstrate that the systems have been satisfactorily maintained under pressure during this interim period. Tests for particulate contamination should be carried out after the systems are filled with the specific gas. The extent of the tests is at the discretion of the Quality Controller (MGPS).

15.99 The “Danger – do not use” label should remain affixed to each terminal unit until all testing is completed.

15.100 When the construction contract has finished, the contractor should record the removal of all special connectors and cylinders from site.

Note 65: Special connectors and cylinders may be required to maintain the systems under pressure. This may be some time prior to the admission of patients. In such circumstances some contracts require systems to be completed and certificated for the purpose of practical completion and handover to the client.

Purging and filling with specific gases

15.101 Each pipeline system must be purged with the specific working gas shortly before use. The following conditions should apply:

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- all sources of test gas must be disconnected;
- all special connectors must be removed from site;
- each pipeline system must be at atmospheric pressure with all AVSUs open;
- each system must be filled to pipeline distribution pressure with the specific gas from the supply system;
- with the supply system on, each terminal unit must be purged at a known flow with a volume of gas at least equal to the volume of the pipeline section being tested;
- all oxygen, nitrous oxide, nitrous oxide/ oxygen mixtures and helium/oxygen mixture discharged during the process must be released to a safe place.

15.102 The results of the purging process may be recorded on Form A19.

15.103 Purging is not necessary for vacuum systems.

Note 66: It may be possible to carry out the tests outlined in para 15.59 to 15.92 with the working gases, either sequentially or consecutively, followed by the appropriate pharmaceutical test. After the tests, “certification” arrangements should be put in place such that the client takes over responsibility for managing the system.

Pharmaceutical testing

15.104 When modifying existing systems, the test programme is agreed by the Quality Controller (MGPS) and Authorised Person (MGPS) and the system is taken back into use only after testing has been completed satisfactorily under a permit-to-work system.

15.105 Three types of work are identified:

- new;
- extension/upgrade; and
- repair.

For new installations, for example a new ward, a new department, or a complete hospital, the Quality Controller (MGPS) will prepare a report containing details of tests carried out and an inventory of outlets tested.

15.106 For extensions, upgrades and repairs, the permit will provide the minimum report, although a longer report may be provided at the discretion of the Quality Controller (MGPS).

15.107 Inclusion of details such as the mounting order of terminal units observed at the time of test should be confirmed by signature of the Authorised Person (MGPS) on the report.

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15.108 This inventory should be checked by the Authorised Person (MGPS) to ensure that all terminal units have been identified and tested. NIST connectors will also need to be identified. The Authorised Person (MGPS) should then amend a copy of the Quality Controller (MGPS) report, confirming in writing that the system can be taken into use.

15.109 Although a structured approach to testing should be adopted, access and time limitations to parts of the MGPS may lead to some disruption of proposed test regimes.

Note 67: Important: These tests are described in the context of commissioning and repair/alteration to existing systems. However, it must be remembered that quarterly testing is also required by this Scottish Health Technical Memorandum and in accordance with Tables 41 and 42 for medical air generated by on-site air compressors, synthetic air from gas blending plant, and oxygen from oxygen concentrators using compressor plant. The Authorised Person (MGPS) should liaise with the Quality Controller (MGPS) to ensure that these tests are carried out and recorded.

Note 68: a)The role, responsibilities and relationships of Authorised Persons (MGPS) – in the context of both existing and new installations, where the Authorised Person (MGPS) may not have responsibility for the systems when in use – is covered in Part B.

b) Although precluded by adherence to the procedures recommended in this Scottish Health Technical Memorandum, there have been instances when a system undergoes further modifications after a Quality Controller (MGPS) has started testing. It is very important that any modifications are documented and that any additional testing required as a consequence of those modifications is performed. Use of the permit-to-work form should be considered in these cases.

c) If it is necessary to modify systems during or after completion of testing, the Authorised Person (MGPS) and Quality Controller (MGPS) will identify the extent of retesting that is required. If the system has been completed and all documentation handed over to the client or operator of the building, any further modification must be carried out strictly in accordance with the permit-to-work procedure.

d) The importance of NIST connectors in facilitating engineering and pharmaceutical testing and their value during shutdowns and emergency situations should not be underestimated. All LVAs are fitted with upstream and downstream NIST connectors.

Quality of medical gas systems

General

15.110 The objective of these tests is to establish whether the pipeline has been contaminated during construction or modification. The tests indicate whether

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work has affected a gas, but they are not tests that indicate compliance with pharmaceutical specifications for licensed products.

15.111 Particulate contamination and odour tests may have been carried out prior to filling with the working gas, particularly if the system has been left for some time before use. However, the Quality Controller (MGPS) will define the extent of repetition of these tests, after the systems have been filled with the specific working gas.

15.112 The Quality Controller (MGPS) will also define the extent of all other pharmaceutical testing, depending on such factors as the extent and nature of the work and the age and condition of the existing systems.

15.113 The Ph. Eur. should be seen as a basic minimum standard when examining medical gas quality, as its principal application is to the manufacture and distribution of medicines according to well-established manufacturing processes. It is not intended to deal with the endless possibilities for contamination that are introduced by an MGPS, or the types of failure that might occur with on-site generation of gases.

15.114 Occasionally, the Quality Controller (MGPS) may need to resort to more sophisticated testing than is permitted by the use of portable equipment.

15.115 Oxygen, helium/oxygen mixture, nitrous oxide, and nitrous oxide/oxygen mixtures discharged during the process must be released to a safe place. These tests are not required on a vacuum system for any work including modifications or new works.

15.116 These test procedures are based on existing practice. The particulate contamination test is subjective in that it requires the QC to make a judgement on whether or not particles are visible on the filter.

15.117 The oil, water, carbon monoxide and carbon dioxide, sulphur dioxide and oxides of nitrogen tests can be carried out with detector tubes, but advances in detection technology have produced a range of suitable alternative instruments. The use of detector tubes giving a quantitative response is recommended but is not intended for re-use. If other equipment is used for validation purposes, it must provide a level of repeatability, resolution and accuracy at least equivalent to that of detector tubes and must be calibrated to appropriate Standards.

15.118 An electronic dew-point meter should be used in preference to water content measurements.

15.119 Detector tubes should be agent-specific. Non agent-specific (polytest) tubes can respond to various agents without identifying or quantifying the contaminants. Nevertheless without their use the degree of release of chemicals from hosing into the gas stream would never have been realised. Although BS5682 did not recommend tests on flexible plastic hosing, this related to theatre pendants where patients were subjected to the medical gases over a short period of time. The introduction of multi-movement pendants within the critical care departments requires research into the effects of prolonged exposure of the

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patient to the leaching of contaminants from the flexible hosing into the gas stream.

15.120 However, it is recommended that the use of the polytest tube be considered as a general test for contamination of pipelines. It would be advantageous for the QC to record and transfer such readings to graphical form.

15.121 Users must be aware of the limitations of all types of detection equipment, including ambient operating conditions and cross-sensitivities specified for each type of detector tube.

15.122 These tests must be carried out on a representative sample of terminal units/NISTs in each system at the discretion of the Quality Controller (MGPS).

15.123 If terminal units are being tested, the sample must include, as a minimum, the most distant terminal unit on each branch. This may be the first terminal unit to be tested, but care must be taken to ensure, for example, that a new extension connected to old pipework is first well purged via a terminal unit/NIST connector as close as possible to the junction of the systems so as to avoid the spread of any contamination into the extension.

15.124 It will not normally be necessary to test the most distant terminal unit if distal NIST connectors are provided.

15.125 Depending on the results of this test, the Quality Controller (MGPS) should decide the number and location of additional terminal units/NISTs to be tested.

Note 69: Provision of NISTs throughout an MGPS is to be encouraged, as this will greatly facilitate testing, particularly QC testing.

15.126 These tests are summarised in Table 42.

15.127 All sources of supply should be tested for quality before the pipeline distribution system is filled with the working gas. This test is not intended as a test of certificated gases but is to ensure that supply source equipment (manifolds, compressors, VIEs etc) does not compromise the quality of such gases when delivering them to the pipeline systems.

15.128 When extending existing systems, supply sources will not normally be retested before being used to fill the extension with the working gases.

15.129 For new installations, quality tests should be carried out on the plant as well as on the pipeline distribution system.

15.130 The results of the test may be recorded on Form A21.

Particulate matter

15.131 MGPS should be free from particulate contamination, as they have been constructed using chemically cleaned, capped components and joined in a controlled process using a filtered shield gas.

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15.132 However, on-site contamination can occur from ingress of building materials, dust etc. The presence of such particles can adversely affect the quality of the delivered gases. Therefore, tests to indicate their absence are important.

15.133 New systems should be purged until the particulate filter is completely clear of visible particles when viewed in a good light.

15.134 Older systems may exhibit particulates, even after considerable purging, as they can be released or carried along by the gas stream after disruption of the system, reverse gas flow, pressure waves down the pipe, or physical vibration.

Note 70: When connecting new pipework to an older (possibly contaminated) system it may be advisable to perform the first purge via the inlet NIST of the first AVSU, or the first terminal unit of the new system, in order to reduce the possible spread of contamination into the new system.

15.135 Where it is evident that extended purging may not completely clear the system of particulates, a decision to accept the level of contamination present, agree a cleansing procedure or, in very exceptional circumstances, condemn the system will be made.

15.136 The test for particulate matter should be carried out at every terminal unit on a new system. It can be carried out either after completion of the construction phase using medical air (see paragraph 15.94) or after the system has been filled with the specified gas. Once the system is filled with working gas, it would not normally be necessary to repeat the test at every terminal unit. The actual number of terminal units sampled is at the discretion of the Quality Controller (MGPS). It would, however, be necessary to repeat the test in full where there is insufficient evidence to show that the system has been satisfactorily maintained under operating pressure with medical air for the interim period.

15.137 When tested with a membrane filter at a flow not less than 150 litres/min for 30 seconds, the filter must be free from visible particles when viewed in good light. A suitable test device is described in Appendix D.

Note 71: a) When testing surgical air terminal units, a flow of 350 litres/min for 30 seconds should be used.

b) When testing nitrous oxide/oxygen mixture terminal units, a flow of 275 litres/min for 30 seconds should be used.

c) When testing helium/oxygen mixture systems, oxygen-free nitrogen is used at the manifold and this will require special connectors.

d) When tests and/or purging is carried out with the sources of supply serving an operational hospital, it is essential to ensure that the test flows used are not detrimental to the continuity or adequacy of supply in operational areas. When a flow rate of 150 litres/min or more may not be possible without compromising the hospital system, a lower flow rate should be used at the discretion of the Quality Controller (MGPS).

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Oil

15.138 This test should be carried out at the plant test point of all newly installed medical/surgical compressed air plant and for all medical/surgical compressed air plant on a quarterly basis.

15.139 When break-ins to a tested (and compliant) medical/surgical air system have been completed, repetition of this test will not normally be required.

15.140 Work involving strip-down of compressor plant and subsequent replacement of oil-sealing components may require a follow-up oil test, at the discretion of the Quality Controller (MGPS).

15.141 Oil may be present as liquid, aerosol or vapour, and an appropriate test device is described in Appendix E.

15.142 The total oil content should be in accordance with Table 42.

15.143 It is desirable to carry out this test at a plant test point before any pipeline system is supplied by that plant so as to prevent inadvertent contamination of the distribution system.

15.144 A representative sample of terminal units on both new and modified medical compressed air and oxygen concentrator systems supplied by compressor plant may be checked at the discretion of the Quality Controller (MGPS).

15.145 Care should be taken in siting the test point to ensure a representative sample.

Water

15.146 This test is intended to identify contamination of the pipeline system by moisture. It should not be confused with the test for compressor plant dryer performance, although it may indicate a failure in the dryer system.

Note 72: a) When testing terminal units supplied via low pressure, flexible connecting assemblies, it is often found that – on initial testing – moisture levels exceed the 0.05 mg/litre limit; this is the result of desorption of minute quantities of moisture into the gas stream. This is particularly noticeable where the test flow is low, and should not cause undue concern. The Quality Controller (MGPS) should establish, however, that the elevated readings at such terminal units result from this effect and not water contamination of the pipeline. (For example, the results should be compared with the readings achieved at nearby terminal units supplied by copper pipework.) New developments in hose materials may lead to hoses with reduced water vapour permeability characteristics.

b) The effects of flow rate through dryer units and sampling times on detection equipment indications should also be taken into account when measuring water content.

15.147 The plant test point and a representative sample of terminal units distributed throughout the pipeline systems should be tested for total water content. The

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water content must not exceed 67 vpm (equivalent to an atmospheric pressure dew-point of approximately –46°C). The typical water content of medical gas cylinders is normally below 5 vpm. Water vapour content may be measured using the appropriate test device described in Appendix E (see also paragraph 15.119).

Note 73: Older compressor/dryer combinations may fail to meet the Ph. Eur. requirement of 67 vpm. In these circumstances, the Quality Controller (MGPS) will decide whether application of the older atmospheric dew-point limit of –40°C (127 vpm) is acceptable (Scottish Health Technical Memorandum 2022: 2001).

Carbon monoxide

15.148 The most distant terminal units on each branch of a medical/surgical air pipeline system supplied from a compressor plant and PSA systems must be tested for carbon monoxide, although it would not normally be necessary to test more than five terminal units. The concentration of carbon monoxide should not exceed 5 ppm v/v. This may be measured at up to five terminal units in each system using the appropriate test devices described in Appendix E.

15.149 When break-ins to a tested (and compliant) medical/surgical air system have been completed, repetition of this test will not normally be required.

Carbon dioxide

15.150 The most distant terminal unit on each branch of a medical/surgical air pipeline system supplied from a compressor or an oxygen concentrator plant must be tested for carbon dioxide.

15.151 The concentration of carbon dioxide must not exceed 500 ppm v/v in medical air or 300 ppm v/v in oxygen from an oxygen concentrator plant.

15.152 When break-ins to a tested (and compliant) medical/surgical air system have been completed, repetition of this test will not normally be required.

Note 74: a) Increasing or fluctuating carbon dioxide readings in air or PSA-generated oxygen can be an early indication of dryer failure or poor compressor maintenance.

b) Carbon dioxide is no longer used as an inert shield gas during pipeline brazing.

c) If carbon dioxide has been installed (see Section11), the test methodology should be at the discretion of the Quality Controller (MGPS).

Sulphur dioxide

15.153 The most distant terminal units in medical/ surgical air pipeline systems supplied from a compressor plant, together with oxygen terminal units supplied from a PSA plant, must be tested for sulphur dioxide. It will not normally be

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necessary to test more than five terminal units in a single system. The concentration should not exceed 1 ppm v/v.

15.154 When break-ins to a tested (and compliant) medical/surgical air system have been completed, repetition of this test (and those in para 15.112 to 15.115) will not normally be required.

Oxides of nitrogen (NO and NO_2)

15.155 The most distant terminal units in medical/ surgical air pipeline systems supplied from a compressor plant, and oxygen terminal units supplied from a PSA plant, must be tested for oxides of nitrogen. It will not normally be necessary to test more than five terminal units in a single system. The concentration should not exceed 2 ppm v/v.

15.156 When break-ins to a tested (and compliant) medical/surgical air system have been completed, repetition of this test (and those in para 15.112 to 15.115) will not normally be required.

Important: See Note (d) applicable to Table 42 on disparity between Ph. Eur. and EH40 with reference to acceptable levels of sulphur dioxide and oxides of nitrogen.

Nitrogen

15.157 Oxygen-free nitrogen is used as the inert gas shield, and all terminal units of all gas systems should be tested to ensure that the systems have been adequately purged.

15.158 For oxygen systems and nitrous oxide/oxygen, an oxygen analyser must be used to ensure that the oxygen concentration is not less than that given in Table 43.

15.159 For nitrous oxide systems, an instrument based on thermal conductivity, or an infrared meter, must be used to check that the system has been adequately purged at every terminal unit.

15.160 If a thermal conductivity meter is used, it will be necessary to prove absence of carbon dioxide (which could have been used inadvertently as a shield gas) by the use of a chemical reagent tube.

Pipeline odour/taste

15.161 An odour test is performed because it incorporates, qualitatively, many impurity checks, as several contaminants are detectable by odour. This test is normally carried out as the final test with the working gases, except for nitrous oxide, nitrous oxide/oxygen mixture and carbon dioxide, which should not be inhaled.

15.162 In certain circumstances (see paragraph 15.94), it may be carried out as the first test after completion of construction of the pipeline installation using

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medical air as the test gas. In such circumstances, a pipeline odour/taste test can be carried out on nitrous oxide and nitrous oxide/oxygen systems.

15.163 In addition to all new terminal units, a representative sample of terminal units on existing parts of the systems must be checked.

Note 75: a) For some time it has been known that materials used in the construction of low-pressure connecting assemblies can present an odour. This was recognised in the 1984 version of BS5682:"Plastics materials currently in use will release small quantities of volatile organic matter into the gas stream throughout the life of the plastics components of the material. The quantities released appear to be below the levels normally considered toxic but, as yet, insufficient research has been carried out to be able to identify and quantify these components, therefore no tests are recommended."

b) More recent work has shown that the quantities of those agents that can be identified are significantly below levels considered to be toxic. It is possible that developments in hose material structure will result in the reduction of odour (and moisture retention).

c) The Quality Controller (MGPS) should perform additional oil and polytest analyses if indistinct odours are detected where flexible hoses are not involved.

d) New developments in hose materials may lead to hoses that are odour-free and do not leach chemicals into the gas stream. Until such hoses are available, present tests including moisture and polytest should continue on flexible hosing with findings recorded.

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Gas and source	Particulates	Oil	Water	CO	CO_2	NO and NO_2	SO_2	Poly-test tube	Odour
Oxygen from PSA plant	Free from visible particles in a 75 litre sample	≤0.1 mg/m^3	≤67 vpm (≤0.05 mg/ litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	No discoloration	None
Nitrous oxide	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/ litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	No discoloration	SAFETY Not performed
Nitrous oxide/oxygen mixture	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/ litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	No discoloration	SAFETY Not performed
Medical and surgical air	Free from visible particles in a 75 litre sample (for medical air) and 175 litre sample (for surgical air)	≤0.1 mg/m^3	≤67 vpm (≤0.05 mg/ litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤900 mg/m^3; ≤500 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	No discoloration	None
Dental compressed air	Free from visible particles in a 75 litre sample	≤0.1 mg/m^3	≤1020 vpm (≤0.78 mg/ litre, atmospheric dew-point of - 20°C)	≤5 mg/m^3; ≤5 ppm v/v	≤900 mg/m^3; ≤500 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	No discoloration	None
Synthetic air	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/ litre, atmospheric dew-point of -46°C)	-	-	-	-	No discoloration	None
Oxygen from bulk liquid or cylinders	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/ litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	<300 ppm v/v	-	-	No discoloration	None
Helium/oxygen mixture O_2, < 30%		-	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	<300 ppm v/v	≤2 ppm v/v	-	No discoloration	None

Table 42: Quality specification for medical gas pipeline tests (working gases)

Notes applicable to Table 42: a) The quality of the gases delivered at the terminal units should also comply with the specifications given in Table 42, above, which is inclusive of the current edition of the Ph. Eur. (see Table 43). Additionally, contamination introduced by the MGPS, and not limited by the Ph. Eur. specification, should not exceed levels that might pose a threat to patients. It should be borne in mind that the safe levels for medical gases delivered to patients are likely to be significantly lower than those permitted for healthy individuals. In addition to the monograph, the official standards section of the general notices should be read.

b) The tests for oil, carbon monoxide, carbon dioxide, sulphur dioxide and oxides of nitrogen are not normally carried out when the source of supply is from cylinders or cryogenic systems, although it should be noted that rare instances of oil contamination arising from the pipeline have occurred.

c) Synthetic air will be tested for identity as shown in Table 43. A GLC (gas-liquid chromatography) test for nitrogen is possible but not without practical difficulties. Nitrogen content will, therefore, usually be inferred from oxygen analyser test results.

d) The Health and Safety Executive has revised its guidance on exposure limits for sulphur dioxide, nitrogen monoxide and nitrogen dioxide. Occupational exposure standards (OESs) for nitric oxide, nitrogen dioxide and sulphur dioxide were removed from EH40 in the Amendment of April 2003.Time-weighted averages (TWAs) for nitrogen monoxide and nitrogen dioxide are now suggested as no greater than 1 ppm, and limits for sulphur dioxide exposure as less than 1 ppm for both 8-hour TWA OES and 15-minute STEL (short-term exposure limit).Some breathing air standards seek to limit the levels of such contaminants to 10% of the 8-hour TWA, as medical gases are intended for use by people who are not in the best of health. Therefore it is suggested, when testing for these specific compounds, or any contaminants not listed in the Ph. Eur., that a limit of 10% of the OES should be confirmed.

e) See Note following paragraph 15.147.

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Gas and source	Oil	Water	CO	CO_2	NO and NO_2	SO_2	Odour/ Taste
Oxygen from bulk liquid or cylinders	-	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	-	-	None
Oxygen from PSA plant	0.1 mg/m^3	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	None
Nitrous oxide	-	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	N/A
Nitrous oxide/oxygen mixture	-	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	N/A
Medical and surgical air	0.1 mg/m^3	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤900 mg/m^3 ≤500 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	None
Synthetic air	-	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	-	-	-	-	None
Helium/oxygen mixture O_2, <30%	-	≤67 vpm (≤0.05 mg/litre, atmospheric dew-point of -46°C)	≤5 mg/m^3; ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	None

Table 43: Ph. Eur. Quality specifications for medical gases

Note 76: Particulate level tests and polytests are not included in the Ph. Eur.

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Gas identification

15.164 The identity of the gas must be tested at terminal units on medical gas pipeline systems. This would include all new terminal units, whether on a new installation or a modification or extension, and a representative sample of terminal units on an existing system, which may have been affected by the work. All systems must have been filled with the specific gas according to paragraph 15.101.

15.165 The composition of all compressed gases must be positively identified. This can be accomplished using an oxygen analyser for oxygen, nitrous oxide/oxygen and air, and a thermal conductivity or infrared meter for nitrous oxide.

15.166 When checking the identity of nitrous oxide and nitrous oxide/oxygen mixture, the gas should be discharged in a manner that minimises pollution and personnel exposure.

15.167 When testing pipelines for helium/oxygen mixture, an initial test is carried out with nitrogen connected after completing the particulate test. An oxygen analyser is used and all terminal units are tested. After a zero reading is achieved, product cylinders are connected and the system is purged. A second test is performed with an oxygen analyser; the oxygen content should be as in Table 44.

15.168 The nominal gas concentration at specific terminal units is given in Table 44; vacuum must be identified by observation of suction at the terminal unit.

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Gas and source	Paramagnetic oxygen analyser reading	Thermal conductivity (TC)/infrared (IR) instrument reading	Carbon dioxide detector tube indication if TC meter used	Vacuum probe
Oxygen from liquid or cylinders	Minimum 99.5%	-	-	-
Oxygen from concentrator	Minimum 94.0%	-	-	-
Nitrous oxide	-0.2%	Indicates “nitrous oxide” or gives a reading of 100% ± 2.0% (TC), ≥98% (IR)	≤300 ppm v/v	-
Nitrous oxide/oxygen mixture	50.0% ± 2.0%	50.0% ± 2.0%	-	-
Medical, surgical and dental air	20.9% ± 0.5%	-	-	-
Synthetic air	95-105% of nominal value of 21.0-22.5%	-	-	-
Vacuum	-	-	-	Suction present
Nitrogen shield gas	0%	0% (IR)	-	-
Helium/oxygen mixture: Test 1. Test 2.	 0% 20.9% ± 0.5%	 0% 20.9% ± 0.5%	-	-

Table 44: Gas concentrations for identification purposes

Note 77: The tolerance of the measuring instrument should be allowed in addition. For oxygen concentrator plant (PSA) supplied system, the minimum concentration must be 94% oxygen. A vacuum gauge may be used to obtain a quantitative reading of vacuum level and verify terminal unit performance.

Test results

15.169 The test results for gas identity may be recorded on Form A20.

AGS disposal systems

General

15.170 BS6834:1987 specifies the tests to be carried out on AGS disposal systems that comply with the British Standard. The tests specified are designed to ensure adequate performance and that the safety provisions of receiving systems will be met.

15.171 The responsibility for the tests should be clearly identified at the contract stage for new installations, in the same way as for the medical gas pipeline system. In general, the contractor should carry out the tests, which should be witnessed by the Authorised Person (MGPS).

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Performance tests

15.172 All equipment should be tested to ensure that it performs satisfactorily during continuous operation under full load for one hour.

15.173 All electrically powered equipment should be tested as follows:

- check for correct rotation;
- check the current through the powered device at full load.

15.174 The disposal system should be tested to ensure that it meets the requirements set out in the table below, with the number of terminal units for which it has been designed in use.

	Disposal system standard			
	Pressure drop		Flow rate	
	BS6834: 1987	BS EN ISO 7396-2: 2007	BS6834: 1987	BS EN ISO 7396-2: 2007
Maximum	1 kPa	1 kPa	130 litres/min	80 litres/min
Minimum	4 kPa	2 kPa	80 litres/min	50 litres/min
Maximum static pressure	20 kPa (-ve)	15 kPa (-ve)	This check is made before performing the flow tests	

Table 45: AGS disposal system standards

Note 78: Since the preparation of BS6834: 1987, developments in anaesthesiology have resulted in reduced flows being used. Depending on local circumstances, it may be possible to commission systems for different flows in accordance with BS EN ISO 7396-2: 2007. Details of the test flows should be recorded in the commissioning documentation.

15.175 The test should be carried out as described in Appendix K of BS6834:1987. The test device is inserted into each terminal unit in turn and checked for pressure at flows of 80 litres/min and 130 litres/min for BS systems, and 50 litres/min and 80 litres/min for ISO systems. Adjustment is then made if necessary.

15.176 The test device and a number of metered leaks are then inserted into the system to replicate the design flow. The measurements above are repeated. If the test results are satisfactory, the test device is removed and substituted by a metered leak.

Note 79: The test device is designed to replicate either type of receiving system for which the disposal system has been designed.

15.177 The other terminal units are then tested in turn by substituting the test device for each metered leak including the test device.

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Note 80: For the purposes of diversity, it may be assumed that in any operating department only one receiving system for each operating room is in use at any time. In a typical theatre suite with two terminal units in the operating room and one in the anaesthetic room, the total number of metered leaks used for testing is two; that is, one being placed in an operating room terminal unit and the other in the anaesthetic room terminal unit.

15.178 The operation of user-controlled switches, power-on indicators and alarm systems should also be checked.

15.179 AGSS terminal units should be checked for correct mechanical operation and that the check valve operates satisfactorily. All AGSS terminal units will incorporate an adjustable flow valve.

Requirements before a medical gas pipeline system is taken into use

General

15.180 Before a system is used, the appropriate persons must certify in writing that the tests and procedures required in para 15.48 to 15.100 and 15.109 to 15.179 have been completed, and that all systems comply with the requirements. This must include certification that all drawings and manuals required by the contract have been supplied and as-fitted drawings are correct (see Form A22).

15.181 All certificates must be dated and signed by the appropriate witnesses, by the CSO and by the representative of the contractor.

15.182 For modifications or extensions to existing systems, the performance tests for flow and pressure drop (as described in paragraphs 15.43 to 15.45) should be carried out on the completed system if practicable. If the performance is in accordance with the specification prepared (as described in paragraphs 15.34 to 15.46), the system may be taken into use, provided that all the other tests have been satisfactorily completed.

Note 81: In many cases, the extension/modification will be relatively small and unlikely to significantly affect the performance of the system.

Operational policy

15.183 A procedure must be available in accordance with Part B, and must ensure continuity of supply of cylinders and bulk liquid. This will incorporate a procedure for recording delivery, handling and storage of full and empty cylinders, with an indication of who is responsible for these activities. The supplier must certify the composition of the cylinder contents. All deliveries of bulk liquid oxygen should be tested for conformance to the product licence specification before dispatch by the supplier, and should be supplied with a certificate indicating compliance.

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Cylinder storage and handling

15.184 There should be recorded visual checks for correct labelling, including batch numbers (see Part B).

Removal of construction labels

15.185 When all tests have been completed satisfactorily, the “Danger – do not use” labels affixed to terminal units should be removed on the authority of, or by, the Authorised Person (MGPS).

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Appendix A: Testing, commissioning and filling for use: forms to be completed during testing and commissioning of piped medical gases systems

Contents:

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Medical Gas Pipeline System Test Summary Sheet – A1

Hospital:	……	Date:	…….	Project No:	……

This is to certify that the following tests have been carried out:

System	Form	Tests Carried out Satisfactorily		
Carcass Tests		CSO	AP	
Labelling and Marking	A2			
Sleeving and Supports	A2			
Leakage Test	A2			
Cross-Connection Test	A2			
System Tests		CSO	AP	QC
Pipeline Pressure Test	A3			
Area Valve Service Unit – Zoning, Closure and NIST Tests	A4			
Line Valve Assembly and Line Valve – Zoning, Closure and NIST Tests	A5			
Pendant/Miscellaneous NIST Connectors - Specificity and Function Tests	A6			
Terminal Unit Schedule and Cross-Connection and Gas Specificity Tests	A7/1 & A7/2			
Terminal Unit Functional Tests	A8			
Plant Performance, Operation and Siting – Liquid Oxygen Systems	A9			
Plant Performance, Operation and Siting – Medical Gas Manifold Systems	A10			
Plant Performance, Operation and Siting – Medical Air / Surgical Air Plant	A11			
Plant Performance, Operation and Siting – Synthetic Air Systems	A12			
Plant Performance, Operation and Siting – Medical Vacuum Plant	A13			
Area Alarm Panel Test	A14			
Central Alarm Panel Test	A15			
Particulate Matter Tests	A16			
Anaesthetic Gas Scavenging System Tests	A17			
Design review and As Installed Drawings	A18			
Purging and Filling	A19			
Medical Gas Identification Tests	A20			
Medical Gas Quality Tests	A21			
Medical Gas Pipeline System – Completion Certificate	A22			
Medical gas permit-to-work form				
Construction labels removed				

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Contract Supervising Officer (CSO) or Authorised Person (AP) and Quality Controller (QC MGPS)

Name:	Signed:.....
Status :	Date : .....
Name :	Signed:.....
Status :	Date : .....

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Carcass Test Sheet –

1st Fix Pressure, Labelling/Marking, Sleeving/Supports and Cross-connection – A2

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Part 1 – Leakage, labelling and marking, sleeving, supports and cross-connections

Service	Gauge No.	Temp (°C)	Test Pressure (kPa)	Test Start (Date/ Time)	Test Finish (Date/ Time)	ΔP (kPa)	Labelling & Markings	Sleeving & Supports	Cross-Connection Test	Pass/Fail Comments
Oxygen										
Nitrous Oxide										
Nitrous Oxide/ Oxygen (50/50)										
Medical Air 4 Bar										
Surgical Air 7 Bar										
Medical Vacuum*										
AGSS										

* - for plastic pipeline systems a pressure of 1.5bar/150kPa should be set.

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Service	Test Pressure	Pressure Drop (max)	Timescale
Oxygen	10bar / 1,000 kPa	0.2 kPa	1 hour
Nitrous Oxide	10 bar / 1,000 kPa	0.2 kPa	1 hour
Nitrous Oxide/Oxygen (50/50)	10 bar / 1,000 kPa	0.2 kPa	1 hour
Medical Air 4 Bar	10 bar / 1,000 kPa	0.2 kPa	1 hour
Surgical Air 7 Bar	18bar / 1,800 kPa	0.5 kPa	1 hour
Surgical Air 9 Bar	18 bar / 1,800 kPa	0.5 kPa	1 hour
Medical Vacuum	5 bar / 500 kPa	0.2 kPa	1 hour
AGSS	70 kPa	10 kPa	15 mins

Part 2 – The following pipeline systems interconnections have been made to facilitate the pipeline tests indicated in Part 1.
Part 3 – The following pipeline systems interconnections have been removed as indicated in Part 2.

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2nd Fix Pressure Test – A3

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Service	Gauge No.	Temp (°C)	Test Pressure (kPa)	Test Start (Date/ Time)	Test Finish (Date/ Time)	ΔP (kPa)	Pass/Fail Comments
Pipeline pressure test							
Oxygen							
Nitrous Oxide							
Nitrous Oxide/ Oxygen (50/50)							
Medical Air 4 Bar							
Surgical Air 7 Bar							
Vacuum leakage test							
Medical Vacuum							

Service	Test Pressure	Pressure Drop (max)	Timescale
Oxygen	4 bar / 400 kPa	0.2 kPa	1 hour
Nitrous Oxide	4 bar / 400 kPa	0.2 kPa	1 hour
Nitrous Oxide/Oxygen (50/50)	4 bar / 400 kPa	0.2 kPa	1 hour
Medical Air 400 kPa	4 bar / 400 kPa	0.2 kPa	1 hour
Surgical Air 700 kPa	7 bar / 700 kPa	0.5 kPa	1 hour
Surgical Air 900 kPa	9 bar / 900 kPa	0.5 kPa	1 hour
Medical Vacuum	450 – 700 mmHg	1 kPa / 7.5 mm Hg	1 hour

Comments

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Area Valve Service Unit – Zoning, Closure and NIST Tests – A4

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Area/Department/Room:……

Service	Gauge No.	Valve No.	No of TUs	Valve Zoning	NIST Specificity	NIST Function	Valve Tightness			
				Pass /Fail	Pass/Fail	Pass/Fail	Start Pressure/ Time	Finish Pressure /Time	Pass/ Fail	Comments
Oxygen										
Nitrous Oxide										
Entonox										
Medical Air 4 Bar										
Surgical Air 7 Bar										
Medical Vacuum						N/A				

Notes: 1. Pressure differential between upstream (working pressure) and downstream (approximately 300 kPa)

2. Vacuum systems to be; on vacuum system plant side at distribution pressure and on terminal unit side at approximately 15 kPa (112 mmHg)

3. Test should be conducted over a period of 15 minutes with no change in pressure.

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Line Valve Assembly and Line Valve – Zoning, Closure and NIST Tests – A5

Hospital:	……			Test by:	……
Project No:	……	Date:	……..	Witnessed by:	……

Area/Department/Room: ……..

Service	Gauge No.	Valve No.	No of TUs	Valve Zoning	NIST Specificity	NIST Function	Valve Tightness			
				Pass /Fail	Pass/Fail	Pass/Fail	Start Pressure /Time	Finish Pressure /Time	Pass/ Fail	Comments
Oxygen										
Nitrous Oxide										
Entonox										
Medical Air 4 Bar										
Surgical Air 7 Bar										
Medical Vacuum						N/A				

Notes:1. Pressure differential between upstream (working pressure) and downstream (approximately 300 kPa)

2. Vacuum systems to be; on vacuum system plant side at distribution pressure and on terminal unit side at approximately 15 kPa (112 mmHg)

3. Test should be conducted over a period of 15 minutes with no change in pressure

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Pendant/Miscellaneous NIST Connectors - Specificity and Function Tests – A6

Hospital:	…………………………	Date:	………..	Test by:	……….………
Project No:	…………………………			Witnessed by:	………..………

Location: ……………………………………………..

Service	NIST Specificity	NIST Function	Comments
	Pass/Fail	Pass/Fail	
Oxygen			
Nitrous Oxide			
Entonox			
Medical Air 4 Bar			
Surgical Air 7 Bar			
Medical Vacuum		N/A	

Location: ……………………………………………..

Service	NIST Specificity	NIST Function	Comments
	Pass/Fail	Pass/Fail	
Oxygen			
Nitrous Oxide			
Entonox			
Medical Air 4 Bar			
Surgical Air 7 Bar			
Medical Vacuum		N/A	

Location: ……………………………………………..

Service	NIST Specificity	NIST Function	Comments
	Pass/Fail	Pass/Fail	
Oxygen			
Nitrous Oxide			
Entonox			
Medical Air 4 Bar			
Surgical Air 7 Bar			
Medical Vacuum		N/A	

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Terminal Unit Schedule and Cross-Connection Tests – A7/1

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Area Department: ……

Room No./Name	Schedule of Terminal Units							Cross-connection						
	O2	N2O	N2O / O2	MA4	SA7	MV	AGS	O2	N2O	N2O / O2	MA4	SA7	MV	AGS

Comments

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Terminal Unit Schedule and Gas Specificity Tests – A7/2

Hospital:	…….....….			Test by:	…….....….
Project No:	…….….	Date:	…….….	Witnessed by:	…….....….

Area Department: ……

Room No./Name	Schedule of Terminal Units							Gas Specificity						
	O_2	N_2O	N_2O / O_2	MA4	SA7	MV	AGS	O_2	N_2O	N_2O / O_2	MA4	SA7	MV	AGS

Comments

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Terminal Unit Functional Tests exemplar – A8

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Room / Department	Service	Terminal Unit Number	Specified Flow (litres/min)	Specified Flow Achieved	Specified Terminal Unit Pressure Drop	Specified Terminal Unit Pressure Drop Achieved	Mechanical Function (Pass / Fail)	Comments
	O_2				15 kPa			
	N_2O				15 kPa			
	N_2O/O_2				15 kPa			
	MA4				15 kPa			
	SA7				70 kPa			
	MV				15 kPa			
	O_2				15 kPa			
	N_2O				15 kPa			
	N_2O/O_2				15 kPa			
	MA4				15 kPa			
	SA7				70 kPa			
	MV				15 kPa			

Note: 1. Mechanical function test to include, probe insertion, capture and release. The anti-swivel pin is present or absent dependent of orientation.

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Plant Performance, Operation and Siting – Liquid Oxygen Systems – A9

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Location:	……	Manufacturer /Model:	……
Type:	Bulk Liquid Supply – Liquid cylinder supply	Function:	Primary / Secondary / Emergency Reserve (delete as appropriate)

Item	Function / Operation	Pass / Fail	Comments
1	Power supplies provided		
2	General operation		
3	Leakage on joints		
4	Indication – System condition panel		
5	Central Alarm Panel		
6	Safety valve exhaust pipes discharge to a safe location		
7	Separation distances in compliance with Table 23 and BCGA CP19		
8	Compound / room provided with hazard / warning signs in accordance with Appendix K		
9	Access to and within compound acceptable		
10	Lighting provided		
11	Plant provided with all necessary valves and ancillaries.		
12	Plant schematic provided		

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Plant Performance, Operation and Siting – Medical Gas Manifold Systems – A10

Hospital:	……			Test by:	……..
Project No:	……	Date:	……	Witnessed by:	……..

Location:	……	Manufacturer /Model:	……
Type:	Oxygen - Nitrous Oxide - Nitrous Oxide/Oxygen Mixture - Medical Air 4 Bar - Surgical Air 7 Bar / Other	Function:	Primary / Secondary / Emergency Reserve (delete as appropriate)

Item	Function / Operation	Pass / Fail	Comments
1	Power supplies provided		
2	General operation		
3	Leakage on joints		
4	Heater operation		
5	Operation of Emergency Manifold		
6	Correct Sequence on start-up / power failure		
7	Indication – System condition panel		
8	Central Alarm Panel		
9	Safety valve exhaust pipes discharge to a safe location		
10	Spare cylinder racks provided in accordance with the specification		
11	Manifold room ventilation adequate		
12	Manifold room provided with hazard / warning signs in accordance with Appendix K		
13	Access to and within manifold room acceptable		
14	Manifold room heating provided, type and method of control acceptable		
15	Lighting provided external / internal		
16	Plant schematic provided		

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Plant Performance, Operation and Siting – Medical Air / Surgical Air Plant – A11

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Location:	……	Manufacturer /Model:	……
Type:	Medical Air 4 Bar - Surgical Air 7 Bar	Function:	Primary / Secondary / Emergency Reserve (delete as appropriate)

Item	Function / Operation	Pass / Fail	Comments
1	Power supplies provided		
2	General operation		
3	Leakage on joints		
4	Excessive vibration and noise		
5	Oil leakage		
6	Earthing / bonding		
7	Correct sequence on start up / power failure		
8	Indication – System condition panel		
9	Central Alarm Panel		
10	Safety valve exhaust pipes discharge to a safe location		
11	Plantroom ventilation adequate		
12	Plantroom provided with hazard / warning signs in accordance with Appendix K		
13	Access to and within plantroom acceptable		
14	Plantroom heating provided if specified, type and method of control acceptable		
15	Lighting provided external / internal		
16	Condensate drain system provided, and drained via oil/water separator to drain point		
17	Plant schematic provided		

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Plant Performance, Operation and Siting – Synthetic Air Systems – A12

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Location:	……	Manufacturer /Model:	……
Type:	Bulk Liquid Oxygen and Nitrogen Supply	Function:	Primary / Secondary / Emergency Reserve (delete as appropriate)

Item	Function / Operation	Pass / Fail	Comments
1	Power supplies provided		
2	General operation		
3	Leakage on joints		
4	Indication – System condition panel		
5	Central Alarm Panel		
6	Safety valve exhaust pipes discharge to a safe location		
7	Separation distances in compliance with Table 23 and BCGA CP19 and BCGA 21		
8	Compound and blending station room provided with hazard / warning signs in accordance with Appendix K		
9	Access to and within compound and blending station room acceptable		
10	Lighting provided		
11	Plant schematic provided		

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Plant Performance, Operation and Siting – Medical Vacuum Plant – A13

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Location:	……	Manufacturer /Model:	……
Type:	Medical Air 4 Bar - Surgical Air 7 Bar	Function:	Primary / Secondary / Emergency Reserve (delete as appropriate)

Item	Function / Operation	Pass / Fail	Comments
1	Power supplies provided		
2	General operation		
3	Leakage on joints		
4	Excessive vibration and noise		
5	Oil leakage		
6	Earthing / bonding		
7	Correct sequence on start up / power failure		
8	Indication – System condition panel		
9	Central Alarm Panel		
10	Vacuum pump exhaust pipes discharge to a safe location		
11	Plantroom ventilation adequate		
12	Plantroom provided with hazard / warning signs in accordance with Appendix K		
13	Access to and within plantroom acceptable		
14	Plantroom heating provided if specified, type and method of control acceptable		
15	Lighting provided external / internal		
16	Condensate drain system provided, and drained via oil/water separator to drain point		
17	Plant schematic provided		

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Area Alarm Panel Test – A14

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Location:……

Make / Model	Service	High Pressure Alarm	Low Pressure Alarm	Pass/ Fail	Function / Operation (Pass / Fail)		Comments
					Sequence / Identification		
					Anti-confusion		
					Mute Function (15 mins.)		
					System Fault / Power Failure		
					System Fault / Open Circuit		
					System Fault / Short Circuit		
					Audible Reinstatement		
					Test Function		

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Location:……

Make / Model	Service	High Pressure Alarm	Low Pressure Alarm	Pass/ Fail	Function / Operation (Pass / Fail)		Comments
					Sequence / Identification		
					Anti-confusion		
					Mute Function (15 mins.)		
					System Fault / Power Failure		
					System Fault / Open Circuit		
					System Fault / Short Circuit		
					Audible Reinstatement		
					Test Function		

Location:……

Make / Model	Service	High Pressure Alarm	Low Pressure Alarm	Pass/ Fail	Function / Operation (Pass / Fail)		Comments
					Sequence / Identification		
					Anti-confusion		
					Mute Function (15 mins.)		
					System Fault / Power Failure		
					System Fault / Open Circuit		
					System Fault / Short Circuit		
					Audible Reinstatement		
					Test Function		

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Central Alarm Panel Test – A15

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

Alarm Panel Location: ……

Service	1	2	3	4	5	6	7	8	9
Oxygen									
Nitrous Oxide									
Nitrous Oxide/Oxygen (50/50)									
Medical Air 4 Bar									
Surgical Air 7 Bar									
Medical Vacuum									

List of tests:

1. for central alarm panels, check that the operation of the mute switch cancels the audible alarm and converts the flashing signals to steady;
2. for repeater alarm panels, check that the mute switch cancels the audible only, and that the flashing signals are converted to steady via the central alarm panel;
3. for area alarm panels, check that the operation of the mute switch cancels the audible only;
4. check power failure operates red system fault indicator and audible;
5. check that a contact line fault operates the system fault indicator, the alarm indicator and the audible;
6. check communication/wiring faults between central and repeater alarms operate the system fault indicator and audible;
7. check audible reinstatement for each alarm panel;
8. check that the audible can be continuously muted via operation of the internal push-button for gas service alarm condition only;
9. check for correct identification of each gas service on alarm panels.

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Particulate Matter Tests – A16

Hospital:	……			Test by:	……
Project No:	……	Date:	……	Witnessed by:	……

The following services where tested for particulate matter:-

Location: ……

Service	Pass/Fail	Observations
Oxygen		
Nitrous Oxide		
Entonox		
Medical Air 4 Bar		
Surgical Air 7 Bar		

Location: ……

Service	Pass/Fail	Observations
Oxygen		
Nitrous Oxide		
Entonox		
Medical Air 4 Bar		
Surgical Air 7 Bar		

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Location: ……

Service	Pass/Fail	Observations
Oxygen		
Nitrous Oxide		
Entonox		
Medical Air 4 Bar		
Surgical Air 7 Bar		

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Anaesthetic Gas Scavenging System Tests – A17

Hospital:	……			Test by:	……
Project No:	……	Date:	……..	Witnessed by:	……

Location: …… Department Served: ……

Manufacturer:		**Model reference:**	
Pump Duty (litres/min):		Duplex/Simplex:	
Number of Remote Switches		Remote Switch Voltage (V)	

Test	1	2	3	4	5	6	7	8
BS 6834;1987								
Single Flow Rates								
AGSS Outlet point@ 1 kPa (130 litres/min maximum)								
AGSS Outlet Point@ 4 kPa (80 litres/min minimum)								
BS EN ISO 7396-2: 2008								
Single Flow Rates								
AGSS Outlet point@ 1 kPa (80 litres/min maximum)								
AGSS Outlet Point@ 2 kPa (50 litres/min minimum)								

Pump Pressure Setting : …… mBar

Pump Total Flowrate: …… litres/min

Pump Design Flowrate: …….. litres/min

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Design Review and As Installed Drawings – A18

Hospital:	……			Test by:	……
Project No:	……	Date:	……..	Witnessed by:	……

This is to certify that the design has been reviewed and verified as compliant with the contract documents and SHTM 02-01, Part A

Comments

The following 'As Installed' drawings schedule records all variations from the contract drawings:-

Drawing Number	Revision	Description	CSO/AP	Date

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Purging and Filling – A19

Hospital:	……			Test by:	……
Project No:	……	Date:	……..	Witnessed by:	……

This is to certify that the medical gas systems have been purged and filled with medical air/Oxygen Free Nitrogen/working gas (delete as appropriate) in accordance with paragraphs 15.95 – 15.101 and/or 15.102 – 15.103 as follows:-

Action	O_2	N_2O	N_2O/O_2	MA4	SA	MV	H_2/O_2	CO_2
Special connectors/cylinders removed from site						N/A		
Filling with working gas								
Purge pipeline via terminal units, gases to be vented to a safe place						N/A		
Particulate tests performed and meet specification						N/A		
Odour tests performed and specification met.						N/A		
All terminal unit Danger stickers applied/removed								

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Medical Gas Identification Tests – A20

Hospital:	……	Date :	……..	Project No:	……

This is to certify that medical gas systems have been tested in accordance with paragraphs 15.165 – 15.169 as follows (insert values for gases and tick for vacuum):-

Gas and Source	Paramagnetic oxygen analyser reading	Thermal conductivity/infra-red instrument reading	Carbon dioxide detector tube indication if TC meter used	Vacuum probe
Oxygen from liquid or cylinders		-	-	-
Oxygen from concentrator		-	-	-
Nitrous oxide				-
Nitrous oxide / oxygen mixture			-	-
Medical, surgical and dental air		-	-	-
Synthetic air		-	-	-
Vacuum	-	-	-	
Nitrogen shield gas			-	-
Helium / oxygen mixture Test 1 Test 2			-	-

Contract Supervising Officer (CSO) / Authorised Person (AP)

Name:	Signed:.....
Status:	Date: .....

Quality Controller (QC)

Name:	Signed:.....
Status:	Date: .....

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Medical Gas Quality Tests– A21

Hospital:	……..	Date:	……..	Project No:	……..

Quality specifications for medical gas pipeline tests (working gases). This is to certify that medical gas systems have been tested in accordance with paragraphs 15.111 – 15.164as follows:-

Gas and Source	Particulate	Oil	Water	CO	CO_2	NO & NO_2	SO_2	Poly-test tube (optional)	Odour	Pass / Fail
Oxygen from bulk liquid or cylinders	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/l, atmospheric dew point -46^{0}C	≤5 mg/m^3 ≤5 ppm v/v	≤300 ppm v/v	-	-	No discolouration	None	
Nitrous Oxide	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/l, atmospheric dew point -46^{0}C)	≤5 mg/m^3 ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	No discolouration	SAFETY Not performed	
Nitrous oxide / oxygen mixture	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/l, atmospheric dew point -46^{0}C	≤5 mg/m^3 ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	No discolouration	SAFETY Not performed	
Medical and surgical air	Free from visible particles in a 75 litre sample	≤0.1 mg/ m^3	≤67 vpm (≤0.05 mg/l, atmospheric dew point -46^{0}C	≤5 mg/m^3 ≤5 ppm v/v	≤900 mg/m^3 ≤500 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	No discolouration	None	
Dental compressed air	Free from visible particles in a 75 litre sample	≤0.1 mg/ m^3	≤1,020 vpm (≤0.05 mg/l, atmospheric dew point -20^{0}C	≤5 mg/m^3 ≤5 ppm v/v	≤900 mg/m^3 ≤500 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	No discolouration	None	

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Gas and Source	Particulate	Oil	Water	CO	CO_2	NO & NO_2	SO_2	Poly-test tube (optional)	Odour	Pass / Fail
Synthetic air	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/l, atmospheric dew point -46^{0}C	-	-	-	-	No discolouration	None	
Oxygen from PSA plant	Free from visible particles in a 75 litre sample	≤0.1 mg/m^3	≤67 vpm (≤0.05 mg/l, atmospheric dew point-46^{0}C	≤5 mg/m^3 ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	≤1 ppm v/v	No discolouration	None	
Helium / oxygen mixture O_2< 30%	Free from visible particles in a 75 litre sample	-	≤67 vpm (≤0.05 mg/l, atmospheric dew point -46^{0}C	≤5 mg/m^3 ≤5 ppm v/v	≤300 ppm v/v	≤2 ppm v/v	-	No discolouration	None	

Contract Supervising Officer (CSO) / Authorised Person (AP)

Name:	Signed: ……..
Status:	Date: .....
Quality Controller (QC) Name:	Signed: ……..
Status:	Date: .....

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Medical Gas Pipeline System – Completion Certificate – A22

Hospital:	……	Client:	……
This is to certify that the following tests have been performed.			
Mechanical Carcass and Functional tests:		Forms A2 to A19 inclusive	
Quality and gas identity tests:		Forms A20 to A21 inclusive	
Validation of MGPS Design: The tests have been performed in accordance with Scottish Health Technical Memorandum 02-01 Part A Section 15, and that the test results are satisfactory.			

Contract Supervising Officer (MGPS) / Authorised Person (MGPS)

Name:	Signed: ……
Status:	Date: .....

Contractor's Representative (MGPS)

Name:	Signed: ……
Status:	Date: .....

Quality Controller (MGPS)

Name:	Signed: ……
Status:	Date: .....

We, the Healthcare Organisation/FM provider/Owner

Accept responsibility for the systems above and undertake to carry out any future work and maintenance in accordance with the recommendations of Scottish Health Technical Memorandum 02-01 and the permit-to-work procedures.

Name:	Signed: ……
Status:	Date: .....

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Appendix B: Gas pressure variation with temperature

General

1 Tests are specified for leakage of the pipeline carcass and the pipeline systems. During these tests, pressure changes may occur that are caused by temperature changes rather than leakage.

2 Pressure changes due to temperature difference may be calculated according to the Gas Laws (see the 'Glossary' in Part B).

3 It is assumed that the temperature in the pipeline is uniform in all branches. If substantial runs are external, an average temperature should be chosen.

Calculation

4 The change in gas pressure with temperature is as follows:

$P_1/T_1 = P_2/T_2$

where:

P_1 = the initial absolute pressure of a fixed volume of gas;

P_2 = the final absolute pressure of a fixed volume of gas;

T_1 = the initial absolute temperature;

T_2 = the final absolute temperature.

Therefore:

$P_2 = (P_1 \times T_2)/T_1$. (1)

5 Care must be taken to express pressure and temperature in absolute values.

6 Pressure is normally expressed in "gauge" pressure: Absolute pressure = gauge pressure + atmospheric pressure.

7 Temperature is normally expressed in K.

Examples

8 The carcass of a surgical air pipeline is tested for leakage at a working pressure of 13.5 bar. The temperature is 13°C at the beginning of the test and 17°C at the end of the test:

P1 = 13.5 + 1.0 = 14.5 bar

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T1 = 273 + 13 = 286 K

T2 = 273 + 17 = 290 K.

9 Therefore, using Equation (1):

P2 = (14.5 x 290)/286

= 14.7 bar (absolute pressure)

= 13.7 bar (gauge pressure).

10 That is, gauge pressure should read 13.7 bar at the end of the test, assuming that no leakage has occurred.

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Appendix C: Pressure-drop test device

General

1 Special test devices are required to measure the pressure at specified flows at each terminal unit.

2 Suitable test devices are commercially available or may be constructed in accordance with the outline specification given below.

Measurement principle

3 Flow at a specified pressure may be measured either with a calibrated orifice or with a flowmeter.

4 Pressure may be measured with a bourdon gauge.

5 A gas-specific probe conforming to BS5682:1998 should be used to connect the device to the terminal unit.

6 The test device is connected to the terminal unit by the gas-specific probe and the pressure at the specified flow is read on the gauge.

Functional requirements

7 The test device should consist of the following components:

- gas-specific probe to BS5682:1998;
- body on/off valve pressure gauge;
- orifice or flowmeter.

8 The body may be of a design that allows exchange of the following components:

- gas-specific probes;
- calibrated orifices;
- pressure gauges.

9 An on/off valve may be incorporated into the body.

10 The complete assembly should be tested for leaks.

Orifices

11 The orifices should be selected from the information on the manufacturer's data sheets or from practical testing.

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12 These devices should be checked against a flowmeter before use.

Flowmeter

13 A bobbin flowmeter calibrated to a flow of 40 litres/min may be used to measure flow under vacuum.

Pressure gauge

14 A 50mm bourdon gauge with an appropriate full scale reading and interval should be used as follows:

Test pressure kPa	Scale	Scale interval
400	0-7 bar	0.1 bar
700	0-11 bar	0.5 bar
Vacuum	0-100 kPa(0-760 mmHg)	5 kPa /50 mmHg
1 bar = 100 kPa approximately		

Table C1: Test pressure gauge scales

Note 82: Generally it is found that three separate test devices for 400 kPa, 700 kPa and vacuum provide greater convenience. Because the test methodology in Section 15 has the potential for exposing the 400 kPa and vacuum devices to pressure or vacuum, it is desirable that they include an appropriate directional check valve.

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Appendix D: Membrane filter test device

General

1 The function of this test device is to collect particulate material which may be present in the pipeline.

2 Filter holders appropriate to the pressure encountered are commercially available.

3 The filter holder should be specified for use at pipeline-distribution pressure and be oxygen-compatible.

Measurement principle

4 A known volume of gas is passed through a membrane filter that will collect all visible particles.

5 Hydrophobic membrane filters of pore size 0.45µm should be used.

Test equipment

6 The following equipment is required:

- a membrane filter holder;
- a supply of white hydrophobic membrane filters of not more than 0.45µm pore size and with high mechanical strength;
- a means of connecting the filter to the pipeline;
- a means of controlling the flow through the filter, which is connected downstream of the filter. One method of achieving this is to use the appropriate Amal jets to achieve a minimum flow of 150 litres/min at 400 kPa and 350 litres/min at 700 kPa;
- all equipment must be oxygen-compatible and hoses should be antistatic.

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Appendix E: Equipment for contaminant testing

General

1 The function of these tests is to establish whether the pipeline has been contaminated during construction or modification. The specifications for the permissible concentrations of each component are summarised in Table 29.

2 Simple equipment that is of the required sensitivity and is suitable for use on site is commercially available.

Measurement principle

3 A known volume of gas is passed through a tube packed with an absorbent, which is coated with specific colorimetric reagents. The reagents react quantitatively with the compound to be measured and produce a colour change along the length of the tube, which is proportional to the concentration of the compound being measured.

4 Tubes are available with appropriate sensitivities for the measurement of oil, water, carbon monoxide and carbon dioxide, sulphur dioxide, and higher oxides of nitrogen.

Note 83: Non-agent-specific detector tubes are difficult to interpret and are not recommended because of their qualitative and non-quantitative response.

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Appendix F: Equipment for gas identification

General

1 The function of these tests is positively to identify medical gases by measuring their oxygen, nitrous oxide and nitric oxide content.

2 Portable equipment of the required specificity and sensitivity is commercially available.

3 Thermal conductivity meters do not give a positive identification of nitrous oxide in the presence of carbon dioxide, and should not be used as a sole means of identification of nitrous oxide. A specific nitrous oxide meter should be used. If carbon dioxide pipelines are present, for example in IVF (in vitro fertilisation) clinics, a carbon dioxide detector tube should be used.

Specificity

Oxygen

4 Oxygen-specific sensors using different measurement principles are currently in manufacture. The oxygen sensor should not give greater than ±1% response in the presence of 100% nitrous oxide or 100% nitrogen.

Note 84: A paramagnetic meter is the specified instrument for identity of oxygen.

Nitrous oxide

5 The nitrous oxide sensor should not give greater than ±1% response in the presence of 100% oxygen, 100% nitrogen or 100% carbon dioxide. An infrared/fuel cell meter is now commercially available.

Specification

6 The equipment should be portable, preferably battery-powered, with digital or analogue indication of 0–100% to one decimal place. The battery should give at least eight hours' continuous running between recharging or replacement.

7 Accuracy better than ±1% is required, with a zero stability of 2.5% per day.

8 The response time must be not more than 15 seconds to 90% of the final reading.

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Appendix G: Pressure loss data

Pipeline pressure-drop calculations

1 Example: Calculate the pressure drop in a 15mm diameter pipe, 11m in length, with two 90o elbows, carrying medical air at a design flow rate of 800 litres/min.

Solution

2 The pressure drop Δp across the pipe can be calculated from the formula:

$$\Delta p = \frac{TL_{ACTUAL}}{L_{TABLEG1}} \times \left[\frac{Q_{ACTUAL}}{Q_{TABLEG1}}\right]^2 \times \Delta p_{TABLEG1} \qquad (2)$$

where:

Δp = Pressure drop across pipe section (kPa)

$\Delta p_{TABLE\ G1}$ = Pressure drop from Table G1 (kPa)

TL_{ACTUAL} = Measured length of pipe, plus total equivalent length for fittings, valve, etc. (m)

$L_{TABLE\ G1}$ = Nearest length of pipe from Table G1 (m)

Q_{ACTUAL} = Design flow (litres/min)

$Q_{TABLE\ G1}$ = Nearest flow from Table G1 (litres/min)

3 Total length of pipe including fittings.

TL = L + EL

Where:

L = Measured length of pipe (m)

EL = Sum off all fitting equivalent lengths from Table G6

TL = Total length

Therefore;

TL = 11 + (0.47 x 2)

TL = 11 + 0.94 = 11.94m

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4 From Table G1, the nearest length to 11.94m is 15m and the nearest flow rate to the design flow of 800 litres/min is 711 litres/min in the 15m column, at which there is a pressure drop of 21 kPa across a 15mm diameter, 15m length of pipe.

5 Using these values, Equation (2) gives a pressure drop across the pipe of:

$$\Delta p = \frac{11.94}{15} \times \left[\frac{800}{711}\right]^2 \times 21$$

Δp= 21.16 kPa

6 If this loss is unacceptable, use the next (higher) pipe size, that is 22mm. The nearest flow rate to 800 litres/min is now 1135 litres/min, representing a pressure loss of 7 kPa over 15m.

7 In this instance:

Note that due to the increase in pipe diameter the fitting equivalent lengths will change thus;

TL = 11 + (0.63 x 2)

TL = 11 + 1.26 = 12.26m

$$\Delta p = \frac{12.26}{15} \times \left[\frac{800}{1135}\right]^2 \times 7$$

Δp = 2.84 kPa

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Old BS 659 size	New British Standard size (BS EN 1057: R250, Table X)				Distance from source at 400 kPa for 7, 14 and 21 kPa (0.07, 0.14 and 0.21 bar) pressure loss					
Nominal bore (inches)	Outside diameter (mm)	Wall thickness (mm)	Mean internal diameter (mm) (inches)		8 m (25 ft)			15 m (50 ft)		
⅜	12	0.6	10.8	0.4252	311	455	564	209	307	382
½	15	0.7	13.6	0.5354	579	845	1038	391	572	711
¾	22	0.9	20.2	0.7953	1677	2441	3023	1135	1656	2053
1	28	1.2	26.2	10.315	3363	4881	6034	2283	3320	4109
1¼	35	1.2	32.6	1.2835	6023	8720	10758	4096	5943	7344
1½	42	1.2	39.6	1.5591	10103	14587	17963	6883	9963	12290

Table G1: Section of pressure drop table for medical air

	6 mm	8 mm	10 mm	12 mm	15 mm	22 mm	28 mm	35 mm	42 mm	54 mm	76 mm	108 mm
Ball valve	0.10	0.10	0.20	0.30	0.30	0.60	0.90	0.90	1.10	1.20	1.40	2.0
Tee (Thru')	0.12	0.15	0.18	0.21	0.32	0.42	0.54	0.70	0.82	1.05	1.56	2.0
Tee (Branch)	0.46	0.52	0.70	0.80	0.95	1.26	1.60	2.10	2.45	3.14	4.67	6.0
90° Elbow	0.17	0.20	0.25	0.33	0.47	0.63	0.80	1.05	1.23	1.58	2.36	3.0

Table G6: Equivalent lengths (in metres) for copper fittings

8 It is possible to insert the above formula into a spreadsheet and use mathematical functions to calculate required pressure drops (see Tables G2-G5).

9 Another alternative is to derive graphs from the tables, although it may be necessary to draw several graphs, at different scales, to obtain accurate results.

10 The graphs of flow versus pressure drop provide a pressure loss per metre of pipe, not a total pressure loss. This figure must be multiplied by the length of the pipe in order to find the actual total pressure drop.

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11 Because a pipe and the fittings in the system cause frictional resistance to the gas flow, a pressure loss occurs that is greater than that which would occur if the gas were flowing through the same distance of straight pipe.

12 Each valve, fitting etc is allocated a “length” equivalent in frictional resistance to a straight piece of pipe of the same diameter. This length is hence known as the equivalent length of the fitting.

13 To calculate design pressure drops, the sum of the lengths of the straight runs of pipe plus the sums of the equivalent lengths of all of the fittings etc. in that run are added.

14 In practice many designers simply add 25–30% to the total measured length or use only 60–75% of the allocated pressure drop when sizing.

15 Equivalent lengths of some fittings are given in Tables G6 and G7.

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British Standard Size Tube BS EN 1057: R250, Table X		Distance from source (m) at 400 kPa for 7,14 ,21 kPa (1, 2, 3 psi) pressure loss																
Outside Diameter (mm)	Pressure loss (kPa)	8	15	30	61	91	122	152	183	213	244	274	305	335	366	396	427	457
		Free air flow rate (litres/min)																
12	7	311	209	141	95	75	64	56	50	46	43	40	37	35	34	32	31	30
	14	455	307	207	139	110	94	82	74	68	63	59	55	52	50	47	45	40
	21	564	382	258	174	138	117	103	93	85	78	73	69	65	62	59	57	55
15	7	579	391	263	177	140	119	105	94	86	80	75	70	66	63	60	58	56
	14	845	572	386	260	207	175	154	139	127	118	110	104	98	93	89	85	82
	21	1038	711	481	325	258	219	192	173	159	147	137	129	122	117	111	107	102
22	7	1677	1135	768	518	411	349	307	277	254	235	220	207	196	186	178	170	164
	14	2441	1656	1123	759	604	513	451	407	373	345	323	304	288	274	262	251	241
	21	3023	2053	1395	945	751	638	562	507	465	431	403	379	359	342	326	313	301
28	7	3363	2283	1547	1047	832	706	622	560	514	476	445	419	397	378	361	346	332
	14	4881	3320	2257	1530	1218	1035	912	823	754	699	653	615	583	555	530	508	488
	21	6034	4109	2800	1901	1514	1287	1135	1024	938	870	814	767	726	691	660	633	609
35	7	6023	4096	2783	1886	1500	1275	1124	1013	928	861	805	758	718	683	653	626	602
	14	8720	5943	4051	2752	2192	1865	1644	1483	1360	1261	1180	1111	1053	1002	957	918	883
	21	10758	7344	5018	3415	2723	2317	2044	1845	1692	1569	1468	1383	1310	1248	1192	1143	1099
42	7	10103	6883	4685	3180	2533	2154	1899	1713	1570	1456	1362	1283	1215	1157	1105	1060	1019
	14	14587	9963	6806	4633	3694	3145	2775	2504	2296	2130	1993	1878	1780	1694	1619	1553	1493
	21	17963	12290	8421	5743	4584	3904	3446	3112	2855	2648	2478	2335	2213	2107	2014	1932	1858
54	7	14974	10588	7487	5294	4323	3743	3348	3056	2830	2647	2496	2368	2257	2161	2076	2001	1933
	14	21176	14974	10588	7487	6113	5294	4735	4323	4002	3743	3529	3348	3192	3056	2937	2830	2734
	21	25935	18339	12968	9169	7487	6484	5799	5294	4901	4585	4323	4101	3910	3743	3597	3466	3348
76	7	37754	26696	18877	13348	10899	9438	8442	7706	7135	6674	6292	5969	5692	5449	5236	5045	4874
	14	53392	37754	26696	18877	15413	13348	11939	10899	10090	9438	8899	8442	8049	7706	7404	7135	6893
	21	65392	46239	32696	23119	18877	16348	14622	13348	12358	11560	10899	10339	9858	9438	9068	8738	8442

Table G2: Pipeline pressure loss: 400 kPa (4 bar) pipelines

Examples:

1. 122m of 28mm pipe would carry 706 litres/min of free air per minute with a pressure loss of 0.07 bar (7 kPa), or 1287 litres/min with a loss of 0.21 bar (21 kPa). ie: $122/122 \times (706/706)^2 \times 7$
2. A flow of 1,200 litres/min in 122m of 28mm pipe would result in a pressure loss of 18.26 kPa. ie: $122/122 \times (1200/1287)^2 \times 21$
3. 140m of 28mm pipe would carry 800 litres/min with a pressure loss of 9.92 kPa. Ie: $140/152 \times (800/912)^2 \times 14$

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British Standard Size Tube BS EN 1057: R250, Table X		Distance from source (m) at 700 kPa for 7, 14, 34 kPa (1, 2, 5 psi) pressure loss																
Outside Diameter (mm)	Pressure loss (kPa)	8	15	30	61	91	122	152	183	213	244	274	305	335	366	396	427	457
		Free air flow rate (litres/min)																
12	7	408	276	186	125	99	84	74	67	61	56	53	50	47	45	43	41	39
	14	599	405	274	185	147	124	109	99	90	84	78	74	70	66	63	61	58
	34	979	664	450	304	242	205	181	163	149	138	129	122	115	110	105	100	96
15	7	759	514	347	234	186	158	139	125	114	106	99	93	88	84	80	77	74
	14	1112	754	510	345	274	232	205	184	169	156	146	138	130	124	118	114	109
	34	1811	1231	836	566	450	383	337	304	279	258	242	227	215	205	196	188	180
22	7	2192	1488	1009	682	542	460	406	366	335	310	290	273	259	246	235	225	217
	14	3198	2175	1478	1001	797	677	597	538	493	457	482	403	381	363	347	332	320
	34	5180	3533	2410	1638	1306	1111	980	884	811	752	704	663	628	598	571	548	527
28	7	4387	2984	2027	1374	1093	929	819	739	677	628	587	553	524	498	476	456	439
	14	6382	4351	2963	2013	1604	1364	1203	1086	995	923	863	813	771	734	701	672	646
	34	10290	7038	4816	3283	2620	2232	1970	1779	1632	1514	1417	1335	1266	1205	1152	1105	1063
35	7	7841	5345	3638	2470	1968	1674	1476	1332	1221	1132	1059	998	945	900	860	825	793
	14	11380	7775	5307	3612	2881	2453	2165	1954	1792	1662	1556	1466	1389	1323	1264	1212	1166
	34	18271	12528	8599	5876	4696	4003	3536	3194	2931	2720	2547	2401	2276	2168	2073	1988	1912
42	7	13128	8964	6113	4159	3316	2823	2490	2248	2061	1912	1789	1686	1598	1521	1454	1394	1341
	14	19010	13012	8901	6070	4847	4129	3646	3293	3021	2803	2624	2473	2344	2232	2134	2047	1969
	34	30392	20892	14381	9849	7881	6723	5942	5371	4930	4577	4286	4042	3833	3651	3491	3349	3223

Table G3: Pipeline pressure loss: 700 kPa (7 bar) pipelines

Examples:

1. 122m of 28mm pipe would carry 929 litres/min of free air per minute with a pressure loss of 0.07 bar (7 kPa), or 2232 litres/min with a loss of 0.34 bar (34 kPa).
2. A flow of 1,800 litres/min in 122m of 28mm pipe would result in a pressure loss of 22.11 kPa. i.e: $122/122 \times (1800/2232)^2 \times 34$
3. 140m of 28mm pipe would carry 1,100 litres/min with a pressure loss of 10.78 kPa. i.e: $140/152 \times (1100/1203)^2 \times 14$

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British Standard Size Tube BS EN 1057: R250, Table X		Distance from source (m) at 1100 kPa for 7, 14, 34 kPa (1, 2, 5 psi) pressure loss																
Outside Diameter (mm)	Pressure loss (kPa)	8	15	30	61	91	122	152	183	213	244	274	305	335	366	396	427	457
		Free air flow rate (litres/min)																
12	7	487	356	252	177	144	124	112	102	94	88	84	79	75	72	69	67	65
	14	689	503	355	249	204	177	158	144	133	124	118	111	106	102	98	94	91
	34	1084	791	560	392	321	277	249	227	210	197	185	176	167	161	154	148	143
15	7	867	634	448	314	257	222	199	181	168	157	148	141	134	128	124	119	115
	14	1226	895	633	444	363	314	281	257	238	222	209	199	189	181	174	168	162
	34	1929	1409	996	698	572	494	443	403	373	350	330	313	298	285	275	264	256
22	7	2332	1703	1205	845	692	598	535	487	452	423	399	378	360	345	332	319	309
	14	3294	2405	1701	1193	977	844	755	689	638	597	562	534	509	487	468	451	436
28	7	4469	3263	2308	1618	1325	1145	1025	935	866	809	764	724	691	660	636	612	591
	14	6311	4608	3259	2286	1872	1616	1448	1320	1223	1143	1078	1022	976	933	897	864	835
	34	9935	7255	5130	3598	2946	2544	2279	2077	1926	1799	1698	1609	1535	1469	1412	1359	1315
35	7	7718	5636	3985	2795	2289	1976	1771	1614	1495	1397	1319	1250	1192	1141	1097	1056	1021
	14	10898	7959	5628	3947	3231	2791	2500	2279	2112	1973	1862	1765	1684	1611	1549	1492	1442
	34	17157	12530	8860	6213	5087	4394	3936	3587	3325	3107	2932	2779	2651	2537	2439	2348	2271
42	7	12550	9166	6481	4545	3721	3214	2879	2624	2432	2272	2144	2033	1940	1855	1784	1718	1661
	14	17724	12944	9152	6418	5255	4538	4066	3706	3435	3209	3029	2871	2739	2620	2519	2426	2345
	34	27902	20377	14409	10104	8273	7145	6401	5834	5407	5052	4768	4519	4312	4125	3966	3819	3692

Table G4: Pipeline pressure loss: 1,100 kPa (11 bar) pipelines

Examples:

1. 122m of 28mm pipe would carry 1145 litres/min of free air per minute with a pressure loss of 0.07 bar (7 kPa), of 2544 litres/min with a loss of 0.34 bar (34 kPa). ie 122/122 x $(1145/1145)^2$ x 7
2. A flow of 2,200 litres/min in 122m of 28mm pipe would result in a pressure loss of 25.43 kPa. i.e: 122/122 x $(2200/2544)^2$ x 34
3. 140m of 28mm pipe would carry 1,300 litres/min with a pressure loss of 10.39 kPa. i.e: 140/152 x $(1300/1448)^2$ x 14

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British Standard Size BS EN 1057, R250, Table X		Distance from source (m) at 59 kPa (450 mmHg) for 1.3, 2.6, 3.9, 6.5 kPa (10, 20, 30, 50 mmHg) pressure loss																
Outside Diameter (mm)	Pressure loss (kPa)	8	15	30	61	91	122	152	183	213	244	274	305	335	366	396	427	457
		Free air flow rate (litres/min)																
15	1.3	59	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2.6	89	59	40	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	3.9	113	76	51	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	6.5	153	103	69	46	-	-	-	-	-	-	-	-	-	-	-	-	-
22	1.3	173	116	78	52	41	-	-	-	-	-	-	-	-	-	-	-	-
	2.6	260	174	117	79	62	53	46	42	-	-	-	-	-	-	-	-	-
	3.9	330	222	149	100	79	67	59	53	49	45	42	40	-	-	-	-	-
	6.5	445	301	203	137	108	92	81	73	67	62	57	54	51	49	46	45	43
28	1.3	350	236	159	106	84	71	63	56	51	48	44	42	40	-	-	-	-
	2.6	525	353	238	160	127	107	94	85	78	72	67	63	60	57	54	52	50
	3.9	666	448	303	204	161	137	120	108	99	92	86	81	76	73	69	66	64
	6.5	900	607	412	278	220	187	164	148	135	125	117	110	104	99	95	91	87
35	1.3	637	427	288	193	153	130	114	102	94	87	81	76	72	69	65	63	60
	2.6	947	638	431	290	230	195	171	154	141	131	122	115	109	103	99	95	91
	3.9	1198	808	548	369	293	248	218	197	180	167	156	147	139	132	126	121	116
	6.5	1614	1091	743	503	399	339	298	269	246	228	213	200	190	180	172	165	158
42	1.3	1074	724	488	328	260	220	194	174	160	148	138	130	123	117	111	107	103
	2.6	1598	1079	731	493	391	331	291	262	240	222	208	196	185	176	168	161	155
	3.9	2016	1363	926	626	497	422	371	334	306	283	265	249	236	224	214	205	197
	6.5	2706	1833	1254	851	677	574	506	456	417	387	361	340	322	306	293	280	270
54	1.3	2191	1480	1001	674	535	453	399	359	329	304	284	268	253	241	230	220	212
	2.6	3246	2196	1493	1010	802	681	599	540	494	458	428	403	381	363	346	332	319
	3.9	4083	2766	1889	1281	1019	865	762	687	629	582	545	513	485	462	441	423	406
	6.5	5448	3699	2549	1737	1384	1176	1037	935	856	794	742	699	662	630	601	576	554
76	1.3	5521	3773	2563	1733	1377	1169	1029	927	849	786	735	692	655	623	595	570	548
	2.6	8070	5563	3807	2586	2058	1749	1541	1389	1273	1179	1103	1038	983	396	894	857	823
	3.9	10041	6968	4801	3274	2609	2219	1957	1765	1617	1499	1402	1320	1250	1190	1137	1090	1048
	6.5	13166	9233	6439	4421	3533	3009	2655	2396	2197	2037	1906	1796	1701	1619	1547	1483	1426
108	1.3	12874	9140	6543	4552	3732	3280	2879	2628	2433	2276	2036	1941	1919	1858	1785	1712	1641
	2.6	18207	12874	9235	6578	5274	4552	4071	3716	3441	3219	3035	2879	2745	2628	2525	2422	2325
	3.9	22494	15905	11374	8114	6509	5657	5030	4592	4251	3976	3750	3557	3391	3247	3119	2992	2870
	6.5	29238	20675	14708	10520	8445	7343	6538	5968	5526	5169	4873	4623	4408	4220	4055	3889	3730

Table G5: Pipeline pressure loss (vacuum)

Examples:

1. 122m of 28mm pipe would carry 71 litres/min of free air per minute with a pressure loss of 10 mmHg (1.3 kPa), or 187 litres/min with a loss of 50 mmHg (6.5 kPa). ie 122/122 x $(71/71)^2$ x 1.3
2. A flow of120 litres/min in 122m of 28mm pipe would result in pressure loss of 2.99 kPa. ie: 122/122 x $(120/137)^2$ x 3.
3. 140m of 28mm pipe would carry 90 litres/min with a pressure loss of 2.20 kPa. ie: 140/152 x $(90/94)^2$ x 2.6

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Fitting Type	6 mm	8 mm	10 mm	12 mm	15 mm	22 mm	28 mm	35 mm	42 mm	54 mm	76 mm	108 mm
Ball valve	0.10	0.10	0.20	0.30	0.30	0.60	0.90	0.90	1.10	1.20	1.40	2.0
Tee (Thru')	0.12	0.15	0.18	0.21	0.32	0.42	0.54	0.70	0.82	1.05	1.56	2.0
Tee (Branch)	0.46	0.52	0.70	0.80	0.95	1.26	1.60	2.10	2.45	3.14	4.67	6.0
90° Elbow	0.17	0.20	0.25	0.33	0.47	0.63	0.80	1.05	1.23	1.58	2.36	3.0

Table G6: Equivalent lengths (in metres) for copper fittings

Fitting Type	40mm	50mm	70mm	100mm	125mm
Tee (Thru')	0.95	1.23	1.65	2.20	2.56
Tee (Branch)	2.76	3.38	4.57	6.12	7.68
90° elbow	1.25	1.71	2.44	3.08	3.84

Table G7: Equivalent lengths (in metres) for ABS (acrylonitrile butadiene styrene) vacuum fittings

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Appendix H: Checklist for planning/installing/upgrading a cryogenic liquid supply system

1 Information given in this Appendix can be used to determine the need for a particular capacity or type of supply system. Many of the factors described will also apply to planning an upgrade to an installation by way of increase in system size or a change of system type.

2 Some factors that should be considered are outlined below.

Delivery frequency

- Does current frequency cause logistical problems for the supplier/your site?

Calculating consumption

- Consumption is rising at approximately 10% per annum. It doubles in seven years.
- Use pharmacy records for cylinder/liquid consumption. Look for peaks in demand, for example winter influenza epidemics.
- When average and peak flow rates are known, calculate the required size of the emergency supply.

Age of current system

- The secondary supply of older VIE systems will be a compressed gas cylinder manifold, which may have very limited capacity. Consideration should be given to either a single VIE plus fully automatic manifold or, preferably, a dual VIE system.

Siting of system and the site survey

- what planning restrictions apply (vessel size, noise etc)?
- what are convenient locations for cylinder/ liquid delivery?
- advantages of separating primary and secondary supplies, if space is available;
- will other facilities be lost/reduced, for example car-parking space?
- it will be less economical in terms of delivery charges and unit gas costs to deliver large loads (for example 20 tons) using rigid vehicles (maximum 12 tons). Articulated vehicles will deliver the largest loads but may require roadway/access modifications;
- cranage access for vessels;
- when choosing liquid cylinder systems, will adequate ventilation be available?

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- emergency supply location;
- pipeline protection and possible need for dual feeds;
- pipeline extension into other sites if applicable, for example two hospitals supplied from the same VIE system. There are possible insurance issues with this arrangement;
- modifications to the alarm system may have to be made;
- alarm panel + telemetry in waterproof enclosures;
- are alarms compatible with the existing system?
- alarm arrangement for dual (but separate) tank installations;
- cable ducts and trays: examine possible routes;
- possible need to move gates/fences to install new pipework;
- clearance of trees/building;
- sealing windows of adjacent buildings;
- position of frame for valve tree (fix to fence for rigidity?);
- position of emergency gate;
- position of fill couplings must allow driver to see tank gauges;
- cabling and alarm runs for the emergency supply manifold (ERM);
- availability and presentation of alarms for ERM;
- power and lighting during work;
- drainage – catch pits, diversions, pad resizing;

Costs

- Make sure a**ll** costs are allowed for, for example:
  - site inspection;
  - cost of continuing delivery using rigid and non-articulated vehicles;
  - gas charge/HCM (hundred cubic metres) and any inflation likely;
  - facility charges (rental);
  - delivery charge for equipment;
  - loan charges and changes in interest rate on any loan if the installer funds any part of the installation;
  - road/compound loans will be seen as £x added to gas price over y years;
  - climate change levy;
  - professional fees (consultancy);
  - planning permission;
  - building Regulations clearance;

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  - all civil engineering work;
  - quoted price for gas/facilities/delivery charges may be dependent on payment by direct debit;
  - introduction/modification and maintenance of services, for example lighting, power supplies, drainage;
  - engineering and pharmaceutical testing;
  - additional emergency provision and any associated cylinder charges;
  - modifications to alarm and telephone systems;
  - security;
  - charges for ERM cylinders during installation (may have to be charged and then recovered);
  - cranage charges;
  - contingency 10%
  - what, if any, commitment is required by the gas company?
- how will gas prices vary during this period?
- is there any agreement to provide, for example, modified roadway facilities if rigid vehicular deliveries are too frequent to be convenient to supplier? Or if such roadway modifications take place within a defined timescale, new rates etc may need to be negotiated;
- check defects liability (usually 12 months).

Emergency provision

- examine the vulnerability of current system and main feeds to hospital;
- consider minimum size of manifold plus cylinder storage to meet four-hour supply requirement. Is a second VIE a better option?
- operational requirements of ERM;
- protection/housing/security of ERM;
- alarm/monitoring systems and power supplies for ERM and its accommodation.

System shutdown during installation

- often it will be necessary to interrupt site supplies during connection of new plant. How will this be managed?
- disruption of two hospitals simultaneously if plant to be upgraded is supplying both sites;
- examine planned plant and pipework systems carefully to ascertain the best way of minimising downtime and facilitating engineering and pharmaceutical testing;

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- while installing, fit extra valves to allow for future expansion and emergency supply manifolds to protect vulnerable parts of the system;
- fit NIST fittings wherever this will facilitate system purging;
- fit test points/emergency inlet ports as recommended in this guidance or investigate any likely requirement for additional (local) manifolds to support high-dependency areas.

Paperwork

- site survey details;
- register of contractors with contact names/ telephone numbers;
- keep a record of all dates, for example:
  - tender invitation;
  - tender open;
  - tender close;
  - award and regret letters to tenderers;
- copies of all letters to/from contractors;
- NICEIC (National Inspection Council for Electrical Installation Contracting) test certificate for electrics;
- validation and verification results (engineering and pharmaceutical);
- Health and Safety policies of contractors;
- method statements from contractors;
- insurance agreement with gas supplier for VIE system(s);
- MGPS operational policy protocols.

Health and safety

- Health and Safety policy (contractors and their employees, and subcontractors and their employees, must comply when employed by the trust and working on trust properties);
- inform contractors of specific site hazards;
- Hazard notices on site and on final installation;
- lighting during installation and for completed compound;
- road markings and signage.

Preparation

- carefully plan phasing of building work to maximise efficiency of installation programme. (Remember concrete plinths will take three days to harden before vessels can be sited.);

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- plan phasing of engineering and QC testing to avoid wasting APs'/QCs' time;
- consider methods of maintaining supplies during essential shutdowns. Cylinder supplies may be needed during commissioning. Gas supplier may be able to arrange multi-cylinder pallets;
- road base preparation, if required, must be completed in an early phase of the work to allow necessary access for cranes and, eventually, delivery vehicles;
- road surfacing/kerbing/drainage/lighting;
- retaining walls around compound if required, for example on sloping sites;
- maintaining rights of way;
- oxygen compound civil engineering work;
- if you are changing supplier, your original supplier will need to remove old equipment before plinth can be extended to fit new vessels;
- electrics for alarms, tank, lighting and, possibly, vehicle pump;
- floodlighting and telephone line;
- plan vehicular parking during (and after) work;
- the old plinth may require skimming to provide a reasonable surface.

Installation

- if an ERM (as a third means of supply) is installed first, this can be used to supply the hospital system during vessel replacement;
- decide who arranges emergency cylinder supplies for ERM. When plinth extensions are required, specify oxygen-compatible sealant for gaps between old and new plinth sections;
- remember to post health and safety notices during the work;
- alarm systems will not be fully functional until system is fully commissioned. Therefore, all staff must be kept aware of the different alarm situation;
- concrete will need two to three days to harden on any pad extension;
- the first vessel filling is a very noisy procedure with much vapour and can take several hours (consider restrictions);
- concrete sample testing will be required during new plinth construction;
- use temporary steel sheeting to support a new vessel on tarmac alongside the plinth;
- access for cranage must be kept open (car parking control);
- drainage (may have to move existing drains/ soakaways and create new pipe runs; remember oxygen separation distances);
- road markings and signage;
- possible new kerbs/footpaths;

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- electrical supplies: single phase can be used for lighting, alarms etc but a three-phase 60 A supply will be needed for delivery vehicle pump if appropriate;
- earth bonding/lightning protection for fences;
- alarm interface/telemetry boxes at a sensible height for viewing;
- lagging of liquid lines;
- if using 200 bar unregulated cylinders for supply during installation or on ERM, take care that they are not mixed up with 137 bar cylinders;
- proximity of flammables and vital services during installation – vulnerability to mechanical damage (cutting discs, etc.), welding and cutting flames/sparks;
- power and lighting supplies during work;
- water supply (washing and concrete) during work.

Follow-up

- routine maintenance and monitoring of complete installation;
- cylinder changes and stock management for ERM;
- establish system management arrangements for vessels supplying more than one site (see Part B, Appendix G);
- update MGPS operational policy and any relevant insurance policies.

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Appendix J: Upgrading surgical air systems

Background

1. An increasing number of surgical air pipeline systems are designed to operate at a line pressure above the nominal 700 kPa, for example 1,000 – 1,100 kPa. This enables the system to deliver 350 litres/min (at 700 kPa) at the front of the surgical air terminal unit.

2. Such a system will comprise a high-pressure supply pipeline installation, in the order of 1,000–1,100 kPa and local pressure regulation (for example adjacent to the operating suite) such that the maximum static pressure does not exceed 900 kPa.

3. Existing Health Technical Memorandum 22 systems run at a line pressure of 700 kPa and will provide a flow of 250 litres/min at the front of the terminal unit.

4. Users must be made aware (preferably by written report) that such systems will not meet the demands of some modern air tools and that use of such tools may result in both a lack of tool performance and frequent low-pressure alarms on the surgical air system.

5. Tools are available that require a flow up to 500 litres/min at an operating pressure of 1,400 kPa. Such tools will require discrete cylinder supplies.

Modifying “old” systems

6 Increasing line pressure to meet the latest recommended flow rates is often proposed, but needs to take account of the following:

- **is the compressor receiver suitable for use at the proposed pressures?** A typical “old” 700 kPa system will employ a receiver operating at typically 10 bar pressure. A “new” system, with a typical line pressure of 10.5 bar, requires a receiver operating at a typical pressure of 13 bar. Ensure that the test, design and working pressures of the current receiver are acceptable, and that the capacity of the receiver is appropriate to the new demand;
- **is the compressor plant capable of meeting the increased duty cycle?** Overheating and premature plant failure may result if this is not the case. The system may be supplying both surgical and medical air. Plant failure/flow reduction resulting from an overburdened surgical air system may have serious consequences in terms of medical air provision, particularly as this is the recommended driving gas for patients’ ventilators;
- **are the pressure safety valves (PSVs) suitably rated?** PSVs on pipelines and the receiver will need to be changed to meet the new operating conditions. Certificated replacement PSVs should be used;
- **Are pressure switches suitably rated and adjusted?** Pressure switches on plant and pipelines will need to be changed or adjusted accordingly;

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- **has the pipeline been suitably pressure-tested?** There may be occasions when existing 4 bar systems (or parts thereof) are proposed for use at 7 bar or higher. 4 bar systems are only tested to 10 bar; they will need to be retested at 18 bar to ensure a leak-free high-pressure system;
- **will you still be insured?** If the pipeline system contains large diameter pipe (120mm or above), the insurance company should be consulted to ascertain whether the system would be capable of withstanding not only the pipeline operating pressure but also any test pressure that may be applied during system refurbishment or extension. A new Written Scheme of Examination will have to be prepared for the new system;
- **labelling.** Ensure that all relevant labels are in place before the system is accepted;
- **other issues.** There may be other system defects discovered during the upgrading process, for example lack of pipeline support/protection. There may also be a potential contamination issue resulting from the transfer of particulate matter from older, silver-soldered systems into new inert gas shield brazed pipework, although it should be noted that this is not an issue limited to air systems. These issues will need to be addressed before the system is accepted for use. Ensure that any system amendments and changes in working practices are documented in the MGPS operational policy.

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Appendix K: Signage requirements

Location	Wording	Notes
Plantroom	Medical Gas Plant Room – No unauthorized Entry	Adjacent to or on external door
	Fire action	On door/wall External or internal
	Keep locked	On door(s)
	Noise Hazard (+ ear defender symbol) Electric shock hazard Permit-to-work must be used	Adjacent to, or on, external door
	Plant is connected to essential electricity supply	"E" symbols can be used on switches etc
	Danger 400 Volts	On plant/switchgear
	Danger 240 Volts	On plant/switchgear
	Danger rotating machines Warning: These machines stop and start automatically without warning Guards must be in position Do not isolate without a Permit	Posted adjacent to plant
	Biological symbol	Vac filters and exhausts Also for AGSS units/exhausts/drain Flasks
	Medical air intake Do not obstruct	On external intakes only
	Emergency Tel No Gas Supplier Estates Pharmacy Porters	External wall
	Health and Safety Law	Internal wall
	First aid	Internal wall

Table K1: General Plantroom Signage

Notes applicable to Table K1: "Bacteria filter change procedure" sign is not available commercially and will have to be made locally.

No "Danger medical gas/vac/AGSS exhaust" sign is commercially available but "Danger explosive gases, no smoking, no naked lights" is available and would suffice.

"Danger 400/240 Volts", "Warning: These machines stop and start automatically/without warning" and "Biohazard" labels would need to be added to AGSS plant remote from main plantroom, plus any relevant plantroom notices.

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Location	Wording	Notes
Manifold room	Medical gases manifold room – No unauthorised entry	Adjacent to or on external door
	No parking	Adjacent to or on external door
	Approved personal protective equipment must be worn	Adjacent to or on external door
	Fire action	Internal/external wall
	Cylinder status tag	On manifold cylinders
	Valve open	On line valves/ERM cylinders
	Valve closed	On line valves/ERM cylinders
	Make sure cylinders are secure at all times	Internal, near cylinders
	Danger No smoking	External (on door or wall)
	Danger compressed gas	External (on door or wall)
	Warning oxidizing agent	External (on door or wall)
	Danger oxygen	External (on door or wall)
	Emergency Tel No Gas suppliers Estates Pharmacy Porters	External (on door or wall)
	Keep locked	On door

Table K2: Manifold Room Signage

Notes applicable to Table K2: Also required:

Cylinder ID charts, manifold cylinder change procedure, emergency manifold operating procedure.

Check with fire officer for any local fire brigade requirements for fitting “HAZCHEM” signs e.g. “HAZCHEM 2SE Cylinders”

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Location	Wording	Notes
Main cylinder store	Medical gases cylinder store – No unauthorised entry	Adjacent to or on external door
	No parking	Adjacent to or on external door
	Keep loading bay/doors clear	Adjacent to or on external door
	Approved personal protective equipment must be worn	Adjacent to or on external door
	Make sure cylinders are secure at all times	Adjacent to cylinders
	Fire action	Internal/external wall
	Full cylinders	On bays
	Empty cylinders	On bays
	Emergency exit keep clear	May be already fitted
	Danger No smoking	On door
	Danger compressed gas	On door
	Warning oxidizing agent	External (on door or wall)
	Danger oxygen	External (on door or wall)
	Emergency Tel No Gas suppliers Estates Pharmacy Porters	External wall
	Keep locked	On door
	Push bar to open	Emergency exit and main door(s)

Table K3: Main Cylinder Stores

Notes applicable to Table K3: “Danger liquid nitrogen” sign is available for a separate liquid nitrogen store (see BCGA CP30).

Cylinder ID chart(s) to be posted

Check with fire officer for any local fire brigade requirements for fitting “HAZCHEM” signs e.g.

“HAZCHEM 2SE Cylinders”.

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Location	Wording	Note
Ready to use cylinder store	Medical gases cylinder store – No unauthorized entry	Adjacent to or on external door
	Make sure cylinders are secure at all times	Adjacent to cylinders
	Emergency Tel No Gas suppliers Estates Pharmacy Porters	External wall
	Danger No smoking	On door
	Danger compressed gas	On door
	Fire action	Internal/external wall

Table K4: Ready to Use Cylinder Stores

Notes applicable to Table K4: Post cylinder ID chart(s) and cylinder change procedure.

Check with fire officer for any local fire brigade requirements for fitting "HAZCHEM" signs, eg "HAZCHEM 2SE Cylinders"

Location	Wording	Notes
Ward (Cylinder parking bay)	Medical gas cylinder parking area	Defines cylinder parking as per new Scottish Health Technical Memorandum
	Emergency Tel No Gas suppliers Estates Pharmacy Porters	External wall
	Gas leak action	On nurses' station

Table K5: Ward cylinder parking bay

Notes applicable to Table K5: Post cylinder chart(s) and cylinder change procedure.

Operational policy may dictate posting of AVSU emergency operation and MGPS alarm responses.

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Location	Wording	Notes
Work area	Maintenance in progress	There may be other site safety notice requirements to fulfil
	Medical gas test area	
	Confined space	
	Hot work in progress	
	Danger pressure test in progress	
	Danger nitrogen purging in progress	

Table K6: Medical equipment workshop (EBME)

Notes applicable to Table K6: These signs should be posted during installation/modification/maintenance of an MGPS. Multiple signs may be required.

Location	Wording	Notes
Pipework	Gas identity	
	Flow direction	

Table K7: Pipeline identification

Location	Wording	Note
Line Valves& Lockable Valve Assembly	Gas identity	On pipeline label
	Flow direction	
	Valve No	Sequential number system
	Key No	

Table K8: Line Valve & Line Valve Assembly identification

Location	Wording	Notes
AVSUs	In emergency break glass and shut off valve	On/off positions to be shown on AVSU body
	Gas identity	
	Flow direction	
	Area controlled	
	Key No	
	Valve No	Sequential number system

Table K9: AVSU identification

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Location	Wording	Notes
Alarm displays	Area monitored	Responses may be posted nearby, in accordance with MGPS operational policy
	Gas names	
	Fault/normal/condition indicators	

Table K10: Alarm system identification

Location	Signage will be determined by the equipment supplier but will usually include plant schematic, safety warnings and emergency actions
VIE/Liquid cylinders/PSA/synthetic air	

Table K11: Bulk liquid oxygen/Liquid oxygen cylinder/PSA/Synthetic Air plant

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Appendix L: Important notes for use of medical vacuum and anaesthetic gas scavenging

Infectious disease units

1 Medical vacuum should neither be extended to an Infectious Diseases Unit (IDU) nor provided to such a unit from a central vacuum system.

2 Portable suction units will be required. Decontamination will require specialised protocols and the advice of the infection control officer should be sought.

Note 84: Systems already exist whereby an IDU is, by local agreement, serviced via a central vacuum system. If such agreements exist, or are to be accepted, great care must be taken to ensure that the exhausts of such a plant are kept well away from all air intakes and the plant is labelled to indicate its function. Ideally, the plant should be housed in separate accommodation but, where this is not possible, safety signage and strict operational protocols are extremely important. Personnel changing filters, or carrying out work on such a system, should wear personal protective equipment and follow protocols that have been devised in liaison with the infection control officer.

Laser/surgical diathermy smoke extraction

3 An additional contamination hazard can arise if smoke from procedures employing laser or surgical diathermy equipment is exhausted using a cannula attached to the vacuum system.

4 Clinical staff should be advised against this practice and either instructed to use dedicated laser smoke removal units (incorporating dedicated, filtered, portable vacuum pumps) or a specially designed laser smoke filter fitted to a medical vacuum system terminal unit.

Dental vacuum systems

5 Medical vacuum systems operate at relatively low flow rates at the terminal units (~40 litres/min). Such flows are unsuitable for use as dental vacuum, which operates at much higher flow rates (typically 300 litres/min). Medical vacuum systems should not be used to provide dental vacuum.

Anaesthetic gas scavenging (AGS)

Active AGS systems (medical)

6 Active anaesthetic gas scavenging systems operate at relatively high flow rates (80–130 litres/min in a BS6834:1987 system; and 50–80 litres/min in a BS EN ISO 7396-2: 2007 system).

7 It is unlikely that receiving systems designed for use with these scavenging systems will operate correctly with a medical vacuum system. Severe spillage of

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waste gases into the operating area may occur. Therefore, medical vacuum systems should not be used as waste anaesthetic gas disposal systems.

Active AGS (dental)

8 Active AGS systems for use with dental nasal scavenging masks operate by maintaining a flow of air through the outer layer of a specially designed concentric nose mask. Waste gases from the patient pass from inner to outer layers of the mask and are carried away to the exhaust termination by this air stream.

9 The flow rate necessary to achieve effective removal of waste gases by such a method is in the order of 45 litres/min, which is less than the flow rate achieved at a dental vacuum system terminal.

10 Active dental scavenging systems using this type of mask must therefore be driven (via a special flow adjuster) from the dental vacuum system, a dedicated separate high-flow vacuum system, or an active medical AGS system. In the case of a medical AGS system, the special flow adjuster would be plugged directly into an AGS system wall terminal. A receiver (air break) system would not be used between the wall terminal and the special flow adjuster.

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Appendix M: Oxygen usage data

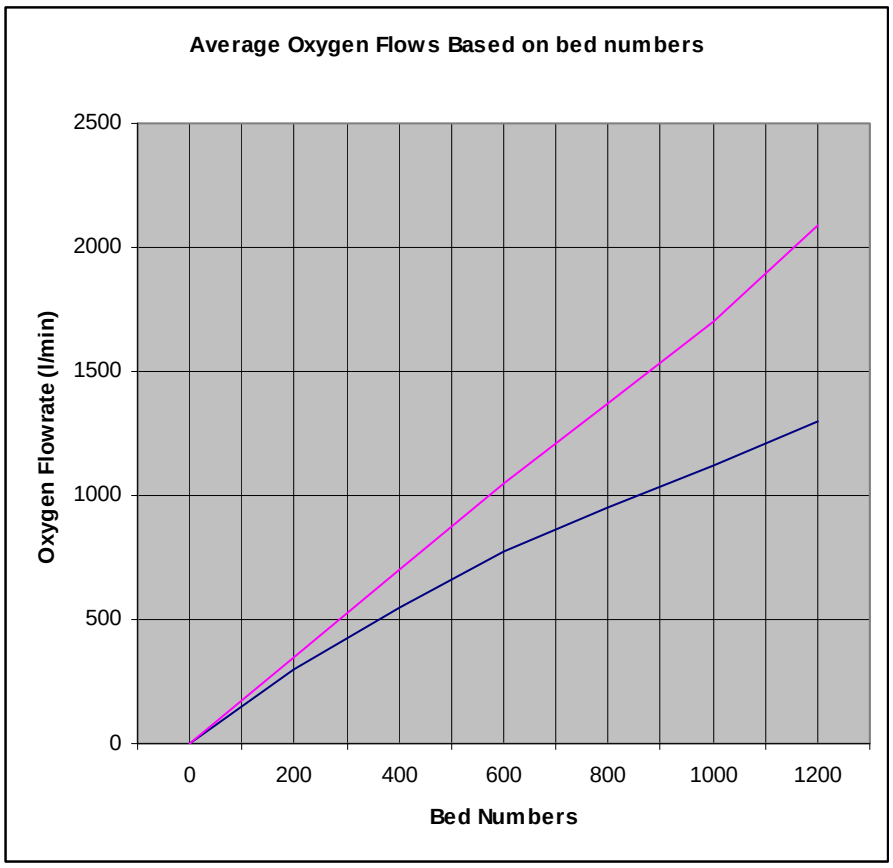

Figure M1: Oxygen usage nomogram

Lower graph shows average flows to be expected in a typical acute hospital.

Upper graph shows flows to be expected when the hospital has specialties using larger amounts of oxygen, e.g. those with multiple large critical care areas (>20 beds) and an increased use of CPAP (>5 machines).

NB. These graphs are issued for guidance only. There will be hospitals for which average flows will, for a given number of beds, be higher or lower than the maxima and minima shown here.

NB. The flows are representative of oxygen provided from a VIE plant and do NOT take into account additional consumption from compressed gas cylinders.

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Appendix N: Pressure conversion table

Pressure	Multiply units in left column by factor below							
	kPa	lb/in^2	lb/ft^2	Int atm	kg/cm^2	mmHg @ 0°C	In Hg @ 0°C	ft water @ 4°C
1 pound/in^2	6.895	1	144	0.0682	0.0703	51.713	2.0359	2.307
1 pound/ft^2	0.048	0.00694	1	0.0005	0.00052	0.3591	0.01414	0.01602
1 int atmosphere	101.3	14.696	2116.2	1	1.0333	760	29.92	33.9
1 kilogram/cm^2	98.07	14.223	2048.1	0.9678	1	735.56	28.958	32.81
1 mmHg (1 torr)	0.133	0.0193	2.785	0.0013	0.00136	1	0.0394	0.0446
1 in Hg	3.387	0.4912	70.73	0.0334	0.0345	25.400	1	1.133
1 ft water	2.984	0.4335	62.42	0.0295	0.0305	22.418	0.8826	1
1 kilopascal (kPa)	1	0.145	20.92	0.0099	0.0102	7.519	0.295	0.3346

Table N1: Pressure conversion table

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Appendix O: Pressure testing procedure

The following provides guidance in relation to the safe procedures related to pneumatic pressure testing of medical gas pipelines. The guidelines are based upon the Health and Safety Executive guidance note GS4; 1998. Note that the appropriate method statements and risk assessments should always be prepared for all pressure testing. All necessary safety warning signs should be posted throughout the test area. All unauthorised personnel should vacate all areas under test.

First Fix Pressure Test

Prior to First Fix test being carried out a leak test should be performed; all pipeline ancillaries which can be affected by the higher pressures should be removed or blanked, e.g. safety valves, pressure switches.

First fix pressure tests should be carried out in the following manner:

1. An initial leak test pressure should be set at no more than 100 kPa. This test should allow significant leaks to be detected and rectified prior to the main pressure test.

2. The pressure should be increased gradually over a period of time, e.g. 200 kPa increments and leave for 10 minutes, while monitoring the pressure reading. If the pressure drops during this period, retest for leaks.

3. If the pressure is stable, continue to increase to the agreed test pressure, leave for 1 hour as indicated in 15.51 and 15.52.

4. The test pressure(s) and temperature(s) should be witnessed by the Authorised Person (MGPS) or CSO at the start and at the end of the test period with all necessary test sheets completed and signed.

5. The pressure should be reduced in a safe manner to a maximum pressure of 100 kPa, or to the pressure agreed on the particular site.

Service	Test Pressure	Pressure Drop (max)	Timescale
Oxygen	10 bar / 1,000 kPa	0.2 kPa	1 hour
Nitrous Oxide	10 bar / 1,000 kPa	0.2 kPa	1 hour
Nitrous Oxide/Oxygen (50/50)	10 bar / 1,000 kPa	0.2 kPa	1 hour
Medical Air 4 Bar	10 bar / 1,000 kPa	0.2 kPa	1 hour
Surgical Air 7 Bar	18 bar / 1,800 kPa	0.5 kPa	1 hour
Surgical Air 9 Bar	18 bar / 1,800 kPa	0.5 kPa	1 hour
Medical Vacuum	5 bar / 500 kPa	0.2 kPa	1 hour
AGSS	70 kPa	10 kPa	15 mins

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Second Fix Pressure Test

Second fix pressure tests should be carried out in the following manner:

1. All pipeline ancillaries such as; terminal units, pendant hoses, pressure switches, etc. should be connected and tested for leakage in the same manner as indicated in 1st fix Pressure Test procedure item 1.

2. The pressure should be increased gradually over a period of time, e.g. 200 kPa increments and leave for 10 minutes, while monitoring the pressure reading.

3. If the pressure drops during this process, retest for leaks.

4. If the pressure is stable, continue to increase to the agreed test pressure, leave for 1 hour as indicated in 15.62 and 15.63.

5. The test pressure(s) and temperature(s) should be witnessed by the Authorised Person (MGPS) or CSO at the start and at the end of the test period with all necessary test sheets completed and signed.

6. If the remaining functional tests are not to be performed immediately after the 2nd fix pressure test, the pressure should be reduced in a safe manner to a maximum pressure of 100 kPa or to the pressure agreed on the particular site.

7. The pressure for each service should be monitored over the period until the pipelines are to be set to working pressures for functional tests.

Service	Test Pressure	Pressure Drop (max)	Timescale
Oxygen	4 bar / 400 kPa	0.1 kPa	1 hour
Nitrous Oxide	4 bar / 400 kPa	0.1 kPa	1 hour
Nitrous Oxide/Oxygen (50/50)	4 bar / 400 kPa	0.1 kPa	1 hour
Medical Air 400 kPa	4 bar / 400 kPa	0.1 kPa	1 hour
Surgical Air 700 kPa	7 bar / 700 kPa	0.5 kPa	1 hour
Surgical Air 900 kPa	9 bar / 900 kPa	0.5 kPa	1 hour
Medical Vacuum	450 – 700 mmHg	1 kPa / 7.5 mm Hg	1 hour

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NB: Access to information related to the following Acts and Regulations can be gained via **www.legislation.gov.uk.**

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Scottish Health Technical Memorandum 2027

(Part 1 of 4)

Overview and management responsibilities

Hot and cold water supply, storage and mains services

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NHSScotland, P&EFEx, June 2001

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1. Introduction

1.1 Scottish Health Technical Memorandum 2027; *Hot and cold water supply, storage and mains services,* is published in four separate parts. It is equally applicable to both new and existing sites and gives comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations' managers on the legal requirements, design applications, maintenance and operation of hot and cold water supply, storage and distribution systems in all types of healthcare premises.

1.2 Current statutory legislation requires both "management" and "staff" to be aware of their individual and collective responsibility for the provision of hot and cold water supplies, storage and distribution in healthcare premises.

1.3 Healthcare premises are dependent upon water to maintain a safe and comfortable environment for patients and staff, and for treatment at all levels of clinical and surgical care.

1.4 The development, construction, installation and maintenance of hot and cold water supply systems are vital for public health. Water quality is influenced by political, environmental and technical issues. It is governed by legislation, water byelaws, building regulations, approved codes of practice and technical standards intended to safeguard quality.

1.5 Interruptions in water supply can disrupt healthcare activities. The design of systems must ensure that sufficient reserve water storage is available to minimise the consequence of disruption, while at the same time ensuring an adequate turnover of water to prevent stagnation in storage vessels.

1.6 While some guidance on the water services applications mentioned below is given in this memorandum, reference should be made to:

laundry – see Health Building Note 25; Health Building Note is suitable for use in Scotland subject to the amendments contained in the Management Executive Letter MEL 94/108

sterile supply departments – see Health Building Note 13; Scottish Hospital Planning Note 13 issued with MEL 94/63

hydrotherapy pools – see Public Health Laboratory service booklet, *Hygiene for Hydrotherapy Pools.*

SHTM 2040; *The control of legionellae in healthcare premises – a code of practice* should be consulted for guidance on the prevention of legionnaires' disease.

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Definitions

1.8 Definitions of terms are as those contained in BS 6100 Sections 2.7 and 3.3, BS 6700 and Model Water Byelaws.

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2. Management responsibility

Management accountability

2.1 Management has the overall responsibility for implementing procedures to ensure that reliable hot and cold water supply, storage and distribution systems operate within the organisation.

2.2 These procedures should demonstrate that any person on whom the statutory duty falls has fully appreciated the requirement to provide an adequate supply of hot and cold water of suitable quality. Though compliance with this guidance may be delegated to staff, or undertaken by contract, accountability cannot be delegated.

2.3 Regular assessments should be made at least annually, using this guidance, to establish the extent of the risk. Shortfalls should be clearly recorded and the proposed control measures, with timescales, developed. A review should be undertaken whenever there is a substantial change in physical or environmental conditions.

2.4 The objective must be to institute management procedures to ensure that compliance is continuing and not notional. The prime purpose of the assessment is to be able to demonstrate that management has identified all the relevant factors, has instituted corrective or preventive action and is monitoring the plans being implemented.

2.5 This guidance should be applied to all healthcare premises, however small, where there is a duty of care under the Health and Safety at Work etc Act 1974.

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Statutory requirements

2.6 It is the responsibility of management to ensure that their premises comply with all statutes.

2.7 Management (owners or occupiers) of healthcare premises have an overriding general duty of care under the Health and Safety at Work etc Act 1974. Therefore, they should ensure that the water supply, storage and distribution services can be provided within the terms of the following legislation.

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Health and Safety at Work etc Act 1974

2.8 Employers have a general duty, under the Health and Safety at Work etc Act 1974 to ensure, so far as is reasonably practicable, the health, safety and welfare of their patients, employees and visitors who may be affected by workplace activities.

2.9 These duties are legally enforceable and the Health and Safety Executive have successfully prosecuted employers including Health Authorities and Trusts under this statute. It falls upon owners and occupiers of premises to ensure that there is a management regime for the proper design, installation and maintenance of plant, equipment and systems. Failure to have a proper system of work and adequate control measures can also be an offence even though an outbreak of, for example, legionnaires' disease or other such incident has not occurred.

The Management of Health and Safety at Work Regulations 1999

2.10 These regulations require every employer to make a suitable and sufficient assessment of all risks to health and safety of employees and the public caused by work activities. In addition to legionella, other risks from a hot and cold water distribution system include deterioration of water quality, scalding at hot water outlets and danger due to bursting at excessive pressures.

Control of Substances Hazardous to Health (COSHH) Regulations 1999

2.11 In the context of hot and cold water supply, storage and mains services, these regulations apply to micro-organisms, such as legionellae and to the chemicals which may be used to control the growth of micro-organisms in water supply. Employers have a duty to assess the risks from exposure to these substances to ensure that they are adequately controlled.

Public Health (Infectious Diseases) (Scotland) Regulations 1975

2.12 These regulations require that a properly appointed officer shall inform the chief medical officer, of any serious outbreak of any disease which to his knowledge has occurred.

For further reference refer to: Public Health (Notification of Infectious Diseases) (Scotland) Regulations 1988, Public Health (Notification of Infectious Diseases) (Scotland) Amendment Regulations 1989. The Scottish Office, Department of Health, Advisory Group on Infection, Scottish Infection

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Manual. Guidance on core standards for the control of infection in hospitals , healthcare premises and at the community interface (1998).

Water Supply Regulations

2.13 The Water Supply (Water Quality) (Scotland) Regulations 1990 (as amended), apply to water supplied to any hospital which is used for domestic purposes such as drinking, washing or cooking. Two additional sources of advice on drinking water quality are:

a. the Director of Public Health;

b. the World Health Organisation 'Guidelines for drinking water quality' 1993.

2.14 The Private Water Supplies (Scotland) Regulations 1992 (Statutory Instrument 1992/574) cover private water supplies such as boreholes and wells.

Food Safety Act 1990

2.15 The Food Safety Act 1990 covers water used for food preparation or food manufacture and also includes water used for drinking. Food Safety (Temperature Control) Regulations 1995 will also apply as will the Food Safety (General Food Hygiene) Regulations 1995.

Approved Code of Practice

2.16 The Health and Safety Commission have published an, 'Approved Code of Practice (ACOP)' and the Health and Safety Executive have produced a guidance note (HS(G)70) entitled, 'The control of legionellosis including legionnaires' disease'. The onus is on management to demonstrate that procedures in place are as good as, or better than, those required by the ACOP.

2.17 Compliance with the guidance given in SHTM 2040 will satisfy the ACOP requirements for the control of legionellosis.

2.18 The health service, with responsibility for the wider aspects of public health and the operation of NHS in Scotland premises, is expected to be particularly vigilant. The number of outbreaks of legionnaires' disease is relatively small, but outbreaks are considered to be avoidable. Management must also acknowledge that incidents or outbreaks cause widespread concern, especially if associated with healthcare premises. Investigation of these outbreaks has shown that they are generally related to a breakdown in management systems. Design flaws and defects have also been implicated as the cause of some outbreaks.

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2.19 Hence, managers need to satisfy themselves by monitoring, that effective control procedures are being implemented. It is not sufficient merely to devise procedures.

Model Water Byelaws

2.20 All water authorities responsible for water supply have a statutory duty to enforce their byelaws for the prevention of waste, undue consumption, misuse and contamination of water supplied by them.

2.21 In 1989 new model water byelaws came into effect and these are set out, along with the water industry's interpretation of these provisions, in the 'Water Supply Byelaws Guide 1989'. The WRc (Water Research Centre) operates the Evaluation and Testing Centre which provides advice on byelaws on a national basis and administers the Water Byelaws Scheme which tests and lists water fittings and materials for compliance with the byelaws. The 'Water Fittings and Materials Directory' contains information on suitable fittings and materials and is updated every six months.

Building Regulations

2.22 Part P of Schedule 1 of the Building Standards (Scotland) Regulations 1990 provides the functional requirements for the unvented hot water storage systems.

Building Services Research and Information Association

2.23 Application Guide AG4/94 Guide to legionellosis - temperature measurements for hot and cold water services. A practical guide which sets out the main activities which are essential for compliance with the HS(G)70 guidance on water temperatures. Its principle on planning, measurement and site procedure are equally applicable to healthcare premises.

British Standards

2.24 BS 6700: 1997 is the British Standard specification for design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages.

2.25 BS 1710: 1984 is the British Standard specification for identification of pipelines and services.

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Operational management

2.26 Managers should ensure that an operational plan is in place for each site under their control. This document should comprise:

a. up-to-date drawings and descriptions of all the supply storage and distribution systems within those premises;

b. step-by-step instructions to operate, maintain, control and shut down the water supply, storage and distribution systems within those premises;

c. a schedule of possible emergency incidents causing loss of the water supply from the water authority. Each item in the emergency incident schedule should include guidance on operational procedures to re-establish a stable wholesome water supply. In re-establishing the water supply, input from the infection control team and the Consultant in Communicable Disease Control may be required.

2.27 A routine of staff training should be implemented by management on the systems' basic operational procedures, and also on those system procedures required during an emergency.

2.28 Only properly trained nominated persons should be appointed by management to control the operation of emergency equipment.

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Designated staff functions

Management

2.29 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the safe operation of healthcare premises.

2.30 A person intending to fulfil any of the staff functions specified below should be able to prove that they possess sufficient skills, knowledge and experience so as to be able to perform safely the designated tasks.

Infection control officer

2.31 Infection control officer-or consultant microbiologist, if not the same person, nominated by the management to advise on monitoring infection control policy and for the maintenance of water quality.

Nominated person

2.33 A nominated person (water), possessing adequate professional knowledge and with appropriate training, should be nominated in writing by management to devise and manage the necessary procedures to ensure that the quality of water in healthcare premises is maintained. The person will be required to liase closely with other professionals in various disciplines.

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In addition, the person should possess a thorough knowledge of the control of legionellae and would ideally be a chartered engineer.

2.34 This person's role, in association with the infection control officer and maintenance staff, involves:

a. advising on the potential areas of risk and identifying where systems do not comply with this guidance;

b. liaising with the water authorities and environmental health departments and advising on the continuing procedures necessary to ensure acceptable water quality;

c. monitoring the implementation and efficacy of those procedures;

d. approving and identifying any changes to those procedures;

e. ensuring that equipment which is to be permanently connected to the water supply is properly installed;

f. ensuring that adequate operating and maintenance instructions exist and adequate records are kept.

2.35 Implementation of an effective maintenance policy must incorporate the preparation of fully detailed operating and maintenance documentation and the introduction of a logbook system. The "nominated person" should appoint a deputy to whom delegated responsibilities may be given. The deputy should act for the nominated person on all occasions when the nominated person is unavailable.

2.36 The nominated person should be fully conversant with the design principles and requirements of water systems and should be fully briefed in respect of the cause and effect of water-borne organisms, for example Legionella pneumophila. The appointment of an engineer as the nominated person is appropriate in that the responsibility can extend to the operation and maintenance of associated plant. It is recognised that the nominated person cannot be a specialist on all matters and must be supported by specialists in specific subjects such as water treatment and microbiology, but he/she must undertake responsibility for calling upon and co-ordinating the activities of such specialists.

Maintenance technician

2.37 A person who, in the opinion of the nominated person, has sufficient technical knowledge and the experience necessary to carry out maintenance and routine testing of the water, storage and distribution system.

Tradesperson

2.38 A person who is appointed in writing by the nominated person to carry out, under the control of the maintenance technician, work on the water, storage and distribution system.

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Installer

2.39 A person or organisation responsible for the provision of the water, storage and distribution system.

Contractor

2.40 The person or organisation designated by management to be responsible for the supply and installation of hot and cold water services, and for the conduct of the installation checks and tests.

Contract supervising officer

2.41 The person authorised by the hospital management to witness tests and checks under the terms of contract. He/she should have specialist knowledge, training and experience of hot and cold water supply, storage and mains services and SHTM 2027.

Record keeping

2.42 Management should ensure that an accurate record of all assets relating to the hot and cold water distribution systems is set up and regularly maintained. They must also ensure that records of all maintenance, inspection and testing activities are kept up-to-date and properly stored.

Water economy and energy management

2.43 Managers should ensure that water economy and energy management policies are set up and adhered to. The requirements of such policies are briefly outlined in Chapter 4.

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3. Description of systems

3.1 The following sections give a brief description of hot and cold water systems.

Source of supply

3.2 Normally, the source of water supply to a health building is by one or more service pipe connections from the mains of a water authority. If the quantity and rate of flow is inadequate, or if the cost of providing the service connection appears to be uneconomical, alternative sources of supply such as boreholes or wells may be investigated.

3.3 The feasibility of a private supply should be decided by comparing the capital and revenue costs with the long-term cost of water supplied from the statutory authority. Due consideration should be given to the long-term costs of a private supply and account should be taken of potential deterioration in water quality and/or capacity of the private supply source.

3.4 Provision should be included for alternative water supply arrangements to meet an emergency, regardless of the source or sources of supply finally adopted. Alternative arrangements would include the provision of a second service connection from the statutory water authority or a private supply. The water quality requirements applicable to the main supply apply also to any alternative supplies.

3.5 Physical interconnection of pipework and valves of a statutory water authority's supply with any private supply is normally prohibited by water byelaws in order to eliminate backflow from one supply into the other. The statutory water authority should be advised of the NHS need to use any private supply as well as the statutory water authority's supply, and advice should be sought on the limitations imposed in respect of break cisterns and interconnection thereafter.

3.6 All water intended for human consumption is required by legislation to comply with the quality standards laid down in the Water Supply (Water Quality) Scotland Regulations 1990. These regulations apply to water sampled at the point where the water is available for use and embrace not just drinking water but also water used for domestic purposes.

Water treatment

3.7 While potability is not normally affected by such characteristics as hardness, colour, and (within limits) smell and/or taste, a measure of treatment may be necessary to provide a more acceptable supply, for example to protect equipment from deterioration.

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3.8 Treatment may also be considered necessary where the water is to be used in humidification plant, steam boilers, laundries or other heating processes.

Water storage

3.9 Water is stored in large developments like health buildings for three basic reasons:

a. to provide reserve supply during failure of the source cold water supply to the development;

b. to reduce the maximum demand on the cold water main;

c. to provide accommodation for displaced cold feed water resulting from the expansion of any water subjected to heat.

3.10 The purpose for which the storage is used can vary, but this has only a minor effect on design. The range of uses is generally covered by the following:

a. cold water for drinking, washing and cooking;

b. cold water feed to hot water services;

c. treated cold water for laundries, heating, cooling, etc. when local supplies are unsuitable;

d. supplies to equipment or areas deemed to present a backflow contamination risk;

e. feed and expansion for heating service;

f. fire-fighting.

3.11 The water byelaws and BS 6700 specify minimum standards for cold water storage cisterns to ensure that the stored water is retained at a potable standard suitable for domestic use.

3.12 Guidelines on the prevention of legionnaires' disease (see SHTM 2040) must also be considered in relation to water storage.

3.13 In general terms, water storage should be designed such that stored water is regularly used and not allowed to stagnate. These aims would be realised by ensuring that the stored volume is no more than the volume of water used within the building on a daily basis. However, the storage capacity should be sized to cover a 12-hour interruption on the assumption that measures will be taken to minimise water usage during any prolonged disruption.

3.14 In the event of an interruption to the supply, staff should be informed of the need to economise on water use, so extending the duration of the stored supply.

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3.15 Storage cisterns should be located to minimise heat gains. To restrict microbiological growth it is important that the temperature of stored water is kept as low as practical, not more than 20°C.

Cold water distribution system

3.16 The design and installation of the cold water distribution system should comply with the water byelaws and BS 6700.

3.17 The design of the pipework should ensure that there is no possibility of a cross-connection between installations conveying potable water and installations containing non-potable water or water supplied from a private source. There should be no possibility of backflow towards the source of supply from any tank, cistern or appliance, whether by gravity backflow, back-pressure backflow or backsiphonage. A schematic drawing of a hot and cold water services distribution system can be found in Figure 1.

Hot water storage and distribution

3.18 Hot water services should be designed and installed in accordance with the water byelaws and BS 6700. The hot water system may be of either the vented or the unvented type.

3.19 The components of a hot and cold service system as used within hospitals are shown in Figure 1; some installations may have fewer, or additional, features or components.

3.20 A vented system usually consists of a cold water storage cistern situated above the highest outlets, which feeds a hot water storage vessel (for example a calorifier or direct-fired boiler).

3.21 An unvented system usually has the hot water storage vessel connected to the mains water supply via a pressure-reducing valve. The components of a directly-heated unvented hot water system are shown in Figure 2 .Refer to BS 7206: 1990, ‘Specification for Unvented hot water storage units and packages’.

3.22 The hot water taken from the top of the storage vessel will be circulated around the building in a piped distribution system. The individual outlets, taps, mixing valves or other outlet devices will be served from the distribution system.

3.23 Particular attention is drawn to the requirement to incorporate within the design, measures to ensure the water is retained in a wholesome condition. Guidance on the control of legionellae in healthcare premises is given in SHTM 2040. In order to ensure that the temperature of the water in the distribution system is within acceptable limits, a hot water secondary circulation will be required in which hot water is continuously circulated between the storage vessel and the various outlets. Alternatively, the

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distribution system may be electrically trace-heated to maintain the required temperature in the pipework.

3.24 Recommendations regarding safe hot water and surface temperatures, given in Scottish Health Guidance Note, 'Safe hot water and surface temperatures', apply to all ward accommodation, residents' rooms and those areas to which patients, residents and visitors have free access (including public areas). Until the recommended precautions are put into effect, staff should be made aware of the potential danger and should take the necessary steps to protect patients, residents and visitors. Areas which do not meet these recommendations should be identified and plans to comply as soon as reasonably practicable should be devised. Reference should also be made to the Model Engineering Specification (MES) DO8 Thermostatic Mixing Valves (Healthcare premises).

Materials of construction

3.25 Systems should be in accordance with BS 6700 and BS 6920 and materials used in hot and cold water distribution should be listed in the latest edition of the Water Fittings and Materials Directory, published by the WRc.

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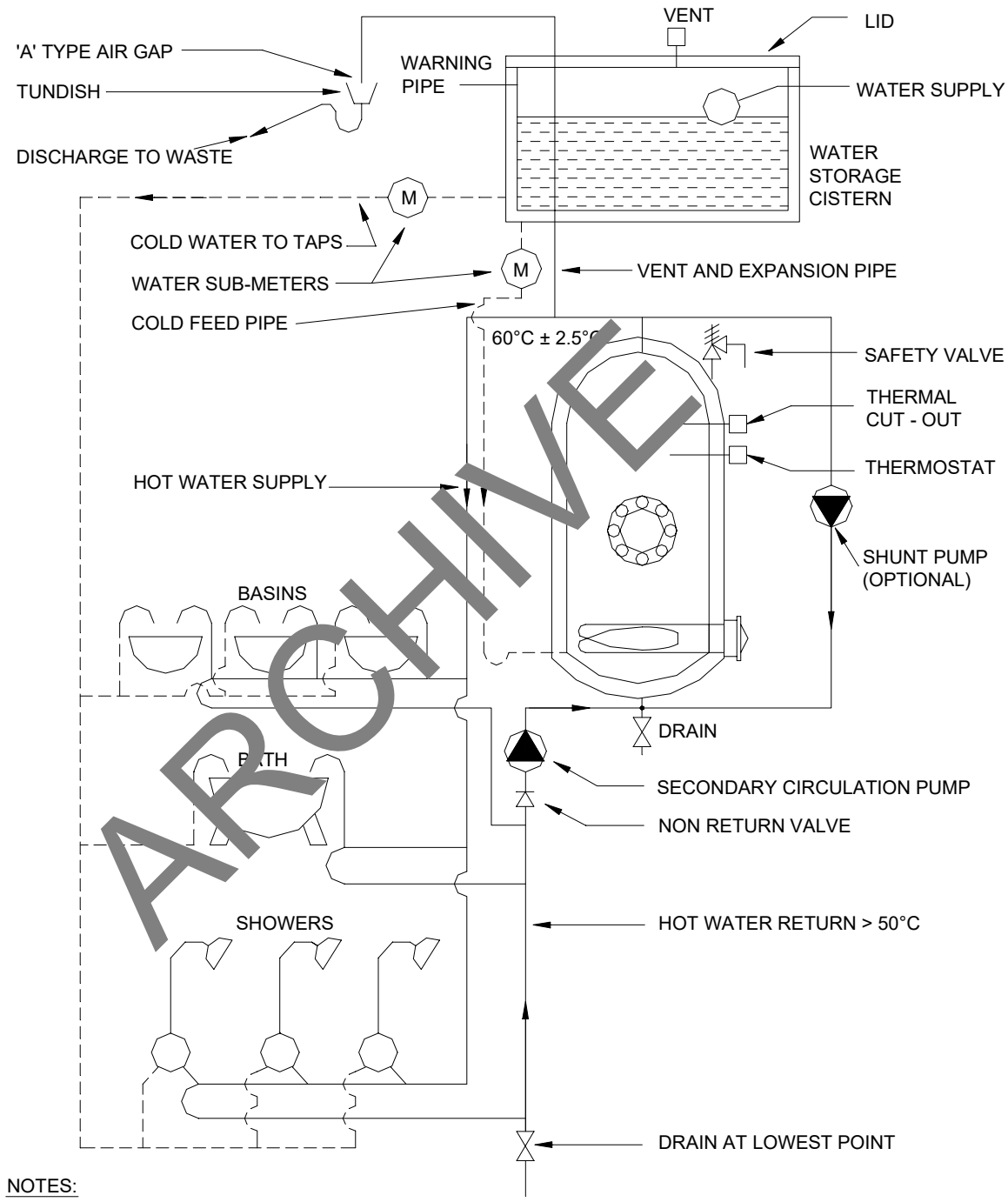
Figure 1: Schematic Hot and Cold Service Distribution



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NOTES:

1. ALL PIPEWORK TO BE INSULATED
2. ISOLATING AND CONTROL VALVES NOT SHOWN
3. ALL DRAINS SHOULD DISCHARGE TO WASTE VIA A TYPE 'A' AIR GAP

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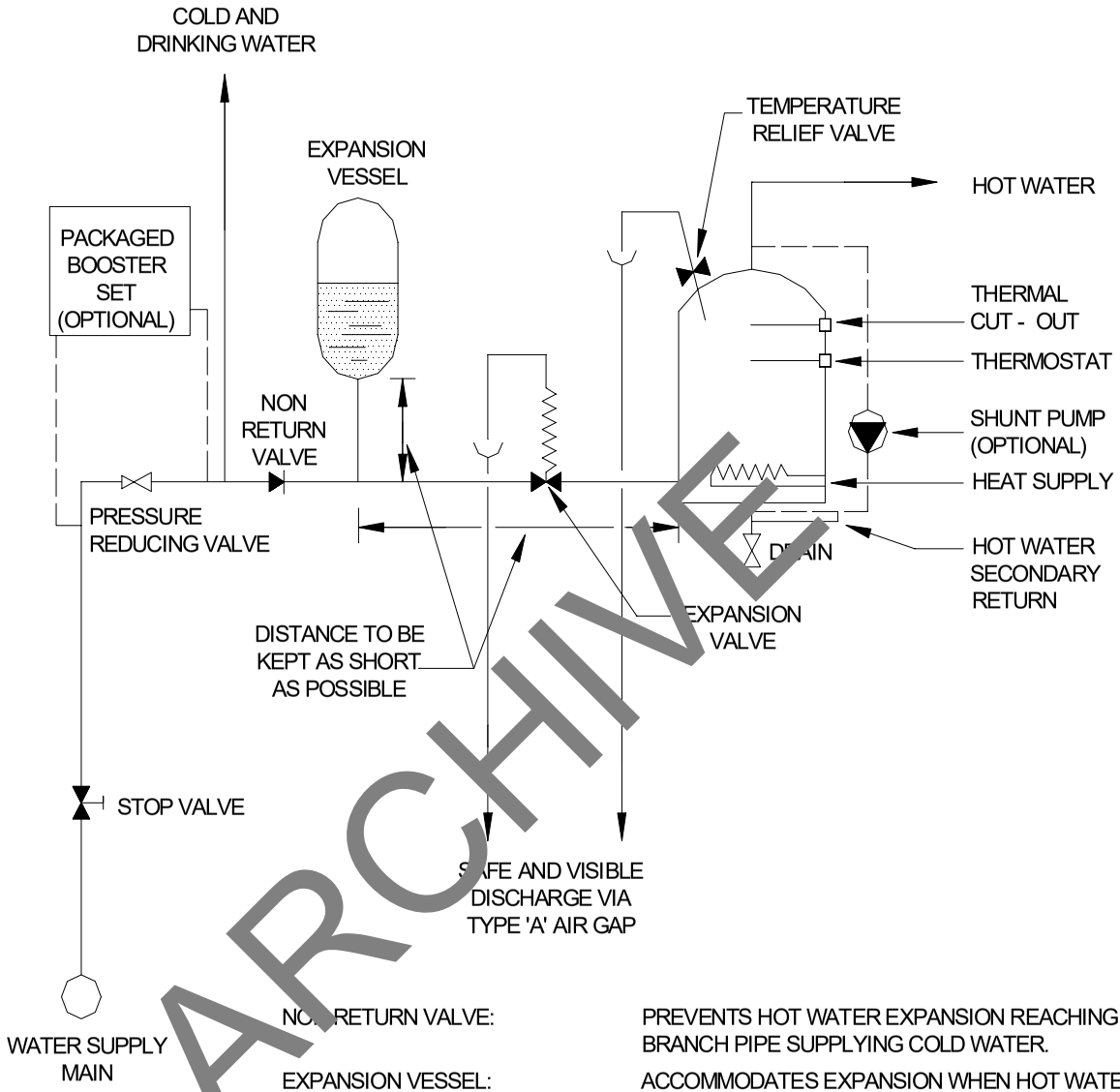
Figure 2: Directly Heated Unvented System



NON RETURN VALVE:	PREVENTS HOT WATER EXPANSION REACHING A BRANCH PIPE SUPPLYING COLD WATER.
EXPANSION VESSEL:	ACCOMMODATES EXPANSION WHEN HOT WATER IS HEATED UP FROM COLD.
EXPANSION VALVE:	DISCHARGES EXPANDED WATER UPON FAILURE OF THE EXPANSION VESSEL.
TEMPERATURE RELIEF VALVE:	USED AS A BACK-UP IN THE EVENT OF FAILURE OF BOTH THE THERMOSTAT AND THE THERMAL CUT-OFF.
THERMAL CUT-OFF:	CUTS OFF HEAT SOURCE AT A PREDETERMINED MAXIMUM TEMPERATURE.
THERMOSTAT:	CONTROLS THE TEMPERATURE OF STORED WATER AT 60°C ± 2°C.

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Validation and verification

3.26 Pre-commissioning, commissioning and testing are activities that must be carried out once the hot and cold water systems have been installed or repaired, to ensure that the systems comply with the specification before handover.

3.27 Commissioning involves setting a static system into motion and adjusting the system so that it operates within specified tolerances.

3.28 Testing involves the checking of pipework, plant, equipment and controls to ensure that they operate within specified limits of temperature, pressure etc.

3.29 Further information on this subject can be found in Part 4 ‘Validation and verification’ of this SHTM.

Operational management

3.30 Operating staff need to be provided with the necessary operation and maintenance manuals and record drawings for any new or refurbished hot and cold water systems, clearly identifying what actions must be carried out to ensure that the system will operate as intended throughout its working life.

3.31 Operation and maintenance manuals should be produced in accordance with established guidelines.

3.32 Further information on this subject can be found in Part 3 ‘Operational management’ of this SHTM.

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4. Management summary

General

4.1 The water supply, storage and distribution service should be periodically re-assessed by management and improved where necessary to ensure that it maintains an adequate water supply to the healthcare premises facilities.

4.2 Where new healthcare premises are to be built in separate phases, the water supply, storage and distribution service for the whole premises should as far as possible be planned and evaluated at the design stage. This will enable the total water supply requirement to be assessed in the planning stages, and appropriate areas of accommodation to be allocated.

4.3 Within this general guideline, the aim should be to keep water services as simple as practicable.

4.4 Where existing facilities do not meet the standards recommended in this SHTM, management should carry out a risk assessment which should involve the infection control team to establish the extent and priority of action required for compliance. Action must then be taken to meet standards recommended in this SHTM.

4.5 A procedure of routine checks to ensure a potable and adequate water supply is recommended in Part 2 'Operational management' of this SHTM. Managers should ensure that tests are done even if they cause minor disruption to hospital services.

Water management

4.6 A water management policy should be set up to define actions which should be taken to ensure that water is used economically and wastage is minimised. Such a policy should include the recommendations of the report of the Audit Commission for local authorities and the NHS entitled, 'Untapped Savings: Water Services in the NHS' and NHS Estates, 'A strategic guide to water and sewerage policy for general managers and chief executives'.

Energy management

4.7 An energy management policy should be set up to define actions which should be taken to minimise energy consumption. An effective maintenance plan will also contribute to minimising energy consumption. Further guidance is given in 'Encode' and 'A strategic guide to energy management for general managers and chief executives'.

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Maintenance

4.8 Management is ultimately responsible for the provision of a wholesome water supply in the premises under its authority. An effective maintenance policy will be instrumental in achieving this end.

4.9 Regulation 6 of the Provision and Use of Work Equipment Regulations 1998 requires that every employer shall ensure that work equipment is maintained in an efficient state, in efficient working order and in good repair. The employer's COSHH assessment should have identified maintenance, examination and control measures to reduce the risk from exposure to hazardous substances. Regulation 9 of COSHH requires those control measures to be implemented.

4.10 Planned maintenance can be divided into two distinct policies:

a. operate plant until failure occurs, where:
   (i) the consequences of failure will not create a safety hazard;
   (ii) the consequences of failure will not affect the business operation of the building occupants;
   (iii) the costs of repair/replacement are not excessive;
   (iv) the reaction to failure can be planned in advance;
b. preventative maintenance: this involves a series of inspections at regular intervals and monitoring operating parameters in order to avoid failure by implementing timely remedial work. Further information on this topic can be found in Technical Note TN14/92, 'Decisions in Maintenance' by the Building Services Research and Information Association (BSRIA).

Maintenance responsibility

4.11 Once a maintenance policy has been decided upon, a maintenance engineer must be given the responsibility for implementing it. Maintenance responsibilities include:

a. the provision of adequately trained and supervised manpower;
b. clear definitions of the equipment and services to be maintained, together with the procedures to be carried out on them;
c. monitoring of the quality of the work carried out to ensure that it is consistently acceptable;
d. the implementation of financial control procedures.

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Contract maintenance

4.12 The increasing complexity of building services equipment has resulted in a growing reliance on contractors for the provision of maintenance services. The decision to use either a contractor or direct labour must be taken in the light of local circumstances. BSRIA Application Guide 4/89 provides advice on aspects to be considered when obtaining contract maintenance. The guidance contained in PROCODE should also be implemented for the appointment of contractors.

Maintenance brief

4.13 The maintenance manager requires a brief from the management which sets out in a clear and unambiguous manner the following requirements:

a. scope of work;
b. budgeting – overall and single-item limits;
c. level of reliability;
d. response time required to correct faults;
e. criteria for quality of service;
f. reporting procedure;
g. accountability and responsibility;
h. energy-saving policy;
i. health and safety policy.

4.14 The above requirements are necessary regardless of whether the work is carried out by contractors or in-house staff.

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Performance monitoring

4.15 This involves the inspection of systems and records at a frequency, and in such detail, as to enable management to form an opinion regarding compliance with the agreed criteria.

4.16 If a contractor is commissioned to carry out maintenance and in-house expertise is not available to monitor their performance, an independent professional adviser should be retained to carry out this function. Using another maintenance contractor in a monitoring role could lead to a conflict of interest. An appropriate consultant may be appointed and reference should be made to PROCODE for such an appointment.

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4.17 A performance monitoring checklist follows:

a. Is the required level of service being met?
b. Is all the required plant being maintained?
c. Are environmental conditions being maintained?
d. Is maintenance carried out to the agreed standard?
e. Are proper replacement parts being used?
f. Are agreed spares being held on site?
g. Are records being correctly maintained?
h. Is the maintainer using the agreed standard of staff and number of staff, and making the agreed number of visits?
i. Is the plant being operated to achieve optimum energy usage?
j. Are health and safety requirements complied with?
k. Are only agreed sub-contractors being employed?
l. Are the client and typical users of the building satisfied?
m. Where maintenance is on a labour-plus-parts basis do invoices accurately reflect work carried out?
n. Are breakdowns occurring too often?
o. Is adequate consideration given to the potential environmental impact of contractors action, for example discharge of chlorinated water, discharge of water treatment chemicals either to river or sewerage systems?

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	Title	Publisher	Date	Notes
Acts and Regulations				
	The Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Electricity Act	HMSO	1989	
	Food Safety Act	HMSO	1990	
	Health and Safety at Work etc Act	HMSO	1974	
	Registered Establishments (Scotland) Act	HMSO	1998	
	The Water (Scotland) Act	HMSO	1980	
	Water Resources Act	HMSO	1991	
SI 2179 & 187	The Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	The Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd 1998)	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 1763	Food Safety (General Food Hygiene) Regulations	HMSO	1995	
SI 2200	Food Safety (Temperature Control) Regulations	HMSO	1995	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	

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Publication ID	Title	Publisher	Date	Notes
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 3139	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 574	Private Water Supplies (Scotland) Regulations	HMSO	1992	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 1550	Public Health (Notification of Infectious Diseases (Scotland) (Amendment)) Regulations	HMSO	1989	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 1333 (S129	Water Supply (Water Quality) (Scotland) (Amendment) Regulations	HMSO	1991	
SI 119 (S11)	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 864	**Capillary and compression tube fittings of copper and copper alloy**	BSI Standards		
BS 1212	**Float operator valves** **Part 1:** Specification for piston type float operated valves (copper alloy body) (excluding floats)	BSI Standards	1990	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 1710	**Specification and identification of pipelines**	BSI Standards	1984 (1991)	AMD 612 10/85
BS 2486	**Treatment of water for steam boilers and water heaters**	BSI Standards	1997	
BS 3505	**Specification for unplasticized polyvinyl chloride (PVC-U) pressure pipes for cold potable water**	BSI Standards	1986	AMD 6130, 11/88
BS 3506	**Specification for unplasticized PVC pipe industrial uses**	BSI Standards	1969	AMD 1152, 9/73; AMD 1777, 7/5
BS 5886	**Methods for field pressure testing of asbestos-cement pipelines**	BSI Standards	1980	
BS 6100	**Glossary of building and civil engineering terms**	BSI Standards		
	Section 2.7: Public Health Environmental Engineering		1992	
	Section 3.3: Sanitation		1992	
BS 6700	**Specification for design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages**	BSI Standards	1997	
BS 6920	**Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water**	BSI Standards		
BS 7206	**Specification for unvented hot water storage package and units**	BSI Standards	1990	
BS 7491	**Glass fibre reinforced plastic cisterns for cold water storage**	BSI Standards		
	Part 1: Specification for one-piece cisterns of capacity up to 500L		1991	AMD 7382, 12/92
	Part 2: Specification for one-piece cisterns of nominal capacity from 500L to 25000L		1992	
BS 7671	**The requirements for wiring installations** *(The IEE wiring regulations)*	BSI Standards	2001	16th edition
BS 8007	**Code of practice for design of concrete structures for retaining aqueous liquids**	BSI Standards	1987	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 1057	**Copper and copper alloys. Seamless, round copper tubes for water and gas in sanitary and heating applications**	BSI Standards	1996	
CP 312	**Code of practice for plastics pipework (thermoplastic material). Parts 1 to 3**	BSI Standards	1973	
CP 2010-2	**Code of practice for pipelines. Design and construction of steel pipelines in land**	BSI Standards	1970	
Scottish Health Technical Guidance				
SHTM 2005	Building management systems	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2023	Access and accommodation for engineering services	P&EFEx	2001	CD-ROM
SHTM 2040	The control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHGN	The Pressure Systems and Transportable Gas Containers Regulations 1989	P&EFEx	2001	CD-ROM
SHGN	'Safe' hot water and surface temperatures	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	HMSO		MEL 94/63
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	P&EFEx	2001	CD-ROM
SHTN 4	General Purposes Estates and Functions Model Safety Permit-to-Work Systems	EEF	1997	
	Strategic guide to water and sewerage policy for General Managers and Chief Executives	HMSO	1993	
Scottish Infection Manual	Guidance on core standards for the infection of hospitals, healthcare premises and at the community interface	HMSO	1998	
	NHS in Scotland – PROCODE	P&EFEx	2001	Version 1.1

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Publication ID	Title	Publisher	Date	Notes
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
UK Health Technical Guidance				
CP 312	Code of practice for plastic pipework (thermoplastic materials)		1973	
EH 40	HSE Occupational Exposure limits	HSE	Annual	
MES	Model Engineering Specifications	NHS Estates	1997	As required
	Strategic guide to water and sewerage policy for general managers and chief executives	NHS Estates	1993	
Chartered Institute of Building Service Engineers (CIBSE)				
	Environmental design; guide A	CIBSE	1999	
	Installation and equipment data; guide B	CIBSE	1986	
	Reference data; guide C	CIBSE	2001	(expected)
	Water distribution; commissioning code series W	CIBSE	1994	
TM 13	Minimising the risk of Legionnaires' disease	CIBSE	2000	
OOM	Guide to ownership, operation and maintenance of building services	CIBSE	2000	

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Miscellaneous References				
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	The microbiology of water: part 1	HMSO	1994	
	Untapped savings: water services in the NHS	HMSO	1993	
ISBN 0117530107	The bacteriological examination of water supplies: methods for the examination of waters and associated materials (Report 71)	HMSO	1982	
ISBN 0901144347	Chemical disinfection in hospitals	HMSO	1993	2nd edition
HS(G)70	The control of legionellosis including legionnaire's disease	HMSO	1993	
	Pre-commission cleaning of water systems	BSRIA	1991	
TN 14/92	Decisions in maintenance	BSRIA		
AG 2/93	Hejab, M. *Water treatment for building services systems application guide*	BSRIA	1993	
AG 1/87	Armstrong, J. H. *Operating and maintenance manuals for building services installations application guide*	BSRIA	1990	
AG 4/94	Guide to legionellosis – temperature measurements for hot and cold water services	BSRIA		
	Water supply byelaws guide	Water Research Centre	1989	
	Guidelines for drinking water quality: recommendations	WHO, HMSO	1993	
	Water fittings and materials directory	Water Research Centre		Published every 6 months
	Dadswell, J. V. *Hygiene for hydrotherapy pools*	Public Health Laboratory Service	1990	
	Water supplies and water consumption (engineering datasheet DY 1)	DHSS	1973	
	Water supplies: conservation (engineering datasheet DY 3)	DHSS	1973	
	The prevention or control of legionellosis (including legionnaires' disease): approved code of practice	HMSO	1991	

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Publication ID	Title	Publisher	Date	Notes
	Standards for commercial spas: installation, chemical and water treatment	Swimming Pool and Allied Trade Association	1989	
	Hygiene for hydrotherapy pools: report of a working party on hygiene for hydrotherapy pools	Hospital Infection Research Laboratories	1986	

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NHS National Services Scotland

Scottish Health Technical Memorandum 04-01: The control of *Legionella*, hygiene, 'safe' hot water, cold water and drinking water systems

Part A: Design, installation and testing

Health Facilities Scotland
Engineering and Environment

December 2008

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Preface

About Scottish Health Technical Memoranda

Engineering Scottish Health Technical Memoranda (SHTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of SHTM guidance remains on healthcare- specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle: Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Scottish Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to repeat unnecessarily international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Scottish Health Technical Memorandum guidance is the main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of nine subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

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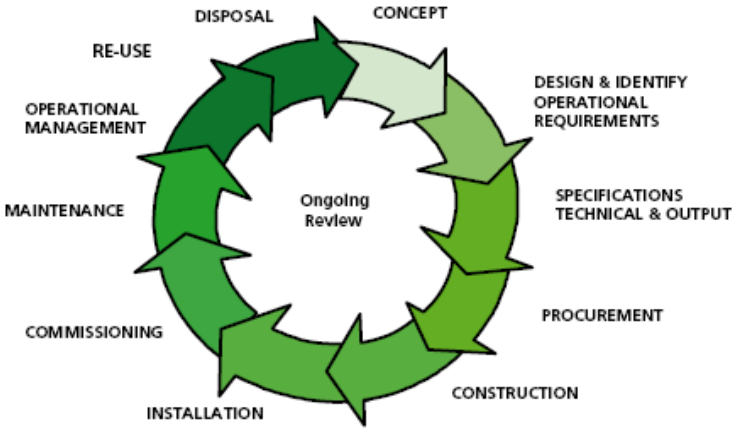

Healthcare building life-cycle diagram

Structure of the Scottish Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of nine core subjects:

Scottish Health Technical Memorandum 00 Policies and principles (applicable to all Scottish Health Technical Memoranda in this series)

Scottish Health Technical Memorandum 01 Decontamination

Scottish Health Technical Memorandum 02 Medical gases

Scottish Health Technical Memorandum 03 Heating and ventilation systems

Scottish Health Technical Memorandum 04 Water systems

Scottish Health Technical Memorandum 05 Reserved for future use

Scottish Health Technical Memorandum 06 Electrical services

Scottish Health Technical Memorandum 07 Environment and sustainability

Scottish Health Technical Memorandum 08 Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Scottish Health Technical Memorandum 06-02 Part A will represent:

Electrical safety guidance for low voltage systems

In a similar way Scottish Health Technical Memorandum 07-02 will simply represent:

Environment and Sustainability – EnCO_2de.

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All Scottish Health Technical Memoranda are supported by the initial document Scottish Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

Health Facilities Scotland wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.

Engineering guidance structure

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Executive summary

Preamble

Scottish Health Technical Memorandum (SHTM) 2027: – 'Hot and cold water supply, storage and mains services' and SHTM 2040: – 'The control of *Legionella* in healthcare premises: a code of practice' have both been revised, and have, at the same time, been combined into this single document: SHTM 04-01 – 'The control of *Legionella*, hygiene, 'safe' hot water, cold water and drinking water systems'.

The guidance has been revised in line with changes to relevant regulations, standards and other guidance, and also technical developments.

SHTM 04 now supersedes SHTM 2027 and SHTM 2040 and absorbs information from Scottish Hospital Technical Note 6 – 'The safe operation and maintenance of thermostatic mixing valves' and Scottish Health Guidance Note – 'Safe' hot water and surface temperatures.

Introduction

The development, construction, installation and maintenance of hot and cold water supply systems are vital for public health. Healthcare premises are dependent upon water to maintain hygiene and a comfortable environment for patients and staff, and for clinical and surgical care.

Interruptions in water supply can disrupt healthcare activities. The design of systems must ensure that sufficient reserve water storage is available to minimise the consequence of disruption, while at the same time ensuring an adequate turnover of water to prevent stagnation in storage vessels and distribution systems.

This Scottish Health Technical Memorandum gives comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the legal requirements, design applications, maintenance and operation of hot and cold water supply, storage and distribution systems in all types of healthcare premises. It is equally applicable to both existing and new sites whether procured conventionally (i.e. owned by the NHS) or via PFI/PPP funding. It is equally applicable to modifications and changes to existing premises and a risk assessment should be carried out to determine, highlight and record where it may not be reasonable or technically possible to implement the SHTM 04-01 guidance.

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Aims of this guidance

This guidance has been written to:

- provide an overview for developing and maintaining a risk register;
- provide information on thermostatic mixing valve configurations, usage and maintenance requirements;
- outline how quality and hygiene of water supply can preserve system components and safe use by occupants;
- provide a point of reference to legislation, standards and other guidance pertaining to water systems;
- provide a basic overview of possible bacterial contaminants;
- outline key criteria and system arrangements to help stop bacteria proliferating;
- give an overview of some of the different water systems components and their safe installation and operation;
- provide typical system layouts and individual component location;
- illustrate the importance of 'safe'delivery of hot water;
- illustrate temperature regimes for sanitary outlets used in healthcare premises to reduce risk of occupant injury;
- identify key commissioning, testing and maintenance requirements for referral by designers, installers, operators and management.

Recommendations

In healthcare facilities, there is a risk of scalding for vulnerable patients, the very young, older people and mental health patients. Therefore, this guidance strongly recommends that thermostatic mixing devices should be considered for many hot water outlets. It is stressed that staff should not be discriminated against and hot water outlets throughout for staff use should also be fitted with thermostatic mixing devices unless otherwise recorded in a risk register. Safe water and delivery devices are summarised as follows:

Area/Activity	Recommended temperature (°C)	Type of device (see MES D08 for explanation of valve types)
Staff bases, ward and consulting rooms etc basinsIn-patient, out-patient hand-wash basins	41	Type 3 Thermostatic
General areas to which patients and visitors may have access	41	Type 2 Thermostatic

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Area/Activity	Recommended temperature (°C)	Type of device (see MES D08 for explanation of valve types)
Paediatric baths	40 - to allow for the cold paediatric bath/sink NB: paediatric nurses should always use a thermometer	Type 3 Thermostatic
General baths	43	Type 3 Thermostatic
Showers	41	Type 3 Thermostatic
Assisted baths	46 - to allow for the cold mass of bath NB: Nurses should always use a thermometer before immersing patients	Type 3 Thermostatic
Hair-wash facilities	41	Type 3 Thermostatic
Bidets	38	Type 3 Thermostatic
All sinks, kitchens, pantries, slop sinks etc	55 - minimum required for food hygiene and decontamination purposes	Separate hot and cold taps or combination tap assembly Type 1; no preceding thermostatic device
Office, staff-only access areas hand-wash basins	43	Type 1

Hot water outlets provided for food hygiene and decontamination purposes should be provided with a notice ‘CAUTION – VERY HOT WATER’

It is preferable that thermostatic mixing devices are fitted directly to the mixed temperature outlet, or be integral with it, and be the method of temperature and flow control.

Because of the complexity of hot and cold water systems found in healthcare facilities and the responsibility of maintaining a temperature control regimen at all times, this guidance suggests that chemical and other water treatments that have been shown to be capable of controlling and monitoring *Legionella* may also be considered (for example chlorine dioxide or silver/copper ionisation)

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Note: As well as complying with the recommendations outlined in this document, the design and installation of the hot and cold water services, new or extended, in any NHS premises must also comply with the Water Byelaws 2000 (Scotland).

a. 1999, recommendations of the water suppliers in the Water Regulations Advisory Scheme's (WRAS) 'Water Regulations Guide', and any other requirements of the local water authority;

b. the Health and Safety Commission's Approved Code of Practice and guidance document 'Legionnaires' disease: the control of *Legionella* bacteria in water systems' (commonly known as L8), which requires that there must be a written scheme in place in respect of controlling *Legionella* in water systems.

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1. Introduction

Preamble

1.1 Scottish Health Technical Memorandum (SHTM) 2027: – 'Hot and cold water supply, storage and mains services' and SHTM 2040: – 'The control of *Legionella* in healthcare premises: a code of practice' (NHSScotland Property and Environment Forum, 1999) have both been revised, and have, at the same time, been combined into this single document: Scottish Health Technical Memorandum 04-01 – 'The control of *Legionella*, hygiene, 'safe' hot water, cold water and drinking water systems'. The guidance has been revised in line with changes to relevant regulations, standards and other guidance and also technical developments and absorbs information from Scottish Hospital Technical Note 6 – 'The safe operation and maintenance of thermostatic mixing valves and Scottish Health Guidance Note – 'Safe' hot water and surface temperatures'.

1.2 Scottish Health Technical Memorandum 04 now supersedes Scottish Health Technical Memorandum 2027 and Scottish Health Technical Memorandum 2040, and absorbs information from Scottish Hospital Technical Note 6 and Scottish Guidance Note regarding 'Safe' hot water and surface temperature.

1.3 This Scottish Health Technical Memorandum gives comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the legal requirements, design applications, maintenance and operation of hot and cold water supply, storage and distribution systems in all types of healthcare premises. It is equally applicable to both new and existing sites.

1.4 In its new form, the document is divided in two parts. This part (Part A) outlines the principles involved in the design, installation and testing of the hot and cold water supply, storage and distribution systems for healthcare premises. Some variation may be necessary to meet the differing requirements for the water authority (see Note 1); Part B covers operational management.

General

1.5 Current statutory legislation requires both 'management' and 'staff' to be aware of their individual and collective responsibility for the provision of wholesome, safe hot and cold water supplies, and storage and distribution systems in healthcare premises. This applies whether premises are NHS owned or procured via PFI/PPP and operated by Consortia Facilities Management staff or subcontractors.

1.6 Premises used for the delivery of healthcare are dependent upon water to maintain hygiene through a safe and comfortable risk assessed environment for all who may interface and support functional care delivery.

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1.7 The development, construction, installation and maintenance of hot and cold water supply systems are vital for public health.

1.8 Interruptions in water supply can disrupt healthcare activities. The design of systems must ensure that sufficient reserve water storage is available to minimise the consequence of disruption, while at the same time ensuring an adequate turnover of water to prevent stagnation in storage vessels and distribution systems.

1.9 Measures to control the spread of micro organisms in healthcare premises include the regular use of alcohol-based hand-rubs, and this can result in a significant reduction in the use of hand-wash basins. Under-use of taps encourages colonisation with *Legionella* and other micro organisms. Designers should be aware of this and, accordingly, consider how local infection policies with regard to hand hygiene and the use of alcohol-based hand-rubs might impact on the frequency of use of hand-wash basins (see also paragraphs 5.7–5.12 in Part B on the extent of utilisation).

Legislation, standards and guidance

1.10 As well as complying with the recommendations outlined in this document, the design and installation of the hot and cold water services, new or extended, in any NHS premises should also comply with:

a. the Water Byelaws 2000 (Scotland), recommendations of the water suppliers in the Water Regulations Advisory Scheme's (WRAS) 'Water Regulations Guide', and any other requirements of the local water supply authority (see Note 1);

b. the Health and Safety Commission's Approved Code of Practice and guidance document L8, which requires that there must be a written scheme in place in respect of controlling *Legionella* in water systems.

Note 1: since April 2008 this has been the private water supplier, following deregulation.

Note 2: The Water Byelaws 2000 (Scotland) are set out, along with the Department for Environmental, Food and Rural Affairs (DEFRA's) (1999) guidance (see References) and with the water industry's interpretation of these provisions, in the WRAS 'Water Regulations Guide'. The WRAS is funded by the water suppliers to provide advice on the Water Byelaws 2000 (Scotland) on a national basis. WRAS also administers the WRAS "approval scheme" that assesses and lists water fittings and materials for compliance with the Regulations. The 'Water Fittings and Materials Directory' contains information on suitable fittings and materials and is updated every six months.

1.11 Designers and installers of hot and cold water distribution systems are required by the Water Byelaws (Scotland) 2000 to notify the water supply authority of any proposed installation of water fittings and to have the water supply authority consent before installation commences. It is a criminal offence to install or use

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water fittings without their prior consent. Liaison with the local water supply authority is strongly recommended at an early stage to avoid problems of compliance in the design.

1.12 All materials used in the construction of systems referred to in this SHTM must comply with the requirements of the Water Byelaws (Scotland) 2000(Regulation 4: "Requirements for water fittings") and be in accordance with relevant British Standards and codes of practice. All materials in contact with wholesome water supplies must be listed in the 'Water Fittings and Materials Directory'.

1.13 Water quality is governed by the Water Supply (Water Fittings) Regulations 1999, building regulations, approved codes of practice and technical standards intended to safeguard quality.

Model Engineering Specification

1.14 Model Engineering Specification C07, which is a procurement specification, supports this SHTM and provides details of the extent of the work required.

Exclusions

1.15 Although many of this SHTM's recommendations will be applicable, it does not set out to cover water supply for fire-fighting services nor water supply for industrial or other specialist purposes, other than to indicate precautions that should be taken when these are used in association with "domestic" water services. The point at which a "domestic" activity becomes an industrial process, for example in food preparation, has not been defined, and the applicability will need to be considered in each case.

1.16 This SHTM does not cover wet cooling systems such as cooling towers. Guidance on these systems is given in the Health & Safety Commission's Approved Code of Practice and guidance document L8.

1.17 While some guidance on other water-service applications is included, it is not intended to cover them fully. i.e:

- for sterile services departments, see SHPN 13: – 'Decontamination';
- for hydrotherapy pools, see the Public Health Laboratory Service's 'Hygiene for hydrotherapy pools';
- for spa pools, see the Public Health Laboratory Service's 'Hygiene for spa pools: guidelines for their safe operation. The report of a PHLS spa pools working party'.

Definitions

1.18 Definition of terms is as those contained in the Water Byelaws (2000).

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The water industry

Water supply

In Scotland, the various water supply authorities were not 'privatised' as in England. The various regional authorities were combined into a single entity 'Scottish Water', remaining in the public sector and hereinafter referred to as 'the water supply authority' (see Note 1).

Regulatory authorities

The Water Act 1989 provided for the establishment of several regulatory bodies whose functions are now set out in the Water Industry Act 1991 and the Water Resources Act 1991 and are summarised below:

a. the Office of Water Services (OFWAT), which regulates the prices set by the water companies, oversees the standards of service provision and protects the interests of water consumers. OFWAT also has ten regional Water-Voice committees that identify customer concerns, pursue them with the companies and report to the director-general of water services;

b. the Environment Agency (EA) regulates the quality and controls pollution of "controlled" waters (that is, most inland and coastal waters) and protects the water resources in England and Wales;

c. the Drinking Water Quality Regulator (DWR) regulates the quality of supply of drinking water.

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2. Source of supply

General

2.1 Normally, the source of water supply to healthcare premises is by one or more service pipe connections from the mains of the water supply authority (see Note 1). If the quantity and rate of flow is inadequate, or if the cost of providing the service connection appears to be uneconomical, alternative sources of supply such as boreholes or wells may be investigated.

2.2 Where the constraint is only that of inadequacy of the water authority's (see Note 1) supply, the healthcare building needs could be met by using a private supply as an additional source to the water authority's supply. In such cases, the water authority's supply should be the priority supply for drinking, culinary and special hygienic services. By limiting the use of the private supply to services not requiring the highest level of hygiene, the extent of treatment of the private supply may be reduced. Private supplies used in this way must convey water through a separate pipework system that is clearly labelled. Outlets served by the private supply system should also be appropriately labelled.

2.3 Provision should be included for alternative water supply arrangements to meet an emergency, regardless of the source or sources of supply finally adopted. Alternative arrangements would include a second service connection from the water authority (see Note 1); or a private supply. In either case the alternative supply should not be vulnerable to the cause of loss of the original supply. Direct physical interconnection of pipework and valves of a water authority's supply with any private supply without adequate backflow protection is prohibited by the Water Supply (Water Fittings) Regulations 1999. The water quality requirements applicable to the main supply apply also to any alternative supplies.

2.4 The water authority (see Note 1); must be advised if it is proposed to use any private supply as well as the water authority's supply, and advice should be sought on the limitations imposed in respect of break cisterns and interconnection thereafter as required by the Water Supply (Water Fittings) Regulations 1999.

2.5 In Scotland all water intended for human consumption is required by legislation to comply with the quality standards laid down by the Drinking Water Quality Regulator with powers as laid down in Section 7 of the Water Industry (Scotland) Act 2002. They can force the statutory water authority (see Note 1); to comply with the standards set out in the Water Supply (Water Quality) (Scotland) Regulations 2000. These regulations apply to water sampled at the point where the water is available for use and also embrace water used in the preparation of food and beverages.

2.6 The responsibility for enforcing this legislation for public water supplies rests primarily with the Drinking Water Regulator and the statutory water authority

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(see Note 1) and the legislation also covers private water supplies. In respect of public water supplies, the statutory water authority has a duty to provide a wholesome supply and to demonstrate – by monitoring – that the supplies meet the standards required.

Supplies from a water supply authority

2.7 The following factors should be taken into consideration in the initial stages of the design:

- the water supply authority's requirements;
- the estimated daily consumption, and the maximum and average flows required, together with the estimated time of peak flow;
- the location of the available supply;
- the quality, quantity and pressure required;
- the cold water storage capacity required;
- the likelihood of ground subsidence due to mining activities or any other reason;
- the likelihood of there being any contaminated land on site;
- the proposed method of storage and probable number and purpose of direct connections to pressure mains;
- the minimum and maximum pressures available at the service connection;
- details of the physical, chemical and microbiological characteristics of the water supply and scope of any possible variations in such characteristics;
- the possibility of an alternative service connection from some other part of the water authority's network, including pressure details;
- the water authority's (see Note 1) contingency plan in the event of no water supply for whatever reason.

Note: Regulations require notification to the water supply authority of any proposed changes and additions to the water supply system in the premises.

2.8 These initial design investigations should normally reveal the need for any further treatment, pressurisation and storage of the water authority's (see Note 1) supply to meet healthcare building requirements and enable an estimate of costs to be made.

2.9 BS 6700:1997 and BS EN 806-2:2005 give further guidance on the procedures that should be followed when carrying out preliminary investigations in relation to new water supplies.

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2.10 During the design stage, close collaboration with the water supply authority should be maintained, and consent must be sought on the final arrangements before proceeding with the installation. These arrangements should include:

- siting of service connection, access chamber, metering, bypassing, flushing out, physical security of service connection, installation and provisions for the fire-fighting service;
- compliance with the Water Supply (Water Fittings) Regulations 1999.

Private supplies

2.11 Private supplies independent of the statutory water authority (see Note 1); are also governed by the Water Supply (Water Quality) (Scotland) Regulations 2000. A license is required from the Scottish Environment Protection Agency (SEPA) before embarking on any private water supply scheme. If, for any reasons of back-up or security of supply, there is a connection to the public supply (regardless of whether, or how often, it is used), the installations must comply with the Water Supply (Water Fittings) Regulations 1999. Private supplies should be registered with the statutory water authority that has the responsibility to monitor the wholesomeness of the supplies where these are used for domestic or food production purposes.

2.12 The standards for private water supply quality are very similar to those for public supplies. Reference should also be made to the Standing Committee of Analysts' (2002) 'The microbiology of drinking water'.

2.13 SEPA keeps records and maps of all known sources of private water supply together with details of the geological strata and water-bearing characteristics of the area under its control.

2.14 The feasibility of such a private supply should be decided by comparing the capital costs (of the construction of works, including mains, pumping plant, treatment plant etc) and revenue costs (of electricity for pumping, water treatment chemicals, direct and indirect maintenance and associated management costs, regular water analysis tests etc) with the long-term cost of water supply from the water authority over the predicted life-cycle of the installation. Due consideration should be given to the long-term costs of a private supply, and account should be taken of potential deterioration in water quality and/or capacity of the private supply source.

2.15 Where consideration is being given to the use of a private supply, specialist assistance should be sought to:

- confirm the long-term availability of water in sufficient quantity, which is either of proper quality or suitable for treatment;
- confirm the long-term quality of water and define requirements for water treatment;
- design and specify the works needed;

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- carry out a full evaluation of the costs and practicability of a private supply compared to a connection from the water supply authority.

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3. Water treatment regimens

3.1 Provided water is supplied from the public mains and its quality is preserved by correct design, installation and maintenance, it can be regarded as microbiologically acceptable for use. It is exceptional, however, for a water supply, either public or private, that is wholly 'potable' to be entirely free from aquatic organisms, and consequently it is important that appropriate measures are taken to guard against conditions that may encourage microbial multiplication.

3.2 Reasons for treatment of water from the supply authority in healthcare premises would be for processing for laundries, domestic hot water systems and steam boiler feed water, where either the degree of hardness proves excessive or exceptional softness causes corrosion. Most private supplies, however, are likely to require some measure of treatment, and in many cases, the installation of pumping and treatment plant needs to be extensive to ensure a constant acceptable quality.

3.3 Treatment systems that are used in conjunction with potable water systems should be selected with care. Addition of any substance must not cause a breach of any requirements in the Water Supply (Water Quality) Regulations 2000. Any substance should be approved in accordance with those Regulations, for example, by being in the Drinking Water Quality Regulators list of approved substances for contact with drinking water, which is included as an appendix in the 'Water Fittings and Materials Directory'.

3.4 Automatic water treatment systems should be fail - safe and have sufficient instrumentation to monitor their operation. The water supply connections to the equipment must be adequately protected against backflow. Monitoring by means of building management systems should be considered.

3.5 In healthcare premises, both hot and cold water are considered to be potable and therefore water treatment supplied to healthcare premises must comply with current legislation on water quality.

3.6 Further details can be found in BSRIA's Application Guide AG 2/93: 'Water treatment for building services systems' (with amendments) and SHTN 2: 'Domestic hot and cold water systems for Scottish health care premises'.

3.7 The continuous chlorination of hot and cold water service systems, after initial disinfection (see section 17), to control the growth of *Legionella* is not recommended because chlorine has a limited ability to penetrate biofilm and inactivate sessile micro organisms.

3.8 Treatment using chlorine dioxide or copper/silver ionisation can be used (see section 15).

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4. Water softening

4.1 Hard waters are unsuitable for many industrial and domestic purposes. Treatment may therefore be necessary to remove or alter the constituents to render the water suitable for particular purposes.

4.2 Hardness is due to calcium and magnesium salts in the water and is expressed in terms of milligrams per litre as calcium carbonate (CaCO3). Temporary (carbonate) hardness is related to the bicarbonate salts of calcium and magnesium. Permanent (non- carbonate) hardness is related to the other salts of calcium and magnesium, that is chlorides, sulphates, nitrates etc. The generally accepted classification of waters is shown in Table 1.

Description	Milligrams per litre (mg/L as $CaCO_3$)
Soft	0 to 50
Moderately soft	50 to 100
Slightly hard	100 to 150
Moderately hard	150 to 200
Hard	200 to 300
Very Hard	Over 300

Table 1: Classification of water hardness

4.3 When the temperature of water is raised, the hardness will be reduced by some of the dissolved salts (temporary hardness) coming out of solution and forming solids in suspension, some of which will be deposited on heating surfaces to form an adherent lime scale, thus reducing the heat transfer rate.

4.4 The extent of treatment required to prevent scale formation will depend upon the process for which the water is being heated; it may therefore be necessary to achieve one of the following conditions:

- replacement of calcium and magnesium salts by their more soluble sodium equivalents;
- removal of all salts, that is, demineralization;
- Where water of greater purity is required for specialized uses, it can be produced from softened water by reverse osmosis or by demineralization.

4.5 Softening is not considered necessary for palatability. In some instances the softening process makes the water less pleasant to taste without affecting the potability.

4.6 Epidemiological studies have shown that the incidence of cardiovascular disease tends to be higher in areas with soft water supplies than in areas with

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hard water supplies. The association is clearest where the soft water supplies contain hardness below about 150 mg/L (as CaCO3).

The explanation is not known, but it is considered prudent, where possible, not to drink water that has been artificially softened to concentrations lower than this. Softened water may also tend to dissolve metals from pipes. Water softeners containing ion-exchange resins may be subject to bacterial contamination if not adequately maintained. Softeners using salt-regenerated ion- exchange resins increase the sodium content of the water during softening, and this may be undesirable for children and anyone on strict salt-restricted diets. These concerns can be avoided if water intended for drinking and cooking is not softened.

4.7 Waters having a hardness of up to 400 mg/L have been used for public supplies without preliminary softening. While it is accepted that supplies for domestic purposes need not be softened, partial softening may be carried out by the water supply authority (see Note 1).

4.8 The need for softened water in hospitals for domestic purposes other than drinking and cooking should be considered on the merits of each case; if treatment is considered essential, the extent of softening should be the minimum to achieve an acceptable level. A generally acceptable level is between 80 and 150 mg/L, and not less than 60 mg/L, but this should not be taken as a requirement for hospitals as it may be impracticable to achieve. The cost and difficulties of treatment may be prohibitive for certain waters if the hardness value is particularly high and the content of magnesium is appreciable.

4.9 Generally, within healthcare premises, softening of a hard water supply will be required on feeds to the following:

- boilers and hot water supply systems – to prevent sludge and lime scale building up in pipework and plant (see BS 2486:1997);
- mixing devices and blending valves – to avoid clogging of control ports and showerheads by lime scale;
- laundries – high maintenance costs and the uneconomic uses of soap or detergents are caused by the presence of hardness.

Note: Problems often occur in thermostatic mixing valves whereby scale is deposited as a result of hard cold water being heated in the blending process**.**

4.10 The most common water-softening process used for the protection of hot water calorifiers is base-exchange softening. This process removes permanent and temporary hardness from water. The technique uses an ion-exchange process in which the calcium and magnesium ions in solution are removed and replaced by an equivalent number of sodium ions. This method of water softening is not recommended for drinking water or water for culinary use, since a raised level of sodium is associated with heart disease.

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4.11 Other water softening methods include physical water conditioning and magnetic water conditioning. Physical water conditioners function by triggering the growth of nuclei or seed crystals in the water. When the water is heated or subjected to pressure change, dissolved salts precipitate onto these seeds to form crystals, which do not adhere to the sides of the pipes and are washed out with the flow. Some hard scale will still form, but it will be dissolved provided sufficient seeds are created. The main problem is to ensure an adequate supply of the seed crystals, which have a relatively short life before they are absorbed back into the water. The efficacy of these water-conditioning measures needs to be considered.

4.12 For further details on processes which control scale formation in hot water services systems, refer to BSRIA's Application Guide AG 2/93: 'Water treatment for building services'.

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5. Filtration

General

5.1 Examinations of domestic water systems in a number of Scottish Hospitals where water had been supplied under the chlorine water supply regime, in a number of Scottish hospitals have revealed significant deposits of sediment and debris in pipework. Such deposits can provide an environment conducive to the development of bacteria as well as biofilms. Filtration may be required to:

- ensure that the domestic water supply and associated pipework is maintained at a high standard of cleanliness throughout the system;
- reduce the accumulation of sediments and biofilms that may promote the growth of water- borne organisms. Subsequent examinations of domestic water systems in a number of Scottish healthcare premises following a change to a chloramine regime have revealed significant improvement in water quality in that minimal deposits of sediment and debris were found in pipework and storage tanks.

5.2 Filtration need not be provided for cold water for non-domestic use, for example fire-fighting, boiler-feed or other chemically treated or dosed systems unless there is a significant and regular suspended solid carry over from the public water supply.

Description

5.3 Filtration is normally used to prevent ingress of suspended solids into plant and pipework, and as such may be defined as the process of separating solids from liquids using a porous medium. The medium can consist of granular materials (sand, clay, carbon etc) assisted by chemical and/or bacterial activity, woven meshes and screens made of metals, fabrics, ceramics and polymeric membranes.

5.4 Filtration plant is usually specified by various criteria including minimum particle size retained, expressed in microns (µm). ‘Absolute filtration’ of a given size indicates that the plant can remove 99.9% of all particles above a given size. ‘Nominal filtration’ is normally taken to mean that 95% of all particles above a specified size will be removed.

5.5 As a guide, suspended materials are normally classified according to Table 2.

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Material	Particle diameter	
	mm	pm
Pebbles	>10	-
Gravel	10 - 2	-
Very coarse sand	2 - 1	-
Coarse sand	1 - 0.5	1000 - 500
Medium sand	0.50 - 0.25	500 - 250
Fine sand	0.25 - 0.10	250 - 100
Silt	0.10 - 0.01	100 - 10
Clay	<0.01	<10
Colloid	10-4 - 10-6	0.1 - 0.001

Table 2: Particle size

5.6 In practice, water will contain a range of sizes of suspended particulates. The rate of blockage by suspended solids for any given filter will depend on a number of factors such as:

- throughput;
- concentration of suspended solids and other fouling debris;
- size distribution;
- shape of particles.

5.7 Particles less than 0.1 µm are invisible microscopically. The smallest visible macroparticle is approximately 40 µm. Particles less than 0.001 µm are considered dissolved and in solution.

Capacity

5.8 To accommodate the variation in flow, and to allow for filter changes etc, the equipment should be installed in association with a storage cistern.

Design features

5.9 The level of filtration where thermoplastic pipework systems are installed should be 5 µm absolute.

5.10 The level of filtration where stainless steel pipework systems are installed should be 0.5 µm absolute. If the stainless pipework manufacturer is prepared to give a guarantee offering a lifespan of the installation that is not less that in CIBSE “Guide to ownership, operation and maintenance of building services”, the level of filtration can be relaxed to 5.0 microns.

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5.11 For small establishments (those with fewer than 100 beds and all other small premises such as health centres and clinics), it will normally be appropriate to use strainer filters with cartridge or membrane elements (see also paragraph 5.16).

5.12 In larger establishments (those with more than 100 beds), the filtration equipment plant should be fully automatic in operation and include self - cleaning and back-washing modes so that the filter medium does not become a reservoir for organisms capable of contaminating the service pipework. To allow for servicing of the plant, a bypass line with strainer filter should be provided, complete with isolation valves and non-return valves. The bypass should be provided with drains and vents to facilitate disinfection prior to bringing it into service.

5.13 As an alternative to the installation of a bypass strainer, the provision of two units to operate sequentially with automatic changeover on a regular basis will minimise potential failures and maintenance. Precautions should be taken to minimise stagnation of water in the dead-legs that may occur with this arrangement – weekly flushing of dead-legs should take place.

5.14 All items in contact with water must be of materials that comply with the Water Byelaws (Scotland) 2000(for example, materials approved by the Water Regulations Advisory Scheme and listed in the WRAS 'Water Fittings and Materials Directory', having been assessed and shown not to have adverse effects on water quality).

5.15 Parameters essential for the continued performance of the plant should be automatically monitored, for example downstream pressures and automatic cycling of back-washing facilities. These should be relayed to a building management system.

Point-of-use filtration

5.16 Point-of-use filters have been found to provide protection from exposure to *Legionella* by preventing the dispersal of the bacterium from showers and other water outlets. To be effective, the filter membrane needs to have a nominal pore size of no greater than 0.2 µm. Before their use is contemplated, two factors should be considered. First, the filters do not eradicate the organism, but prevent discharge to the environment from the filtered outlet only; secondly, by retaining the organism within the pipework, it may be possible for the organisms to multiply and regressively 'seed' other parts of the distribution system. Filters will also need to be changed routinely, depending on usage of the outlets. Their use, therefore, should be considered only as part of an overall regimen of *Legionella* control to be used where the most vulnerable patients are to be treated. Continuous long-term use of point-of-use filters is not recommended, except where there is no effective alternative.

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6. Metal contamination

6.1 Copper piping is no longer routinely specified for Scottish hospitals (Scottish Hospital Technical Note 2 refers) and the following section applies to existing installations where extensions are being provided retaining the existing specification or to very small, stand-alone facilities, or to temporary accommodation with a short life-span.

6.2 Analytical results have shown that there can be a serious problem from lead contamination of water supplies. The Water Supply (Water Quality) Regulations 2000 set an upper concentration for lead in drinking water of 0.01 mg/L to be achieved by 2013. This value is likely to be exceeded if lead pipes are present or if copper pipes have been joined with solder containing lead. In general, if hospital drinking water contains more than 0.01 mg/L of lead, remedial action should be taken. The use of lead solder is prohibited on all plumbing installations where water is required to be wholesome.

6.3 Copper concentrations above 1 mg/L may cause staining of laundry and sanitaryware and increase the corrosion of galvanised iron and steel fittings. Whilst the maximum allowable copper concentration in drinking water is 2 mg/L, most supplies will give a level at the tap of less than 1 mg/L.

6.4 Water supplies to certain specialist units such as maternity, neo-natal paediatric, general paediatric and renal dialysis units (see the Renal Association, 2002) should be monitored to ensure that water quality is within acceptable limits. The designer should seek epidemiological advice to ascertain the exact water quality requirements for specialist units.

6.5 Where the water supply is known to dissolve metals (that is, soft water), regular sampling should be carried out at strategic sampling points to ascertain that the level of metal contamination in the water supply to the premises, plus any added during its passage through the distribution system, does not result in limits above the stated safe levels. This will especially apply if the distribution pipework includes a multiplicity of leaded solder capillary joints. In soft water areas, metal contamination can occur by simple dissolution. Pitting corrosion arising in hard water areas, as a result of deleterious carbonaceous films laid down during the manufacturing process, does not normally give rise to elevated copper levels in the water and is not nowadays a problem if independently certified tubes to BS EN 1057:1996 are used. Excessive use of acidic flux in the making of capillary joints can lead to corrosion of copper plumbing, especially if the system is allowed to stagnate after commissioning. WRAS Information and Guidance Note 9-04-02: ‘Solder and fluxes’ (available on its website http://www.wras.co.uk) gives further information on solders and fluxes.

6.6 If the proposed water supply is likely to take up metals in excess of acceptable limits, it will be necessary to consider treatment of the water such as raising hardness.

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7. Water storage

General

7.1 Where there is an interval of time between final testing and commissioning of domestic hot and cold water systems, the systems should be drained dry until put into use. This will include storage, where provided. The design and installation of the system must be such as to facilitate effective draining.

Water is stored in healthcare premises for the following reasons:

- to provide a reserve supply during failure of the main cold water supply;
- to reduce the maximum demand on the cold water main;
- to provide accommodation for the expansion of any water subjected to heat, that is, hot water and heating services;
- to reduce the pressure from that of the distribution system.

7.2 The purpose for which the storage is used can vary, but has only a minor effect on its design. The following generally covers the range of uses:

- cold water services, domestic, laundry etc;
- cold water feed to hot water services;
- drinking water supplies;
- treated cold water for laundries, heating etc when local supplies are unsuitable;
- break tanks on cold water supplies serving points of use where backflow is, or is likely to be, harmful to health due to a substance representing a serious hazard, for example, supplies to pathology laboratories;
- feed and expansion for heating service;
- fire-fighting.

Extent of storage

7.3 There is a conflict between the water supply authority's desire to have 24 hours water storage and the requirements of HSE L8 which recommends 12 hours, the latter being intended to maximise turnover and avoid stagnation of stored water. The requirements of each individual project require to be risk assessed and discussed with the water supply authority at the earliest possible design stage. Storage should be designed to minimise residence time in the cistern and maximise turnover of water to avoid stagnation and deterioration of water quality. Storage volume should be calculated on the basis of peak demand and the rate of make-up from source of supply. There may be more than one peak

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period in each 24 hours. The interval between peak periods is important as it affects the storage capacity based on the make-up flow. It also determines the available time for maintenance if twin cisterns are not installed.

7.4 Appendix 1 is based on the results of studies into water consumption in various types and sizes of hospitals. CIBSE's Guide G: 'Public health engineering' gives further guidance on sizing cold water storage. While it is accepted that the desirable minimum for total storage will vary with the classification of the particular health building, the upper limit of storage for a district general hospital is 900 L per bed per day and for a teaching hospital 1350 L per bed per day, excluding provision for the staff residences, laundries and any special storage for fire-fighting purposes.

7.5 It must be borne in mind that the overall pattern of healthcare is changing and the data available now is a best estimate of what is required. The guidance in Appendix 1 is known to overestimate water usage in healthcare premises and, moreover, yields data in litres per second. Reference should be made to SHTN 2: 'Domestic hot and cold water systems for Scottish health care premises'. (As an example, a hospital of between 400 and 600 beds might consume 100,000 m^3 of water annually, that is, about 11 m^3/h over a 24-hour period. Peak hourly demand, however, may reach 50 m^3/h.)

7.6 A summation of the average daily consumption for each ward unit contained in a building should be made. From the requirements of each building, the policy of water storage for the whole complex should be decided. It does not always follow that peak demands for each building will coincide, and therefore there may be scope for applying a diversity factor to the whole site.

7.7 Where the water requirement is to be met from a private supply, the summation for each building may require assessment on the basis of storing and using water according to the minimum treatment of the water for each particular use. Likewise, where the water is hard enough to require softening for certain domestic and/or laundry purposes, separate storage will be required, and this should be taken into account when assessing the total stored water.

7.8 Appendix 1 does not cater for water requirements for staff quarters or such support services as laundries, bulk stores and workshops etc. The staff quarters and industrial areas may be remote from the main hospital and supporting departments. The laundry may serve a number of healthcare buildings as well as the premises at which it is located. The storage requirement for such accommodation should therefore be calculated separately and integrated with the accommodation whenever this is practical. Appendix 1 provides data on typical demands expected from staff residences.

7.9 Where new healthcare premises are to be built in separate phases, the water storage, supply and distribution service for the whole premises should, as far as possible, be planned and evaluated at the design stage. This will enable the total water supply requirement to be assessed in the planning stages, and appropriate areas of accommodation (but not tank storage) to be allocated.

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Location and form of storage

7.10 It is more convenient and more secure to house water storage cisterns at sufficient height to provide adequate flow to all parts of the development by gravity, thus avoiding reliance on pumps etc. This is achieved by siting cistern rooms at roof level. Where buildings are widely dispersed, it is preferable to install a number of smaller cisterns rather than building a water cistern tower.

7.11 The location of storage will depend on the total volume required, the topography and layout of the site proposed for development, and the sources and adequacy of the water supply. A limited site footprint may call for much higher buildings to achieve the required accommodation. Depending on the supply water pressure, it may be necessary to install pressurisation equipment to boost the incoming supply. The cost of the supporting structure will have an important bearing on the solution adopted.

7.12 A hospital built on a restricted site might need both central and local storage to be provided in each building or in one of the buildings to serve other buildings in the development. Local storage at high level should give an average supply of about four hours if gravity-fed, but if the building structure will economically accept greater tankage this should be adopted. The total supply should be based on the average usage over 24 hours. There are some advantages in locating central storage at low level, for example easier access for maintenance, and reduced structural costs.

7.13 Where such storage is located in individual buildings and an adequate supply is available from the water authority (see Note 1), a connection in accordance with the Water Byelaws (Scotland) 2000 to each point of storage may be the most economical arrangement. In such cases, interconnections between selected points of storage should be provided to deal with emergency and maintenance requirements, always providing that such interconnections do not contravene the Water Byelaws (Scotland) 2000and do not result in water stagnating within the storage or distribution system. Where the development is widespread and a water authority's multiple connections are not the best solution, the general arrangement might consist of a total storage reservoir, strategically sited, serving cisterns located as conveniently as possible to the major centres of usage.

7.14 To maintain good water quality, common practice favours the use of smaller decentralised storage capacity as opposed to large central storage and distribution. The use of smaller local cisterns helps to avoid the problem of water stagnation in cisterns and also avoids long runs of distribution pipework between cisterns and points of use. Shorter pipework runs reduce the amount of heat gain in the cold water service en route to points of use.

7.15 Although the final assessment of the capacities of storage cisterns will emerge from the design requirements of Appendix 1, the building's structural design will influence the number of cisterns required and the cistern layout. Standard sizes of tank should be used where possible.

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7.16 Cisterns must not be located in any position where there is any likelihood of flooding, excessive heat gain or any other factor that could affect the contents of the cisterns. They should not be installed in any location where access for general inspection or maintenance is restricted.

7.17 Separate systems should be provided for pathology and mortuary departments.

External storage

7.18 The ideal location for external cold water storage cisterns is the roof of the highest building, provided the structural design can support the load. If concrete water cisterns are to be considered, they should be designed to form an integral part of the building structure. The materials of construction, however, must comply with the Water Supply (Water Fittings) Regulations 1999.

7.19 Where storage is below ground, as distinct from being housed within a building, it is essential to ensure that there is no risk of contamination. Investigations of such risk require careful consideration of site conditions and should include such aspects as flooding; subsidence; the location of sewers and drains and other buried services; the maximum and minimum height of the water table in the area; the natural drainage of surface water; ingress of contaminants such as dust, debris etc; and, in the event of storage below a car parking area or roads, the danger of oil/fuel seepage. The future development of the healthcare building and probable extensions should also be taken into account in this respect.

7.20 Storage below ground should be adopted only as a last resort, and cisterns should be installed within a watertight bund allowing sufficient space all around and beneath the storage vessel to permit inspection and maintenance. Any underground construction arrangement, concrete or otherwise, not directly against earth will reduce the risk of contamination. The tank chamber must include provision for a sump to collect drainage water and any piping necessary to pump out tanks to the site drainage. The Water Byelaws (Scotland) 2000 require any buried concrete reservoir to be designed, constructed and tested in accordance with BS 8007:1987.

7.21 The economic depth for reservoirs constructed in concrete is a function of the quantities to be stored. It should be considered at the outset of the planning stage, and will be influenced by load - bearing characteristics of the locality and take account of the outlet main's position and particulars. If it is found necessary to exceed a depth of 3.3 m, a specialist should be consulted. A rectangular or square concrete reservoir will generally provide a more economic proposition than one or more circular reservoirs.

Internal storage

7.22 As in the case of external storage, cisterns should be installed in positions where they can be readily inspected and maintained and where they will not be affected by frost or high temperatures.

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7.23 It is essential in all cistern installations that a clear working space of not less than 0.5 m – but ideally 1 m – is maintained around the cistern. Minimum clearances of 0.5 m below and 0.75 m above the cisterns are necessary to facilitate erection, inspection and maintenance. A minimum of 0.5 m should be provided between the floor of the catchment basin and the underside of the cistern.

7.24 Roof spaces in which cisterns are to be installed must have adequate trap doors or other means of access and adequate lighting to facilitate inspection and maintenance.

Construction of cisterns

7.25 All storage cisterns should be constructed in accordance with manufacturers' recommendations and should comply with the Water Supply (Water Fittings) Regulations 1999, be WRAS-approved, and comply with BS 6700:1997. Glass-reinforced plastic (GRP) tanks should comply with BS EN 13280:2001. The WRAS Information and Guidance Note 9-04-04: 'Cold water storage systems – design recommendation for mains supply inlets' provides useful advice regarding the design of the inlet arrangements to ensure compliance with the Regulations.

7.26 Depending on size and/or capacity, tankage should be divided into convenient compartments suitably interconnected and valved to facilitate cleaning, disinfection, repair, modification and inspection, without seriously disturbing the cold water service. Tank strengthening shall be by means of stainless steel tie-bars and not baffle plates.

7.27 Separate cisterns should also be provided for storage of different water supplies, for example cold water storage, recovered or recycled water, softened water and fire-fighting water. Precautions must be taken to ensure that mixing does not take place between such supplies, and it should be noted that isolation by means of shut-off valves between them is not acceptable.

7.28 Normally the materials used for storage cisterns serving healthcare premises are predominantly GRP, but concrete or steel may also be considered. The material selected should comply fully with the Water Supply (Water Fittings) Regulations 1999. Pre-insulated sections are recommended where practical.

7.29 Sectional cisterns fabricated from GRP or pressed steel provide a convenient means of bulk storage of water at atmospheric pressure. The components can be readily transported to site and, subject to unit multiples, they can be erected to give varying proportions of length to breadth and depth. It is also possible to make provision for future extension in capacity by an increase in available base area or, within limits, depth.

7.30 If sectional cisterns are selected, designs with external assembly flanges and self-draining profiles should be used, since this arrangement facilitates easy cleaning of internal surfaces of the cisterns.

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7.31 The Water Byelaws (Scotland) 2000 lay down the minimum requirements for potable water storage cisterns. Recommendations to comply with these are given in the WRAS 'Water Regulations Guide'. The requirements are indicated in Figure 1.

Note: Cisterns should be sited away from heat sources and be protected from heat gains by insulation. Adequate access should be provided for inspection and maintenance (both internally and externally).

7.32 Each storage cistern or its compartment should also be provided with the following:

- internal and external access ladders as necessary to comply with current health and safety requirements;
- a full-way servicing valve at each inlet and outlet connection, except for cisterns providing water to primary circuits or heating circuits, vent pipes, overflow pipes, and warning pipes. Where practicable, all outlets should be taken from the base of the system and be sited opposite to the inlet;
- a suitably-sized drain connection complete with isolating valve. The invert of the drain connection should be positioned so as to provide maximum drainage of the cistern.

7.33 Cisterns should be adequately supported on bearers placed under the longitudinal or lateral cistern section joints. To avoid distortion, a flat section of marine ply or equivalent should be sited between the support structure and the cistern. Final siting should be in accordance with the manufacturers' recommendations.

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Comment [h1]: Requires to be re-drawen.

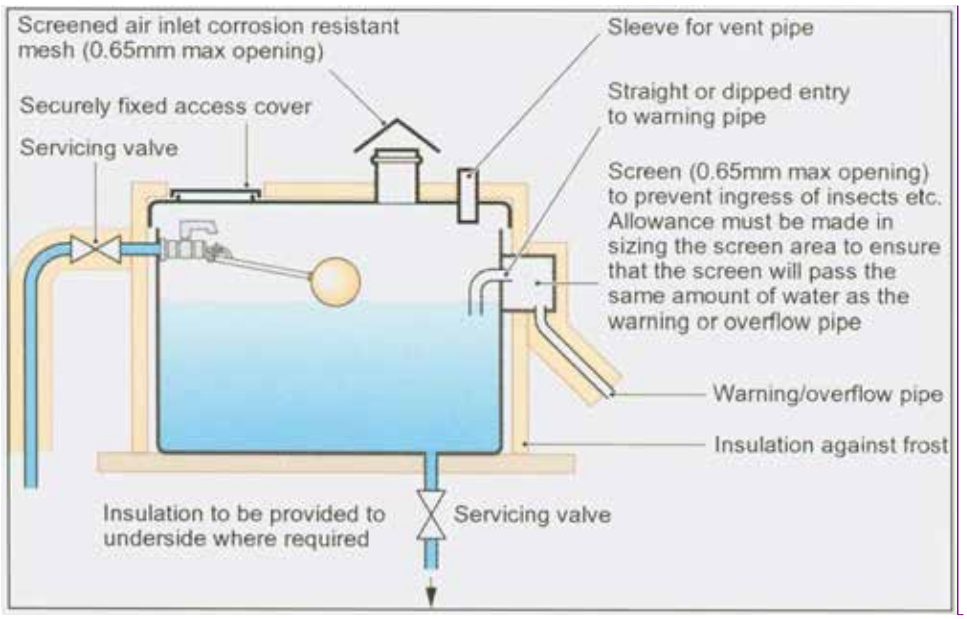

Figure 1: General potable water storage cistern arrangements

7.34 The design may incorporate a watertight drip tray under the cistern to contain condensed water or leakage so as to avoid damage to accommodation below. The necessity of a drip tray or watertight bund with drainage will depend on individual case requirements. The floor of the drip tray or bund should be graded to a drainage sump complete with drain pipe. A single pipe should drain off any overflow water from the sump and lead to a discharge point at ground level where any water flow would be readily noticed. If it is not possible to terminate the discharge pipe from the sump so that any discharge of water can be seen, an audible alarm should be installed to warn of overflow conditions. Cistern support levels should be constructed to keep the valves clear of the water level in the drip tray or bund in the event of cistern leakage. Special requirements apply to the supporting of GRP sectional cisterns on bearers, and manufacturers' recommendations should be observed. The cistern should be provided with a warning pipe or a no less effective device to indicate leakage through the inlet control valve if this should occur.

7.35 On no account should a cistern be installed on a concrete plinth (directly or on steel beams) that is protected by an asphalt membrane. Subsequent irregular settlement into the asphalt may lead to cistern distortion and leakage.

7.36 A consideration in deciding cistern shape and layout is the location of the services duct. Whereas the cistern room may be positioned aesthetically in relation to the building elevation, the duct serving it will be located to suit the internal layout. The pipe route from the system to the service duct will require access for inspection and protection from frost and heat gain.

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7.37 A typical potable water storage cistern, piping and valve arrangements, for break-tank operation during normal running and maintenance, is shown in Figure 2. The dotted line indicates that the pipe is disconnected. Supply and draw-off connections should be arranged to facilitate good through-flow and turnover of stored water.

Comment [h2]: Figure 4 is on the same section, why is hyperlink required?

Cistern rooms

7.38 GRP or steel cisterns should be installed in well ventilated but draught-proof housings constructed so as to prevent the ingress of birds, rodents and insects. The housing accommodating the cistern and the positioning of the cistern within the room must be designed to permit easy access for inspection and maintenance.

7.39 Prefabricated GRP housings, protected from extremes of temperature by thermal insulation, can provide an economical and aesthetic solution.

Note: Referring to figure 4, the break-tank can be maintained during rundown of the main tank from full. When not in use 'dotted' piped sections are removed and stored dry.

7.40 The load-bearing capacity of the main structure will limit the distributed load that the cistern room and its contents can impose, and will ultimately limit capacity. If, however, cisterns can be located above main service ducts or stairwells, this will minimise the effects.

7.41 General space lighting should be provided in cistern rooms, together with suitable power points for low voltage small tools and inspection lamps.

7.42 The contents and capacity of all cisterns should be clearly labelled in letters not less than 100 mm high on a white background.

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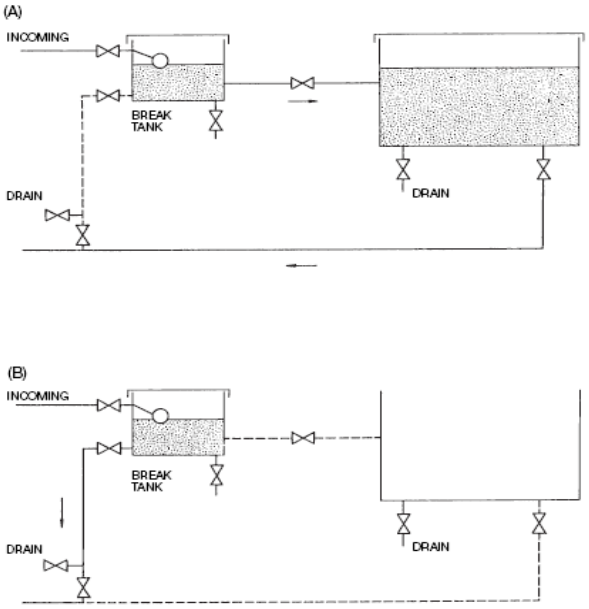

Comment [h3]: Requires to be re-drawen.

Figure 2: Piping and valve arrangements for break tank operation. (A) normal running; (B) during maintenance

Ancillary pipework, valves and fittings

7.43 The arrangement of the cisterns in the room should be such that the pipework runs are as short as possible, but accessibility and walkway clearance are ensured. Flanges on parallel runs should be staggered.

7.44 Adequate allowance should be made in the pipework layout for possible future cistern extension.

7.45 All cistern-room pipework and valves should be insulated and clearly labelled to identify their purpose.

7.46 The use of delayed-action ball valves on water storage cisterns should be considered, since these help avoid stagnation of water in the cistern.

7.47 Strainers should be fitted within the water pipework system to protect thermostatic valves etc against ingress of particulate matter. The installation of these fittings should allow adequate access for maintenance/replacement, and they should be provided with means of upstream and downstream isolation. Strainers can be a source of *Legionella* bacteria and should be included in routine cleaning, maintenance and disinfection procedures (see Section 7, Part B).

7.48 Service isolation valves should be fitted to all pipework preceding sanitary tapware and WCs etc for servicing, repair or replacement. Drain-valve provision may also be appropriate for certain installations, for example, service pipework to en-suite facilities etc.

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Buffer vessels for cold water boosting sets

7.49 Buffer vessels are typically vertical in orientation and normally have a diaphragm to separate the water from the gas space above. They introduce a potential problem of colonisation by *Legionella*, as the plantroom space temperature will exceed that of the incoming water. They should preferably be of a design such that water flows through the vessel, entering at low level, and discharging at a higher level below the water line. Interconnecting pipework should be kept to a minimum, and the vessel should be insulated to minimise heat gain. All materials in contact with water should be WRAS-approved (see also paragraph 9.41).

Water meters

7.50 BS 6700:1997 gives guidance on the design and installation of water meters.

7.51 Revenue meters are normally supplied and installed by the water authority, whereas the consumer may install sub-meters.

7.52 Adequate sub-metering of water supplies should be provided so that supplies can be monitored for individual heavy-use departments. Such monitoring will assist in the detection of leaks or abnormal water demands. Water meters can be connected to a BEMS, which can identify anomalous consumption and lead to the early detection of leaks.

7.53 Appropriate bypass arrangements with valves immediately upstream and downstream should be provided; the bypass loop should be as short as practicable and be arranged to be in the horizontal plane.

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8. Cold water distribution system

General

8.1 The design and installation of the cold water distribution system should comply with the Water Byelaws (Scotland) 2000and relevant parts of BS 6700:1997 and BS EN 806-2: 2005. A simple cold (and hot) water system is shown in Figure 3.

Comment [h4]: Figure 5, resides in this section, is a hyper link nessasary?

Note: All pipework to be insulated; isolating and control valves not shown; all drains should discharge to waste via a type A "air" gap.

8.2 The installation should be designed to avoid waste, undue consumption, misuse and contamination. Every water fitting through which water is supplied for domestic purposes should be installed in such a manner that no backflow of fluid from any appliance, fitting or process can take place. An assessment of the level of backflow contamination risk (the fluid category) should be made for each fitting, appliance etc. The system should be designed and installed so that each risk is adequately protected against backflow, either by means of the design or by use of backflow prevention devices. Devices are listed in the WRAS 'Water Regulations Guide' together with the degree of backflow protection they provide.

8.3 The design of the pipework should ensure that there is no possibility of a cross-connection between installations conveying potable water and an installation containing non-potable water or water supplied from a private source. There should be no possibility of backflow towards the source of supply from any tank, cistern, fitting or appliance, whether by back-siphonage or otherwise.

8.4 From an early stage in the design process of the water installation, liaison and consultation should take place with the designer of the building, the building owner or his agent, the water supply authority and all other public and private utilities, highway and local authorities, landowners and others involved. There is a legal duty to notify the water authority of proposed installation work and have its consent for the work before installation commences.

8.5 All cold water distribution pipework, mains and cistern down-feeds should be located, as far as is practicable, to minimise heat gains from their environment. Pipework should not be routed through hot ducts or run adjacent to heat sources, such as radiators. Where hot and cold water pipes are run horizontally together, the cold water pipe should be located beneath the hot water pipe to minimise local warming by means of convection.

8.6 All pipework should be insulated, except for any exposed final connections to sanitary appliances, and should be arranged to eliminate or minimise dead-legs.

8.7 The Water Supply (Water Quality) Regulations permit cold water to be delivered at temperatures up to 25°C, although in normal circumstances it will be well below 20°C. As far as possible, the objective should be to design the cold water

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systems to ensure that the inlet, outlet and surface water temperatures of cisterns and cold water feed/header tanks for the hot water calorifiers are not greater than 2°C above that measured at the main water meter. Also, at cold water draw-off points, a temperature of no greater than 2°C above the temperature measured in cistern and cold water header tanks should be reached within two minutes.

Note: For the control of *Legionella* and other water-borne organisms, 20°C is the quoted upper value above which multiplication of *Legionella* in particular begins to take place (see Part B, Section 4).

8.8 The control of water temperature in the cold water service, however, will essentially rely on good insulation and water turnover. Cold water services should be sized to provide sufficient flow at draw-off points. Stagnation should be avoided.

8.9 Pumped circulation of cold water and refrigerated cold water should only be considered in specialist units where people are at particular risk as a result of immunological deficiency; for example bone marrow transplant units. Such systems require careful design. For other accommodation the aim should be to promote turnover of cold water by means of the design of the distribution circuitry.

8.10 In ward areas provided with en-suite facilities, the aim should be to supply sanitary assemblies in series, with the WC connected to the final element. Elsewhere, pipeline routings should be run so that other outlets are connected with a WC or flushing device, for example sluice hopper or pantry sink, providing the final element at the distal end of the branch – this may require pipe routeing reversal. See Figures 3 and 4.

8.11 In other clinical areas, a similar arrangement for the distribution of cold water should be adopted.

8.12 The cold water distribution system should be designed so that the pressure is the same as that for the hot water service at draw-off points. This may require the inclusion of pressure-reducing valves in the distribution pipework. If unequal pressures exist in the hot and cold water supplies to combination taps where water mixes in the body of the tap, a single check valve is required on each feed pipe to the tap to prevent backflow of water from one to the other.

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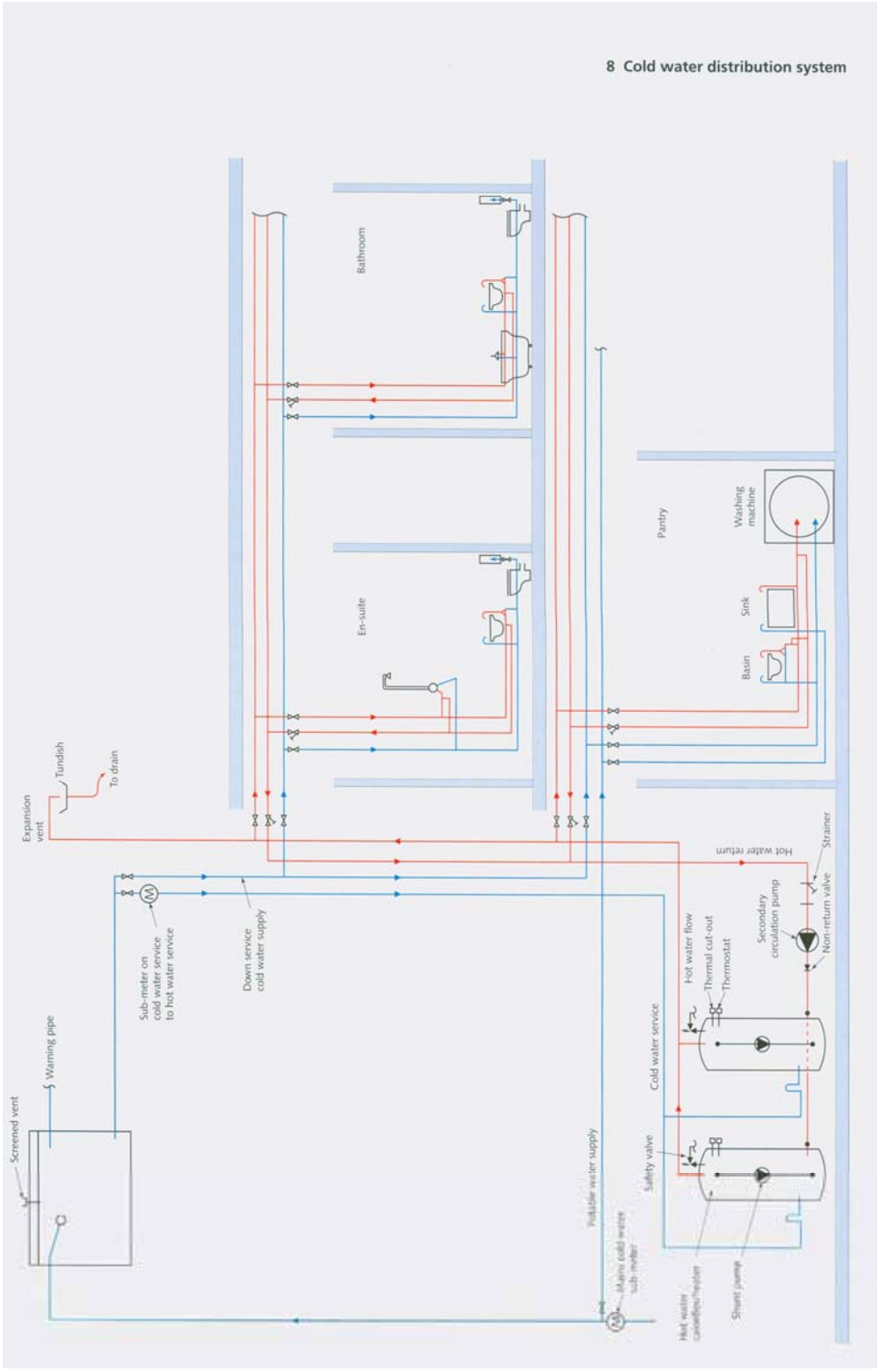

Figure 3: Schematic layout of a cold (and hot) water service system

Comment [h5]: Diagram requires to re-drawen.

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Drinking water

8.13 When separate drinking water systems have been provided the policy has normally been to distribute directly from the mains without storage, with stored cold water (down service) being used solely for supplies to WCs, hand-wash basins etc. Providing drinking water without storage may not be appropriate in healthcare premises because of the need to have some security of supply. The advantage of separate drinking and cold water services chiefly lie in the possibility of treating the latter (softening or other forms of treatment) without adulterating the drinking supplies. However, low water flows in dedicated Drinking Water piping lead to stagnation, temperature build-up and the possibility of exceeding the 20^0C limits.

Softening will avoid the scale problems associated with thermostatic mixing devices. (Problems often occur when scale is deposited as a result of hard cold water being heated in the blending process.) However, this will be wasteful if the cold water supply is to be used for WC flushing.

8.14 A possible strategy, therefore, is to have a drinking water system that also provides WC flushing and, to some extent, this will assist water turnover and the maintenance of water quality. The disadvantage of the concept, apart from installation cost, is that the use of WCs, particularly in en-suite facilities, as the mechanism for achieving good utilisation in the cold water service no longer becomes possible (see paragraph 8.10). The concept for water turnover in en-suite facilities could still be achieved, however, if the cold water service were run in series to en-suite facilities with minimum dead-legs to draw-offs, with the final connection on the system being a highly utilised outlet, for example a sink.

Many hospitals now store all water in tanks arranged to contain water of drinking quality, having sealed lids and screened vents. This offers complete flexibility avoids problems with stagnation and is recommended practice.

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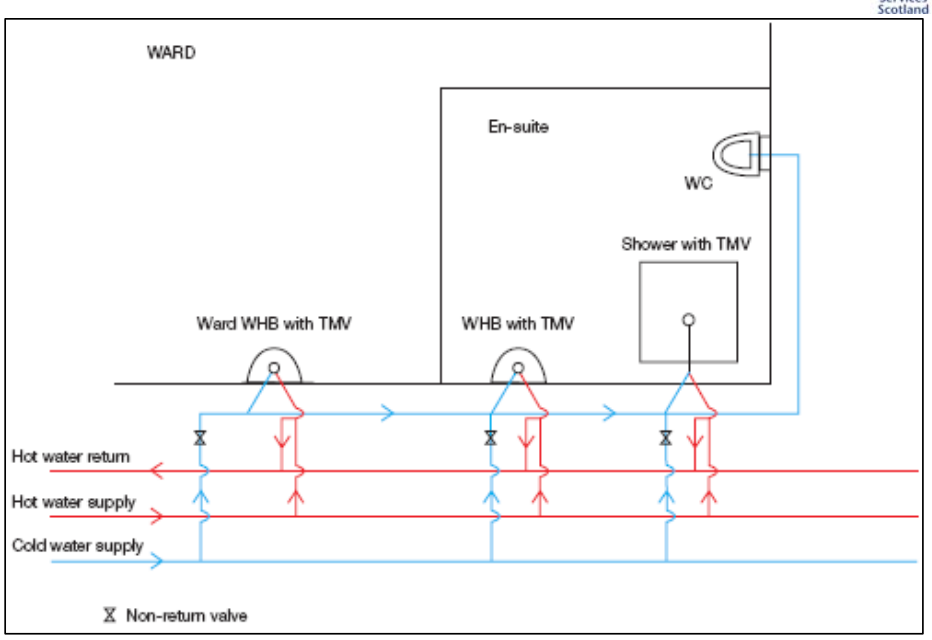

Figure 4: Piping arrangements for an en-suite facility

Comment [h6]: Requires to be re-drawen.

Pumped systems

8.15 Water supply authorities are reducing pressure to reduce mains leakages. Where the pressure of the water supply is inadequate, it will be necessary to utilise pressurisation plant. Similarly, pumping or pressurisation may be required for fire-fighting purposes.

8.16 Various arrangements of pumping system are indicated in BS 6700:1997. Where booster pumps are to be installed, a break cistern will be required between the mains supply pipe and the pumps. This is required in order to comply with the Water Byelaws (Scotland) 2000with regard to prevention of backflow. Any pump delivering more than 12 L/min must be notified to the water authority whose consent is required.

8.17 Control of the pump(s) should be fully automatic in operation and controlled by pressure sensors for the following reasons:

- to reduce energy consumption;
- to prevent heat gain from the pump to the water, which could become significant if large pumps are used;
- to reduce wear on the pumps and hence reduce maintenance.

8.18 Factors to be considered when selecting pumps are:

- quantity and pressure of water to be pumped;

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- the number of units required to obtain the necessary output and to provide adequate standby capacity;
- the desirability of speed variation;
- the degree of automatic sequence control required;
- the characteristics of the system on both the delivery and suction sides, and in pumping efficiency and priming requirements;
- the type of materials used in manufacturing the pumps relative to the chemical analysis of the water to be pumped.

8.19 The operation and shutdown of pumps may be controlled by various methods depending on the circumstances, such as water-level float switches, pressure switches, flow switches, electrode probes or pneumatic systems. Certain services may also require the pumping equipment to be energised from the emergency electrical service as recommended in SHTM 06-01: Electrical services supply and distribution'.

8.20 Where two or more pumps are installed, the design flow should be achieved with one pump stationary (or out of service). Automatic control should be provided to control all pumps cyclically and sequentially to ensure that each is regularly brought into service.

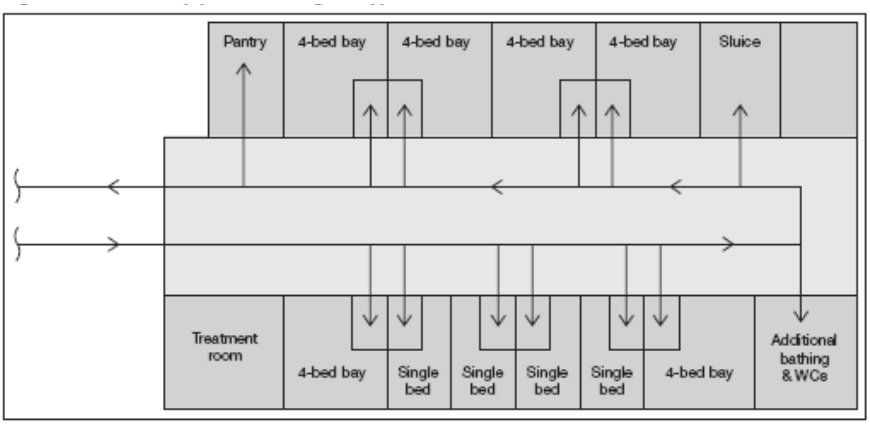

Figure 5: Direction of pipeline routing in a typical ward

8.21 The pumping sets for lifting to higher-level storage should be controlled from the level in the high-level tanks by transmitting sensors, level switches or other suitable devices. A low level alarm should be arranged to give a warning when the storage volume of water falls to a predetermined low level.

8.22 The expansion vessels forming part of the pumping sets are typically pressurisation vessels are typically vertical in orientation and have either a diaphragm or nitrogen fill in the upper space. They introduce a potential problem of colonisation by *Legionella*, as the plantroom space temperature will exceed that of the incoming water. They should be preferably of a design such that water flows through the vessel, entering at low level, and discharging at a higher level below the water line. Interconnecting pipework should be kept to a

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minimum, and the vessel should be insulated to minimise heat gain. All materials in contact with water should be WRAS-approved. It is important that the expansion vessel is located on the cold feed rather than on the hot water side of the system.

8.23 The plantroom should be constructed with a waterproof and non-dusting type of floor with a slight fall to a drainage trench that should terminate in a trapped gully. The trapped gully should incorporate provisions to either avoid or replenish any trap-water-seal loss. The plantroom will require adequate lighting, ventilation and heating (to prevent freezing or condensation), with electric power points and/or provision for low-voltage supplies for portable lighting and tools.

8.24 If heavy plant is to be installed which may, on occasion, need to be removed for testing, maintenance or replacement, fixed lifting beams of suitable capacity should be provided.

Specialist systems

8.25 Where water supplies are required for specialist systems such as endoscope cleaning installations, dialysis units etc, the designer should consult the hospital infection control team to establish any specific water treatment requirements for the process, and also the local water supply authority to clarify any special precautions that may be necessary, such as backflow prevention devices. The advice of the water supply authority should also be sought as to any possible variation in the quality of supply or possible change in the source of supply (see also Health Building Note 53:'Facilities for renal services: Volume 1 − Satellite dialysis unit').

Vending, chilled water and ice-making machines

8.26 The water supply to this equipment should be taken from a potable supply via a double check valve to prevent backflow and be upstream of a regularly used outlet with the minimum of intervening pipe-run, that is, less than 3m. The supply should not be softened. Additionally, it should be established that the usage is sufficient to avoid deterioration in water quality, for example that the inlet water temperature does not exceed 20°C.

8.27 The equipment should be positioned so that the warm air exhaust does not impinge directly on taps or hoses supplying cold water.

8.28 Reference should also be made to the Food Safety (Temperature Control) Regulations 1995 and Food Safety (General Food Hygiene) Regulations 1995. The Automatic Vending Association of Britain (AVAB) codes of practice should be followed regarding hygiene and water quality and hygienic operation of vending machines (http://www.ava-vending.org). Vending machines dispensing carbonated drinks require special materials of construction which should be WRAS-approved.

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9. Hot water services

General

9.1 Hot water services should be designed and installed in accordance with the Water Byelaws (Scotland) 2000and relevant parts of BS 6700:1997 and BS EN 806-2:2005. The hot water system may be of either the vented or the unvented type.

9.2 The basic components of a hot and cold service system as used within hospitals are shown in Figure 5; most installations will have additional features and components.

9.3 A vented system usually consists of a cold water storage cistern situated above the highest outlets, which feeds a hot water storage vessel (for example a calorifier or direct-fired boiler).

9.4 An unvented system usually has the hot water storage vessel connected to the mains water supply via a backflow prevention device and a pressure-reducing valve. The components of a directly heated unvented hot water system are shown in Figure 6.

9.5 Hot water is taken from the top of the storage vessel, or water heater, and will normally be circulated around the building in a piped distribution system. The flow temperature should be set to 60°C and the minimum temperature of all return legs to the vessel or water heater should be 50°C. Correct grading of pipework is essential to maintain correct circulation. In all but very small domestic installations, circulation is essential and trace heating should only be used in existing installations to overcome local problems with circulation where rectification would otherwise be disruptive to the operation of the accommodation served. In all but domestic systems, if recirculation is not used, some form of trace heating will be required. Such systems, however, should be restricted to areas where backflow contamination is a potential problem, for example pathology laboratories: these should be supplied from separate systems. The individual outlets, taps, mixing valves or other outlet devices will be served from the distribution system; this should be designed such that the minimum temperature at the most distant taps or outlets is 55°C.

Note: The control of *Legionella* requires there to be a minimum temperature of 50°C in hot water service systems (see Part B of this SHTM). A minimum of 55°C may be required for the operation of suitable fail-safe mixing devices required to provide 'safe' hot water at the upper limit of the recommended range. Hot water at 55°C is required for many applications such as washing in kitchens and laundries.

9.6 A small number of localised hot water distribution systems can have advantages over one large centralised system. With smaller systems, hot water

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heaters are located closer to points of use and it is therefore easier to maintain hot water distribution temperatures within recommended values. Balancing water flow rates in the hot water secondary distribution system becomes less of a problem, and distribution losses are reduced. A small, localised hot water distribution system may comprise a gas-fired water heater, a storage calorifier, a semi-storage calorifier or plate heat exchanger. The adoption of localised hot water distribution systems will require the provision of local plantrooms.

9.7 With large centralised hot water systems, it is more difficult to maintain secondary distribution temperatures within recommended values; also, water flow rates in large secondary distribution systems can prove difficult to balance. At periods of low draw-off, detritus can lodge within the large horizontal distribution pipes forming part of centralised systems.

9.8 There are also maintenance factors to be considered. With a central hot water system, plant maintenance can be focused in one location, whereas with localised systems there will be a number of plantrooms at remote locations.

Hot water heater types

9.9 In most healthcare premises, hot water storage vessels include the heating source, which can be steam, high- or medium-pressure hot water, or electric immersion heating elements. The flow to the pipeline distribution system is normally taken from the top of the vessel, as too is the open vent, which may or may not be combined. The cold feed is usually taken in towards the base of the vessel and the return water circulation at about one-third of the height. Instantaneous water heaters for distribution systems have similar pipeline connections. All water heaters must be WRAS-approved and listed in the 'Water Fittings and Materials Directory'.

9.10 Traditional design practice has been to provide a non-check-valved cold feed and expansion pipe to the calorifier/water heater and an open vent discharging over the cold feed cistern. Means should be taken to prevent warm water entering the cold feed line and possibly leading to conditions conducive to colonisation by *Legionella*. A check valve can be provided in the cold feed to prevent such circulation, but this will prevent the operation of the cold feed as an expansion pipe. An alternative is to provide a U-bend or S-bend in the cold feed sufficient distance from the connection to the calorifier so that water, which is warm, is not displaced (on heating up) beyond the bend and the vertical pipe rise. Similarly with a need to preserve the potability of water at all times in the storage cistern, the practice of terminating the vent pipe (air vent) over the cistern is no longer permitted by regulations. The vent should be arranged to discharge over a separate tundish arrangement, with visible Type AA air gap, sited at a level that takes account of the hydrostatic head of the system: the tundish should discharge to drain. The calorifier or water heater should be provided with a suitable safety valve of appropriate size and vacuum release arrangement.

9.11 Most vessels have some means of access for inspection, either via a special panel or by removing the heating coils/elements. When new calorifiers are

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required, it should be specified that they have separate and adequately sized access panels.

9.12 Where water quality indicates the need, cathodic protection from galvanic action by means of sacrificial anodes should be provided.

9.13 The combined storage capacity and heater output must be sufficient to ensure that the outflow temperature, at continuous design flow (at least 20 minutes) from calorifiers or other heaters, should not be less than 60°C. This applies to both circulating and non-circulating hot water systems. The positioning of the control and high limit thermostats, cold feed and return water connections must ensure that these temperatures are achieved.

9.14 There are basically three types of water heater:

- instantaneous heater;
- storage calorifier;
- limited storage calorifier.

Instantaneous water heaters

9.15 This type of heater can be further subdivided into:

- instantaneous water heaters for single or multi- point outlets: these devices are usually either electrically or gas heated. The general principles and limitations of instantaneous water heaters are given in BS 6700:1997. In essence:
    - the hot water flow rate is limited and is dependent upon the heater's power rating;
    - the water in instantaneous water heaters is usually heated to about 55°C at its lowest rate, and its temperature will rise and fall inversely to its flow rate. Where constant flow temperature is important, the heater should be fitted with a water governor at its inflow. Close control of temperature is of particular importance for showers. To attain constant temperatures on delivery, water flow and pressure must also be controlled. Variations in pressure can cause flow and temperature problems when the heater is in use, and when setting up or adjusting flow controls;
    - they are susceptible to scale formation in hard water areas, where they will require frequent maintenance;
    - this form of hot water heating should be considered only for smaller premises or where it is not economically viable to run a hot water circulation to a remote outlet;
- instantaneous-type water heaters for distribution systems: these devices, which normally use steam or high/medium pressure hot water

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as the primary heating medium, are designed to heat their rated throughput of water rapidly from cold to the design outlet temperature. They can be used either to feed directly into a hot water distribution system, or in conjunction with a storage vessel which reduces the load on the heater during periods of peak demand. This type of heater includes:

- hot water generators: these are vertical instantaneous water heaters that contain modular helical primary coils normally served by steam, medium temperature hot water (MTHW) or high temperature hot water (HTHW). The unit incorporates a temperature control device, which varies the rate of primary energy input so as to maintain a constant hot water flow temperature over a range of secondary flow rates through the heater;

- plate heat exchangers: plate heat exchangers consist of a number of rectangular plates sandwiched between two flat endplates and held together by tie bolts. The plates have ports in all four corners that allow entry and discharge of the primary and secondary liquids. Primary liquid is directed through alternate pairs of plates while the domestic hot water is normally fed in a counter flow direction through the remaining pairs of plates. Each plate is sealed round the edges by a gasketing system, the design of which should ensure that fluids cannot, under normal operating conditions, either leak to atmosphere or mix. This type of heat exchanger can be extended easily, or shortened, to suit changes in hot water demand.

Storage calorifiers

9.16 Storage calorifiers are usually cylindrical vessels mounted either vertically or horizontally; the base of a vertical calorifier can be concave or convex, with the vessel being supported on feet. The latter design is preferred, as it avoids the annular space where the base joins the cylinder wall. Heater batteries are usually located near the bottom of the cylinder, which can give rise to an area of water beneath the battery significantly below the storage temperature. This “dead” area can provide an ideal breeding ground for bacteria. Galvanised cylinders are particularly susceptible to scale formation, which can also provide a source of nutrition and shelter for bacteria.

9.17 As a result of this, galvanised cylinders are not recommended in new hospital installations or for replacement.

9.18 The following points should be considered during the design process (see also paragraphs 9.28–9.29):

- the entire storage volume should be capable of being heated to 60°C without permanent pockets of lukewarm water;

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- the shell lining should be resistant to bacterial growth;
- sufficient access to ensure adequate cleaning of the shell must be provided;
- a suitably-sized drain should be connected to the base of the calorifier.

Limited storage calorifiers

9.19 These calorifiers can either have an independent heating facility such as oil or gas burners or electric elements, or use primary water/steam from a boiler to heat the water via a heat exchanger. The equipment is available in a range of storage capacities and recovery flow rates. This type of equipment is particularly suitable where systems are being decentralised and water heaters are required close to the point of use.

Sizing of hot water storage vessels

9.20 Storage should be calculated on the requirements of peak demand and the rate of heat input. There may be more than one peak period in each 24 hours. The interval between peak periods is important, as it affects the recovery time.

9.21 The CIBSE Guide G: 'Public health engineering', gives guidance on sizing hot water storage.

9.22 Since the original study set out in Appendix 1 a review of systems indicates that the overall capacity and consumption predicted is excessive (see paragraphs 7.4–7.5).

9.23 Where storage calorifiers are used, the hot water storage capacity should be sufficient to meet the consumption for up to two hours; this must include the period of maximum draw-off. The installed hot water capacity should be sized for current needs and should not be designed with built-in capacity for future extensions.

9.24 Some devices are optimistically rated so that, at a continuous demand equal to their design rating, the flow temperature can fall below 60°C. Semi-storage or high-efficiency minimum storage calorifiers and instantaneous heaters are especially prone to this if under-sized.

Connection arrangements for calorifiers and water heaters

9.25 Where more than one calorifier or heating device is used, they should be connected in parallel, taking care to ensure that the flow can be balanced so that the water temperature from all the calorifiers exceeds 60°C at all times (see also paragraph 9.42).

9.26 Installations must not include for series operation of calorifiers.

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Stratification in storage vessels

9.27 Stratification will occur in any storage calorifier or heater; the temperature gradient will depend on the rate of draw-off and heat input. In some calorifier designs, stratification is significantly more pronounced and is a feature of their design. There will always be a volume of water in the temperature range that encourages maximum growth of *Legionella*.

Note: Water temperatures in the range 20°C–45°C favour growth of *Legionella*. It is uncommon to find proliferation below 20°C, and *Legionella* do not survive long above 60°C. The optimum laboratory temperature for the growth of *Legionella* is 37°C, that is, body temperature. *Legionella* may, however, remain dormant in cool water, multiplying only when the temperature reaches a suitable level.

Note: Stratification: in a storage calorifier the upper level, above the heating element, will be at operating temperature (60°C) during normal periods of demand. Below this level will be a volume of water between the feed water temperature and operating temperature. This level will vary as draw-off takes place according to the thermal input and rate of demand.

9.28 Storage and semi-storage calorifiers should be provided with independently pumped circulation from the top to the base of the calorifier; this is referred to as a 'shunt pump'. The pump should be run continuously for about an hour during periods of minimum demand to raise the entire contents of the calorifier to 60°C. During periods of low draw-off, the temperature will readily achieve 60°C to effect disinfection. Control should be by a timing device that can be adjusted when the profile of demand has been established.

9.29 Some semi-storage/high-efficiency calorifiers are supplied with an integral pump that circulates water in the calorifier; in this case a second shunt pump is not required.

Provisions for maintenance

9.30 There should be adequate access to calorifiers for inspection and cleaning, removal and replacement of tube bundles and removal and replacement of the entire calorifier.

9.31 All calorifiers and water heaters must be fitted with a drain valve located in an accessible position at the lowest point on the vessel so that accumulated sludge may be removed effectively from the lowest point. The drain should be of sufficient size to empty the vessel in a reasonable time. A schedule of approximate calorifier emptying times is given in Table 3.

Comment [h7]: The table is in the same section.

9.32 Drain valves should be of the ball type to avoid clogging, and a drainage gully should be provided of sufficient size to accommodate the flow from the calorifier drain.

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Unvented hot water systems

9.33 Hot water storage systems have traditionally been provided with an open vent pipe that relieves any steam generated in the event of failure of temperature controls. The open vent pipe also protects against rupture of the cylinder by expansion of water.

9.34 The use of unvented hot water systems is now permitted in the UK and is covered in Section 4: Safety section of Section 6 Energy in the Non-Domestic Scottish Technical Handbooks, 2007, which covers installation, specification and discharge.

9.35 Where an unvented hot water system is connected directly to the water mains, no back-up will exist in the event of a water supply failure. Such an arrangement may also be unacceptable to the local water supply authority, since they will be required to meet the maximum demand at any time over a 24-hour period.

Calorifier type	Diameter/ length ratio	Capacity: Litres (Gallons)	Drain valve sizes mm (inch)		
			25 (1.0)	38 (1.5)	50 (2.0)
Horizontal	1:2.5	13,500 (3000)	3 hr 00 min	1hr 20 min	45 min
		9000 (2000)	2 hr 10 min	1 hr 00 min	30 min
		4500 (1000)	1hr 10 min	30 min	20 min
		2250 (500)	39 min	17 min	10 min
		1800 (400)	32 min	14 min	8 min
		1400 (300)	25 min	11 min	6 min
Horizontal	1:1.5	13,500 (3000)	3 hr 00 min	1 hr 20 min	45 min
		9000 (2000)	2 hrs 10 min	1 hr 00 min	30 min
		4500 (1000)	1 hr 10 min	30 min	20 min
		2250 (500)	39 min	17 min	10 min
		1800 (400)	32 min	14 min	8 min
		1400 (300)	25 min	11 min	6 min
Vertical	1:1.5	13, 500	2 hr 45 min	1 hr 15 min	40 min
		9000 (2000)	2 hr 00 min	55 min	30 min
		4500 (1000)	1 hr 10 min	30 min	20 min
		2250 (500)	38 min	17 min	9 min
		1800 (400)	31 min	14 min	8 min
		1400	25 min	11 min	6 min
			Times assume no hose and simple ball-type valve		

Table 3: Approximate emptying times for calorifiers

9.36 The design and installation of unvented hot water systems should comply fully the Non-Domestic Scottish Technical Notebooks, 2007 of the Water Byelaws (Scotland) 2000.

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9.37 The key requirements are that the temperature of stored water should be prevented at any time from exceeding 100°C and that discharges from safety devices should be conveyed to a safe and visible place and protected to prevent blockages by the ingress of birds, rodents or insects etc.

9.38 A schematic layout of a typical directly heated unvented hot water system is illustrated in Figure 6 along with a brief description of the main components.

9.39 The discharge pipes from the temperature relief valve and expansion valve should be carefully located so that they are readily visible but do not present a risk to people and protected to prevent blockage by the ingress of birds, rodents or insects etc.

9.40 Where the hot water is heated directly, for example by a steam or LTHW primary coil, a non-self-resetting thermal cut-out wired to a motorised valve on the primary coil must be provided for control of excessive temperature. This should be further protected by a direct-acting protection device, particularly with a plastic pipework installation.

Sealed expansion tanks for unvented hot water systems

9.41 These vessels are typically vertical in orientation and normally have a diaphragm to separate the water from the gas space above. They introduce a potential problem of colonisation by *Legionella*, as the plantroom space temperature will exceed that of the incoming water. It is important that the expansion vessel is located on the cold feed rather than on the hot water side of the system. All materials in contact with water should be WRAS approved.

Hot water distribution system

9.42 To control the possible colonisation by *Legionella*, it is essential to maintain the temperature within the hot water circulating system. To some extent, if properly maintained, the calorifier/water heater will provide a form of barrier to *Legionella* and other water-borne organisms. For premises with intermittent use, the generation of domestic hot water must be continuous unless there is an anticipated prolonged shut down, in which case systems should be drained dry, as occurs between final commissioning and putting systems into use in a new build situation.

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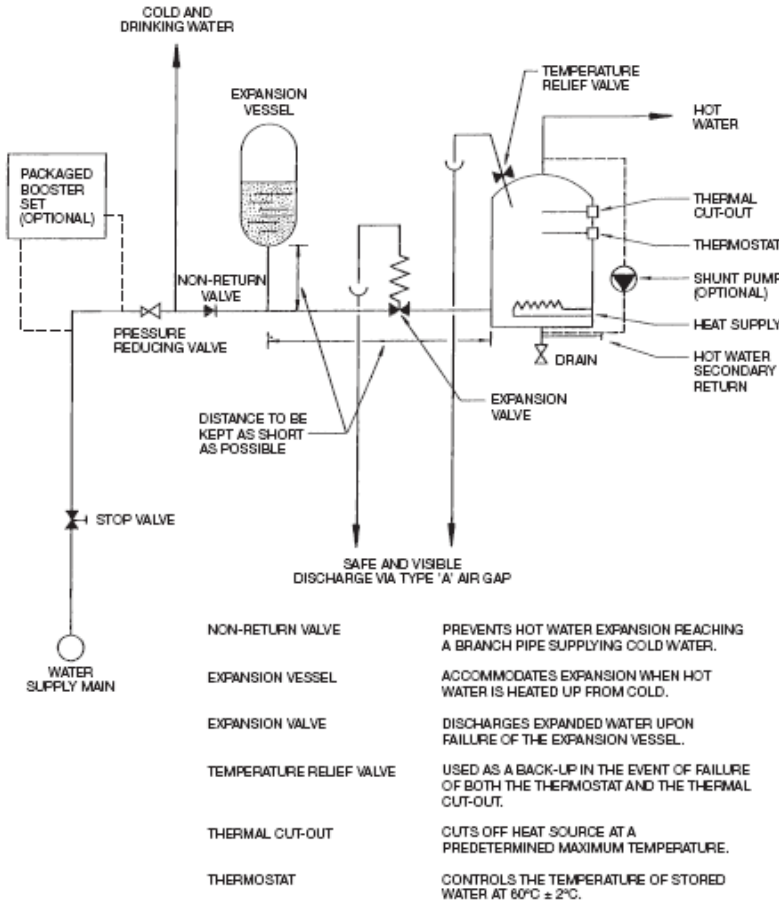

Figure 6: Directly heated unvented systems

9.43 The minimum flow temperature of water leaving the calorifier/water heater should be 60°C at all times, and 55°C at the supply to the furthermost draw-off point in the circulating system. The minimum water temperature of all return legs to the calorifier/water heater should be 50°C.

Note: A minimum of 55°C may be required for the operation of suitable mixing devices required to provide 'safe' hot water at the upper limit of the recommended range.

9.44 To achieve the required circulating temperatures, it will be necessary to provide some form of regulation to balance the flow to individual pipe branches serving groups of draw-off points, for example each washroom/toilet and en-suite facility etc.

9.45 The means of balancing the hot water circulation can be achieved by either manual or thermostatic regulating valves installed in the return. There should be means of isolation, both upstream and downstream. Adequate access for servicing is also essential.

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9.46 In ward accommodation where en-suite facilities are provided, it is recommended that the hot water circulation be extended to draw-off points in series, for example the supply to a basin, bath and/or shower should be run as one circuit (see Figures 6).

9.47 The operating pressures for both hot and cold water at draw-off points should be the same.

9.48 The domestic hot water system must not be used for heating purposes. This includes all radiators, towel rails, heated bedpan racks etc, whatever the pipework configuration.

9.49 Particular attention should be given to ensuring that pipework containing blended water is kept to the minimum. Generally, the downstream dead-leg should not exceed 2 m, and the complete length of the spur should not exceed 3 m. The length is measured from the centre line of the circulation pipework to the point of discharge along the centre line of the pipework. The same restriction applies to "communal" blending, that is, where more than one outlet is served by one device. Central blending systems should not be used, since the length of distribution pipework containing water in the temperature range that supports *Legionella* growth would far exceed these maximum permissible lengths.

Water temperatures and delivery devices

9.50 The risk of scalding for patients (children and young people, older people, and people with disabilities) and staff is a particular problem in healthcare premises caring for such individuals, and therefore thermostatic mixing devices will be needed for many hot water outlets, with different temperatures required for differing toiletry needs. A risk assessment will be necessary to establish the need and type of device to be installed.

9.51 Hand-washing is best performed under running water in basins/sinks without plugs, as they easily become soiled especially where usage is high – this necessitates the installation of a mixing device.

Note: The Water Byelaws (Scotland) 2000 place limits on the flow of water to draw-offs where plugs are not provided. Spray-type mixer taps are not recommended in healthcare premises; therefore, the type of tap should be carefully selected to minimise the formation of aerosols (With regard to the requirement for plugs, see also the section on baths, sinks, showers and taps in DEFRA's (1999) guidance document to the Regulations.)

9.52 Thermostatic mixing valves should comply with the standards of the MES D08 – 'Thermostatic mixing valves (healthcare premises)'. Thermostatic valves should be tested and accepted by the BuildCert TMV Scheme (http://www.buildcert.com/TMV).

9.53 The types of mixing device are specified in Table 4.

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Showers

9.54 Showers with fixed heads are preferred for prevention of backflow. Where flexible hoses and moveable shower outlets are provided, the outlet must not be capable of being accidentally immersed into a drain, WC or other potential source of contamination. Some shower heads are provided with a means for adjusting the flow, for example fine spray, pulsating flow etc, selected by utilising different sets of nozzles. As this will exacerbate possible stagnation problems, they should not be installed in healthcare premises. Taps and showers should be flushed at least twice weekly, or the retained water flushed to waste immediately before use without the generation of aerosols.

9.55 To facilitate the required regular removal of shower thermostatic mixing valves for inspection, careful consideration will be required to ensure that these are not recessed in such a way that access can damage thermal insulation on connecting pipework or to the removable panels themselves in wet areas. Surface mounted thermostatic mixing valves with smooth protective panels concealing isolating valves, strainers and check valves will eliminate this problem and avoid repetitive damage to waterproof membranes.

Strainers

9.56 Strainers should be fitted within the water pipework system to protect expansion vessels, mechanical backflow protection devices, thermostatic valves etc against ingress of particulate matter. The installation of these fittings should allow adequate access for maintenance/replacement and they should be provided with means of upstream (and downstream where appropriate) isolation. Strainers can be a source of *Legionella* bacteria and should be included in routine cleaning, maintenance and disinfection procedures (see Chapter 7, Part B).

Cold feed cisterns and tanks

9.57 When separate cold feed cisterns are provided for hot water service installations, they should comply with the requirements for cold water systems.

Note: Hot water cylinders with an integral feed and expansion tank are not recommended.

Service isolation valves

9.58 Service isolation valves should be fitted to all pipework preceding sanitary tapware and WCs etc for servicing, repair and replacement. Drain-valve provision may also be appropriate for certain installations, for example service pipework to en-suite facilities etc.

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Table 4: Safe water temperatures and delivery devices

Area/activity	Recommended temperature (°C)	Type of device (see MES D08 for example explanation of valve types)
Staff bases, ward and consulting rooms etc basins In-patient, out-patient hand-wash basins	41	Type 3 Thermostatic
General areas to which staff and visitors may have access See note 3 below	41	Type 2 Thermostatic
Paediatric baths	40 - to allow for the cold paediatric bath/sink NB: Paediatric nurses should always use a thermometer	Type 3 Thermostatic
General baths	43	Type 3 Thermostatic
Showers	41	Type 3 Thermostatic
Assisted baths	46 - to allow for the cold mass of the bath NB: Nurses should always use a thermometer before immersing patients	Type 3 Thermostatic
Hair-wash facilities	41	Type 3 Thermostatic
Bidets	38	Type 3 Thermostatic
All sinks, kitchens, pantries, slop sinks etc	55 - minimum required for food hygiene and decontamination purposes	Separate hot and cols taps or combination tap assembly Type 1; no preceeding thermostatic device
Office, staff-only access areas hand-wash basins	43	Type 1

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Notes:

1. It is preferable that thermostatic mixing devices are fitted directly to the mixed temperature outlet or be integral with it, and be the method of temperature and flow control, i.e. the mixing device should not be separate and supply water via second tap or manual mixer since there will be many cases where draw-off of cold water will not occur. If a separate thermostatic device is used, it should be fitted as close to the outlet as possible, which should be a flow only control. Where “T” type mixing valves are installed they will require access for maintenance and consideration should be given to their location behind sanitaryware partitions.

2. In the case of bidets with ascending sprays, or a handled douche, which may be accidentally immersed in an adjacent WC, water taps must be supplied via a suitable air gap, normally from a storage cistern.

3. Automatic taps should be considered for general public access washroom/toilets, surgical scrub sinks and hand-wash basins in main kitchen/food preparation areas; because the temperature is non-user adjustable they should be supplied from a Type 2 TMV set to 41°C. they are not recommended where the frequency of use of sanitary assemblies is low; part of the operational management regime will necessitate “flushing” of outlets. Such flushing can be time-consuming and is not facilitated by automatic taps that require a continual presence. The proximity detector should include a timer than can be adjusted to take account of the optimum washing time: this is particularly important for scrub sinks.

4. Automatic flushing WCs can also be considered for similar areas.

5. In the case of a dual function delivery device. I.e. shower/bath diverter, a risk assessment will be necessary to establish what temperature setting is required.

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10. Building and energy management systems

10.1 The continued safe operation of domestic hot and cold water systems requires a number of routine checks to be made by physical means using separate thermometric equipment. A number of the control parameters can, however, be monitored by Building and Energy Management Systems (BEMS) continuously, even though routine checks will still be required for “calibration purposes”. Parameters that should be monitored are as follows:

- incoming mains temperature (at the water meter), inlet, outlet, and surface water temperatures of cisterns and cold water feed tanks for hot water calorifiers;
- calorifier flow and return temperatures;
- hot water service flow and circulation temperatures at the furthermost outlets in individual wards;
- cold water service at the furthermost point from the pipeline entry to the ward/department.

Smaller premises without a Building and Energy Management System will require the same routine checks and monitoring carried out manually with the interval between checks determined by experience and risk assessments.

10.2 In addition to temperature, the BEMS should also monitor pressurisation and circulating pumps, and water treatment systems for fault conditions or change of status likely to result in a fault.

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11. Materials of construction

General

11.1 Any materials that come into contact with the water in a hot and cold water installation must comply with the requirements of the Water Byelaws (Scotland) 2000. A list of products and materials that have been assessed for compliance with the requirements of these Regulations is given in the current edition of 'Water Fittings and Materials Directory', which is updated every six months. Further information on the selection of materials can be found in BS 6700:1997, BS EN 806-2:2005 and BS 6920-1: 2000.

11.2 Materials of construction should be selected to take account of water quality and its potential corrosive properties. The water supply authority should be asked to provide details of any specific requirements and variability from standard conditions.

11.3 Water supplied by the water supply authority, although remaining uniformly wholesome, will nevertheless differ chemically. Some waters are slightly acidic while others are slightly alkaline, and this affects the choice of materials for pipes, fittings and cisterns. The water supply authority also blends water and accordingly, the character of the water supply may vary from time to time. It will therefore be necessary to consult the water supply authority for advice on what materials should be avoided.

11.4 The choice of materials for buried piping and fittings should also take into account the nature of the soil in which the piping is to be laid. The materials selected should, where necessary, resist possible corrosion both inside and outside. The extent, if any, of anti-corrosion treatment of the outside of the piping will depend on the analysis of the soil. The advice of the water authority (see Note 1); should be sought on the protective measures usually adopted in the area.

11.5 Corrosion (or erosion) can be caused by the motion of water when it is in a turbulent state and thus subject to rapid changes in pressure. Minute vapour or gas bubbles may be released at instants of low pressure; these collapse with implosive force the moment the pressure is increased. The collapse of such bubbles upon a metallic or concrete surface will quickly cause deep pitting or erosion of that surface. The designer should therefore avoid high velocities, the sudden increase of pressures or pulsating pressures.

11.6 Metallic piping should not be installed in contact with corrosive building products and materials.

11.7 Corrosion may result from galvanic action where dissimilar metals are connected. Dissimilar metals should be avoided as far as practicable, but if that is not possible, it should be determined that deterioration through galvanic

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action is unlikely to occur, or else effective measures should be taken to avoid deterioration.

11.8 The materials generally used for the conveyance of water in healthcare premises are stainless steel or plastics. Copper is only used in exceptional circumstances such as, an extension to existing premises with short life expectancy, or very small stand alone premises. Where this is specified, only lead-free solders should be used.

11.9 Substances leached from materials of construction of pipes, cisterns or other water fittings in contact with water must not adversely affect the quality of water stored or drawn for domestic or food production purposes (Water Byelaws (Scotland) 2000).

11.10 Direct gas-fired water heaters are particularly prone to corrosion and scale formation, and the inside of these heaters should be provided with suitable linings to limit these effects.

Steel pipes and fittings

11.11 Where steel is used for bolts, nuts and slip-on couplings, adequate protection from corrosion should be provided. This usually takes the form of bitumen coating, but bitumen is not permitted in contact with water required to be wholesome (that is, to be used for normal domestic or food production purposes).

11.12 The character of water in Scotland is such that steel, whether galvanised or not, should not be used at all for domestic hot and cold water installations. Any existing premises with such pipework shall have this scheduled for early replacement.

Stainless steel

11.13 Stainless steel is being increasingly used in hot and cold water service systems. Reference should be made to SHTN 2: ‘Domestic hot and cold water systems for Scottish health care premises’.

Copper pipes and copper/copper alloy fittings

11.14 As described previously, careful consideration will be required if copper pipework and fittings are to be specified for healthcare premises in Scotland. Where this is considered to be acceptable either due to the size of the project or the anticipated lifespan of the facility, the following will apply.

11.15 Copper in general is resistant to corrosion. Unless resistant to dezincification, brass fittings must not be used where water conveyed is capable of dissolving undue amounts of zinc from the fitting. External protection from corrosion for buried pipework may be obtained by using copper tube with a factory-applied polythene sheath. Dezincification-resistant material must be used for fittings that

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are concealed or inaccessible, for backflow prevention devices, and for temperature and pressure-relief devices on heating systems. Copper piping should conform to BS EN 1057: 1996 as appropriate for underground or above - ground installations. When soldering copper tube and fittings, refer to WRAS Information and Guidance Note 9-04-02: 'Solder and fluxes'. If wax-based soldering fluxes must be used, they should be used sparingly. They pose a risk of bacterial contamination to the system, which can be difficult to eradicate.

11.16 Fittings should comply with the requirements of BS EN 1254-1−5:1998. Copper piping may be jointed by means of compression joints or capillary joints. Effective capillary joints in copper pipes can be achieved if care is taken in their construction. Where compression joints are used with fully annealed copper piping, these should be manipulative joints; that is, joints in which the tube ends are flared or grooved.

11.17 Lead-free materials must be used in the formation of all potable water pipe capillary joints.

Plastics

11.18 Most water systems operate at modest pressures and at a maximum temperature of 70°C. Such operating conditions are within the specified performance of plastics being produced in a range of sizes and costs suitable for healthcare premises. Plastic pipework is not suitable for renal dialysis applications where water at a temperature of 95 C is regularly circulated for sanitisation and there is an incompatibility with reverse osmosis treated water used in renal dialysis and in endoscope cleaning.

11.19 Advantages of plastic include corrosion resistance, lightness of weight and ease of handling.

11.20 Disadvantages include poorer mechanical strengths than metals, greater thermal expansion (about seven times that of copper), low temperature (and possible long-term embrittlement [20–25 years]) and shorter distances between pipe supports. The latter can be alleviated by employing the manufacturer's profiled longitudinal tray that snaps into place and extends the distances between supports.

There have also been difficulties with ring seal failures that have required wholesale replacements of all fittings.

11.21 Materials in common use for plastic pipework are medium-density and high-density polythene, the latter being stronger. Unplasticised polyvinyl chloride (PVC-U) pipework has mainly been replaced by the stronger chlorinated polyvinyl chloride (PVC-C) equivalent. All materials used for the transportation of water can give rise to contamination by differing processes. It is therefore important when introducing new materials that care is taken to ensure that appropriate standards are maintained. In the case of plastic materials, this can often be achieved by introducing a suitable "flushing" routine during the commissioning period.

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11.22 PVC pipes to BS 3505:1986, BS EN 1452:2000 (parts 1−5) and BS 3506:1969 are of a rigid material that has a greater tensile strength than polythene, but is less resistant to fracture. These materials are less susceptible to frost damage than metal pipes. Although freezing is unlikely to damage the pipe, it will result in interruption of supply, and subsequent leakage from joints may occur.

11.23 Polythene pipes are generally not susceptible to corrosion from either the water or the ground in which they are laid. However, they are not recommended in any soils contaminated with organic materials likely to permeate the plastics and taint the water such as coal gas, methane, oils, petrol or other organic solvents. Further advice is available in the WRAS Information and Guidance Note 9-04-03: 'The selection of materials for water supply pipes to be laid in contaminated land'.

11.24 It is essential to consider the locality of exposed plastic pipes to ensure that there is no likelihood of mechanical damage and effects of UV daylight; otherwise suitable protection around the pipe will be necessary.

11.25 Further advice on flushing regimes is given in SHTN 2: 'Domestic hot and cold water systems for Scottish health care premises'.

11.26 Methods of jointing employed include compression joints with insert liners, flanged, screwed and fusion-welded joints, as well as joints of the spigot and socket type. The method of jointing employed is dependent on the bore of the pipe and the applied internal pressure, and should be in accordance with the manufacturer's recommendations. A competent fitter who has been trained under an approved scheme should make joints.

Composite materials

11.27 Less proven, but available on the market, are composite pipes, for example aluminium pipe with an external and internal sheath of plastic. Little evidence on the performance of such pipes is so far available, and questions remain over earth bonding.

Iron pipes and fittings

11.28 Ductile iron is not used nowadays but it may be encountered in the course of a refurbishment project. Iron has good resistance to corrosion, and this is further enhanced if the casting skin on the metal is still intact. Although ductile iron pipes are thinner than grey iron pipes, their resistance to corrosion is at least as good, and there is evidence that they tend to be rather more resistant. In assessing the life expectancy of ductile iron pipelines, account should be taken of any intended higher operating pressures that may be used or permitted. Any iron pipework encountered should be risk assessed with a view to early replacement, dependent upon the anticipated life span of the accommodation served.

11.29 In made ground containing ashes and clinker, or in certain natural soils, such as aggressive waterlogged clays, saline and peat marshes, additional external

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protection may be required. This may be provided by the use of protective coatings such as bitumen or coal-tar sheathing, by protective tapes, by loose polythene sleeving or, in certain circumstances, by concrete. The water supply authority is using more composite materials in pipework to overcome the risks.

Lead

11.30 No new lead piping should be installed in any building. In the unlikely event of any lead pipework being discovered in existing healthcare premises, it should be removed as soon as practical.

Concrete

11.31 Protection of concrete pipes may be required against sulphate and acid attack. The minimum size available in concrete pipework is 150 mm diameter, and therefore its practical use for healthcare premises is very limited.

11.32 Standard concrete pipes may be used when not subjected to internal pressure. Pre-stressed concrete pipes are available as pressure pipes, but only in larger sizes.

Asbestos cement pipes and fittings

11.33 Asbestos cement pipework should not be used and, if encountered in the course of a refurbishment project, it should be stripped out and replaced as a high priority with modern materials such as medium density polyethylene.

11.34 Specialist advice should be obtained if stripping out materials containing, or suspected of containing, asbestos is carried out.

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12. Pipework installations

General

12.1 All hot and cold water pipework should be designed and installed in full accordance with the Water Byelaws (Scotland) 2000 and relevant parts of BS 6700:1997 and BS EN 806-2:2005.

12.2 It is essential to include within the system facilities for measuring, regulating, isolating, venting, draining and controlling the flow of water. Regulating valves with built-in pressure tappings or orifice plates with manometer tappings will be required for the measurement of pressure drop, which enables the volume rates of flow to be determined. Care must be taken to ensure that regulating valves or orifice plates are sited well away from bends or fittings.

Sizing

12.3 Mains should be capable of a rate of flow to satisfy the combined maximum demand of all the services to be supplied. All the maximum demands of the separate services may not occur simultaneously, and the actual combined maximum demand may be a proportion of the sum of the separate maximum demands, which will be determined by the number and character of the services.

12.4 Hot and cold water pipework should be sized using the procedure outlined in CIBSE Guide G: 'Public health engineering.

Routeing of pipework

12.5 Pipework in buildings should be designed and routed in a manner that will promote good turnover of water, particularly in cold water service systems (see Figure 5). It should be installed so that it is accessible for inspection, maintenance and repair as far as is practicable. Ducts, trenches and chases containing pipework should be large enough to facilitate repairs.

12.6 Pipework distribution networks should be divided into sections by the provision of isolating valves in accessible locations to facilitate isolation for repairs, maintenance and flushing.

12.7 Underground mains need not be laid at unvarying gradients but may follow the general contour of the ground. As far as possible, however, they should fall continuously towards drain points and rise continuously towards the air vent. They should not rise above the hydraulic gradient; that is, there should always be a positive pressure, greater than atmospheric, at every point under working conditions. The gradient between air release and drainage valves should be not

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less than 1:500 rising in the direction of flow and not less than 1:200 falling in the direction of flow.

12.8 Underground pipes entering a building should do so with a cover of not less than 0.75 m below the external ground surface and should pass through the wall within a watertight built-in sleeve. The sleeve should be filled in around the pipe with a suitable material for a minimum length of 152 mm at both ends to prevent the ingress of water or vermin. External underground pipes should be at a depth, or otherwise sufficiently protected, to prevent damage by traffic and any consequent vibrations. A minimum depth under roadways of 1 m measured from the top of the pipe to the surface of the roadway is necessary. In other underground locations the depth should not be less than 0.75 m, subject to this depth being sufficient protection against frost; frost penetration depends on the nature of the subsoil and the ground surface. Freezing can occur at depths of up to 1.1 m. Local information on the prevalence of frost should be sought.

12.9 Marker tapes should be laid over the whole length of all underground water services pipework. The tapes should be clearly marked with the description of the service and should be coloured blue.

Vents and drains

12.10 Air-release valves should be provided at summits and drainage valves at low points between summits, unless adequate provision is made for the discharge of air and water by the presence of service connections. Large-orifice air valves will discharge displaced air when mains are being charged with water. When air is liable to collect at summits under ordinary conditions of flow, small orifice air valves, which discharge air under pressure, may be required. “Double-acting” air valves having both large and small orifices should be provided where necessary. Air-valve chambers should be adequately drained to avoid the possibility of contamination.

12.11 Automatic air-release valves should be installed where accessible for maintenance. Installation in ceiling voids is not recommended.

12.12 Drain points should not discharge directly into a drain or sewer or into a manhole or chamber connected thereto without a type A air gap. Where a wash-out discharges into a natural watercourse, the discharge should at all times be well above the highest possible water level in the watercourse. Consent for this discharge may be required from the Scottish Environment Protection Agency. In some cases it may be necessary for the wash-out to discharge into a watertight sump, which has to be emptied while in use by portable pumping equipment.

12.13 In order to minimise quantities of water that may collect in stub pipes at drain points, the length of such stub pipes should be kept to an absolute minimum. This relates in particular to drains from hot water calorifiers, storage cisterns and distribution pipework.

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Valves

12.14 A clear indication should be given on all valves of the direction of rotation needed to close the valve. Normal practice is to have clockwise closing when looking down on the valve.

12.15 Where blending valves have been installed at the end of a run of hot water pipework, consideration should be given to the inclusion of a drain valve adjacent to the mixer. This should be located upstream of the mixing valve so as to facilitate flushing out and routine temperature testing of the hot water without having to dismantle the blending valve.

Prevention of contamination

12.16 In all cold water installations it is important that adequate protection be provided to all supplies against backflow. In healthcare facilities, there should be a high degree of protection not only to the water in the water supply authority's mains, but also within the installations to protect the patients and staff. In addition to backflow protection at all points of use, the whole installation protection should be provided as required by the Water Byelaws (Scotland) 2000.

12.17 Healthcare buildings and medical premises have been identified as involving Fluid Category 5 backflow risks (see Schedule 1 "Fluid Categories" from the Water Byelaws (Scotland) 2000 which are defined as points of use or delivery of water where backflow is likely to involve fluids contaminated with human waste. Within healthcare facilities, water usage covers a wide range of applications, from domestic use by patients and staff to specialised use in operating departments and pathology laboratories, and with equipment such as bedpan washers and haemodialysis machines. In addition, many apparently "commercial" usages may be classed as high-risk because they are for healthcare purposes, such as centralised laundries.

12.18 The hot and cold water storage and distribution systems should be designed so as to avoid the risk of contamination of the water supply. Such contamination may be caused by backflow, interconnections between potable and non-potable water supplies, stagnation, contact with unsuitable materials or substances, *Legionella* growth etc. The Water Byelaws (Scotland) 2000require the identification, by colour-coding or labelling, of all pipework carrying fluids other than wholesome water.

12.19 Comprehensive guidance on the measures required to prevent contamination of the water supply is given in the WRAS 'Water Regulations Guide' and in relevant parts of BS 6700:1997 and BS EN 806-2:2005.

12.20 Certain departments such as pathology laboratories present particular risks of water contamination. Attention is drawn to section G15.24 in the WRAS 'Water Regulations Guide' on supplementing point-of-use protection by zone protection, where the pipes supplying a high-risk area can be given additional protection by installation of a secondary backflow protection device.

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12.21 Instances of water use in hospitals where backflow is likely to be harmful to health include bidets, bedpan washers, dental spittoons and equipment, mortuary equipment, and water outlets located in laboratories.

12.22 Where any doubt exists with regard to the level of protection required against water supply contamination, reference should be made to the Water Byelaws (Scotland) 2000 and guidance contained in the WRAS 'Water Regulations Guide', or water supply authority.

Frost protection

12.23 The Water Byelaws (Scotland) 2000 require that all cold water pipework and fittings be adequately protected against damage from freezing.

12.24 In the case of external pipework that is run underground, the Regulations require that consent be sought from the water supply authority if pipes are to be run at depths of less than 750 mm or greater than 1350 mm. Permission from the water supply authority must be sought if any deviation is required.

12.25 Particular care is required when routeing pipework externally above ground or through unheated areas within buildings. The WRAS 'Water Regulations Guide' gives guidance on the minimum thickness of thermal insulating materials that should be applied in such cases.

12.26 Adequate provisions for isolating and draining sections of cold water distribution pipework will ensure that disruption caused by frost damage can be minimised.

12.27 For further guidance on frost protection, refer to the WRAS 'Water Regulations Guide'.

Flushing

12.28 Prior to taking systems into use, they should be subject to a thorough regimen of flushing before disinfection (see paragraph 17.15).

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13. Noise and vibration

Pump noise

13.1 Noise generated by centrifugal pumps will not cause problems if water velocity in the pipes and the speed of the pumps are low, for example about 1 m/s and 960 rpm respectively.

13.2 Care should be taken in locating water-boosting pumps within healthcare buildings to ensure that they will not cause interference to wards and other quiet zones.

13.3 Such interference may result from break-out noise from the boosting equipment, or noise transmitted through the pipework system or through the building structure. Pump noise may also result from cavitation caused by low suction head.

13.4 Where pumps are located close to sensitive areas, provision for noise and vibration reduction must be incorporated within the design. Such provision will include selection of quiet-running motors, vibration isolation of boosting equipment from pipework and structure and, if required, acoustic lining to the booster plant enclosure.

13.5 Guidance on recommended noise levels for various locations is given in CIBSE Guide A: 'Environmental design'.

Other forms of system noise

13.6 Other forms of nuisance noise that may be generated by hot and cold water distribution systems are listed below:

- noise from pipework due to excessive water velocity;
- water hammer caused by rapid closure of valves or taps;
- oscillation of the float of a float-operated valve;
- tap washer oscillation;
- noise caused by water discharging from float- operated valves into cisterns;
- noise caused by thermal movement of pipes;
- noise due to trapping of air within pipework, particularly on hot water systems.

13.7 Further details on the above sources of noise, including guidance on avoiding such noise problems, are given in the WRAS 'Water Regulations Guide'.

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14. Water economy and energy conservation

Water

14.1 Hot and cold water distribution systems for healthcare buildings should be designed so as to minimise the use of water. The cold water distribution systems should incorporate an adequate number of water meters to allow for close monitoring of water consumption. Where practicable, consideration should be given to linking water meters to a building management system.

14.2 Measures to minimise water consumption that should be considered at design stage include:

- provision of automatic systems to control flushing of urinals;
- use of showers rather than baths wherever practicable;
- WC pans and flushing cisterns that use more than 6 L per flush are prohibited by Water Byelaws (Scotland) 2000;
- control of water pressure to a level that is not excessive for the purpose required;
- provision of water flow restrictors at hot and cold water taps – these must not be used in conjunction with thermostatic mixing valves unless approved by the manufacturer of such valves; restrictors or regulators should not be installed at the inlets of thermostatic mixing valves;
- use of percussion taps in appropriate circumstances;
- locating warning pipes from cisterns and discharge pipes from relief valves in such a way that any discharge can be readily observed, and/ or fitting alarms on such pipes.

14.3 Further guidance on the prevention of wastage of water is given in the WRAS 'Water Regulations Guide'. Reference should also be made to the Audit Commission's (1993) 'Untapped savings: water services in the NHS'.

Energy

14.4 Energy used in the generation of hot water can be minimised by ensuring that the hot water storage and distribution system is adequately insulated and that thermostats controlling water temperature in hot water storage vessels are set no higher than is necessary for the control of *Legionella*.

14.5 Hot and cold water systems should be designed to operate by gravity as far as possible. Where water - boosting pumps are necessary, the pump motors should be selected to operate at maximum efficiency at the required duty.

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14.6 The practice of pre-heating of the cold feed to calorifiers should not be carried out. The only time it is acceptable is when under all flow/demand conditions a temperature greater than 45°C can be guaranteed at the entry to the calorifier. Any pre - heater should have a low water capacity.

14.7 Further guidance on energy conservation in relation to hot and cold water systems is given in Scottish Health Technical Memorandum 07-02: EnCO_2de – making energy work in healthcare, environment and sustainability, 2006 (see also the Carbon Trust's website, http://www.carbontrust.co.uk).

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15. Water treatment

Chlorine dioxide

15.1 Chlorine dioxide is an oxidising biocide that is capable of reacting with a wide range of organic substances and has been shown to be effective in the control of organisms in water systems. Use of chlorine dioxide as a chemical treatment for drinking water treatment is now subject to a European Standard (BS EN 12671:2000).

15.2 The use of chlorine dioxide as a control measure should only be considered strategically on a complete site/campus basis to ensure continuity of control measures. This will depend on the water supply quality and on the design of the systems in use and, in an existing system, their operational history.

15.3 There are two aspects to be taken into consideration:

a. in the cold water distribution system, chlorine dioxide may be injected into the system upstream of all parts of the distribution, storage and boosting equipment or at the break-tank serving the booster set. There must be close monitoring and control of the dose, which should normally comply with the Water Supply (Water Quality) Regulations 2000 for the equivalent use of chlorine dioxide in the treatment of water supplies by the water authority;

b. in the case of hot water distribution systems with calorifiers/water heaters operating conventionally, that is, at 60°C, there will be a tendency for chlorine dioxide to be lost by 'gassing off', especially if the retention time in a vented calorifier/water heater is long. In most cases, however, some total oxidant should be found in the hot water, although at levels far less than the 0.5 ppm injected. The calorifier/water heater should act as a barrier to dispersal of any pathogenic material by the hot water system.

15.4 Where copper supply pipes are used, chlorine dioxide can result in high concentrations of copper being measurable in the water supplies.

15.5 Additional information on chlorine dioxide is given in Appendix 4.

Silver/copper ionisation

15.6 Ionisation systems release copper and silver ions into the water stream by means of electrolytic action. Ionisation as a water treatment method is covered in BSRIA's Technical Note TN 6/96 following a study in which it was shown that copper and silver ion concentrations maintained at 400 µg/L and 40 µg/L respectively can be effective against planktonic *Legionella* in hot water systems. In soft waters a silver level as low as 20 µg/L can be effective.

15.7 The use of ionisation as a control measure should only be considered strategically on a complete site/campus basis to ensure continuity of control

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measures. This will depend on the water supply quality and on the design of the systems in use and, in an existing system, their operational history.

15.8 The electrodes can be susceptible to accumulation of scale unless effective anti-scaling electrode cells are fitted. The system should be designed to take account of water quality, otherwise additional treatment may be necessary. Copper and silver ion treatment is also sensitive to pH, and thus pH control may be required.

15.9 In hard water areas there have been cases of staining of sanitaryware, but in a properly controlled system where dosing levels of silver are not exceeded, this should not be a major problem.

15.10 The opinion of the Committee on Products and Processes for Use in Public Water Supply concerning the use of silver as a disinfectant in public water supplies can be found on the Drinking Water Regulator website: http://www.dwi.gov.uk/cpp/silver.htm.

15.11 Additional information on copper and silver ions is given in Appendix 5.

Ozone and ultraviolet treatment

15.12 Whereas the previous treatments are intended to be dispersive (that is, they result in a residual agent within the system), ozone and ultraviolet are intended to be effective close to the point of application. They are not, therefore, necessarily effective in hot and cold water service systems.

15.13 Ultraviolet and ozone are methods that are suitable for water systems used for dialysis equipment. However, allowance must be made for the aggressive effects of ozone on materials exposed to it, particularly the degradation of rubber compounds and the corrosion of metallic materials.

15.14 The systems should be fail-safe and have adequate instrumentation to monitor operation. For example, UV systems should be preceded by particle filtration to prevent microorganisms being shielded by particles, and incorporate a detector so that any loss of transmission can be corrected immediately. They require appropriate pre-filtration to remove particulate matter that may shield bacteria from the UV rays.

Purging the systems

15.15 When the system is initially dosed, checks should be made at various parts of the system to ensure that satisfactory concentrations of treatment chemicals are being achieved.

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16. Testing and commissioning

Introduction

16.1 While testing and commissioning is regarded as a discrete activity, continuous monitoring is required throughout the installation to ensure that:

a. materials and equipment installed comply with the Water Byelaws (Scotland) 2000 and other British Standards, and are not otherwise unsuitable. Equipment that is listed in the latest edition of the 'Water Fittings and Materials Directory' and installed in accordance with any of its relevant conditions will comply;

b. the work is done entirely within the specification for the scheme;

c. all the requirements of current legislation are met, both during construction of the installation and when it is completed, particularly with regard to the Health and Safety at Work etc Act 1974.

Installation checks

16.2 The system should be regularly checked during installation to ensure that open pipes, valve ends, cylinder connections etc are sealed to prevent the ingress of dust/debris that could cause problems during commissioning and subsequent operation. Checks should also be made to ensure that fittings and materials comply with the Regulations and are those listed in the 'Water Fittings and Materials Directory', and that lead solders are not being used. Equipment that requires to be maintained or which is likely to fail or be replaced during the life of the system should be de-mounted and re-instated during the installation process to ensure that it is maintainable and that appropriate isolation is provided to ensure safety and continuity during operational use.

Inspection of joints

16.3 Before pressure testing, the site engineer should identify a number of fittings to be cut out for examination to establish whether the quality of the finished joint meets the specification. The exact number to be cut out will vary according to the size of the installation, but as a guide, a ratio of one fitting per 400 installations should be cut out. In any event, a minimum of two, and not normally more than five, fittings should be cut out for examination.

16.4 The fittings cut out should be cut open (quartered longitudinally) and examined. If unacceptable joints are found, adjacent fittings should be cut out until the extent of any faulty workmanship has been established.

16.5 The pipeline should be made good.

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16.6 The tube and fitting should be internally clean and free from particulate matter. Some oxidation will be evident when hot “joints” are made on copper piping.

16.7 When copper pipe and capillary fittings are used, because of the viscosity of the brazing filler, full penetration may not be achieved.

16.8 The minimum penetration at any point must be three times the wall thickness of the tube or 3 mm, whichever is the greater.

Commissioning

16.9 Correct commissioning is vitally important for the satisfactory operation of the hot and cold water systems. The designer should prepare a commissioning brief for use by the contractor’s commissioning engineer. This brief should specify fully and clearly the extent of the commissioning and maintenance and the objectives which must be achieved, and should include:

- full design data on temperatures, water flow rates and pressures;
- plant and equipment data;
- number commissioning procedures for thermostatic mixing valves in accordance with specification MES D08;
- drawings and schematics;
- a list of test certificates to be provided.

16.10 The designer’s attention is drawn to CIBSE Commissioning Code W: ‘Water distribution’, which provides guidance on information that will be required by the commissioning engineers.

16.11 In the preparation of commissioning instructions for domestic hot and cold water services, designers should ensure that their work is in accordance with up-to-date guidance from the Department of Health’s Estates & Facilities Division.

16.12 The designer should prepare for inclusion in the contract documents a list of tests and measurements that are to be taken by the contractor and recorded by him/her. These should be witnessed by the contract supervising officer or project engineer on his/her behalf and he/she, if approved, will circulate the results, in accordance with the client’s instructions.

16.13 The commissioning manual should be prepared by the contractor and submitted to the client’s commissioning adviser for review before being issued in final form.

16.14 Typical schedules of checks and performance tests should be included in the commissioning manual together with record sheets. These should be amended and supplemented as the designer/client advisor considers necessary.

16.15 The supervising officer or project engineer, who should countersign any relevant test record documents, should witness commissioning and testing.

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16.16 'As installed' record drawings, schematic diagrams, operating and maintenance instructions must be supplied at the time of handover. Certified records of pressure testing and disinfection should also be made available.

16.17 The whole commissioning procedure should be carried out under the guidance of a single authority, although the involvement of specialists or manufacturers may be required for specific items of plant.

16.18 Valid calibration certificates should be submitted and checked for all measuring equipment to be used by the commissioning engineers prior to commencement of commissioning.

16.19 The commissioning should be carried out in a logical and methodical manner.

16.20 The installation, on completion, should be operated by the contractor as a whole, and subjected to specified functional or performance tests.

16.21 Once the system meets the design intent, the final completion record sheet(s) should be completed. In the event of performance not being acceptable, the matter should be dealt with in accordance with the contract requirements.

Commissioning and testing checklists

16.22 The following is a summary of the key activities associated with pre-commissioning and commissioning of hot and cold water storage and distribution systems. The list is not intended to be comprehensive.

Cold water installations

16.23 Pre-commissioning checks can be carried out on completion of the system installation, filling and pressure testing.

16.24 Pre-commissioning checks and tests to be applied are as follows. Check that:

- systems have been provided and installed in accordance with specification and drawings, and that the systems are charged with water, vented and free from leaks;
- water storage cisterns are free from distortion and leaks, are properly supported and secured, are provided with correctly fitting covers, and are in accordance with the Water Byelaws (Scotland) 2000;
- distribution pipework is rigidly supported, insulated, and incorporates adequate provisions for venting, draining, expansion, isolation and measurement of flow, temperature and pressure;
- pipework systems have been pressure tested;
- pipework systems and storage cisterns have been flushed, disinfected, appropriate certification received, and that specified residual chlorine levels are attained;

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- pipework systems and storage/break tanks are correctly identified and marked;
- regulating valves and flow control devices operate freely;
- water meter(s) is/are fitted correctly;
- electrical isolation, cross-bonding and wiring of system components are installed in accordance with the current edition of BS 7671:2008.

16.25 Upon satisfactory completion of the pre-commissioning tests, the commissioning tests can commence.

16.26 Commissioning checks and tests to be applied are as follows. Check that:

- overflows run freely and discharged water does not cause flooding or damage, and that drain- down points flow when released and are free from leaks when shut;
- float-operated valves function satisfactorily and are adjusted to give the correct water level;
- control valves operate correctly and shut-off valves close tightly;
- all electrical circuits are tested and the pump motor direction of rotation is correct, and that electrical controls and alarms function correctly;
- operation of any safety or anti-flood device is satisfactory;
- circulating or lifting pumps are free from excessive noise, vibration and leaks;
- remote control of pumps (if appropriate) is satisfactory;
- the installation is vented and regulated;
- the flow rate into, and out of, storage cisterns is recorded;
- all taps, mixers and outlets operate satisfactorily, and test and record mass flow from outlets in positions shown on contract drawings. (TMVs require hot and cold water for testing and commissioning. Type 3 TMVs are commissioned in accordance with MES D08.);
- temperature of water in storage cisterns and at taps is appropriate;
- full load current of components does not exceed the recommended values;
- the running current of components does not exceed the recommended values;
- pump thermal overload trips are set;
- system schematic is displayed in a frame in the relevant plantroom, complete with valve schedule.

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Hot water installations

16.27 Pre-commissioning checks can be carried out upon completion of system installation, filling and pressure testing.

16.28 Pre-commissioning checks and tests to be applied are as follows. Check that:

- systems have been provided and installed in accordance with the specification and drawings;
- the system is charged with cold water, vented, and free from leaks;
- hot water storage vessels are free from leaks and are properly supported and secured;
- distribution pipework is rigidly supported, insulated, and incorporates adequate provision for venting, drainage, expansion, isolation, and measurement of flow, temperature and pressure;
- pipework systems, storage cylinders etc have been pressure tested, flushed and disinfected, and appropriate certification has been received, and that specified residual chlorine levels are attained;
- pipework systems, calorifiers and cisterns are correctly identified and marked;
- regulating valves and flow control devices operate freely;
- all control and regulating valves are labelled or marked to correspond with reference numbers on contract drawings;
- electrical isolation, cross-bonding and wiring of system components is installed in accordance with the current edition of BS 7671:2008;
- system schematic is displayed in a frame in the relevant plantroom.

16.29 Upon satisfactory completion of the pre-commissioning checks, the commissioning checks and tests can then be started.

16.30 Commissioning checks and tests to be applied are as follows. Check that:

- drain down points flow when released and are free from leaks when shut, and that air vents and release valves open correctly and are airtight when shut off;
- all temperature and other controls are adjusted and calibrated to agreed design limits of system performance;
- all electrical circuits are tested and the pump motor direction of rotation is correct, and that electrical controls and alarms function correctly;
- control valves operate correctly and shut-off valves close tightly;
- heat exchangers operate satisfactorily;
- primary heating circuits are adjusted and regulated, and thermostatic settings are correct; and that bypass circuits and automatic control valves operate correctly;

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- circulating pumps are free from excessive noise, vibration and leaks;
- remote and automatic control of pumps (if appropriate) is satisfactory, and there are no leaks at joints under maximum flow conditions;
- secondary circuits are regulated and vented;
- thermostatic mixing devices and regulating valves are adjusted and set to desired values (TMVs require hot and cold water for testing and commissioning, and should be commissioned in accordance with MES D08);
- all taps, mixers and outlets operate satisfactorily;
- water flow quantities at all plant items, regulating valves and flow-measuring valves are recorded;
- mass flow from taps, main and other outlets in positions shown on contract drawings is satisfactory;
- pressure drop at heat exchangers at full design demand flow is tested and recorded;
- hydraulic balancing of hot water secondary circulation system is carried out to ensure that minimum temperatures are achieved in all parts of the circuit;
- full load current of components does not exceed the recommended values;
- the running current of components does not exceed the recommended values;
- pump thermal overload trips are set.

Pressure testing

16.31 Pressure testing must be carried out before disinfection. Except where otherwise specified, testing of underground pipelines should be carried out in accordance with the requirements of the Water Byelaws (Scotland) 2000.

16.32 Open pipes should be capped and valves closed to avoid contamination.

Temperature testing

16.33 These tests should be performed prior to contractual handover and bringing the system into use. Separate thermostatic measuring and recording equipment should be used, that is, independent of any building management system. It will be necessary to have systems fully operational and to simulate typical draw-off of water.

16.34 Tests should include:

- measuring the incoming water temperature at the main water meter;
- testing the inlet, outlet and surface water temperatures of cisterns and cold water feed/ header tanks for the hot water calorifiers. The temperature

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should not be greater than 2°C above that measured at the main water meter;

- testing the flow and return temperatures at connections to calorifiers and water heaters. These should not be less than 60°C and 50°C respectively;
- testing the temperature in branches of hot water circulating systems installed in all departments to ensure that the system has been balanced, and that under "no draw-off" conditions 55°C is achieved in the circulating system at outlets furthermost from the calorifier/heater;
- testing single hot water outlets and inlets to mixing valves to ensure that a minimum of 55°C is achieved within 1 minute;

Note: The Health and Safety Commission's (2000) Approved Code of Practice L8 permits a period of 1 minute to achieve an equilibrium temperature of 50°C. A minimum of 55°C may be required for the operation of suitable mixing devices required to provide 'safe' hot water at the upper limit of the recommended range. Hot water at 55°C is required in many cases for reasons of food hygiene or decontamination requirements, for example in kitchens and sluice rooms. In a properly balanced hot water circulating system, with the circulation taken close to the draw-off point, achieving temperature should be virtually instantaneous. (At a typical flow to a wash-hand basin of 4.5 L/m, 1 min to achieve temperature would indicate a 25 m dead-leg of 15 mm pipe or that the system is out of balance.)

- testing single cold water outlets and inlets to mixing valves to ensure that temperature equilibrium below 20°C is achieved within 2 min.

Note: The Health and Safety Commission's (2000) Approved Code of Practice L8 permits a period of 2 min to achieve an equilibrium temperature below 20°C. Achieving this minimum requirement would be indicative of an exceptionally under-utilised water system in an unoccupied building. During commissioning, therefore, it is essential to encourage draw-off to simulate normal usage. (At a typical flow to a hand-wash basin of 4.5 L/m, 2 min to achieve temperature would indicate a 50 m dead-leg of 15 mm pipe or that stagnation is occurring.)

- Testing the temperature at hot water draw-off points to ensure that they comply with the recommended temperatures in Table 4. (Note: the maximum temperatures should not exceed those shown in Table 4 by more than 2°C.)

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17. Disinfection

17.1 Guidance on disinfection is given in BSRIA's (2004) Application Guide 1/2001.1: 'Pre - commission cleaning of pipework systems', which contains recommendations for the design, installation, system-flushing and chemical cleaning of pipework systems. Disinfection should be applied to the complete hot and cold water service systems. When considering a contractor to carry out the work, preference should be given to companies/individuals who are members of the *Legionella* Control Association (formerly, the Code of Conduct Association for the Control of Legionellae).

17.2 Alternative disinfectants may be used, provided satisfactory disinfection is achieved. The infection control team should be consulted, and advice should also be sought from the Drinking Water Regulator.

Note: Disinfection is a requirement of the Water Regulations. Additional advice on the use of alternative disinfectants is given in SHTN 2: 'Domestic hot and cold water systems for Scottish healthcare premises'.

17.3 Proprietary solutions of disinfectant should be used in accordance with the manufacturers' instructions. The COSHH Regulations require that the risks from using the disinfectant for each task be assessed to ensure that the control procedures adopted are suitable for the particular application.

17.4 Disinfection should not be undertaken before materials, for example linings in cisterns, have fully cured. Advice should be sought from equipment manufacturers to ensure that proposed disinfection chemicals will not adversely affect performance. No heat source should be applied during the disinfection procedure, including final flushing.

17.5 Pipework under pressure from the mains should be disinfected through an injection point and the disinfectant residual measured at the end of the pipeline. BS 6700:1997 and the Approved Code of Practice L8 advise 50 mg/L (ppm) for one hour or 20 mg/L (ppm) for two hours; it is usual practice to leave the chlorine solution in the pipes for 24 hours before thoroughly flushing out with fresh water. Junctions that are to be inserted into existing pipelines should be disinfected prior to installation.

17.6 All disinfection of pipework under pressure from the mains must be carried out in accordance with the requirements of the water supply authority. Failure to ensure close liaison between the contractor and the water authority during design, construction, pressure testing or commissioning could present a potential risk of back-flow of contaminated materials or chemicals into the public water supply. Site supervision to ensure compliance with any requirements specified by the local water supply authority is recommended.

17.7 All cisterns should be internally cleaned to remove all visible dirt and debris. Cisterns and distributing pipework should be drained, filled with fresh water and

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then drained completely. The cisterns should then be refilled and the supply servicing valves closed. On re-fitting it is normal practice to add high doses of sodium hypochlorite to the water in the cisterns, for example, to give a calculated chlorine concentration of 50 ± 10 mg/L (ppm) in the water, and leave the water to stand for one hour. Whatever disinfection method is used, the concentration should be adjusted if necessary. The use of a high dose ensures an adequate residual concentration to allow proper disinfection of the downstream services. Each tap or fitting should then be opened, progressively away from the cisterns, and water discharged until the disinfectant is detected. Each tap or fitting should then be closed, and the cistern and pipes left charged for a further hour. The tap(s) furthermost from the cisterns should be opened, and the level of disinfectant in the water discharged from the taps measured. If the levels set are not achieved, the disinfection process should be repeated.

17.8 As soon as possible after disinfection, the distribution pipework should be drained and thoroughly flushed through with fresh water and refilled (see paragraphs 17.14 and 17.15). Appropriate hazard warnings should be placed on all taps throughout the building during disinfection procedures.

17.9 After disinfection, microbiological tests for bacteria colony counts at 37°C and coliform bacteria, including Escherichia coli, should be carried out under the supervision of the infection control team to establish that the work has been satisfactorily completed. Water samples should be taken from selected areas within the distribution system. The system should not be brought into service until the infection control team certifies that the water is of potable quality.

Discharge of waste water used during disinfection procedures within buildings

17.10 Contaminated water that is run to waste into a natural watercourse or a drain leading to it should be treated in accordance with the requirements of the authority responsible for land drainage and pollution control. The authority responsible for that sewer should be informed.

Thermal disinfection (of hot water service systems)

17.11 The process introduces a serious scalding risk, and it is essential that steps are taken to ensure that access is limited to authorised personnel only until such time that the system has returned to normal operating temperature: it is unlikely to be a practicable alternative for a large system. It also requires the removal of thermostatic elements, thus introducing additional practical difficulties.

17.12 This process can be performed by raising the temperature of the entire contents of the calorifier, or hot water heater, followed by circulating the water throughout the system for at least an hour. The calorifier/heater temperature must be sufficiently high to ensure that the temperature in all parts of the circulating system, and at the return connection, does not fall below 60°C. After this period, each tap or draw-off-point should be run sequentially from the nearest point to the furthermost outlet. At branches it will be necessary to draw-off water to at

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least one outlet, the nearest, to ensure adequate purging. The draw-off at the tap or outlet should be for a period of at least five minutes at full temperature.

Maintaining control of systems

17.13 Once disinfection has taken place, it is essential to put in place measures to ensure that hot and cold water temperatures are maintained. This will require regular flushing, at least weekly, and possibly more frequently during periods of hot weather.

17.14 Once filled, systems should not be drained unless full disinfection is to be carried out prior to building occupancy and use. However, allowing water in newly installed capillary-jointed copper plumbing to stagnate can result in serious corrosion of the copper. To reduce the risk of this, it is recommended that flushing should take place on a weekly basis to introduce fresh water throughout the system.

17.15 To prevent the accumulation of biofilm during construction and testing, continuous dosing of water systems with appropriate biocides should be considered. Such treated systems should be regularly flushed to ensure that the biocide reaches all parts of the systems, and particularly outlets. Dosing with an appropriate level of biocide as soon as water hits a pipe or storage vessel, along with regular flushing, can control the accumulation of biofilm more effectively.

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18. Documentation

General

18.1 It is essential that a full report of all commissioning and testing activities is compiled and handed over to be incorporated within the operation and maintenance manuals.

18.2 These commissioning and testing records will be required so that subsequent maintenance and periodic checks can be made to ensure that the installation continues to operate as intended. Such information will includes results of temperature checks on the cold water supply and hot water circulating systems and commissioning and in-service test data for Type 3 TMVs. The information should also include identification of, and test results for, sentinel taps.

18.3 Where continuous water treatment is installed, the commissioning records should include details of settings of the equipment, dosing rates and requirements for testing.

18.4 Operation and maintenance manuals should be in accordance with BSRIA's (1990) Application Guide 1/87: 'Operation and maintenance manuals for building services installations'.

18.5 As a minimum, for new installations or major refurbishment, the contract should require the following documents and drawings to be supplied:

a. full manufacturing details, including batch numbers of all pipes and fittings;
b. full records and certificates of pressure tests for all sections of pipework;
c. settings of all balancing valves, with readings of flow rates where applicable;
d. full details of each item of plant, including arrangement drawings and appropriate test certificates;
e. as-fitted drawings showing clearly the location of balancing valves, flows and settings, isolation valves, drain valves;
f. schematic drawings for installation in plantrooms showing all valves and items of plant;
g. full details of water treatment parameters and operating modes and settings;
h. full details of maintenance requirements;
i. detailed confirmation of disinfection procedures to BS 6700:1997, and results of post-disinfection microbiological analysis;
j. full records confirming that all materials and fittings hold WRAS or equivalent accreditation.

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Appendix 1 Water consumption

Ward unit

For the purposes of this study, a ward unit is defined as a combination of all the rooms which make up the working area for patient care, that is, patients' bedrooms, day spaces, treatment, utility and test rooms, bathrooms, showers, WCs, pantry, staff rooms, cleaners' room etc and circulation spaces. Figure A1 shows the average daily consumption of stored water and Figure A2 shows the rate of supply of mains water to cistern.

Designers should consider the impact on water consumption of such specialist departments such as Renal Dialysis and the dumping of water as part of the filtration processes.

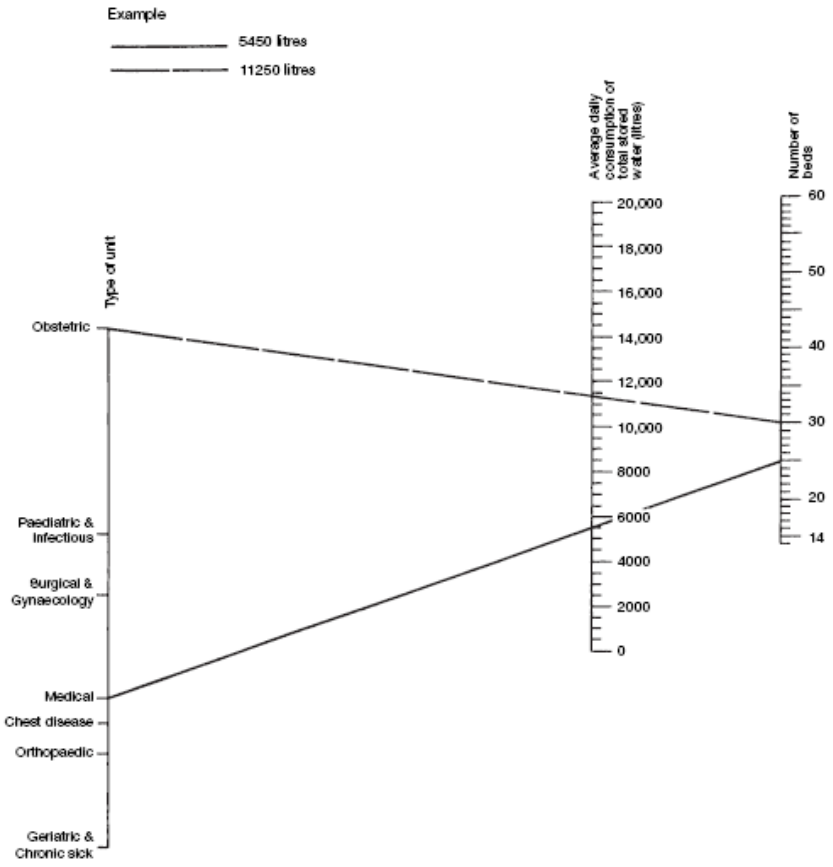

Figure A1: Average daily consumption of total stored water

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Use of nomogram
Project line from point ⊕ to number of beds. The intersection on 8000 scale gives rate of supply of mains water in litres/hour. The result obtained relates to one ward unit. For a given number of ward units, multiply by the number.

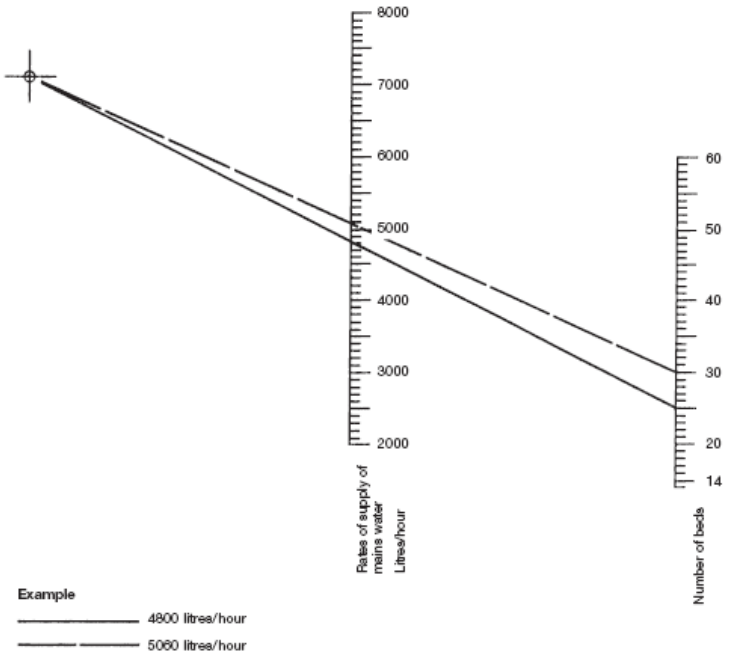

Figure A2: Rate of supply of mains water to cistern

Average water consumption by type and size of hospital

Table A1 (the results of a survey of NHS hospitals by the Department of Health and Social Security in 1974) provides basic data for design guidance on the estimation of water storage and consumption for whole hospitals.

The definitions which have been used for the classification of hospitals are shown in Table A2. 'Excluded departments' are those for psychiatry (mental illness), psychiatry (mental handicap), diseases of the chest, chronic sick, geriatrics and convalescence (including rehabilitation, but not pre-convalescence).

Relative intensity of water consumption

Whilst water consumption per bed content is a convenient estimating and planning yardstick, it does not show the widely differing floor areas which are provided per bed in hospitals of different sizes and type.

To illustrate the relative rates of consumption as seen against a basis of comparable patient density and showing the amount of water consumed − not only directly by the patient but also in the supporting treatment departments − a

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graphical presentation of the figures given in Table A1 is presented on a per bed and per floor area basis in Figures A3 and A4.

Sire band (no of beds)	No of hospitals in sample	Total no of beds in sample	Average size of hospital (no of beds)	Total consumption m³ per annum	Average consumption litres/bed/day
Acute (Types 1, 2, 3 and 17)					
0-50	150	4,208	28	458,900	299
51-100	58	4,151	72	602,909	398
101-200	70	9,946	142	1,780,700	490
201-400	62	18,167	293	3,914,351	590
401-600	23	10,741	467	2,348,682	599
Over 600	3	2,023	674	721,887	978
Specialist acute (Types 11, 14, 15, 16 and 18)					
0-25	53	931	18	108,336	319
26-50	18	651	36	82,455	347
51-100	38	2,664	70	352,133	362
101-200	16	1,952	122	341,004	479
Over 200	7	1,633	233	316,874	531
Long stay (Types 4 and 5)					
0-50	30	1,126	38	74,009	180
51-100	45	3,463	77	339,791	569
101-200	44	6,222	141	560,731	247
201-300	10	2,300	230	182,617	217
Over 300	3	1,121	374	125,247	306
Recovery and convalescent					
0-25	6	126	21	9,965	216
26-50	35	1,339	38	100,721	206
51-100	19	1,357	71	91,947	185
Over 100	3	449	150	29,663	181
Geriatric and chronic sick (Type 19)					
0-50	18	573	32	51,520	246
51-100	20	1,460	73	108,163	203
101-200	6	788	131	46,987	164
Over 200	2	512	256	23,748	127
Psychiatric (Types 12 and 13)					
0-100	46	2,186	48	166,588	209
101-200	12	1,773	148	156,814	242
201-400	13	3,782	291	976,559	273
401-600	10	4,884	488	443,662	249

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601-1000	7	5,112	730	654,024	350
Over 1000	5	6,098	1,220	747,676	336

Sire band (no of beds)	No of hospitals in sample	Total no of beds in sample	Average size of hospital (no of beds)	Total consumption m³ per annum	Average consumption litres/bed/day
London teaching (all types)					
0-100	20	1,161	58	789,422	680
101-200	15	1,896	126	1,642,106	866
201-300	10	2,580	258	2,141,166	830
301-500	8	3,161	395	2,859,434	904
Over 500	4	2,611	652	3,207,658	1,228

Table A1: Average water consumption by type and size of hospital

Type of hospital	Type number	Definition
Acute	1	Hospitals with not more than 15 per cent of their beds allocated to the "excluded departments"
Mainly Acute	2	Hospitals with more than 15 per cent and up to 40 per cent of their beds allocated to the "excluded departments"
Partly Acute	3	Hospitals with more than 40 per cent and up to 60 per cent of their beds allocated to the "excluded departments"
Mainly Long-stay	4	Hospitals with more than 60 per cent and up to 85 per cent of their beds allocated to the "excluded departments"
Long-stay	5	Hospitals with more than 85 per cent of their beds allocated to the "excluded departments"
Pre-convalescent	7	Hospitals with 90 per cent or more of their beds allocated to patients who have already received elsewhere the most intensive part of their treatment, but who still require active nursing care and medical oversight
Convalescent	8	Hospitals with 90 per cent or more of their beds allocated to patients recovering from a disability who no longer require active medical supervision or nursing care in bed though they may need such simple nursing procedures as renewal of dressings or the administration of medicines
Rehabilitation	9	Hospitals with 90 per cent or more of their beds allocated to patients who no longer require nursing care in bed and who, with or without the aid of appliances, can get about and attend to their own needs with occasional assistance but who require remedial and re-educative treatment with a view to attaining the maximum degree of use of functions

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Maternity	11	Hospitals (including General practice maternity Hospitals) with 90 per cent or more of their beds allocated to obstetrics
Type of hospital	**Type number**	**Definition**
Psychiatric (Mental Illness)	12	Hospitals with 90 per cent or more of their beds allocated to mental disorder and 50 per cent or more of the psychiatric beds allocated to metal illness
Psychiatric (Mental Handicap)	13	Hospitals with 90 per cent or more of their beds allocated to mental disorder and more than 50 per cent of psychiatric beds allocated to handicapped and/or severely handicapped patients
Orthopaedic	14	Hospitals with 90 per cent or more of their beds allocated to traumatic and orthopaedic surgery, including bone and joint tuberculosis
Tuberculosis and Chest	15	Hospitals with 90 per cent or more of their beds allocated to tuberculosis (both respiratory and non-respiratory) or diseases of the chest (including thoracic surgery) or both
Tuberculosis and Chest Isolation	16	Hospitals with 90 per cent or more of their beds allocated to tuberculosis (both respiratory and non-respiratory) or diseases of the chest (including thoracic surgery) or both, and infectious diseases
Children's (Acute)	17	Hospitals with 90 per cent or more of their beds allocated as in Type 1 but for children only
Eye	18	Hospitals with 90 per cent or more of their beds allocated to that one function
Other hospitals	19	These include Dental and ENT hospitals and also: All hospitals with 90 per cent or more of their beds allocated to a single department not specifically named above unless that department is "General Medicine", "General Surgery" or "General Practice (Medical)", in which event the hospital would be classified as "Acute" (Type 1) Type 19 will include Geriatric and Chronic Sick Hospitals

Table A2: Definition of types of hospital

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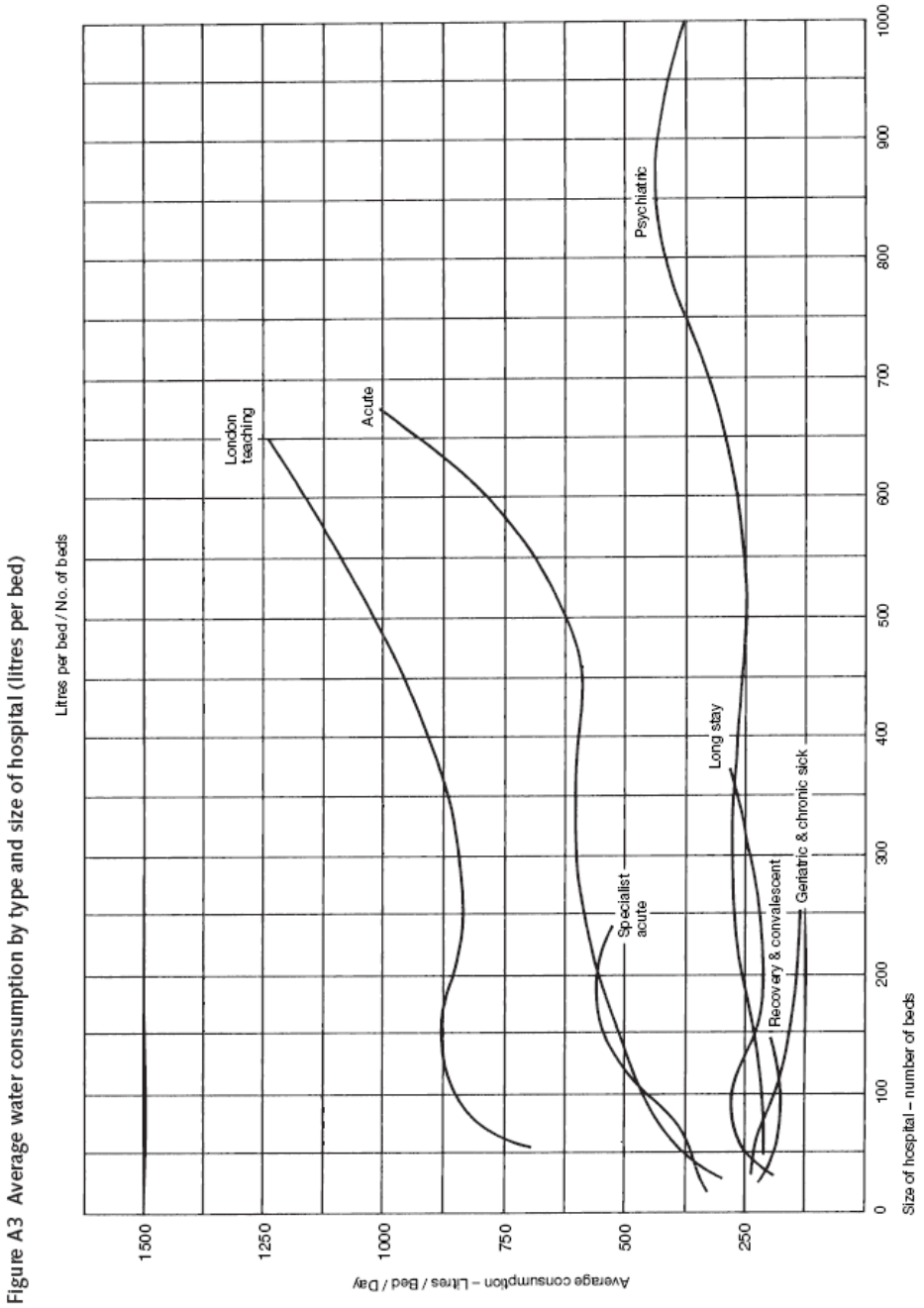

Figure A3: Average water consumption by type and size of hospital (litres per bed)

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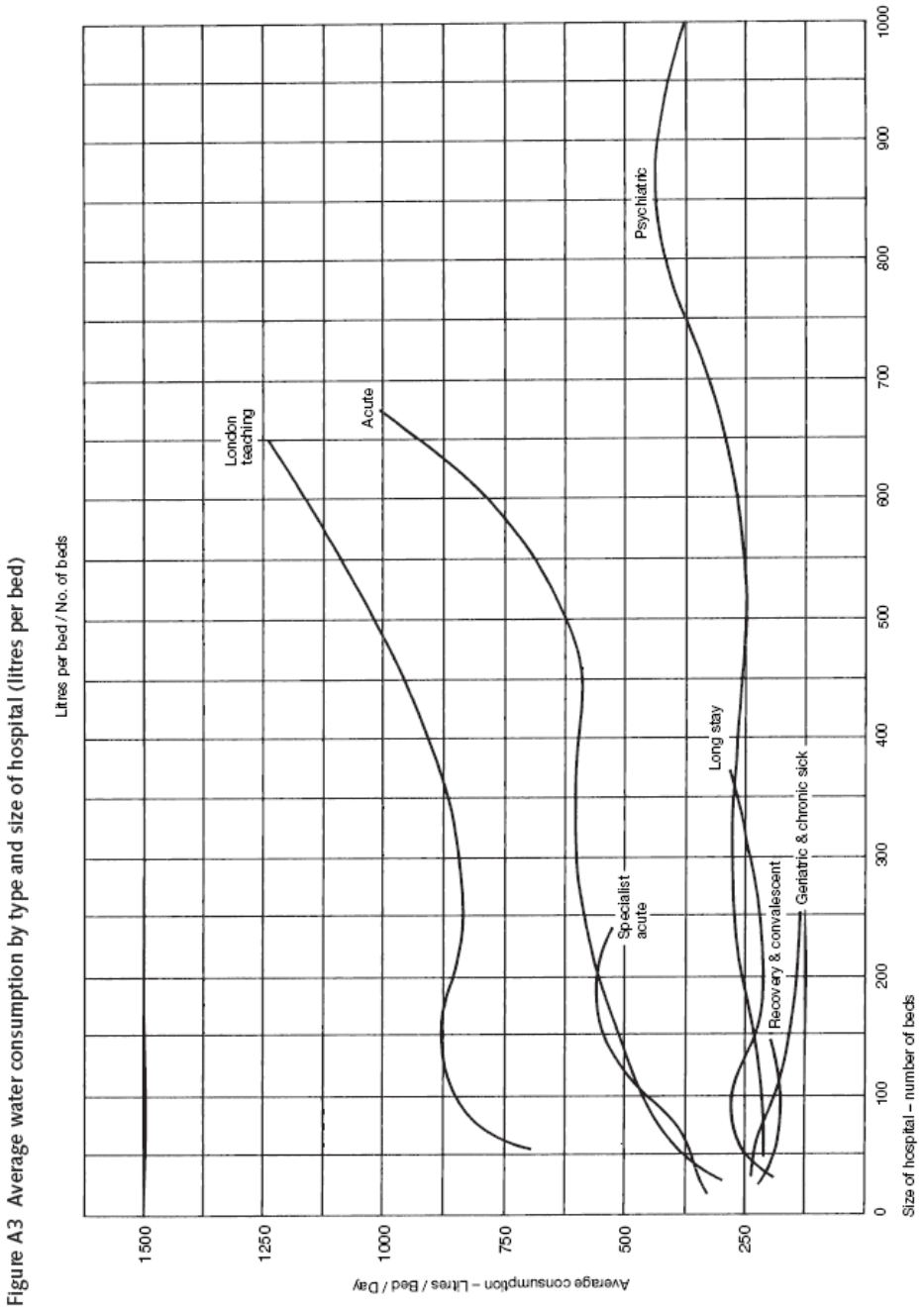

Figure A4: Average water consumption by type and size of hospital (litres per floor area)

Table A3 and Figure A5 provide a worked example of water consumption by nursing staff in residential accommodation.

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Residential accommodation for nursing staff			
1. Data			
Type of accommodation	**Number of residents**	**Allocation of fittings**	**Total fittings**
A Student nurses	150	1 LB per person 1 Bath per 5 persons 1 WC per 5 persons 1 Sink per 5 persons 1 Laundry per 50 persons	150 LBs 30 Bath 30 WCs 30 Sinks 3 Laundries
B Staff nurses	50	1 LB per person 1 Bath per 4 person 1 WC per 4 persons 1 Sink per 4 persons	50 LBs 12 Baths 12 WCs 12 Sinks
C-F Deputy matrons MOs etc	50 plus 50 family residents	1LB per flat 1 Bath per flat 1 WC per flat 1 Sink per flat	50 LBs 50 Baths 50 WCs 50 Sinks
Totals	300	-	250 LBs 92 Baths 92 WCs 92 Sinks 3 laundries
2. Daily usage per fitting			
Type of fitting	**Accommodation A**	**Accommodation B**	**Accommodation C**
LB	3	3	6
Bath	2.5	2	1
WC	20	16	8
Sink	5	4	6
Washing machine	8	-	-
3. Consumption per use			
LB	4.5 litres		
Bath	72 litres		
WC	6 litres		
Sink	6 litres		
Washing machine	114 litres		
4. Estimated daily consumption - 34,090 litres **Daily consumption per person** - 114 litres			

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5. Peak demands -

If two-thirds of resident staff work three shifts commencing at 06.00, 14.00 and 22.00 hours, peak demands will occur from 05.00 to 07.00, 13.00 to 15.00 and 21.00 to 23.00 hors. Peak demand may reach 1.5 litres per sec, with an average demand of 1.06 litres per sec over three periods.

Table A3: Example of water consumption by nursing staff in residential accommodation

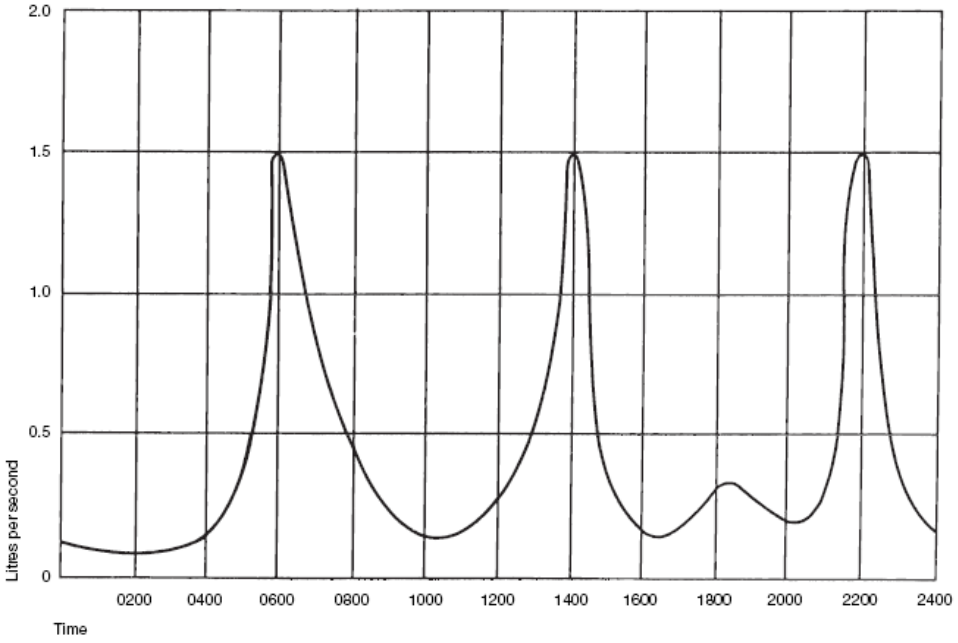

Figure A5: Water consumption profile for residential accommodation of nursing staff

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Appendix 2 Water treatment

General

All water supplied to healthcare premises must comply with current legislation on water quality.

The following sections on water treatment are intended to provide a brief overview only. Further details can be found in BSRIA Application Guide 2/93: 'Water treatment for building services systems'. Some of the more common water treatment processes are mentioned below. The extent of treatment will vary for each application depending on water quality, intended usage etc, and specialist advice should be obtained when considering the adoption of any water treatment processes.

The need for water treatment, and the treatment processes used, depend on the purposes for which the water is to be used and the quantity required for each purpose. While potability is not normally affected by such characteristics as hardness, colour, and (within limits) smell and/or taste, a measure of treatment may be necessary to provide a more acceptable supply.

A supply from a water supply authority should not normally require any further treatment when used for hospital purposes other than laundries, domestic hot water systems, humidification plant and steam boiler feed water. Private supplies, however, will require some measure of treatment, and in many cases the installation of pumping and treatment plant needs to be extensive to ensure a constant acceptable quality.

Water is not naturally found in a state of chemical purity. Surface waters in upland reservoirs, rivers and lakes often contain organic matter including algae, tree foliage and silt. River water may also be polluted by sewage and industrial effluents and chemicals leached from agricultural land etc. Groundwaters in springs, wells and boreholes collect impurities from the surrounding strata; shallow wells collect impurities from surrounding soil.

The impurities which must therefore be removed include tree foliage and matter in suspension consisting of mineral particles, algae, organic matter and various kinds of living organisms and bacteria. Other dissolved chemicals may also require removal.

Suspended matter in water covers a wide range of particle size varying from the large organic particles and silt found in fast-flowing rivers, to colloidal matter with a size of 1 micron or less. Natural filtration takes place as water percolates through the permeable strata and generally reduces suspended solids.

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Water treatment processes

For high quality groundwater sources, the only treatment that may be required is disinfection, which is covered in Chapter 17. However, for other water sources such as grey water, further treatment will be required, and this may be extensive, depending on intended use.

There are a wide range of treatment options available, but the most relevant to health establishments are:

- coagulation and flocculation;
- settlement;
- dissolved air flotation;
- filtration;
- iron and manganese removal;
- pH adjustment;
- solids treatment and disposal.

Coagulation and flocculation

This is the addition of a coagulant (often aluminium sulphate or an organic polymer) followed by gentle agitation. The process is used to destabilise fine particles in the water so that they agglomerate together such that they will settle out more easily in the settlement process or that they can be removed more easily by filtration.

Settlement

In this process, water is passed through tanks in which solid particles settle out. Settlement covers a range of designs from simple horizontal flow tanks to complex upflow sludge blanket clarifiers and lamella flow separators. Settlement is basically a gravity process, although the sludge blanket used in some designs of tank is part of a flocculation process.

Dissolved air flotation

Dissolved air flotation uses fine bubbles of air to lift particles present in water to the surface of a tank, from where they are removed by a skimming system. Water to be treated passes through a rectangular tank. High-pressure water, saturated with air, is introduced into the bottom of the tank. The air in this water comes out of solution because of the pressure drop, and forms fine air bubbles on solids within the water; these solids then rise. The process is particularly suitable for the removal of low-density solids such as algae. It is a sophisticated process and is unlikely to be used except in special circumstances.

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Filtration

Filtration is a solids removal process that involves passing water through a filtering medium, which is normally sand. The most likely form of sand filter to be found in a modern small treatment plant is a pressure filter; these are normally vertical cylindrical steel or GRP pressure vessels.

Water enters at the top of the vessel and passes down through 50 cm of sand. The sand rests on gravel which, in turn, is supported on a perforated floor. After passing through the sand and gravel, the filtered water leaves through the bottom of the vessel.

As the water passes through the vessel, the sand becomes increasingly clogged with dirt, and the pressure drop across the filter increases. Once the pressure drop becomes excessive, the filter is cleaned. This is done by flow reversal with water, and sometimes air, flowing up through the sand to waste. This expands the bed and frees the dirt from the sand.

The need to clean filters involves a fairly complex system of pipes and valves. On modern filters, cleaning is normally done automatically, with electrically-operated valves.

Filtration removes solids, and for relatively clean waters it may be the only treatment process needed apart from disinfection. For dirtier waters, pre-treatment by settlement or dissolved air flotation is required in order to prevent too great a frequency of backwashing. For sources liable to pollution from animal waste, filtration is essential for the removal of cryptosporidium and/or giardia cysts. The filtering medium may be sand but may also be granular activated carbon, to remove tastes and odours, or a catalytic medium (for example manganese dioxide) to oxidise and remove iron and manganese.

Modern packaged plants may also use other sorts of filtration system.

Iron and manganese removal

A common problem, particularly with ground water, is excessive iron and manganese levels. This problem is often solved by oxidising the iron and manganese to an insoluble form by chlorination, pH adjustment and filtration to remove the iron and manganese. Filtration is often done in pressure filters with a catalytic medium.

pH adjustment

This is often needed either to oxidise iron and manganese or to render water less corrosive to the distribution system.

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Solids treatment and disposal

It should always be borne in mind that a water treatment plant will produce wastes from settlement tanks and filters. These wastes will need to be disposed of, probably to the site foul sewerage system.

Contaminated water that is run to waste into a natural watercourse or a drain leading to it should be treated in accordance with the requirements of the authority responsible for land drainage and pollution control. The authority responsible for that sewer should be informed. Dechlorination can be achieved using either sulphur dioxide or sodium thiosulphate. 20 g of sodium thiosulphate crystals are required to dechlorinate 500 L of water containing 20 mg/L free chlorine. For water requiring dechlorination, an automated system dosing bisulphite solution or similar solutions can be linked to the BEMS.

Scottish Hospital Technical Note 2

Further advice on filtration methods and standards can be found in SHTN 2.

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Appendix 3 Chloramine (and chlorine) in public water supplies

The Water Authority in Scotland has been introducing chloramine as a disinfecting agent in water supplies as an alternative to free chlorine. Chloramines tend to be more stable and provide better residual antibacterial activity with lower total chlorine levels. The protection lasts longer and avoids or reduces the need for additional disinfectant dosing stations along the network between water treatment plant and the end–user to ensure that the strict microbiological standards set within the Regulations are met. This explains why chloraminated supplies have been introduced in rural areas.

In Scotland, the drinking water standards are identified in within The water Supply (Water Quality) (Scotland) Regulations 2001, in line with all European community (EC) requirements. This is a legal document with which the Water Authority is required to comply. The Drinking Water Regulators (DWQR) monitor the Water Authority to ensure that the Regulations are complied with and the 2001 Regulations detail the acceptable levels of certain characteristics, elements and substances allowed in drinking water for which these permissible levels are known as Prescribed Concentration of Value (PCV).

It has been recognised by Scottish Water that the secondary disinfection of water supplies with choramine offers a number of benefits, mainly comprising of

- a longer lasting treatment process within the distribution network than would apply if chlorine was used on its own;
- the process helps prevent the formation of trichloramine (THM) compounds that are formed with traditional chlorination;
- it removes the need to add further chlorine further along the pipework distribution network;
- there is the benefit of having no significant taste or odour when correct dosing rations are applied.

There is evidence that the use of free chlorine as a disinfecting agent in surface water supplies containing natural organic residues can combine to form trihalomethanes (THMs), for example chloroform ($CHCl_3$), bromodichloromethane ($CHCl_2Br$) and other compounds that are carcinogenic. (Free chlorine is still preferred for disinfecting borehole waters.)

The local water supply authority carries out chloramination at the water works by introducing both chlorine (Cl_2) and ammonia (NH_3), which combine in aqueous solution to form monochloramine (NH_2Cl), dichloramine ($NHCl_2$) and a small quantity of trichloramine (NCl_3).

The quantities of these depend upon the ratio of chlorine and ammonia and the acidity of the water; it is important to achieve the correct balance, as

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dichloramine and trichloramine can lead to problems of taste and odour and their formation needs to be minimised.

In the UK there is no standard for chloramines in water. The World Health Organisation (WHO) recommends a maximum concentration of 3 mg/L. This is based on a tolerable daily intake that is derived from the 'no observable adverse effect level' (NOAEL) to which a safety factor of 100 is applied. The levels of chloramine that the UK will use (and dialysis treatments units should be designed to handle) is likely to be in the order of 1 mg/L total chlorine, most of which is present as monochloramine.

Problems associated with aquaria have been reported in the USA, where much higher levels of chemicals are used than is proposed in the UK.

Chloramine is also extensively used in Europe for disinfection of public water supplies.

Implications for healthcare

In systems where free chlorine is rapidly lost, such as typical hot and cold water service systems, chloramines can remain for much longer, posing particular problems for dialysis patients. The effect of chloramine-induced acute haemolytic anaemia and methaemoglobinaemia has been well reported. Little other information is available on chloramine.

Chloramines, and to a lesser extent chlorine, in dialysis water can cause haemolysis – a condition whereby red blood cells are ruptured. In addition, all renal patients suffer from anaemia to some extent because they are lacking in erythropoetin (EPO). This natural hormone, which stimulates bone marrow to produce red blood cells, is not available in sufficient quantities in patients with damaged or diseased kidneys. Synthetic EPO is administered to dialysis patients but, apart from its high cost, can have unpleasant side-effects. Where chlorine or chloramines are present, the need for EPO escalates, and therefore it is imperative to eliminate chlorine and chloramines from water supplies to dialysis equipment to minimise the dosage of EPO.

Dialysis requires a water supply that has the minimum of chemical and bacterial impurities. This requires water treatment – typically reverse osmosis and softening; neither process removes chloramines or chlorine.

Some reduction of chloramine occurs in deionisation equipment because of adsorption onto ion-exchange resin molecules, but performance of the ionisation process is unpredictable in this respect and cannot be relied upon. The Renal Association sets limits of 0.1 mg/L and 0.5 mg/L respectively for chloramines and total chlorine in water for dialysis. (The European Pharmacopoeia specifies a maximum limit of 0.1 mg/L for chloramine: studies have shown, however, that levels as low as 0.25 mg/L can cause haemolysis.) Therefore, it can be seen that the margin for error is low. (See also Health Building Note 53 – 'Facilities for renal services', Volumes 1 and 2 which have not been adapted for Scotland but may be used with general caution.)

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There remain some concerns about chloramine, but in the main, these are about high concentrations for bathing water disinfection. Further studies are taking place.

Removal of chloramines

The use of granular-activated carbon (GAC; filtration upstream of the reverse osmosis (RO) equipment) is recognised as an effective means of dealing with chloramine. (In hard water areas, water softening will also be required.)

Chemical reduction by use of ascorbic acid (vitamin C), which is capable of neutralising many oxidising agents, is also an effective method. There is some concern about the use of ascorbic acid because of its toxicity for dialysis patients. Management of vitamin C intake has to be carefully monitored in dialysis patients; therefore chemical reduction, particularly for domiciliary patients, is undesirable.

GAC is manufactured from a variety of products, but mostly bituminous coal. The charcoal derived is pulverised and “activated” by exposure to superheated steam. This increases the total surface area for adsorption, which can be as high as 1500 m^2/g. This highly porous substance is formed into disposable cartridges, or used in rechargeable tanks.

The critical factor in the selection of the carbon filter is the empty bed contact time (EBCT), which can be calculated as follows:

$$EBCT = \frac{volume(GAC(L))}{flow(water(L/m))} \times 50$$

The aim should be an EBCT of about 6 min.

As a yardstick, the Drinking Water Regulator has advised the Renal Association to design water treatment systems, whether domiciliary or hospital-based, to remove up to 1 mg/L total chlorine.

Summarising

The following facilities require special attention

a) Renal Departments

The Renal association identifies that dialysis water purification plant should be capable of accepting 1mg/I total chlorine, while setting limits of 0.1 mg/I and 0.5 mg/I, respectively, for chloramines and total chlorine in water for dialysis. Dialysis requires a water supply that has the minimum of chemical and bacterial impurities and to achieve this, further water purification is required, typically reverse osmosis and softening, neither of which is an effective means of removing chloramines and chlorine.

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The use of Granular Activated Carbon Filtration (GAC – filtration) upstream of the Reverse Osmosis (RO) equipment is recognised as an effective means of chloramines and chlorine and the impact of dealing with chloramines is limited only to the increased contact time within the activated carbon filters associated with the renal water purification plant because chloramines take longer to be absorbed than free chlorine. It has been estimated that an increase in contact time of around 6 to 10 minutes will be required, increasing the total surface are for absorption. The assessment would normally be calculated by the specialist water treatment company specialising in renal water supply and plant selection.

b) Pharmacy Departments

The residual levels of chloramines within a water supply can affect the manufacturing of pharmaceuticals and therefore pharmacy departments within healthcare premises may be more effected by a chloraminated water supply. For this reason, monitoring of the water supply is required and any subsequent review of any existing purification processes and procedures currently operating may have to be enhanced, upgraded or renewed.

c) Laboratories

Areas within healthcare facilities that require specialised water, such as science laboratories, would also require their water treatment and purification to be reviewed and, where necessary, enhanced, upgraded or renewed.

d) Hydrotherapy Departments

Water treatment processes and procedures to hydrotherapy pools, etc., may also require their water treatment processes to be reviewed as the introduction of additional chlorine may induce the production of dichloramine and trichloramine. The water treatment and procedures to these areas may require to be enhanced, upgraded or renewed where necessary.

There have been instances in which chloraminated water supplies have been introduced in Scotland by the Water Authority without advance warning or consultation. To avoid this, the maintenance if close liaison with the Water Authority is essential and that the quality of incoming supplies is monitored at all times to avoid adverse effects, principally on vulnerable patients.

Chloramines and the effect on pipework materials

There is no test data available identifying that a chloraminated water supply affects pipework or pipework components, neither within the various UK water authorities' nor undertakings' infrastructure, nor within industrial, commercial or domestic premises. The Water Research Council (WRc) advise that no recent product testing had been carried out on any plumbing components or material to assess the long-term affects that chloramine may bring.

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However, the fact that such supplies have been delivered in the Thames Water, Northumbrian and Anglian Water areas for so many years without any reported detrimental affects leads to the confidence that traditional and contemporary plumbing materials and components are unaffected as a result of handling chloraminated water supplies.

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Appendix 4 Chlorine dioxide

Chlorine dioxide is an oxidising biocide that is capable of reacting with a wide range of organic substances. Its effectiveness in the control of organisms in water systems has been demonstrated in a study carried out by BSRIA (see BSRIA's (1998) TN 2/98: 'Chlorine dioxide water treatment − for hot and cold water services').

For hot and cold water services, chlorine dioxide is usually generated by sodium chlorite reacting with gaseous chlorine or hydrochloric acid:

$5NaClO_2 + 4HCl \longrightarrow 4ClO_2 + 5NaCl + 2H_2O.$

Alternatively, a number of systems use proprietary solutions that release chlorine dioxide on acidification.

Use of chlorine dioxide as a chemical for drinking water treatment is now subject to a European Standard (BS EN 12671:2000). National conditions of use require that the combined concentration of chlorine dioxide, chlorite and chlorate do not exceed 0.5 mg/L as chlorine dioxide. Chlorine dioxide dissolves unchanged in water, but is very slowly hydrolysed to chloric and chlorous acids. In alkali, chlorate and chlorite are formed:

$2ClO_2 + 2OH^-\ ClO_3^- \longrightarrow ClO_2^- + 2H_2O.$

It is essential that the maximum amount of chlorine dioxide is available for reaction with organic molecules and not total chlorite or chlorate.

In water, the oxidising properties of chlorine dioxide result from two reactions. Chlorine dioxide gains one electron to form chlorite:

$ClO_2 + 1e^- \longrightarrow ClO_2^-.$

If available, the chlorite gains four electrons to form chloride:

$ClO2^- + 2H2O + 4e^-\ Cl^- + 4OH^-1.$

The first of these reactions proceeds readily in the range of pH found in potable water.

The latter reaction, to complete the five-electron transfer, does not always occur.

In the inactivation of microorganisms, the chlorine dioxide molecule acts as a free radical (oxidising biocide) that readily bonds with the amino acids − the basic building blocks of proteins − which form the living cells. This results in their destruction.

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Note: The difference between the chlorine dioxide injected into the system and the levels at the furthermost parts of the system, where its presence can be measured, is an indication of the bio-burden oxidised.

Chlorine dioxide is also effective in the destruction and removal of biofilms, which contribute to the nutrients within the systems and provide protection for bacteria against the effects of heat and chlorine.

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Appendix 5 Copper and silver ionisation

Ionisation as a water treatment method has been shown to be effective against planktonic *Legionella* in hot and cold water systems at 400 µg/L and 40 µg/L respectively. In soft waters a silver level as low as 20 µg/L can be effective. Ionisation systems release copper and silver ions into the water stream by means of electrolyte action. Copper and silver ionisation involves the release of copper and silver ions by electrolytic generation for use as a water treatment.

Copper and silver ionisation is concerned with releasing silver and copper ions into water by passing an electrical current between two copper electrodes and between two silver electrodes placed in running water.

The copper and silver ions attach, through electrostatic bonds, to negatively charged sites on bacterial cell walls. This distorts and weakens the cell wall, allowing penetration of the silver ions. The silver ions attack the cell by binding at specific sites to DNA, RNA, cellular protein and respiratory enzymes, denying all life support systems to the cell, causing paralysis and death. The copper and silver ions act synergistically to kill bacteria.

Silver/copper ionisation's effectiveness in the control of *Legionella* bacteria in water systems has been demonstrated in a study carried out by BSRIA (1996; TN 6/96: 'Ionisation water treatment for hot and cold water services'). Results show that where silver and copper ion concentrations could be maintained at 0.04 ppm and 0.4 ppm respectively, copper and silver ionisation was effective against *Legionella* bacteria in both cold and hot water systems with reduced water temperatures as low as 35°C. pH levels above 7.6 may affect the efficacy of this technology.

Water analysis certificates-of-analysis results from samples collected from outlets at sites that operate silver/copper ionisation systems in the UK show that where silver and copper ion concentrations are maintained at outlets at between 0.01 and 0.08 ppm and at between 0.2 and 0.8 ppm respectively, *Legionella* contamination is avoided and controlled.

The study carried out by BSRIA also showed that the copper and silver ions not only reduce the biofilm coverage in cisterns and within pipework circuits, they also reduce the number of *Legionella* bacteria present within the biofilm.

Further studies by Walker et al (1997) showed that when copper and silver ionisation was operated at concentrations of 0.04 ppm of silver and 0.4 ppm of copper, it is an effective non-chemical disinfectant for the control of bio-fouling.

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Scottish Health Technical Memorandum 2030

(Part 1 of 3)

Design considerations

Washer-disinfectors

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Executive summary

SHTM 2030 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer-disinfectors (WDs) in use in the National Health Service for processing medical devices, laboratory ware and sanitary products. No guidance is given on WDs intended for use in processing textiles or for dishwashers in general catering applications.

This SHTM is intended as a guide for technical personnel with appropriate training and experience and also for users responsible for the day to day running of WDs. It will also be of interest to architects, planners, estates managers, supplies officers, and others.

Detailed information on the planning and design of a sterile services department, including the provision of WDs, is given in Scottish Hospital Planning Note 13; *Sterile Services Department* and Health Building Note 13 Supplement 1 *'Ethylene oxide sterilization'* section. Guidance for Laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

Although this edition of SHTM 2030 reflects current WD technology it is recognised that considerable scope exists for improvements in the operational and management standards used with WDs.

NOTE: The term washer-disinfector is abbreviated to WD throughout this publication.

The current British Standards for WDs, although only in force since 1993, are expected to be replaced by European Standards within the next two to three years. These Standards include consideration of the requirements arising as a result of European Union Directives on medical devices which are of concern for WDs in two ways; firstly, some WDs will themselves be considered to be medical devices and therefore must meet the relevant requirements of the Medical Devices Directive and secondly, the manufacturer of a medical device which is intended to be reprocessed is required to specify the method to be used for reprocessing which will include any necessary washing and disinfecting stage.

When practicable the information in this SHTM has been aligned with existing or anticipated Standards and advice is offered when no Standard has yet been formulated.

The WDs described in this SHTM may not be suitable, without modification, for safely processing articles contaminated with either Hazard Group 4 Pathogens or with agents which are unusually resistant to disinfection.

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The guidance previously given in HTM 2030 ‘Management policy’ has been incorporated into SHTM 2030 ‘Operational management’. HTM 2030 is superseded.

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1. General

Introduction

1.1 This part of SHTM 2030 covers the specification, purchase and installation of the various types of washer-disinfectors (WDs) used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in washing and disinfection has long been inconsistent and this has often led to ambiguities. This SHTM introduces a set of terms which, it is hoped, will provide workers in the field with a vocabulary that will be consistent with the European Union (EU) standards that are to be introduced in the near future. The glossary provides a definition of terms referred to in this part of SHTM 2030.

1.3 Full references for all the documents referred to in this volume and for selected documents providing additional information of which the reader should be aware are listed at the end of this part.

Purpose of washer-disinfectors

1.4 WDs are used to decontaminate items intended for re-use. They may be used in relation to both medical devices and medicinal products as well as other items. For example, they may be used for reprocessing, within their intended use, medical devices, sanitary equipment, laboratory equipment, manufacturing equipment (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery.

1.5 The decontamination process is intended to:

a. make the item safe for staff to handle;

b. make the item safe for use on a patient (after any necessary additional processing) – including when relevant ensuring freedom from contamination that could lead to an erroneous diagnosis.

1.6 WDs may also be used as part of the manufacturing process for medical devices, medicinal products, in-vitro diagnostics or laboratory products – in processing “single-use” products or components such as bottles and vials.

1.7 When items being decontaminated by a WD are intended to be used again without further treatment (such as a terminal sterilization process) before being re-used, the disinfection process in the WD must produce an item which is microbiologically safe for its intended use.

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1.8 When the items being decontaminated by a WD are intended to be subjected to further processing (such as a terminal sterilization process) before being re-used, the disinfection stage must produce an item which is microbiologically safe to be handled during preparation for subsequent processing.

1.9 The decontamination process involves two distinct stages: cleaning and microbial inactivation (disinfection). WDs are used to decontaminate items intended for re-use by subjecting the items to an automated process of cleaning and disinfection.

1.10 The efficacy of the cleaning stage of the process is of crucial importance to the successful outcome of the disinfection stage. This is especially relevant in the circumstances when a liquid chemical disinfection or sterilization process has to be used.

Legal framework for washing and disinfection

1.11 WDs are used in relation to both medical devices and medicinal products as well as for sanitary equipment, laboratory equipment and cutlery/crockery.

1.12 WDs may be used for reprocessing medical devices, sanitary equipment, laboratory equipment, manufacturing equipment (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery, within their intended use.

1.13 WDs may also be used as part of the manufacturing process for medical devices, medicinal products, in-vitro diagnostics or laboratory products in processing ‘single-use’ products or components such as bottles and vials.

Medicinal products

1.14 The manufacture and supply of medicinal products are controlled by extensive legislation based on EU Directives for medicinal products. These are enacted in the UK by the Medicines Act and a number of Regulations.

1.15 The requirements for the manufacture and supply of medicinal products are set out in the ‘Guide to good manufacturing practice for medicinal products’ (GGMP) published in Volume IV of ‘The rules governing medicinal products in the European Community’.

1.16 The GGMP contains guidance on cleaning of components and manufacturing equipment which have implications for the design, installation and operation of WDs. When a WD is to be installed for processing containers, components or manufacturing equipment for use with medicinal products the GGMP should be consulted at an early stage.

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1.17 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) when necessary.

Medical devices

1.18 SHTM 2030 Part 2, 'Operational management' refers to the three EU Directives on the manufacture and supply of medical devices and in-vitro diagnostics.

1.19 Whether, and if so in what circumstances, the Medical Devices Directive (93/42/EEC) applies to medical devices which are being reprocessed for further use – either within a particular healthcare facility or externally under a service contract – is a complex issue beyond the scope of this SHTM. Guidance is given in the Medical Devices Agency (MDA) Directives Bulletin 18. If necessary further advice should be sought from the MDA.

1.20 The essential requirements of the Medical Devices Directive require inter alia:

a. that devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (annex I, paragraph 8.1);

b. that devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues, to persons involved in the transport, storage and use of the devices and to patients (annex I, paragraph 7.2).

1.21 There is no direct equivalent of the GGMP for medical devices. The same role is fulfilled by general quality system Standards (the BS EN ISO 9000 series), supplemented by Standards tailoring the requirements specified in the general standard for medical devices (BS EN 46001 and BS EN 46002) and Standards providing guidance on compliance with these Standards (BS EN 724 and BS EN 50103).

1.22 These are mandated Standards and as such compliance with them affords the presumption of compliance with the relevant essential requirements of the Directive.

Published Standards

1.23 British Standard 2745: 1993 specifies requirements for WDs for medical purposes. The standard is in three parts: Part 1: 'Specification for general requirements'; Part 2: 'Specification for human-waste container washer disinfectors'; and Part 3: 'Specification for washer-disinfectors except those used for processing human-waste containers and laundry'.

1.24 There are no European Standards, as yet, for WDs. CEN Technical Committee TC102 is developing a series of mandated Standards relevant to the Medical Devices Directive for WDs. There are four parts with the working titles 'General Requirements', 'Washer-disinfectors for human-

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waste containers', 'Washer-disinfectors for medical devices and surgical instruments' and 'Washer-disinfectors for thermo-labile medical devices (for example endoscopes)'.

1.25 IEC Technical Committee TC66 is developing Standards for 'Safety requirements for washer-disinfectors'.

1.26 When published, compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.

1.27 This edition of SHTM 2030 has been written while the new Standards are in the course of development. The guidance given here is designed to be broadly consistent with the emerging Standards but SHTM 2030 should not be regarded as a substitute for the Standards themselves when ascertaining compliance with the EU Directives and the UK Regulations that implement them.

1.27 If the WD is purchased with the intention of processing both medical devices and components, or equipment for use in the manufacture of medical products, purchasers should ensure that the requirements for both types of load are met.

Washer-disinfectors as medical devices

1.28 The Medical Devices Directive (93/42/EEC) Annex IX, Classification Criteria, Rule 15 classifies as medical devices "all devices intended specifically to be used for disinfecting medical devices" and places them in Class IIa for conformity assessment purposes. It specifically excludes products that are intended to clean medical devices, other than contact lenses, by means of physical action.

1.29 WDs for cleaning and disinfecting medical devices are thus covered by the medical devices legislation and those supplied on or after 14 June 1998 will have to bear the CE marking in accordance with the provisions of the Medical Devices Directive.

This will apply to many of the WDs described in this SHTM.

1.30 Detailed guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency.

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Key Personnel

1.31 The following personnel are referred to in this part of SHTM 2030.

Management

1.32 Management is defined as the owner, occupier employer, general manager, chief executive or other person who is ultimately accountable for the operation of the premises.

1.33 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small autonomous units the user may take on this function.

User

1.34 The user is defined as the person designated by management to be responsible for the management of a WD.

1.35 In a hospital the user could be a sterile services manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager; in primary care he/she could be a general practitioner, dentist or other health professional. When a WD is used to process equipment or containers for use in the preparation of medicinal products the user is normally the production manager in charge of the manufacturing process.

1.36 The principle responsibilities of the user are as follows:

a. to certify that the WD is fit for use;

b. to hold all documentation relating to the WD;

c. to ensure that the WD is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records.

Competent Person (Pressure vessels)

1.37 The competent person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the ‘Pressure Systems Safety Regulations 2000’. The shorter term “competent person” is used in this SHTM.

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1.38 The following guidance on the qualifications for the competent person is based on the HSC Approved Code of Practice, Safety of Pressure Systems:

a. where required to draw up or certify schemes of examination, the competent person should be qualified at least to technician engineer level, with adequate relevant experience and knowledge of the law, codes of practice, examination and inspection techniques and understanding of the effects of operation of the pressure vessel concerned. He or she must have established access to basic design and plant operation advice, materials engineering and non-destructive testing (NDT) facilities. The competent person must have sufficient organisation to ensure a reasonable data storage and retrieval system with ready access to relevant laws, technical standards and codes;

b. where required to carry out examinations, the competent person should have sufficient practical and theoretical knowledge and actual experience of the type of pressure vessel which is to be examined to enable defects or weaknesses to be detected and their importance in relation to the integrity and safety of the WD to be assessed.

1.33 The principle duties of the competent person under the Regulations are as follows (they need not all be exercised by the same individual):

a. advising on the scope of the written scheme of examination;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

1.34 Most insurance companies maintain a technical division able to advise on appointing a competent person. Advice may also be obtained from Scottish Healthcare Supplies, Trinity Park House, Edinburgh.

Test Person (Washer-disinfectors)

1.39 The test person (washer-disinfectors) is defined as a person designated by management to carry out validation of washer-disinfectors and to provide advice on testing, maintenance and procedures. The shorter terms test person or TP are used in this SHTM. The test person should either:

a. be a Test Person (Sterilizers) (see SHTM 2010 for a definition of this role);

b. be qualified to at least HNC level in engineering or relevant sciences and have at least two years experience in the validation of washer-disinfector processes; or

c. have at least five years experience in the testing of washer-disinfector processes.

1.40 The principle responsibilities of the TP are as follows:

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a. to advise on programmes of periodic testing and periodic maintenance of WDs;

b. to advise on operational procedures for routine production;

c. to conduct the validation test specified in SHTM 2030 Part 3, 'Validation and verification' and to prepare the validation report;

d. to conduct the periodic tests specified in SHTM 2030 Part 3, 'Validation and verification' and to prepare reports as required by the user;

e. to conduct any additional tests at the request of the user.

Maintenance Person (Washer-disinfectors)

1.41 The Maintenance Person (washer-disinfectors) is defined as a person designated by management to carry out maintenance duties on washer-disinfectors. The shorter terms maintenance person or MP are used in this SHTM.

1.42 The Maintenance Person should be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of washer-disinfector. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.

1.43 The principle responsibilities of the Maintenance Person are as follows:

a. to carry out the maintenance tasks outlined in SHTM 2030 Part 2, 'Operational management';

b. to carry out additional maintenance and repair work at the request of the user.

1.44 A Maintenance Person who has a minimum of 5 years experience in the maintenance of washer-disinfectors may, by agreement, perform the duties of the Test Person for the daily, weekly and quarterly tests described in SHTM 2030 Part 3, 'Validation and verification'.

Microbiologist

1.45 The microbiologist is defined as a person designated by management to be responsible for advising the user on microbiological aspects of disinfection.

1.46 The microbiologist should have a degree in microbiology and will normally be a member of the hospital staff.

1.47 The principle responsibilities of the microbiologist are as follows:

a. to provide general and impartial advice on all matters concerned with washing and disinfection;

b. to advise the user on the microbiological aspects of all disinfection procedures;

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c. to arrange for the culturing of biological indicators used in microbiological tests;

d. to audit the documentation from all washer-disinfectors which have been tested by microbiological methods.

Control of Infection Officer

1.48 The Control of Infection Officer is defined as the person designated by management to be responsible for advising the user on all infection control aspects.

Production Manager

1.49 The Production Manager is defined as a person designated by management to be responsible for production of medicinal products and medical devices.

Quality Controller

1.50 The Quality Controller is defined as a person designated by management to be responsible for quality control of medicinal products and/or medical devices with the authority to establish, verify and implement all quality control and quality assurance procedures.

Laboratory Safety Officer

1.51 The Laboratory Safety Officer is defined as a person designated by management to be responsible for all aspects of laboratory safety in respect of equipment, maintenance, personnel and training relating to safety issues, and to ensure compliance with safety legislation and guidelines.

Operator

1.52 An operator is defined as any person with the authority to operate a WD. Their duties may include the noting of WD instrument readings, replenishment of consumable items, such as detergent, and simple housekeeping duties.

Manufacturer

1.53 The manufacturer is defined as a person or organisation responsible for the manufacture of a WD.

Contractor

1.54 The contractor is defined as a person or organisation designated by management to be responsible for the supply and installation of the WD, and for carrying out the installation checks and tests. The contractor is usually the manufacturer of the WD.

Purchaser

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1.55 The purchaser is defined as the person or organisation who orders the WD and is responsible for paying for it.

Authorised Person (Sterilizers)

1.56 The authorised person (sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness validation (see SHTM 2010 Part 1 for a full definition of the responsibilities of the authorised person (sterilizers) with respect to sterilizers and the qualifications and experience required). AP(S) are also able to provide independent auditing and advice on washing/disinfection and WDs and to review and witness validation of these processes and machines.

Independent Advisor

1.57 The Independent Advisor is defined as a person who may or may not be registered as an AP(sterilizers), but can demonstrate to the satisfaction of management previous training and experience appropriate to carry out the designated tasks in respect of WDs as the AP(S) would carry out in respect of sterilizers. AP(S) is a suitable person to carry out the functions of an Independent Advisor.

Water supply

1.58 All the organisations responsible for water supply have the statutory power to make and enforce byelaws to prevent waste, excessive consumption, misuse or contamination of the water supply. The Model Water Byelaws form the basis for such byelaws. WDs must be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant byelaws.

Safety

1.59 Guidance on the safe operation of the various types of WD is given in SHTM 2030 Part 2; ‘Operational management’. As far as testing is concerned, normal safety precautions are adequate except in the case of WDs using liquid chemical germicides. In this case users are recommended to operate a permit-to-work system to ensure that such WDs are declared safe to work on, and that personnel working on them have documented authority to do so.

Chemical additives

1.60 Many of the chemical additives used in WDs and their associated ancillary equipment, for example water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.

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1.61 The 'Control of Substances Hazardous to Health (COSHH) Regulations 1999' place upon management an obligation to ensure that suitable measures are adopted to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a special ventilation system.

1.62 Some of the substances which may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH40 published annually by the Health and Safety Executive. These limits are statutory maxima but should not be regarded as representing a safe working exposure. Employers have a legal obligation to ensure that exposure is reduced as far as reasonably practicable and to carry out regular Occupational Health review of "at risk" staff..

1.63 The WD, including any special ventilation equipment necessary for its safe operation will be subject to the COSHH Regulations. These Regulations introduced controls on biological agents which are of relevance to purchasers of WDs. Detailed guidance on ventilation systems is provided in SHTM 2025.

Infectious materials

1.64 All WDs have the potential to process infectious materials. The user should therefore ensure that personnel working on WDs wear appropriate protective clothing and are fully informed of any hazards that may be present. In case of doubt the microbiologist should be consulted.

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2. Procurement of a washer-disinfector – an overview

Introduction

2.1 This chapter gives a short synopsis of the steps involved in purchasing a WD. More detailed information, including information relevant to specific types of WDs, is given in subsequent chapters.

Purchasing a washer-disinfector

2.2 The first step is to form a consultative group which could consist of User, Control of Infection Officer, Maintenance Person and Independent Adviser.

2.3 The purchase of a WD can be broken down into a stepwise sequence of decisions. These are summarised in the following paragraphs (see also Table 1).

What type of load is to be processed?

2.4 A knowledge of the load(s) which will be processed by the WD is an essential pre-requisite in making the correct decision about which WD to purchase; the difficulty in obtaining a clean product, the standard of cleanliness and the disinfection required vary for different product types. For example, some products with intricate interstices or long narrow lumens require specific provision if they are to be cleaned satisfactorily.

Purchasers should be aware of the need to specify all the items requiring processing to allow the tenderer to offer the most appropriate machine and accessories.

What suitable washing-disinfection processes are available?

2.5 In this SHTM, WDs are classified by:

a. the product range which they are intended to process;

b. their configuration and load handling type;

c. the nature of the cleaning and disinfection process.

Eight product-specific categories are recognised but, in many cases, WDs are available in which a single machine is designed to process two or more of these product categories. Guidance on the selection of a WD is given in Chapter 3.

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What models are available?

2.6 Once the type of WD which will be required has been agreed sales literature and product data sheets should be sought from a number of manufacturers. The development of EU Standards on WDs should widen the choice open to purchasers. Guidance on the information which should be sought is given in Chapter 4.

Where will the washer-disinfector be sited?

2.7 The location available for the WD will have a significant influence on the type of machine which can be used. Many of the larger continuous process machines require considerable space. Guidance on siting is given in Chapter 5.

What services are available?

2.8 A WD will require one or more of the following services: electricity, water, steam, compressed air, drainage, ventilation and chemical additive (detergent, rinse aid etc.) supply. The manufacturer's product data sheets will show which services are required for each model. Determine which of these are available at the proposed site and the capacities of each service. It may be necessary to plan for a new service which would add significantly to the cost of the installation. Further information about services is to be found in Chapter 6. Water supply is crucial and is discussed in detail in Chapter 7.

Who will operate the equipment?

2.9 If the equipment is to be sited in a general area, eg. a ward sluice room, intended for use by a wide range of ancillary and nursing staff the machine should be simple to operate and as foolproof as possible.

Conversely, a machine which will be located in a centralised processing unit under the care of specially trained staff – whose sole or principle activity will be the operation of the WD – may be a more complex machine offering a number of different operational cycles and loading systems to optimise the washing and disinfection of diverse products.

What capacity is required?

2.10 Establish the likely daily and weekly work load, and the peak hourly work load, that the WD will have to process. Calculate the number of WDs required to process the workload. Throughput figures for different manufacturer's machines and different models within any given range vary considerably. For continuous process machines a distinction must be made between the time required to process one load and the total number of loads which may be processed in a period of one hour. Further guidance is given in Chapter 3.

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What ancillary equipment is required?

2.11 A WD may require ancillary equipment such as water softeners, de-ionisation or reverse osmosis (RO) water treatment plant, steam generators, air compressors, extract ventilation (with or without condensers), bulk storage and dispensing facilities for process chemicals.

2.12 In addition some WDs will require load staging facilities, before and after processing, purpose-built load carriers for different categories of product and means for returning load carriers from the unloading side of the WD back to the loading side.

What Standards or published specifications are relevant?

2.13 Most WDs for clinical applications (see Chapter 3) should have been constructed to British and EU Standards. In some cases, eg. for endoscopes, there are no published British or European Standards and additional specifications will be required. Advice on preparing a detailed specification for the WD is given in Chapter 4.

What sort of contract?

2.14 Once the specification has been completed a contract should be drawn up for the supply and installation of the WD. Chapter 4 gives guidance on suitable forms of contract.

Which manufacturer?

2.15 Two or more manufacturers should be invited to tender for the supply of the WD. While no manufacturer should be excluded unnecessarily from the tendering process they should not be invited to tender unless there is a realistic prospect of their being awarded the contract. Guidance on tendering is given in Chapter 4.

What installation and commissioning arrangements?

2.16 Chapter 4 contains advice on the documentation that the manufacturer should provide with the WD. After delivery and installation, the WD should be subjected to a formal documented programme of installation, commissioning checks and validation testing. This is discussed in detail in SHTM 2030, Part 3 ‘Validation and verification’.

What arrangements for service and repair?

2.17 It is common practice for the initial purchase contract to include all service and repair costs for the first year after installation, ie. during the warranty period. A number of manufacturers also offer an “extended warranty” facility which, for an additional fee, provides an all-inclusive service and repair option.

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What are the likely running costs?

2.18 Advice should be sought at the time of tender on the operational costs of the various machines which would be suitable. The operational costs should include the anticipated requirements for services (water, electricity, steam etc.), consumable items (detergents, rinse aids etc.) and maintenance. This data should be used in the evaluation of the tender bids.

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3. Choice of washer-disinfector

Introduction

3.1 This chapter contains information relevant to the choice of a new WD. It discusses the different types of WD and the way in which they are classified in this SHTM. It summarises the loads for which each type is suitable and gives guidance on choosing the size and number of WDs required for a given application.

Classification of washer-disinfectors by nature of load to be processed

3.2 This SHTM groups WDs into two broad categories according to their intended use, ie. the nature of the load which they are intended to process:

a. clinical WDs are designed to process medical devices which may be intended for use without further processing or may be subjected to a terminal sterilization process before further use.

b. laboratory WDs are designed to process equipment for use in the manufacture of medical devices and medicinal products, or to process laboratory goods that are neither medical devices nor medicinal products and are not intended for use in the clinical care of patients.

3.3 WDs can be further classified both by their configuration/load handling system and by the nature of the operational process.

Clinical washer-disinfectors

Human waste containers

3.4 These are intended for use in emptying, cleaning and disinfecting bed pans, urinals, suction bottles and similar containers, and for the rigid supports used to hold disposable bedpans.

3.5 They may have a large volume or mass of material to be removed (faeces, urine, blood, serum, mucous) and many of these materials have a high biomass of potentially infective organisms.

3.6 The processed product will usually be used without further treatment.

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Surgical instruments and associated products

3.7 These are intended for processing a wide range of products used in clinical practice. WDs may be dedicated for use with one particular category of products or may be intended for use with a range of products, often by the use of dedicated load carriers for each product type.

Surgical instruments

3.8 This includes the whole range of surgical instruments but some particular instruments, such as those with long narrow lumens or intricate interstices, may require disassembly and/or specific adapters if they are to be cleaned effectively.

Anaesthetic accessories

3.9 This includes tubing, face masks and re-breathing bags for both anaesthetic use and for respiratory therapy and diagnosis.

Bowls and utensils (hollowware)

3.10 This includes instrument trays and containers, receivers, gallipots, specula etc.

Endoscopes

3.11 Endoscopes may be considered in two categories based on the method of construction of the endoscope. This will often determine which of the available washing-disinfection processes is suitable. However, in all cases, users should seek advice from the manufacturer of the endoscope on the most suitable method of decontamination.

3.12 Rigid endoscopes and their accessories may often be processed through conventional WDs used for surgical instruments – provided the WD is fitted with appropriate load carriers which direct water and wash solutions through the lumen(s).

3.13 Flexible endoscopes are often unsuitable for processing through a conventional WD – parts of the endoscope may not withstand immersion and valved channels may not be accessible unless the valve is open during the cleaning process. In addition, most flexible endoscopes will not withstand the elevated temperatures used during thermal disinfection and drying in a conventional WD.

3.14 Dedicated WDs are available which are intended specifically for processing endoscopes. These may incorporate a chemical disinfection or sterilization stage or may require that, after processing in the WD, the endoscope is terminally sterilized using a suitable low temperature sterilization process.

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Dishwashers

3.15 Dishwashers in general are not covered by this SHTM. However there is an occasional need for the crockery and cutlery used by immunologically compromised patients to be disinfected to a higher standard than is found in standard commercial or domestic dishwashers. Consideration should be given to using a terminal steam sterilization process for items processed through a standard dishwasher or to specifying a dishwasher with a thermal disinfection process as shown in Table 2.

3.16 In the latter case the WD should be fitted with a temperature indicating instrument to show the temperature attained during the disinfection stage.

Laboratory washer-disinfectors

Laboratory equipment

3.17 Laboratory washers are available to process a range of laboratory items. These items may include bottles and vials – either new or after previous use – intended for containing reagents, culture media, etc. and other laboratory equipment, predominantly glassware. Most do not include a disinfection stage except when the WD has been designed for a particular application, eg. animal cage washing and disinfection.

Pharmaceutical equipment

3.18 Laboratory washers specifically intended for processing equipment and containers for use in the manufacture of pharmaceutical or in-vitro diagnostic products may be configured for a single product or family of products, eg. vials, or may be required to process a range of items.

3.19 The process specification may include high requirements for cleaning efficacy and levels of process residuals. This may incorporate a disinfection stage for items to be used without further treatment in the preparation of a non-sterile product.

Classification of washer-disinfectors by configuration/load handling type:

3.20 WDs can also be classified by the construction of the WD and the manner in which the load is processed through the machine.

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Cabinet (single chamber) machines (Type 1)

Installed machines

3.21 Type 1 machines have a single chamber in which the full range of process stages are carried out. Type 1 machines may have more than one chamber but the full range of process stages are carried out in each chamber. They are batch process machines in which all stages of the cycle are completed on one chamber load before another load can be processed in that chamber.

3.22 These may have either a single door through which both loading and unloading takes place or double doors with one door being used for loading and the other for unloading.

"Table top" machines

3.23 These are a particular category of Type 1 machines which have only a single door and are distinguished by their small size – having a chamber which will not accommodate two standard sterilization modules (SSMs) each of 600 mm x 300 mm x 300 mm dimensions – and by their limited requirements for connected services. These machines can be operated by connecting to a single phase outlet (normally drawing 20 Amps or less at 230 V), a potable water supply and discharging into a domestic drain or sink.

NOTE: They may be intended to be floor standing or may be placed on a work surface to provide a convenient loading height.

Continuous process machines (Type 2)

Sequential chamber machines

3.24 These all have double doors, ie. a loading door at one end of the machine and an unloading door at the other end of the machine, and also have doors or some other means of segregation between adjacent chambers.

3.25 Sequential chamber machines have two or more chambers through which the load is moved in sequence. Each chamber is employed for one, or more, different stages in the process. Two or more loads may be processed simultaneously, with the loads at different stages in the cycle at any one time. Adjacent chambers are separated by an intervening door.

Conveyor machines

3.26 These may be equipped with double doors, air-flow baffles at each end, or a door at one end and an air-flow baffle at the other.

3.27 Conveyor machines have a continuously, or intermittently, moving load carrier which progresses the load through a series of tanks, chambers or zones – in each of which one stage of the process takes place. Two or more loads may be processed simultaneously, with the loads at different stages in

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the cycle at any one time. The separation between adjacent stages may be spatial only or there may be baffles (eg. strip curtains) interposed.

Classification of washer-disinfectors by the nature of the process

3.28 WDs can be further classified by the nature of the process employed in each of the three principle processing stages: cleaning, disinfection and drying. A limited range of WDs also provide a chemical sterilization facility.

Cleaning

Flushing machines

3.29 Cleaning is achieved by flushing with water; no detergents are employed.

Washing machines

3.30 Water and detergents are used to clean the product. Detergents act both as wetting agents – in which the reduction of surface tension allows contact with all surfaces – and also as a solvent and/or dispersant of soil. Enzymatic detergent systems are intended to work by converting insoluble soil into a water-soluble form.

3.31 The mass of water and the force with which the water comes into contact with the surface to be cleaned plays a significant part in the soil removal process.

Ultrasonic machines

3.32 Ultrasound energy is used to effect the mechanical removal of soil from the surface of the product.

Solvent cleaning machines

3.33 These machines use cleaning processes which employ specific solvents in which the particular soils to be removed are soluble. An example of this type of process is the de-greasing systems which employ organic solvents to remove mineral oils. These processes are not commonly used in reprocessing healthcare products and are not covered by this SHTM.

Disinfection

Thermal disinfection

3.35 In this process disinfection is achieved by the action of moist heat maintained on the surface to be disinfected at a particular temperature for a particular time (see Table 2) or some other time-temperature relationship of demonstrated equivalence.

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Chemical disinfection

3.36 Disinfection is achieved by the action of a solution of a microbicidal chemical maintained on the surface to be disinfected at a particular concentration for a particular time at, or above, a specified temperature.

3.37 The removal of the chemical disinfectant after the disinfection stage is of importance also and must be achieved without compromising the microbial quality of the product.

Drying

3.38 Drying may be an integral part of the cycle, usually by the circulation of hot air over the product, or may be provided as a separate drying cabinet. Some products, eg. corrugated anaesthetic tubing, require prolonged drying times and a separate drying cabinet can improve the productivity of the WD.

3.39 Solvent drying systems have also been used but their relevance is limited to specific applications.

3.40 A dry product can also be obtained by the flash evaporation of residual moisture from product items which are hot following a high temperature thermal disinfection stage. This method is often employed in low cost machines, eg. bed pan washers.

Liquid chemical sterilization

3.41 Sterilization by means of solutions of microbicidal chemicals is also employed for a limited range of products which, although required to be sterile for their intended use, cannot be sterilized through conventional terminal sterilization processes (see SHTM 2010; *Sterilization*).

3.42 Key factors in determining the efficacy of the process include:

a. the concentration of the chemical sterilant;

b. the temperature at which it is used;

c. the contact time with the product;

d. the absence of inhibitory materials, such as residual soiling.

3.43 The removal of the chemical sterilant after the sterilization stage is of importance and must be achieved without compromising the microbial quality of the product. The control of the microbial quality of the rinse water is critical in this respect.

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3.44 The sterile product obtained from a liquid chemical sterilization process is not usually packaged for transport and may not have been dried. Under these circumstances the product is only suitable for immediate use and the machine must be installed close to the point of use. Prolonged storage (eg. for more than two or three hours) may permit contamination to occur followed by the growth of a large microbial population. The storage conditions are also important determinants of contamination.

NOTE: The microbicidal chemicals used for disinfection and sterilization are usually toxic and may also be sensitisers in low concentrations. Many have defined exposure limits (see HSE guidance on occupational exposure). Control of environmental emissions and personnel exposure are important considerations in the design and operation of the processing equipment and in the siting of such equipment. Specific ventilation provision may be required.

When is a washer-disinfector required?

3.45 For many products used in healthcare practice there are two choices available:

a. products which are intended to be re-used after they have been decontaminated and subjected to any necessary reprocessing (eg. terminal sterilization);

b. single-use products – ie. those which are intended to be discarded after use.

3.46 Products which are intended to be re-used may be decontaminated, in accordance with the manufacturer's instructions, by:

a. manual cleaning followed by disinfection and/or sterilization;

b. machine cleaning followed by disinfection and/or sterilization;

c. automated machine decontamination incorporating cleaning and disinfection (or more rarely sterilization).

For further guidance, see Device Bulletin 9501 'The re-use of medical devices supplied for single-use only' published by the Medical Devices Agency.

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NOTE: The decontamination and subsequent re-use of items intended for single-use requires extensive technical investigation to establish the compatibility of the process and that the performance of the item has not been impaired. To undertake such studies is beyond the competence and expertise of hospital departments and routine laboratories and is rarely justified on economic terms. There are also serious legal implications for both management and user.

3.47 When both re-usable and single-use devices are available a choice may need to be made based on several considerations including: clinical acceptability; economics; local constraints, such as the storage space needed for single-use items or engineering services (electricity, water, drainage) required for a WD processing re-usable devices.

This situation is most relevant in the disposal of human excreta from bed-dependent patients and is discussed in more detail in Chapter 9.

Choice of washer-disinfector

3.48 The choice of WD will be governed by the nature of the loads required to be cleaned and disinfected. Detailed guidance on appropriate processes for different load items can be found in a number of documents: ‘Sterilization, disinfection and cleaning of medical equipment: Part 1 Principles’ published by the Medical Devices Agency; ‘Sterilization and disinfection of thermo-heat labile equipment’; ‘Bed pan washers’ published by the Central Sterilising Club; and in SHTM 2030 Part 2, ‘Operational management’.

3.49 Purchasers should be aware that items suitable for a particular type of WD may still require different operating cycles, which need to be specified before purchase.

Guidance on the modification of operating cycles to suit different loads is given in SHTM 2030, Part 2 ‘Operational management’.

More information about the different types of WD is given in Chapters 10 to 14.

Advice on individual cases should be sought, if necessary, from the AP(S) before any decision is made. When a chemical disinfection process is being considered the microbiologist should also be consulted.

3.50 Once the type of WD has been decided, preliminary enquiries should be made with a number of manufacturers to obtain specifications and price lists. Table 1 indicates some of the information that will be useful for planning purposes and which should be obtained at this stage.

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Table 1: Information to be obtained before inviting tenders

Information required	Objectives
The standards to which the WD is designed and constructed and a statement of compliance.	To confirm that the WD meets recognised specifications for design, construction, safety and performance.
Installation data including the overall dimensions and the mass of the WD (fully loaded, the number of supports), floor loading at each. The clearance space required for installation access. The mass of the principle components. Access space required for maintenance. Doors and necessary space for movement of the doors.	To enable the user to establish whether the proposed location is suitable for the WD and the extent of any site improvement work required (see chapter 5).
The usable chamber space expressed as volume, the principle internal dimensions, and the number of standard load carriers or load items which can be accommodated.	To enable the user to determine the capacity of the WD for the load which it is intended.
Specifications for each of the engineering services required by the WD.	To enable the user to establish that the required quality and quantity of each utility required is present or can be provided, and to assess operational costs.
The mean and peak sound power levels generated by the WD (see BS 2745: Part1).	To enable the contractor to confirm that the sound power level after installation will not exceed that specified for the location (see Chapter 5).
A description of the operating cycle including overall cycle time(s) for classes of goods to be processed, length of individual stages: cleaning, disinfection, drying.	To enable the user to determine the throughput of the WD and hence calculate the number of WDs required for the anticipated workload.
The maximum temperature which may be attained during each stage, the range within which cycle variables can be adjusted, the nature and quality of chemical additives required.	To enable the user to assess their compatibility with the load.

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Cycle variables

3.51 For the purposes of this SHTM the following definitions have been adopted.

3.52 The **Cycle Variables** are the physical factors – such as time, temperature, water volume, flow rate, pressure, detergent concentration – that influence the efficacy of the cleaning and disinfection processes.

3.53 Most operating cycles have a stage in which the load is exposed to the disinfection conditions for a specified length of time. This period is known as the **Holding Time** (see Table 2).

3.54 The **Disinfection Conditions** are the range of conditions that may prevail throughout the chamber and load during the holding time.

3.55 The holding time may be preceded by a period in which the disinfection conditions are present in the chamber but not yet present on all surfaces of the load which are to be disinfected. This period is the **Equilibration Time**.

3.56 Together the equilibration time and the holding time constitute the **Plateau Period**. The plateau period can always be determined from the indicated or recorded temperature in the chamber during each cycle. The equilibration and holding times cannot be ascertained unless the temperature in that part of the load which is slowest to reach the disinfection temperature is also being recorded or measured.

3.57 For thermal (moist heat) disinfection the disinfection conditions are specified by a **Disinfection Temperature Band**, defined by a minimum acceptable temperature, known as the **Disinfection Temperature**, and a maximum allowable temperature.

3.58 The higher the disinfection temperature the shorter the holding time which will be required to achieve the same level of disinfection.

3.59 For liquid chemical disinfection/sterilization processes the plateau period is equivalent to the **Disinfectant/Sterilant Exposure Time**. The holding time can only be determined by thermometry when the chemical agent is supplied at an elevated temperature to a load which was not pre-heated to the required temperature.

3.60 The disinfection temperature band may also be quoted for liquid chemical disinfection/sterilization processes but is not a complete specification of the disinfection conditions since the efficacy of such processes depends also on the concentration of the chemical agent.

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Table 2: Thermal disinfection temperature bands

Disinfection[a] temperature (°C)	Minimum exposure time (minutes)	Maximum allowable temperature (°C)
65	10	70
73	3	78
80	1	85
90	0.2[b]	95
93[c]	10	98

Notes.

a. The disinfection temperature is measured at the surface to be disinfected.

b. The exposure time of 1 second (as specified in BS 2745 Part1) is too short for reliable measurement and a minimum time of 12 seconds (0.2 min) should be used.

c. This time/temperature relationship is only used for items known to be contaminated with large amounts of pathogenic organisms, for example in laboratories.

3.61 The dispensed volume of the chemical additives (eg. detergents), including the accuracy and reproducibility of the dosing system(s), should be specified.

3.62 For WDs employing jet washing systems, the pump pressure and water flow are also critical variables.

3.63 For ultrasonic cleaners, the frequency, amplitude and power density (Watts/litre of usable chamber space) are critical variables.

3.64 In all cases, the duration of each process stage must be determined with sufficient accuracy to ensure that consecutive cycles have the same efficacy.

Sizes and numbers

3.65 Precise information on the sizes and numbers of WDs required for particular applications is difficult to give since there are considerable variations in patterns of use. The number of WDs required will depend on the cycle time and the loading capacity of the machine and in some circumstances on the flexibility of operation that may be required, eg. whether items to be processed can wait until there is a full load for the WD or need to be processed immediately. Within the clinical applications for WDs, the size and number will also depend on the configuration and load handling type and the operational type. Guidance on calculating the size and number of WDs required for a particular application is given later.

3.66 The methods which may be used to estimate the size and number of WDs varies with the application for which the WD is to be purchased. A detailed description of two approaches is given for WDs intended to be used to process surgical instruments and associated products with brief complementary notes for WDs for other applications. The cycle times quoted by manufacturers of WDs will usually be based on the assumption that the water supply is no less than the mid-point of the specified range for an

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acceptable supply. It should be noted that lower pressures may significantly extend cycle times.

Assessment of workload and throughput

3.67 A combination of different types of WD and cleaning processes will often be required to deal with the extensive range of instruments to be processed, eg. in an SSD. This needs to be taken into account in calculating the capacity (size and number) of WDs required.

3.68 The provision of separate drying facilities for items which are difficult to dry (eg. corrugated tubing for anaesthetic and respiratory use) can dramatically increase throughput by reducing overall cycle times.

3.69 Bowls and receivers occupy a large volume but are relatively easy to clean. For a large SSD, consideration needs to be given to using a relatively simple washer to process bowls and receivers rather than occupying space in a more sophisticated machine which is better utilised processing more complex instruments.

3.70 Two distinct methods of assessment should be considered:

a. aggregated workload and throughput capacity;

b. throughput time.

Aggregated workload and throughput capacity

3.71 For items in sufficiently plentiful supply, minimising the turn-round time (the time between receipt of the used item and its having been reprocessed and made available for further use) is not a priority. An assessment based on the weekly workload generated by users is appropriate.

Throughput capacity

3.72 Throughput capacity is affected by a number of variables.

These include:

a. The number of operational hours per week for the department in which the WD is located.

b. The machine utilisation factor expressed as a percentage of the number of operational hours. This will be influenced by several factors including:

   (i) delivery schedules from clinical areas;

   (ii) staff availability for loading and unloading (meal and comfort breaks may total one hour/day);

   (iii) start-up and shut-down time each day (approx. one hour/day);

   (iv) planned and breakdown maintenance time (approx four hours/week);

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(v) routine, periodic and annual testing.

3.73 Precise estimations are difficult to make and may have limited value due to continually changing and developing clinical workloads. SHPN 13 recommends an assumed utilisation factor of 60% for most types of WDs and in practice this is reputed to be appropriate.

Throughput time

3.74 Throughput time may be the controlling factor:

a. for items, usually sophisticated and expensive devices such as endoscopes, where the shortest practicable turn-round time may be required in order to maintain an effective clinical service;

b. for items where anything more than a short delay in initiating processing would be unacceptable (eg. human-waste containers).

3.75 Throughput time is affected by three key factors:

a. cycle time;

b. machine capacity;

c. machine availability.

Sizing calculation

Cycle time

3.76 The processing time varies depending upon:

a. the number and the duration of the flushing and washing stages;

b. the disinfection time;

c. the drying time.

With modern microprocessor-based control systems, several cycle options may be programmed into the same machine.

NOTE: The cycle time may be adversely affected by inadequate services such as low water pressure and low water temperature.

3.77 Some WDs now include a load identification system which reads a label attached to a load carrier in order to identify the nature of the load. The machine then automatically switches to the required process cycle.

3.78 The cycle time may be determined from the WD manufacturer's specification either for the particular item to be processed or for the "worst case" load for which the cycle time will equal or exceed that required for the products to be processed.

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Machine capacity

3.79 The machine capacity, specified by the manufacturer, will normally be stated in terms of the number of “baskets” or “trays” that can be accommodated in one load.

The EU standard on sterilizers BS EN 285 has standardised 600 mm x 300 mm x 300 mm as a single sterilization module. Rigid re-usable containers for use in sterilizers are also standardised to fit either singly, or in multiples, within the modular unit. Current proposals in the committee draft for the EU Standards on WDs have adopted this size as the basic module for WDs also. However, until these standards are finalised it will be necessary to determine the size of the baskets referred to by the manufacturer.

Aggregated workload for theatres

3.80 An approximate assessment of the workload can be determined from the total actual, or the expected, case load on a weekly basis.

3.81 Each case may be assumed to require the use of at least two baskets in the WD load carrier; one for the instruments and one for the Edinburgh tray, instrument orientation tray or re-usable container used to package the instrument set. Large instrument sets will often require additional baskets – eg. for orthopaedic, cardio-thoracic or large abdominal sets – and careful notes should be made of which specialities may be served by the installation.

3.82 Dedicated load carriers or separate provision (eg. ultrasonics) will be required for particular items eg. micro-surgical instruments, laparoscopes and their accessories.

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Workload estimate

3.83 The workload should be estimated from historical records of operational activity or based on proposed work loads.

Theatre case load per week = C_S[1]

Number of acute beds = C_A

Average number of machine baskets:

– per theatre case = B_S[1]

– per acute bed/week = B_A[2]

Workload: W_{TOTAL} (= number of baskets to be processed/week)

$W_{TOTAL} = (C_S \times B_S) + (C_A \times B_A)$

1. It may be necessary to carry out this assessment on the sum of several subsets when there are a number of operating theatres with diverse instrument demands per case.
2. This assessment should be based on the total number of acute beds, including maternity and geriatric, but excluding mental health. If a factor of approximately 0.2 baskets per acute bed is assumed, this should be sufficient to allow for demands from other areas with lower volume requirements such as A&E, community, etc.

Throughput estimate

3.84 The following data are required to estimate the throughput

Machine baskets per load B_N

Machine cycle time (in hrs)[1] C_T

Number of operational cycles per week H

Machine utilisation (%)[2] A

1. If a number of different operating cycles are to be run with widely differing cycle times, it may be advisable to calculate the workload and throughput separately for each category of instruments/process cycle and sum the individual components. Alternatively, a weighted mean cycle time may be calculated from the proportion of each cycle that is expected to be required.
2. An assumption of 60% utilisation is appropriate in most cases (see also SHPN 13).

Then the throughput $T_{TOTAL} = \frac{B_N \times H \times A}{CT}$ baskets per week

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Number of machines required

3.85 The number of machines required may be calculated as follows:

W_{TOTAL} : Workload as machine baskets per week

T_{TOTAL} : Throughput as machine baskets/week/machine

No. of machines required =

$$\frac{[W_{TOTAL}]}{[T_{TOTAL}]}$$

Worked example

If W_{TOTAL} = 1400 baskets/week

and T_{TOTAL}= 1600 baskets/week/machine

then no. of machines required =

$$\frac{[1400]}{[1600]}$$

= [0.875]

i.e. 1 machine

Clinical washer-disinfectors for surgical instruments and associated products

3.86 WDs for this application present the greatest diversity of operational, configuration and load handling types. They range from small table-top models suitable for use in general practice to large, fully automated continuous process models capable of processing the full range of surgical instruments, utensils, containers and anaesthetic accessories with high throughput rates.

3.87 WDs for small units where a single, low volume WD is adequate are considered under WDs for use in general practice.

3.88 Most WDs for surgical instruments and associated products, other than flexible endoscopes, are located in centralised units such as sterile service departments (SSDs).

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Clinical washer-disinfectors for human-waste containers

3.89 These machines are equipped with load carriers built to accept standard numbers and/or patterns of specified containers including bedpans, urine bottles, suction bottles and bedpan carriers (for use with disposable bedpans), raised toilet seats, commode bowls, enema and emesis containers.

3.90 The workload will depend on the number of beds to be served, the bed-dependency of the patients in these beds and the nature of the medical or surgical speciality – for example an orthopaedic ward may be expected to have a high level of bed-dependency.

3.91 Human-waste containers need to be processed as soon as possible after use if they are not to become offensive or a potential infection hazard. The peak workload and the maximum throughput are factors that need to be considered. A high proportion of bed-dependent patients may be expected to use a bedpan in the hour following breakfast and the capacity of the WD should be sufficient to process this within an hour.

3.92 Two capacities of WD are widely available: one that will process one bed pan or two urine bottles per cycle; and one that will process two bed pans or four urine bottles. The latter affords more flexibility at times of peak demand.

Clinical washer-disinfectors for anaesthetic accessories

3.93 Many WDs for surgical instruments and associated products can be adapted to process anaesthetic accessories, eg. corrugated tubing, face masks, airways – usually by the provision of a dedicated, interchangeable load carrier.

There are also dedicated WDs intended solely, or principally, for processing anaesthetic accessories.

NOTE: Simple deluge washers (normally used for bowls and utensils) and ultrasonic washers cannot usually deal with anaesthetic accessories or other tubing.

3.94 Current clinical practice makes frequent use of single-use items and/or protects patient connected circuitry from contamination by the use of filters. These have dramatically reduced the throughput of such items. In many SSDs only those items used in respiratory diagnosis, where filters cannot be used, are sent for reprocessing.

3.95 When the projected throughput is low the use of a WD for surgical instruments with a suitable load carrier is to be recommended. However, the drying stage will necessarily be greatly extended beyond that required for surgical instruments leading to a longer cycle time.

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3.96 When a higher throughput is anticipated but where it is still not economical to provide a dedicated WD for anaesthetic accessories, consideration should be given to the provision of a separate drying cabinet.

3.97 Capacity should be assessed based on the number of items of each type that can be processed in a single load.

Clinical washer-disinfectors for endoscopes

3.98 Users are reminded that they should seek advice from the manufacturer of the endoscope as to the most suitable method of decontamination.

Rigid endoscopes

3.99 Many rigid endoscopes and most of the re-usable surgical accessories used for minimal access therapy (MAT) can withstand steam sterilization and may be processed through WDs employing a thermal disinfection stage to make them safe to handle during packing, etc.

3.100 It is essential that the WD is designed or adapted to ensure that during the flushing, cleaning and disinfecting stages water flows though the lumen(s) of the device.

3.101 Many cabinet WDs and continuous process WDs of the discrete chamber type can be equipped with dedicated load carriers to process rigid endoscopes, gas cannulae, etc. There are also a number of dedicated endoscope cleaners including ultrasonic cleaners.

3.102 The capacity of the WD should be assessed on the number of items of each type that can be processed in a single load.

Flexible endoscopes

3.103 Most fibre-optic endoscopes cannot be processed in conventional WDs used for surgical instruments. Fibre-optic endoscopes are unable to withstand the high pressures generated during the cleaning process or the high temperatures attained during the disinfection process. Dedicated endoscope WDs are available.

NOTE: Many fibre-optic endoscopes are stated by the manufacturer to be incompatible with ultrasonic cleaning.

3.104 In general, the re-usable accessories, biopsy forceps, etc. can be processed through a WD for surgical instruments.

3.105 For most fibre-optic endoscopes, the throughput time is the critical factor. Most endoscope WDs will only accept one endoscope per cycle. Those which will take two endoscopes or more may be of little benefit in reducing

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throughput time unless each endoscope is accommodated in a separate chamber and cycles can be run independently.

3.106 The disinfection stage of WDs for fibre-optic endoscopes is also critical since there are few suitable terminal sterilization processes with sufficiently rapid cycle times.

Clinical washer-disinfectors for use in general practice

3.107 These are generally small machines, eg. “table-top” cabinet washers, intended for use in dental, medical or veterinary general practice, clinics, mortuaries, etc. where there is a low level demand for thorough cleaning and disinfection of surgical instruments and utensils such as bowls and receivers.

3.108 The maximum anticipated demand and required turn-round time will usually be readily identified by the user for comparison with the loading capacity and cycle times specified for the WD.

3.109 Purchasers should note the importance of the effect of low water supply pressure and, where a hot water supply is required, the effect of low feed water temperature on process cycle times.

Laboratory washer-disinfectors

3.110 Laboratory WDs, whether intended for use in a clinical laboratory or in the laboratory of a manufacturer of a medical device or medicinal product, are equipped with one or more load carriers specific to the nature of the items to be processed.

3.111 The number of each type of item that can be accommodated and the length of the operating cycle may then be used to estimate throughput by comparison with anticipated workload. This can be used to calculate the size and number of machines required.

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4. Specification and contract

Introduction

4.1 This chapter discusses general specifications for WDs and the steps to be taken in inviting tenders and issuing a contract. The validation procedure which begins on installation of the WD is discussed in detail in SHTM 2030 Part 3, 'Validation and verification'.

Preparing a specification

4.2 Purchasers are strongly recommended to seek assistance from the Independent Advisor when preparing a specification for a WD.

4.3 Standards and other specification documents are continually being updated and purchasers should ensure that they consult the latest editions of such documents, including any amendments issued after publication, to keep abreast of changing requirements. Advice should be sought from the Independent Advisor on this.

4.4 Most WDs are constructed to British Standards or the standards of another European country, eg. the German Standards Authority (DIN). In some cases the Standards specification may not be adequate for WDs to be used in the public service. In these cases additional specifications are listed below for general design considerations and, where appropriate, under an additional specification heading in each chapter.

4.5 Details of the proposed location of the WD should be stated clearly in the specification sent to suppliers.

4.6 Purchasers should specify all of the items requiring to be processed through the WD to allow the tenderer to offer the most appropriate machine and accessories.

4.7 Except where the manufacturer is responsible for installation of the machine the type and standard of packing and delivery of the WD should be specified. When site conditions are likely to be poor and damage could occur a substantial dust proof transit case may be necessary.

General design considerations

4.8 The following design considerations are applicable to all or most types of WD, but are not necessarily required by the current standards. When applicable they should be included in the specification for any WD to be operated in the NHS.

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4.9 All WDs and associated equipment are classed as “work equipment” and should comply with the ‘Provision and Use of Work Equipment Regulations 1998’. Purchasers are reminded that under the Regulations it is the responsibility of the employer, not the manufacturer, to provide a WD that is “suitable for the purpose that it is used or provided”.

4.10 All WDs made or sold in the UK from the 1 January 1996 should conform to the emission and immunity requirements of the ‘Electromagnetic Compatibility Regulations 1992 (as amended)’. This may be achieved by compliance with BS EN 50081 (Emission) and BS EN 50082 (Immunity). The manufacturer should be informed of any local sources of electrical magnetic disturbance which may effect the operation of the WD.

4.11 For maintenance purposes one or more panels of free standing WDs should be easily removable and replaceable.

4.12 Special foundations are not normally required. The weight of the WD, which can be as much as 2500kg for a large continuous process WD when fully loaded, should be borne by at least four pads each measuring at least 150 mm x 50 mm. Floor mountings should be designed to minimise vibration.

Safety features

4.13 Safety features should be designed in accordance with the Standard PD 5304: 2000 and the standard for the ‘Safety of electrical equipment BS EN 61010’.

4.14 The design of the control system should ensure that the door can not be opened until the cycle is complete. When a fault is indicated the door should only be able to be opened by a key code, or tool, when the WD is returned to a safe condition.

4.15 The manufacturer should provide a list of all safety devices together with their settings and methods of adjustment.

4.16 All safety devices should be designed to fail in a manner which does not cause a safety hazard to personnel.

4.17 A safety hazard should not be caused by an error in the control or indication system.

Over pressure protection

4.18 Over pressure safety valves should be fitted to protect components that may be damaged by inadvertent high pressures. This includes any pressure vessel, eg. the steam generator or compressed air reservoir, used within the machine. The discharge from safety valves should be terminated in a safe position.

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Instrumentation

4.19 The WD should be fitted with means to verify and/or record the attainment of the specified process conditions. The nature and extent of monitoring should be commensurate with the intended use of the load and the risk arising from the inadvertent use of an improperly cleaned or disinfected load. Particular requirements for different types of WD are described in subsequent chapters.

A “cycle control” recorder may be of value in fault diagnosis but does not provide verification of attainment of the specified operating conditions.

NOTE: WDs may be fitted with either, or both, of two separate recording systems. A “cycle control” recorder which records the values of control variables as seen by the controller; or a “process verification” recorder which, independently of the controller and its sensors, records the values attained for some or all of the critical variables which determine the adequacy of the process.

4.20 Within this SHTM, three levels of process verification are identified:

a. Verification by the operator of the attainment of disinfection conditions – the WD is equipped with a temperature indicator, independent from the controller, to allow the operator to verify attainment of the programmed disinfection temperature.

   This may be used when, because of the intended use of the load, the risk arising from use of the product after an unsatisfactory disinfection process is low. This may include, for example, WDs for human-waste containers.

b. Verification by process record, independent from the controller, of the attainment of disinfection conditions – the WD is equipped with a temperature recorder, with sensors and signal processing independent from the controller, to record the attainment of the programmed disinfection conditions.

   This may be used when, because of the intended use of the load, it is necessary to provide confirmatory evidence that the disinfection process has taken place within the limits established during validation.

c. Verification by process record, independent from the controller, of the attainment of process variables affecting both the cleaning and disinfection processes – the WD is equipped with a multi-channel recorder, with sensors and signal processing independent from the controller, to record the process variables which were determined during validation studies to be critical to the satisfactory outcome of the cleaning and disinfection processes.

   This may be used when, because of the intended use of the load, it is necessary to provide confirmatory evidence that both the cleaning and disinfection processes have taken place within the limits established

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during validation. This may include WDs for products which will be used without further processing and where the risks arising from an unsatisfactory cleaning and/or disinfection process are unacceptable.

4.21 A temperature indicator, independent of the controller, should be fitted to all WDs having a chemical disinfection stage to enable the user to verify the attainment of the specified disinfection temperature.

4.22 WDs used in SSDs and other similar production environments should be fitted with recorders to record process temperatures and the values of other key variables, eg. volume of chemical additive admitted.

NOTE: The use of recording devices may be required for compliance with the various quality systems under which the WD may be operated but in addition may be cost effective in producing the information to optimise the decontamination process.

4.23 When an instrument has a facility to allow it to be adjusted the adjustment should require the use of a key code, or tool, which is not available to the operator.

4.24 When a fault is indicated in the form of an error message shown on a visual display unit, it should be clearly distinguishable from the normal messages – for example, by use of a different colour or larger size of text. The indicator should remain displayed until cancelled by the operator.

4.25 The contractor should be required to carry out adjustments to the instruments on site so that the accuracy specified at the disinfection temperature can be met with the plant running and under the conditions normally prevailing on site.

4.26 An indicator should show which stage of the operating cycle is in progress and indicate “cycle complete” at the end of the cycle. For continuous process machines, separate indication of the operational status should be provided for each chamber or section.

4.27 A five digit counter should be provided to indicate the cumulative number of cycles started. The counter should be non re-settable, tamper evident or sealed. For continuous process machines the counter should indicate the number of loads which have entered the WD.

4.28 Provision should be made for the attachment of the test instruments required for the tests specified in SHTM 2030 Part 3, ‘Validation and verification’.

For temperature testing – a connection should be provided to permit the entry of sensors into the chamber, as described in BS 2745 Part 1. A suitable form of temperature connection is described in BS EN 285.

For pressure or flow testing – test tees and valve cocks with sealing plugs should be fitted to permit connection of test instruments for the verification

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and calibration of all pressure and flow instruments permanently fitted to the WD.

When the WD is provided with instruments to monitor other variables – such as electrical conductivity of water supply or ion selective electrodes (ISE) for the determination of detergent concentration – means should be provided to enable test instruments to be connected to verify the readings obtained from the installed sensors.

Programmable electronic systems

4.29 Modern WDs frequently use programmable electronic systems (PES) for control and data recording. Such systems should be designed in accordance with the principles set out in the two parts of the HSE document 'Programmable electronic systems in safety related applications'.

4.30 When a PES is used to control or monitor the process, the values of cycle variables critical to process performance and determined during validation should be documented in the validation report regardless of whether or not they are held in the PES memory.

4.31 The version number of the software used in the PES should be available for display when required.

4.32 Combined control and instrumentation systems that are wholly operated by means of a PES should incorporate at least two timing systems independent of each other. When one timing system is used to control the holding time during the disinfection stage it is verified by the other timer.

Steam supply

4.33 When the WD is fitted with a steam supply, the steam pipework should include a pressure reducing system with a separator on the high pressure side. The system should be fitted with a strainer and trap to prevent condensate accumulating in the system.

Doors

4.34 WDs may have a single door or a door at each end (double door or pass through machines). Double door machines are preferred since they allow full physical segregation of clean disinfected items from dirty contaminated items. However, the increased complexity of a two door system may present additional maintenance requirements. Without special provision these may be inadequate for effective use of the WD as a "pass-through" machine from a "dirty" to a "clean" area since they allow a continuous, large, loss of air from the clean area.

NOTE: Some continuous process machines are fitted only with baffle stops at each end of the machine, and in some cases between sections of the machine.

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4.35 Other continuous process machines may be in the form of a series of tanks into which the load is moved by an overhead conveyor. Each tank is protected by horizontally hinged spring loaded flaps which are pushed open by the load as it is lowered into, or raised from, the tank.

4.36 Discrete chamber or cabinet type machines (Type 1) may be fitted with manual or power operated doors whereas continuous process machines (Type 2) are normally fitted with power operated doors. Power operated doors will usually be vertical sliding doors. When manually operated doors are used they may be either vertically hinged or horizontally hinged. Horizontally hinged doors which fold down may offer the additional benefit of providing a loading and/or unloading platform.

4.37 The choice of design for any particular installation will depend on the workload, space restriction, price and ease of maintenance. If hinged doors are specified it should be clearly stated whether they are to be hinged on the left hand side, the right hand side or horizontally hinged.

4.38 It should be possible to clean the contact surfaces of the door seal without removing parts of the WD.

Materials of construction

4.39 Those parts of the WD which come into contact with the load should be manufactured from materials which have corrosion and abrasion resistant properties equal to or better than stainless steel.

4.40 The wet and chemically aggressive environment within the WD will cause corrosion and galvanic attack when dissimilar metals come into contact –a fact which should be taken into account when choosing the materials of construction.

4.41 The chamber should be designed to withstand 25,000/T operating cycles where T is the minimum operating cycle time in hours, specified by the manufacturer.

4.42 The method of construction of the chamber should ensure that it is self draining and free from sharp internal corners which cannot be cleaned during the normal cleaning cycle.

4.43 Floor mounted WDs shall be fitted with adjustable feet to compensate for irregular surfaces.

Integral steam generators designed to operate at pressures exceeding 200 mbar gauge

4.44 Steam generators fitted to WDs should be designed and manufactured to conform to BS 5500: 2000.

4.45 The integral steam generator should be equipped with blow down facilities to enable sludge to be expelled.

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Integral air compressors

4.46 WDs may require a supply of compressed air for either the operation of valves and powered door systems and/or during the drying stage of the cycle.

4.47 When compressed air is intended to come into contact with the washed and disinfected product the compressed air supplied should be “medical grade” ie. it should be oil and particulate free (see SHTM 2022).

4.48 Built-in air compressors should be suitable for the duty imposed upon them. Current experience suggests that certain small compressors of the type fitted to domestic refrigerators are not suitable for use in WDs. Without meticulous maintenance a small air leak can cause them to run continuously thus causing carbonisation of the oil and a consequent failure of the WD pneumatic system.

Integral calorifiers and tanks

4.49 All integral calorifiers should conform to BS 853: 1996 and should be designed and constructed to allow thermal disinfection to be achieved throughout the calorifier and associated pipework before water and/or steam can be supplied to the WD during the thermal disinfection and subsequent stages.

4.50 Water tanks within the WD should be self draining and located so that they are cleanable by the operator and fitted with a drain down system which either works automatically when the machine is switched off or which is accessible to the user.

4.51 All tanks should be fitted with an overflow (see Water Bye-laws 1989).

When water is to be heated the heat source should be controlled by a thermostat and it should employ a heating medium as specified by the purchaser. The heat sources should be removable for replacement or maintenance purposes.

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Dosing systems

4.52 The WD should be fitted with not less than two systems for controlling the admission of chemicals (detergents, disinfectants, rinse aids, lubricants etc.) and should be provided with the facility for at least one additional dosing system to be fitted.

NOTE: This requirement does not apply to WDs for human-waste containers.

4.53 Each dosing system should be provided with means to adjust the volume admitted. Access to the means of adjustment should require the use of a key, code or tool.

NOTE: The means of adjustment can be manual or automatic.

4.54 The stage(s) in the process cycle at which each dosing system admits chemical to the WD should be under the control of the automatic controller.

4.55 Each dosing system should be provided with means to determine the volume admitted and the time within the operational cycle when the admission occurred. This data should be available to the operator.

Failure to admit the specified minimum volume should cause a fault to be indicated.

4.56 The manufacturer should specify the accuracy and reproducibility of the control of volume admitted for each of the dosing systems used (detergents, disinfectants, rinse aids, lubricants) per cycle.

4.57 The WD should be fitted with a system that will indicate when there is insufficient chemical(s) available for the next cycle.

Door controls

Control of manually operated doors

4.58 An explanation of the manual action required to lock the door should be provided for the operator. In addition, if the unlocking procedure is not the reverse of the locking procedure, there should be an indication to the operator of the manual action required to unlock the door.

The indication should be clearly displayed either on the door or on its handle or handwheel. Explicit instructions should be displayed on the facing panel adjacent to the door or on the operator's control panel.

4.59 The door mechanism should be such that the force to be applied by an operator in order to either lock or unlock the door does not exceed 250N at the intended point of grip.

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Control of doors of a double-ended WD

4.60 In double-ended WDs the control initiating the automatic cycle should be at one end only. When the loading door is closed and locked, it should not be possible to open the unloading door until the WD has completed a successful operating cycle – ie. without showing a fault.

4.61 If a fault develops, it should only be possible to open the loading door.

4.62 It should not be possible for an operator to open or close a door at the opposite end of the WD or for more than one door to be open at one time.

4.63 A visual display should be provided at both ends of the WD to indicate when the cycle is in progress.

4.64 The indication “cycle complete”, or an equivalent indication, should be cancelled when the unloading door is unlocked, and the loading door should remain locked until the unloading door has been locked again.

Internal doors and access ports

4.65 Doors between consecutive sections of a multi-section machine and access ports fitted to the outside of the machine for maintenance purposes.

Loading systems

4.66 The WD should be provided with carriers to locate the load during the washing and disinfection process. When interchangeable load carriers and baskets are provided each load carrier should be capable of being fitted and removed without the use of tools.

WD loading systems should be designed with regard to the Manual Handling Operations Regulations 1992. Reference should be made to the Lifting Operations and Lifting Equipment Regulations 1998 (LOLER).

4.67 When the WD is supplied with a system for supporting the load – and/or a system for transferring the load into and/or out of the chamber – the following should apply:

a. the load should be wholly supported and retained within the usable chamber space for the duration of the operating cycle;

b. the force required by the operator, either directly or by the application of a mechanical device supplied with the equipment, to remove the whole, or part, of the load from the chamber should not exceed 250N when loaded and operated in accordance with the manufacturer’s instructions;

c. the load carrier should either be retained in the chamber by a mechanism which is only released when the transfer system is in place, or remain stable when withdrawn for a distance equal to two-thirds of the chamber length, and be fitted with a retaining device, which has to be released if the load is to be withdrawn further.

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4.68 Means should be provided such that the transfer of the load into and out of the chamber does not cause damage and wear to the chamber.

NOTE: Systems which cause high levels of local stress, eg. point loadings, may also initiate corrosion in stainless steel materials.

4.69 The system used to support the load should be constructed from durable, corrosion-resistant materials and should withstand, without damage, the environment within the chamber.

4.70 The system used should neither prevent the attainment of the pre-set cycle variables nor the free drainage of water from the load and the penetration of water and/or steam into the load.

The load carrier(s) should be designed so that they cannot be mis-positioned in a manner which will prevent such attainment.

4.71 Any accessory used for handling the load which can be used outside the WD (eg. a trolley) should remain stable when it is supporting its maximum design load and a force of 250N is applied horizontally in any direction to the highest point of the load or accessory.

4.72 The trolley should be designed to allow the operator to align the trolley with the WD for ease of loading and unloading.

4.73 The trolley should be provided with means to collect liquid residues from the load to prevent these from dripping onto the floor. The means provided should be detachable for cleaning and for sterilization at 134–137°C in a porous load sterilizer.

4.74 The trolley should be provided with swivel wheels to facilitate manoeuvring.

4.75 The trolley should be provided with a parking brake.

4.76 The trolley should be designed to secure the load carriers on the trolley during loading and unloading, and while traversing a gradient at a slope of up to one in 20.

4.77 Trolleys intended for use with single door machines should be designed and constructed to facilitate cleaning and disinfection of the trolley between use for dirty and clean loads.

4.78 Load conveyors outside the WD which are intended to, or may reasonably be expected to come into contact with, soiled/contaminated goods should be designed and constructed to be easy to clean and disinfect. When practicable the load conveyors should be demountable and be able to be sterilized at 134–137°C in a porous load sterilizer.

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Cleaning the washer-disinfector

4.79 The design, construction and operation of the WD should ensure that during the process the surfaces of the chamber and the load carrier presented to the operator are cleaned and disinfected.

4.80 For manually filled and emptied cleaning machines with no disinfection cycle, eg. stand alone ultrasonic cleaners, the manufacturer should advise on the cleaning/disinfection method.

Invitation to tender

4.81 Once detailed specifications have been drawn up, manufacturers should be invited to tender for the supply and, if required, installation of the WD.

4.82 When inviting tenders purchasers should follow the principles described in Scottish Capital Investment Manual and Scotconcode.

4.83 The purchasers should specify that the WD manufacturer operates a quality system in accordance with the principles described in the BS EN ISO 9000 series and, when applicable, the BS EN 46000 series.

If the manufacturer has both designed and manufactured the WD the quality system should conform with BS EN ISO 9001/BS EN 46001.

If the WD has been manufactured to a design supplied by a third party the manufacturer's quality system should conform to BS EN ISO 9002/BS EN 46002.

In either case the manufacturer should ensure that each supplier of accessories, fittings and other materials also operates an appropriate quality system.

4.84 Prospective contractors should be given the following information:

a. that each WD will be subject to a validation process as described in SHTM 2030 Part 3, 'Validation and verification';
b. unless otherwise specified, that the installation checks and test specified in the validation process must be satisfactorily completed before the WD can be accepted;
c. whether the installation checks and tests are to be witnessed by the purchasers representative (normally the TP);
d. the date by which all services will be available;
e. the date by which the validation process is expected to be completed.

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4.85 Under the Public Supply Contract Regulations an exceptionally low offer may only be rejected after the contracting authority has requested and taken into account any explanation given by the supplier in writing (Statutory Instrument 1995 No 201 Part V 21/71).

Contract

4.86 For procurement of WDs reference should be made to the latest issue of PROCODE and the procedures advised in the Scottish Capital Investment Manual.

Guidance on the various contract types is available from the Property and Environment Forum Executive.

4.87 Consideration may also be given to the use of alternative forms of contract, for example MF/1 (available from the Institution of Electrical Engineers, the Institution of Mechanical Engineers or the Association of Consulting Engineers) or the Joint Contracts Tribunal (JCT) suite of documents (available from RIBA publications) or the New Engineering Contract issued by the Institution of Civil Engineers. Addresses are given in Appendix III.

4.88 Purchasers using other forms of contract are strongly advised to seek legal advice especially where a contract proposed by the prospective contractor is being considered.

4.89 Other contracts – notably for the authorised person, test person, maintenance person, competent person, and microbiologist – may need to be considered at this time (see SHTM 2030 Part 2, ‘Operational management’ and Part 1 of SHTM 2010).

4.90 In awarding these contracts purchasers should ensure that there is no conflict of interest that would compromise the validation process as set out in SHTM 2030 Part 3, ‘Validation and verification’.

Delivery

4.91 On or before delivery of the WD the manufacturer should provide the purchaser with the information specified in Appendix 4. WDs for a particular scheme should not be ordered and stored on site for long periods prior to installation and validation. Disregard of this recommendation may invalidate the manufacturer’s warranty and cause deterioration of the WD prior to installation.

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5. Siting

Introduction

5.1 This chapter sets out some of the considerations to be taken into account when siting a WD. WDs are commonly installed in sterile service departments (SSDs), operating departments, wards and laboratories. A comprehensive review of the requirements for SSDs is given in SHPN 13 and for operating departments in SHPN 26.

5.2 The room in which a WD is installed and operated should meet the requirements of the Workplace (Health, Safety and Welfare) Regulations 1992. These Regulations have considerable implications for the design of accommodation for WDs.

5.3 Fire safety precautions should comply with NHSScotland Firecode.

Operating department dirty utility room

5.4 This area should be equipped for the storage, preparation for use, and disposal of contents after use, of human-waste containers including vomit bowls, bedpans and urine bottles. Specific guidance is given in SHPN 26.

Endoscope cleaning room

5.5 Provision may be made within the operating department for an endoscope cleaning room to provide facilities for cleaning and disinfection or sterilization of those endoscopes which cannot be returned to the central SSD or TSSU for reprocessing. When practicable this is best provided by means of an automated endoscope WD. Manual cleaning facilities will also be required.

5.6 A toxic vapour extract system at bench level to exclude all possibility of inhalation should be installed whenever a liquid chemical microbicide is to be used other than in an enclosed ventilated automatic WD.

5.7 The same area may also be used to accommodate an automated WD for emptying, cleaning and disinfecting suction bottles.

Specific guidance is given in SHPN 26 Operating Department.

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Sterile services department

Decontamination area

5.8 A soiled returns hold area, where collection trolleys containing soiled returns can be marshalled, is normally located adjacent to or within the washing area and adjacent, or with easy access to, the hospital corridor or loading bay.

5.9 The washing area provides space to:

a. off-load soiled returns from trolleys;

b. sort items for disposal or appropriate cleaning and disinfection;

c. clean and disinfect reprocessable items;

d. transfer cleaned and disinfected items to the packing room.

When the transfer is automatic (ie. from an automatic WD) means should be provided to allow for the return of items which, when inspected in the packing room, are found not to have been properly cleaned.

5.10 The necessary cleaning and disinfection processes for the routine range of items to be processed may require several different types of WD. These may include, for example:

a. Single door cabinet WDs which may be used with a pass through hatch to the packing room.

When a hot air drying cabinet is used this should be of the pass through type with interlocking doors for transferring items from the washing area to the packing area.

b. Continuous process “pass through” WDs which will usually be equipped with a conveyor system to return the load carriers from the packing room to the decontamination room.

The conveyors should be designed and constructed to be easy to clean and disinfect (see also paragraph 4.78).

The decontamination room should provide a facility for cleaning trolleys used to transport returned items for decontamination and a suitable holding space for the number of trolleys which will be in use.

The room should also provide sorting benches with sufficient space for unloading trays from the trolleys and transferring items to WD baskets/load carriers.

Proper insulation of WD and exposed pipework from services is essential, together with appropriate ventilation, in order to maintain a comfortable working environment.

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5.11 Manual cleaning facilities may also be required. A stainless steel double sink, double drainer and water gun unit (hot and cold water) should be provided. The manual cleaning area should be provided with a hood and extract ventilation (to microbiological safety cabinet Class 1 – 0.7m/sec face velocity) to protect the operator from aerosols created during the cleaning process.

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6. Engineering services

Introduction

6.1 A WD installation will require external service connections. These may include water (of various qualities), electricity, steam, compressed air, drainage, ventilation and supplies of process chemicals.

6.2 The manufacturer should make clear at an early stage which services will be needed and give detailed requirements for each service (see Table 3).

6.3 For most WDs the water and drainage services are the most critical although for user comfort, especially in the case of WDs using chemical disinfectant/sterilant, the ventilation and extraction system are also of importance.

6.4 If the services are to be installed by a contractor, other than the contractor installing the WD, care must be taken to ensure that the size and location of terminations are agreed before the contracts are placed.

Electrical services

6.5 The electrical power requirements will depend on a number of factors, such as the type of WD and the method used to heat water, hot air dryers etc. Some WDs will need a three phase supply. The manufacturer should provide details of the type of supply (a.c. or d.c.), number of phases, frequency and voltage, with tolerances and loading.

6.6 Each WD should be connected via an isolator. The type of isolator will depend on the nature of the supply:

a. for small WDs and table top WDs with a maximum current demand not exceeding 13A on a single phase supply, isolation may be provided by a simple plug and socket connection using a correctly fused plug and a switched socket-outlet;

b. when a three phase and neutral supply is required or when the maximum demand from a single phase supply is more than 13A, the WD should be wired directly to the isolator. The switch should isolate all poles simultaneously and each pole should be fused separately. The cable from isolator to WD should be fixed and protected from the effects of heat and water.

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Table 3: Information on services to be obtained from the washer-disinfector manufacturer

Steam	a) acceptable range of supply pressures; b) maximum flow and usage rates; c) usage per operating cycle d) when steam is generated within the WD, the acceptable limits for hardness, pH and conductivity of feed water.
Electricity	a) type of supply eg. a.c. or d.c; b) number of phases (normally one or three) and whether neutral is required for a three – phase supply; c) supply voltage and frequency including nominal and acceptable minimum and maximum values; d) maximum continuous power demand in kW or kVA.
Compressed air	a) acceptable range of supply pressures; b) the flow required at minimum pressure; c) the volume of air used for each cycle; d) the quality or quantity of air required including dew point, maximum size and concentration of particulate material, oil content, and microbial contamination level as relevant.
Water	For each grade of water required, a) the acceptable range of supply pressures; b) the flow at minimum pressure; c) the volume used per cycle; d) the acceptable temperature range for incoming water; e) the quality of water required when relevant: - the maximum permissible hardness expressed as mg/l $CaCO_3$; - the acceptable range of pH; - the maximum permissible conductivity; - the limiting concentration of heavy metals, halides, phosphates and nitrates; - the maximum acceptable microbial population.
Drainage	a) the maximum flow of effluent to the drain; b) the maximum temperature of the effluent on leaving the WD; c) the maximum effective diameter of the discharge orifice from the WD chamber; d) requirement for sealed drainage system if hazardous fumes or gases are produced from chemicals used in the process.
Ventilation	a) the peak value during a cycle and the average value throughout a cycle of the heat in Watts transmitted to the environment when the WD is operated in still air at an ambient temperature of $23 \pm 2\ ^{o}C$; b) the heat in watts transmitted by a full load being unloaded from the WD into still air at an ambient temperature of $23 \pm 2\ ^{o}C$; c) the maximum flow of air extracted from the environment of the WD as exhaust ventilation; d) ventilation requirements for removal of fumes or gases from hazardous chemicals used in the process.
Process chemicals	Details of all process chemicals required (eg. detergents, rinse aids, sequestering agents, descalers, microbicides) for the regeneration of integral water treatment system), the quantity required per cycle, the nature and size of containers in which they are supplied, the necessary storage conditions for safe handling.

6.7 Within the loading area an additional switch should be provided so that the operator can electrically isolate the WD or group of WDs in the event of an

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emergency. The switch should be placed between the normal operating position and the exit door.

6.8 It is not normally necessary for WDs to be connected to the essential supplies circuit, when this is available. Exceptions might include the decision to ensure that a limited number of WDs within the SSD remains on the essential supplies circuit. Guidance on the supply of electricity in the event of failure of the normal supply is given in SHTM 2011; *Emergency electrical services*.

6.9 All electrical installations should conform to IEE Regulations contained in BS 7671. Further guidance is given in SHTM 2007; *Electrical services: supply and distribution* and SHTM 2020; *Electrical safety code for low voltage systems (Escode–LV)*.

Steam

6.10 Steam may be used to supply a heat exchanger as a source of indirect heating for water or air to be used in the cleaning, disinfection or drying stages of a WD operating cycle.

6.11 Steam may also be used to heat process water directly, or to heat the load directly during the thermal disinfection stage, and for this purpose may be supplied either with an integral steam generator or from an external (“mains”) supply.

Steam for indirect heating

6.12 Steam heat exchangers used for heating water or air may be of the shell, tube or plate design. In all cases, the steam supplied should be substantially free from non-condensable gases and free from oil since these contaminants will seriously impair the efficiency of the heating process. The effect of thin films of air on the surface of the heat exchanger may increase heating costs by 25% or more.

6.13 Suitable steam may be available from the high-pressure hot water systems used in some hospitals.

6.14 The steam service should be designed to meet the maximum demand of the WD, while keeping the fall in pressure before the final pressure reducing system to no more than 10%.

6.15 Except for vertical rises between floors or at intermediate points on long runs, the pipework should have a continuous fall such that any condensate flows by gravity in the same direction as the steam. Air vents and steam traps should be fitted at each vertical rise.

6.16 The condensate discharge system should be sized to ensure that the high volume of condensate found during the initial stages of heating can be discharged without “water-logging” the heat exchanger.

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6.17 When the steam supply pressure at the inlet to the WD exceeds the maximum value specified by the manufacturer, a pressure reducing valve should be fitted to the supply pipe at least 3 m from the WD (this may be supplied by the manufacturer and be integral to the WD).

6.18 Careful attention should be paid to the siting of all pressure relief valves to ensure that the WD is properly protected.

6.19 Relief valves and their discharge pipes should be large enough to prevent the pressure in the supply pipes rising to more than 10% above the design pressure for the heat exchanger. The discharge pipe should terminate in a safe position outside the building.

6.20 Steel and copper piping traditionally used for steam supply are acceptable for this application.

6.21 Excessive moisture in the steam supply will impair the heating efficiency of the heat exchanger.

Steam for direct heating

6.22 Steam for direct heating should meet the requirements described above but should also be of an appropriate chemical and microbiological quality.

6.23 Any contaminants carried with the steam supply will be transferred to the load being processed either through contact with water which was steam heated or heated directly.

6.24 Filming amines or similar volatile corrosion inhibitors used to prevent corrosion in condensate return pipes should not be employed in steam used for direct heating.

6.25 The quality of steam required will depend on the nature of the load to be processed and, in particular, on the intended use of the load items. In heating for loads intended for use in surgically invasive procedures, the condensed steam should meet the chemical purity Standards specified for Water for Irrigation EP and should contain no more than 0.25 Endotoxin units/ml. Detailed guidance is given in SHTM 2031; *Clean steam for sterilization* and the same Standards are applicable.

6.26 When direct heating of the load by steam is used, the design of the WD should include adequate venting to the chamber to ensure that there is no possibility of pressurisation during a single fault condition.

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Integral steam generators

6.27 Some WDs are equipped with small electrically heated steam generators to raise steam to heat the load directly by thermal disinfection.

6.28 They may be of the “open-boiler” type which are so designed and constructed that they are unable to generate an internal pressure above atmospheric pressure. The design should ensure that, under a single fault condition eg. obstruction of the steam discharge port, the boiler cannot become pressurised.

6.29 Integral steam generators which are pressure vessels should comply with the requirements of BS 5500: 2000.

Condensate recovery

6.30 Condensate from steam heating systems (calorifiers, dryers) and steam traps on the pipeline is suitable for recovery and should be returned to the steam generating plant when recovery is economically justifiable.

Compressed air

6.31 A compressed air supply may be required for the operation of controls and also for air drying. When the WD does not contain an integral air compressor (see paragraph 4.45) the air may be supplied from a piped service (mains supply) or from a local compressor.

Mains supply

6.32 If air is supplied by pipeline from a central air-compressor system a pressure gauge of the Bourdon type, complying with BS EN 837, should be fitted on the supply line to the WD via an isolation valve.

6.33 A reducing valve, or other automatic device, should be fitted to reduce the pressure of air delivered to the WD to no more than the maximum supply pressure specified by the manufacturer. A pressure relief valve will normally be required.

Local compressor

6.34 When it is not practical to obtain compressed air from a mains supply, a dedicated compressed air system should be installed to supply the WDs.

6.35 The compressors may be too noisy to install with the WD and may need to be located in a dedicated location away from noise sensitive areas.

6.36 Components of the compressed air system which require servicing and maintenance, such as dryers and filters, should be located where they are readily accessible for service or exchange.

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Air quality

6.37 The quality of air may be critical for some applications and some WDs will incorporate appropriate filters. When the purchaser is to be responsible for the provision of filtered air the TP should ensure that the quality of air available meets the WD manufacturer's specification or the requirements given below.

6.38 Air that could come into direct contact with the load, such as air used for drying the load or testing the free-passage of lumens, should be oil-free (ie. should have no more than 0.5mg of oil per cubic metre of free air measured at 1013 mbar and 20°C; see BS EN 554), be filtered to an efficiency of at least 95% when tested in accordance with BS 3928 and be free of bacteria (see SHTM 2022, *Medical gas pipeline systems*).

6.39 Air for control purposes should be free of liquid water, filtered to 25 µm (5 µm for precision controls) and lubricated with micro-fog oil particles of 2 µm or less.

Drainage

6.40 All effluent from a WD is potentially contaminated and should be disposed of to the main drain.

6.41 Effluent may originate from each of the stages of the process which may include:

a. flushing to remove gross contamination;
b. washing with detergent and/or enzymatic cleaners;
c. rinsing, with or without the addition of a neutraliser, rinse aid or instrument lubricant;
d. chemical disinfection or thermal disinfection;
e. post-disinfection rinsing;
f. drying.

6.42 Effluent from the initial stages [(a) and (b) above] of the process may contain significant concentrations of organic contaminants and potentially infective micro-organisms. Effluent from the middle stages [(b), (c) and (d) above] may contain some organic contaminants and potentially infective micro-organisms and high concentrations of process chemicals. Effluent from the latter stages [(d), (e) and (f) above] may be at high temperatures (90–100°C).

6.43 Effluent from WDs (other than WDs for human-waste containers) should pass via an air break into a tundish or tank before being discharged to drain. The air break should be preserved at all times to prevent the WD and its associated pipework being contaminated by reverse flow from the drainage system.

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NOTE: WDs for human-waste containers are connected directly to a soil pipe but are tested to ensure that back siphoning cannot occur under severe operating pressure.

6.44 When a tank supplies water to a pump on the WD, the overflow discharge from the tank should also include an air break.

6.45 The drainage system from the installation should be trapped and designed to pass the flow rate of water, air and condensed steam specified by the manufacturer, with account taken of the peak output during the operating cycle.

6.46 The drainage system should be designed to pass and maintain in suspension the solids removed from the load during the flushing process. The minimum diameter of the drainage system should be greater than the maximum diameter of the most restricted section of the discharge from the WD chamber.

6.47 Means shall be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical equipment.

6.48 The discharge temperature from a WD may be as high as 95°C. The materials used for the construction of the discharge system should be chosen to withstand temperatures up to 100°C.

6.49 Attention is drawn to the legal requirement (Public Health (Scotland) Act) that the maximum temperature of any liquid to be emptied into the public sewer or communicating drain is 43°C. This should be interpreted as referring to the main building connection to the sewer and not to the internal building drain.

Hazardous effluents

6.50 The discharge of soil from WDs should be regarded as being no more, but no less, hazardous than the discharge from any other sanitary appliance eg. a WC.

6.51 The discharge of process chemicals, including detergents and microbicides, may require special attention. The local water undertaking should be consulted before such chemicals are discharged into the drainage system as it may be necessary to neutralise or inactivate them before discharge.

6.52 A sealed and vented drain should be used for the discharge of chemicals with a significant vapour pressure – determined at the maximum attainable temperature of effluent in the drain – which may be hazardous to health or a nuisance. Possible backflow from the drain should be prevented by the inclusion of a check valve and a vacuum breaker.

6.53 WDs should not be used to process items known to be contaminated with high titre pathogens in Hazard Group 3, eg. arising from research activities, or any pathogens in Hazard Group 4 unless the items have been sterilized

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by an appropriate steam sterilization cycle in a laboratory sterilizer designed and operated for the purpose (Further guidance is given in SHTM 2010 and advice should also be sought from the HSE).

Ventilation

6.54 Ventilation of the area near WDs may be needed to remove excessive heat and humidity, and also vapours from disinfectants such as glutaraldehyde.

6.55 General room ventilation will be sufficient for most WDs, but local exhaust ventilation may be required for chemical disinfection/sterilization systems.

6.56 Electrical systems used in ventilation systems should take account of the high levels of humidity that may be discharged and the potential for this to condense within the ventilation system.

6.57 All ventilation systems should meet the ventilation requirements of the Workplace (Health, Safety and Welfare) Regulations 1992.

6.58 Further guidance on ventilation systems may be found in SHTM 2025; *Ventilation in healthcare premises*.

General room ventilation

6.59 WDs for most healthcare applications do not require a filtered air supply in the room in which they are located unless there is no physical segregation between this area and the packing/sterilizing area.

6.60 The ventilation system in the area of a WD used to decontaminate used items should be a “full fresh air” system without recirculation. In designing the ventilation system reference should be made to SHTM 2025 ‘Ventilation in healthcare premises – Design considerations’.

6.61 Decontamination areas should generally be at a pressure below atmospheric; a 5-10Pa pressure difference is sufficient to minimise the dispersion of potentially infective aerosols into adjacent areas.

6.62 In designing the ventilation system two factors are of particular importance:

a. the provision of adequate cooling so that working conditions remain comfortable for staff;

b. correct sizing of the room ventilation system and/or interlocking with operation of both the room ventilation system and the machine/process specific extraction system(s) when extraction fans on WDs and/or extraction hoods are in operation.

6.63 WDs, particularly those employing thermal disinfection processes and a drying stage, may discharge significant heat energy to the surrounding environment. In designing a ventilation system for single ended WDs,

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account should also be taken of the heat emitted from the load after it has been removed from the WD.

6.64 Current experience suggests that a 250 litre capacity cabinet WD, with a thermal disinfection stage and hot air drying installed as a free standing unit with the door closed and the machine operating, will release by radiation and convection heat energy at the rate of approximately 1.0 kW. A full load of processed items being removed from the WD will release energy at a declining rate but having a peak rate of approximately 0.5 kW immediately upon removal from the WD. Large multi-cabinet machines can release by radiation and convection energy over their operating cycles at rates up to 4 or 5 kW.

Machine ventilation

6.65 WDs are often run under a slight negative pressure to minimise the potential for the discharge of aerosols into the environment.

6.66 WDs not equipped with an air extract system may require siting under an extraction hood. The capture velocity in the vicinity of the process should be within the range 0.25–0.5m/s to ensure adequate extraction of steam and water vapour.

6.67 The extracted air from WDs is discharged into the atmosphere. In large installations significant quantities of useful energy may be discharged as a result. A heat recovery system may be economically viable and a full assessment of the benefits and costs should be carried out. Additional guidance is given in SHTM 2025 Part 2 ‘Ventilation in healthcare premises – Design considerations’.

6.68 The air extracted from WDs, both during the washing and the drying phases of an operating cycle, will normally have a high moisture level. The extraction system should, therefore, be equipped with a drain to discharge the condensate and should be designed and constructed so that it may be cleaned periodically. The drainage system should be constructed with a continuous fall to discharge, without any upstand at the point of connection to the ventilation system to prevent pooling.

6.69 The extraction system should be constructed from corrosion resistant materials. The discharge from some WD dryer systems is at high temperature (105°C) which is sufficient to melt or distort some lightweight plastic ducting materials. Typical worst case values are temperatures >105°C and 100% saturation.

6.70 Current experience suggests that flow rates for built-in extraction systems are in the order of 100 m^3/hr for a single cabinet 250 litre capacity machine, and up to 800 m^3/hr for a multi-cabinet continuous process machine of 1500 litre total capacity (ie. three 500 litre chambers).

6.71 The output from the extraction system should be considered as potentially containing infective aerosols and should, therefore, be discharged away from

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opened windows, air intake systems or where down draughts occur. It is important that adequate dispersal is achieved and roof-level discharge is preferred.

6.72 The extraction ductwork connected to the WD is an efficient transmission system for noise originating within either the WD or extraction plant. Care is needed in the design and construction of the ducting to ensure that noise does not become a problem. This may require the use of sound attenuators as part of the ductwork design. Additional guidance is given in SHTM 2025 Part 2 'Ventilation in healthcare premises – Design considerations'.

6.73 Extraction hoods to protect operators against aerosol dispersion of potentially infective material, eg. over a manual washing sink or an unlidded ultrasonic bath, should have extraction velocities at working level of no less than 0.7–1.0 m/s.

NOTE: Although higher velocities will not impair extraction they are wasteful of energy.

6.74 Extraction systems, eg. bench extraction ventilation designed to protect operators against contact with vapours or gases such as those arising from chemical microbicides including glutaraldehyde, should have extraction velocities of 5.0–6 0 m/s.

6.75 Extraction hoods should be provided with local controls, or a control system interlocked with the equipment with which they are intended to work, so that they may be shut down when not required.

6.76 Purpose built work stations for glutaraldehyde disinfection/sterilization with built-in ventilation systems are also available. These are generally installed in a similar manner to laboratory fume cupboards (see BS 5728: 1990).

6.77 Extract from WDs and extraction hoods should not be discharged through general ventilation extraction systems. The extract from two or more WDs and/or extraction hoods should not use common ducting unless provision is made to ensure that there is no risk of contamination of a disinfected load from the cross-connection.

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Chemical additives

6.78 Safe storage provision is needed for containers of chemical additives used in the WD. These chemicals are frequently corrosive, irritant and toxic and provision should be made in, or adjacent to, the storage area for an emergency eye wash station and a source of running water to dilute any spillage.

6.79 In large installations with two or more Type 2 machines, as may often be required in SSDs, bulk storage tanks for chemical additives required for the process may be preferred with a piped distribution system to each WD.

6.80 For each chemical additive to be used there should be two storage tanks in parallel, one of which may be a small reserve tank, to permit cleaning and maintenance of the system without interrupting the use of the WDs, to facilitate segregation between separate batches of chemical additive and to allow for an orderly change to a different formulation if required.

6.81 The liquid concentrates are often viscous and chemically aggressive. The pipework, valves etc. used for the distribution of these chemicals will need to withstand the corrosive effects of these materials. Advice should be sought from the manufacturer of the chemical additives on suitable materials, construction and pumping systems for the distribution system.

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7. Water supply

7.1 The number, nature and quality of water supplies required are dependent on the size and type of WD.

7.2 WDs may be supplied with both hot and cold water. When hot water is required as part of the operating cycle, it is generally advantageous to supply hot water to the WD rather than heat cold water to the required temperature within the WD.

7.3 The quality of water used at all stages in the decontamination process is critical to the successful outcome of the process.

7.4 At each stage the water quality should be compatible with:

a. the materials of construction of the WD;
b. the load items to be processed;
c. the chemical additive used;
d. the process requirements of that particular stage.

7.5 The key factors are:

a. hardness;
b. temperature;
c. ionic contaminants (eg. heavy metals, halides, phosphates and silicates);
d. microbial population;
e. bacterial endotoxins.

Water hardness

7.6 Hard water is caused by the presence of dissolved salts of the alkaline earth (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (lime-scale) when water is heated or evaporated.

7.7 The fouling of electrical heating elements or heat exchange components by hard water dramatically reduces the heat-transfer efficiency and can quickly lead to an increase in heating costs of 50–100%.

7.8 The deposition of lime-scale within pipes and around the edges of spray nozzles will seriously impair the performance of a WD. Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.

7.9 The presence of hardness in water seriously impairs the efficiency of most detergents and disinfectants. If the use of hard water is unavoidable it will be

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essential to use process chemicals that contain sequestering agents. This adds considerably to the cost of the process.

7.10 Using hard water in the thermal disinfection and final rinse stages of the WD cycle is one of the major causes of white powdery deposits on load items. These are not only unsightly and an unwelcome contaminant but act as a focus for soiling and recontamination of the item in use. In some applications (eg. with optical systems) such deposits may seriously impair the utility of the item.

7.11 Most WDs will operate with water of hardness values up to 125mg/l $CaCO_3$ but are more effective and cheaper to operate when the hardness of the water does not exceed 50 mg/l $CaCO_3$

7.12 Some WDs are fitted with integral water treatment systems (see paragraphs 7.31 to 7.33).

7.13 The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.

7.14 Water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to “fix” proteinaceous soil to the surface of the load items. The British Standard (BS 2745) recommends that the initial temperature should not exceed 35°C. The initial flushing stage should be supplied with water from a cold supply.

7.15 Water at too low a temperature during the washing stage of the cycle will often impair the ability of detergents used to remove soils composed largely of fats, oils or grease.

7.16 When enzymic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.

7.17 When chemical disinfectants are used the rate of activity generally increases with increased temperature. Too low a temperature will cause failure to attain the required microbial activation. However, too high a temperature with particular compounds can lead to degradation of the active components, evolution of toxic vapours or adverse reactions with the load items being processed.

7.18 The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

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Ionic contaminants

7.19 Water used in the cleaning and disinfection of stainless steel instruments should have a chloride concentration between 0 and 120 mg/l Cl – to avoid the risk of corrosion. Chloride concentrations greater than 240 mg/l Cl – cause pitting to occur.

7.20 Tarnishing of stainless steel instruments, shown by blue, brown or iridescent surface colouration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discolouration.

Microbial population

7.21 The purpose of the decontamination process is to remove soiling and reduce the microbial contamination to an acceptable level for the intended use of the items to be processed. The water used at each stage of the WD process cycle should not increase the bioburden of the load items.

7.22 For items which are intended to be used without further decontamination processing (eg. terminal sterilization) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the patient, either through infection or by leading to a erroneous diagnosis. Appropriate treatment to control or reduce the microbial contamination in water may be required.

Bacterial endotoxins

7.23 Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse effects (for a more detailed explanation see SHTM 2010 *Sterilization*, part 5). They are not readily inactivated at the temperatures used for disinfection or sterilization.

7.24 Water used for the final stages of processing in a WD, where there is a significant risk of residual water remaining on the load items, should not contain more than 0.25EU/ml when the WD is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.

Water treatment

7.25 Despite the cost involved in treating water from the public supply to provide the optimum quality for use at each stage in the WD process cycle, this is usually cost-effective.

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Chemical purity

7.26 There are generally four methods of water treatment available for use on water supplies to be used in WDs:

a. water softeners;

b. water de-ionisers;

c. distillation;

d. reverse osmosis.

Water softeners

7.27 Water softeners, or “base-exchange” softeners, consist of an ion-exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride).

Table 4: Use to which water of various qualities may be put

Types of water	Application
Cold water	Flushing ie. removal of gross soiling
Potable water	Flushing/cleaning
-soft eg. <50 mg/l $CaCo_3$	Cleaning with detergents or enzymatic cleaners Thermal disinfection in WCs for human-waste containers Final rinse water in WDs for human-waste containers
-hard eg. >125 mg/l $CaCo_3$	Flushing for WDs for human-waste containers will require use of descalers
Softened water -base exchange softener	Desirable in all water >50 mg/l $CaCO_3$ Essential in all water >125 mg/l $CaCO_3$ for use in WDs
Purified water	Final rinse water for laboratory WDs
De-ionised water	Thermal disinfection in all WDs Final rinse water
Reverse osmosis	Diluent for chemical disinfection Final rinse water
RO/0.22μm filtered recirculated, heated and or UV disinfected	Post-disinfection/sterilization rinsing of products intended for immediate use in critical applications eg. fibre-optic endoscopes
Sterile purified water	Post-disinfection/sterilization rinsing of products intended for immediate use in critical applications eg. fibre-optic endoscopes

Note: The above table shows suitable applications for the various qualities of water commonly available. Although water of lower quality may be used, this will normally require additional chemical additives and may entail some impairment of the WD performance.

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7.28 The concentration of total dissolved solids in the water is not reduced by this process. The sodium salts which remain do not readily form hard deposits to foul heat exchangers or spray nozzles but if used as the final rinse will leave white deposits on the load items as they dry.

7.29 The process is simple to operate with an automated in-line system, will handle water with varying levels of hardness, and is simple and safe to regenerate. After regeneration, however, high levels of chloride ions may be present in the initial output from the softener which should be run to waste.

7.30 In common with other water treatment systems, the base-exchange softener needs to run to a minimum volume of out-flow if the required water quality is to be achieved. This volume should be specified by the manufacturer of the treatment plant. The output from the softener should be to a water tank and the volume demanded each time additional water is fed to the tank should exceed the minimum flow.

Integral water softener

7.31 WDs are available with built in base-exchange water softeners although these are generally laboratory WDs.

7.32 Water softeners should be chosen based on the total demand of softened water in the unit eg. SSD including when necessary provision for manual washing facilities and other plant.

7.33 Base-exchange softeners may cause a significant increase in the microbial content of the water.

De-ionisers

7.34 De-ionisation or demineralisation systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in a separate column.

7.35 Operating costs of mixed bed de-ionisers are usually higher than for two-stage systems.

7.36 Systems are available in a range of sizes from small wall-mounted units in which ion-exchange resins are contained in disposable cartridges to large industrial units. Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers.

7.37 De-ionised water may be heavily contaminated with micro-organisms and de-ionised water will be colonised rapidly because the chloride ions normally present to control microbial growth have been removed. De-ionised water should not be used for the final rinse of products intended for invasive use without further decontamination processing by heating, filtration etc. (see below).

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7.38 For a given output volume, the initial cost of providing de-ionisation equipment will be lower than for reverse osmosis (RO). However, the inconvenience and cost of the regeneration process for de-ionisers, and the better microbial quality of the RO process, makes RO the preferred option.

Reverse osmosis (RO)

7.39 RO treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.

7.40 The initial capital cost of an RO plant is generally higher than for a de-ionisation system supplying a similar volume of water but operational costs are generally lower. When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.

Distilled water

7.41 Distilled water may equal or exceed the purity of RO water but, despite the relatively low capital cost of the necessary plant, is very expensive to produce due to the high energy usage.

7.42 Distilled water is only used in laboratory WDs and RO is usually an acceptable alternative.

7.43 When indirect steam heating of WD water tanks and air dryers takes place, the condensate formed may provide an acceptable quality of water for use instead of distilled water.

Microbial purity

7.44 Potable water from the public supply has a low microbial content and should be free from pathogenic organisms, other than those which may cause opportunistic infections in immunologically compromised patients.

7.45 On storage in tanks and cisterns, the microbial content may increase considerably.

7.46 Attention is drawn to the requirement under the code of practice for control of legionella that water in intercepting tanks must be stored below 20°C or above 55°C.

7.47 The extent and nature of microbial contamination in the water supplied to a WD will depend on the stage in the process cycle at which it is to be used and the intended use of the decontaminated load at the end of the process.

7.48 Water stored at 60°C or above may be assumed not to have a proliferating microbial population.

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7.49 When sterile water is required for final rinsing in critical applications, eg. WDs for endoscopes, this should be provided by using a single-use container of sterile water for each cycle whenever practicable. The pipework, valves and pumps through which the water will pass should be subjected to an appropriate sterilization/disinfection process.

7.50 When water is treated by filtration, eg. through a 0.22 μm filter to remove microbial contaminants, rigorous controls are needed to ensure that the system works effectively. This should include:

a. either maintaining the pressure drop across the filter throughout its working life – a decrease in differential pressure being cause for rejection of the process cycle and a change of filter – or, a bubble point test before and after each process cycle (see BS 1752);

b. a continuous recirculation system so that the filter is not left wet in static water;

c. treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited either by use of elevated temperature (eg. >60°C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J.m^{-2}). (See also report of the Expert Advisory Committee on biocides).

Pipework

7.51 The pipework used to supply the various grades of water should be appropriate to the quality of water carried. Sterilized uPVC or stainless steel pipes are preferred for all qualities of purified water.

7.52 All pipework should be run with a continuous fall to the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.

Water supply byelaws

7.53 All the organisations responsible for water supply within the UK have the statutory power to make, and the duty to enforce, byelaws for the prevention of waste, undue consumption, misuse or contamination of the water supplied by them.

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7.54 Attention is drawn to the following points:

a. Bye-laws 38 to 41 require storage cisterns to be fitted with warning pipes (and an overflow if in excess of 1000 litre capacity). The warning pipe and overflow should not comprise, or have connected to it, a flexible hose.

b. Byelaw 25 Schedule A gives examples of points of use or delivery of water where backflow is, or is likely to be, harmful to health owing to a substance continuously or frequently present (Byelaw 25 (1)(a)).

c. This schedule lists amongst other things water softening treatment plant, bedpan washers, bottle washers, dishwashers and disinfection equipment and clearly applies to all WDs.

d. The required protection is a Type A air gap at the point of use or an interposed cistern.

e. Water softeners, regenerated only by means of sodium chloride solutions, need only be protected by a Type B air gap.

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8. Chemical additives (detergents, enzymic cleaners, rinse aids, lubricants and disinfectants)

Introduction

8.1 Chemical additives are not necessary for all applications while they may enhance the removal efficacy they then in turn have to be removed during the rinsing stage. For applications in the laboratory and in the preparation of components and equipment used in manufacturing medical devices and medicinal products, it may be better not to use chemical additives when their use is not essential. Further guidance is given in the chapter on each type of WD.

8.2 In choosing the various chemical additives which may be required for effective cleaning and disinfection, it is important to ensure that the formulation of each chemical additive is compatible with:

a. the materials of construction of the WD;

b. the process being operated in the WD;

c. the quality of water available;

d. the items to be processed and their intended use;

e. any other additives to be used in the WD process;

f. any intended subsequent decontamination process (eg. sterilization).

It is also important that the required concentration can be accurately and reproducibly generated by the dosing system(s) on the WD.

Compatibility with the materials of construction of the washer-disinfector

8.3 The pH, redox potential and ionic nature of the chemical additive is important in determining whether it will cause corrosion or electrolytic attack (either between different materials in the WD or between the WD and items in the load).

8.4 Chemical additives which can be absorbed into, or adsorbed onto, surfaces of the WD (eg. plastic pipework) may be carried over into subsequent stages of the process (see also paragraphs 8.7 and 8.15).

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Compatibility with the process

8.5 The performance of the additive must be matched to the physical characteristics of the operating cycle, eg. jet washing action systems require low foam detergents, if the washing action is not to be impaired.

Compatibility with the items to be processed

8.6 The chemical additives used must be compatible with the materials of which the load items are constructed and should not cause chemical or physical damage – eg. phenolic compounds used in detergents and disinfectants may cause material changes in rubber and plastics, while the anodic coating on the surface of anodised aluminium is removed by strongly acid or strongly alkaline compounds. The precise formulation of the chemical additive will affect its compatibility. It is not sufficient to determine only the compatibility of the principle active constituents.

8.7 The chemical additives used must be readily removed from the load items by rinsing with water and should be biologically compatible with the intended use of the load items. Chemical additives which are intended to persist on the surface of items processed through the WD (eg. lubricants) should be biologically compatible with the intended use of the load items.

Compatibility with the quality of water

8.8 Many detergents and disinfectants are seriously impaired in their activity by hard water. If only hard water is available formulations should be sought which are intended for use with water of that quality.

8.9 Detergent formulations intended for use only with soft water may give rise to precipitation if used with hard water, particularly at elevated temperatures. Once this precipitation has occurred on the surfaces of the WD or the load it is particularly difficult to remove (see paragraph 8.7).

Compatibility with other chemical additives

8.10 Many of the chemical additives which might be used are incompatible with one another – eg. quaternary ammonium compounds which are often used as surfactants will rapidly destroy the activity of enzymic cleaners, while many detergents will inactivate chemical disinfectants.

8.11 The additives used should be both compatible with other chemicals used in the same process stage and, as far as may be practicable, with those used in preceding and subsequent stages to minimise the adverse effect of any carryover.

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Compatibility with subsequent decontamination processes

8.12 Chemical additives which may persist on the surface of items processed through the WD should be compatible with any subsequent decontamination process which may be required, such as terminal sterilization. An in-process instrument lubricant which deposits a lubricant film on all surfaces of the instrument should only be used if it has been demonstrated to be compatible with any subsequent sterilization process.

General

8.13 In almost all cases, attainment of the specified concentration of chemical additives is essential to effective processing. The addition of too little will impair the process while too much is wasteful, may also impair the process and may contribute to unacceptably high residual levels.

8.14 Suppliers of chemical additives should provide product data sheets and material safety data sheets for the products supplied. These should include details of biocompatibility studies.

8.15 Suppliers of chemical additives should provide details of the analytical methods which may be use to detect residual concentrations of product. The sensitivity of the method should be sufficient to determine the presence of the compound below the level at which any adverse biological reaction may be determined.

Detergents

8.16 For most applications, mild alkaline detergents in the pH range 8.0–11.0 are preferred. Alkalinity improves the efficacy of detergents both by enhancing their inherent cleaning capabilities – neutralising and helping to remove acid soils, emulsifying oils and fats and peptidising proteins – and by synergistic action with other detergent compounds. Many surfactants work better in the presence of alkaline “builders” such as sodium tripolyphosphate (STPP).

8.17 Alkaline detergents inhibit the growth of most micro-organisms. Alkaline detergent residues are readily detected by pH measurement.

8.18 Acid-based detergents should only be used for stainless steel surfaces and then only for limited applications, eg. for de-scaling instruments that have been processed in hard water.

8.19 Cleaning agents for use in WDs should be:

a. liquid – to facilitate accurate dispensing;

b. non-abrasive;

c. low foaming;

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d. free rinsing;

e. biodegradable.

8.20 Cleaning agents should not contain:

a. artificial colouring agents;

b. optical brighteners;

c. perfumes;

d. halides at an in-use concentration greater than 120mg/l;

e. fatty soaps, glycerine or lanolin.

Enzymic cleaners

8.21 Enzymes are organic catalysts through which the normal metabolism of most living organisms takes place. Although produced by living organisms they are not themselves alive. Enzymes are large organic molecules whose steric configuration (shape) affords them the ability to catalyse many reactions in the living cell.

8.22 Enzymes are classified into groups depending on the nature of the chemical reaction that they catalyse. Generally the enzymes used in enzymic cleaners are hydrolases ie. they promote the hydrolysis of the substrate with which they interact.

8.23 Enzymic cleaners are themselves proteins (often derived from the bacteria B subtilis and B stearothermophilus) and may be sensitising or allergenic agents. A similar adverse reaction is allegedly produced in some people by domestic biological washing powders.

8.24 Many of the developments in enzymic cleaners originated with the pre-soak cleaners and subsequently the biological washing powders used in domestic laundry applications.

8.25 A considerable proportion of the soiling found on medical items contains proteins which act as binding agents. Particulate dirt can be bound by the coagulation of these proteins on the surface.

8.26 If the binder proteins can be broken down into a simpler molecular form this binding action is destroyed and the bound soil, as well as the protein, can be released from the surface.

8.27 Formulations will often include buffering agents to maintain the pH within the preferred range. Most enzymes have an optimum pH at which their activity is greatest and a pH at which the enzyme itself is most resistant to thermal degradation, although these two values are not necessarily the same.

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8.28 For example the proteolytic hydrolase derived from B subtilis, subtilisin A, withstands temperatures up to 60°C and displays its greater stability at pH 9.4.

8.29 The importance of the enzymic solution being at the correct temperature and pH, as well as being used for the specified contact time, cannot be too strongly emphasised.

8.30 Enzymes are not themselves cleansing agents. A properly balanced detergent may still be needed to remove the simpler molecular forms resulting from the enzymic action.

8.31 It is important to ensure that any detergents used are compatible with the enzymes – quaternary ammonium compounds (QACs) deactivate many of these enzymes (the deactivation of enzymes in the bacterial cell is one of the proposed mechanisms of action for the microbicidal action of QACs).

8.32 Enzymic formulations for cleaning solid surfaces are available in two forms:

a. a pre-soak formulation which is used to digest proteinaceous soil and is then followed by normal washing process using detergent;

b. a combined enzyme and detergent formulation.

Cleaning additives for ultrasonic cleaners

8.33 Only detergents specifically intended for use in ultrasonic cleaners should be used. The use of other detergents may impair rather than enhance the cleaning process.

Rinse aids

8.34 Rinse aids are generally formulated from surfactants and are designed to make the water more free rinsing. They are often at low pH in order to remove deposited salts arising from the use of hard water.

Lubricants

8.35 The addition of oil-based compounds to the cleaning process is wrong in principle. They deliberately cause contamination over the entire cleaned surface. If they are to be used the water-soluble type should be used. Mineral oils have poor biocompatibility and may inhibit the penetration of steam or sterilant gases on terminally sterilized product.

8.36 Lubrication should only be applied to those areas where it is required during the inspection/packing process after thorough cleaning of the instrument.

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Disinfectants and/or sterilants

Choice of disinfection method

8.37 Thermal disinfection using moist heat is the preferred method and should be used whenever it is compatible with the load to be processed.

8.38 Temperatures in excess of 65°C and up to 95°C (or in some cases 100°C) can be used for disinfection; the lower the temperature the longer the exposure time in order to obtain the same reduction in microbial population. The thermal disinfection process is reliable, reproducible, free from toxic residues and capable of easy and economical physical monitoring and recording.

8.39 Chemical disinfection should only be used for products which cannot be treated using thermal disinfection methods.

Criteria for selecting a chemical disinfectant

8.40 Chemical disinfectants differ in their ability to kill micro-organisms.

8.41 In order to choose a disinfectant for a particular application it is necessary to know the microbicidal activity required – both the number and types of organisms that may be encountered and the assurance that may be required that they have been inactivated. The technical information from the manufacturer of disinfectants should provide the required information about the activity of the product.

8.42 The major application for chemical disinfection is in processing for re-use thermo-abile equipment such as fibre-optic endoscopes. Two distinct standards are applicable: for those instruments that will only come in contact with intact mucosa; and for those that will invade a sterile body space. While the same or similar disinfectant formulations may be used for both applications the operational controls required may be different. This is addressed in Chapter 12. Further guidance is given also in SHTM 2030 Part 3, ‘Validation and verification’.

8.43 Although there are numerous disinfectant formulations available on the market, there are relatively few generic types of disinfectant suitable for chemical disinfection in WDs.

8.44 A solution containing 2% glutaraldehyde is the most commonly used disinfectant. Other aldehydes, quaternary ammonium compounds, hydrogen peroxide, peracetic acid, chlorine dioxide and alcohol solutions have also been recommended by various workers and may have particular benefits in certain applications.

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8.45 The guidelines from various professional bodies are not in agreement as to the disinfectant contact time to be used and few recognise the need to specify the temperature or minimum concentration. Furthermore, these guidelines may not be in accord with the recommendations from the manufacturer of the item to be sterilized or from the manufacturer of the disinfectant.

8.46 Current guidelines from the UK Departments of Health are given in Health Circular HC (91)33. These recommend:

a. a freshly activated solution containing 2% glutaraldehyde at room temperature for 30 minutes for dealing with contamination with HIV or HBV;

b. a 2% solution of glutaraldehyde for 60 minutes if mycobacterial contamination is suspected.

8.47 'Guidance for Clinical Health Care Workers: Protection against infection from HIV and hepatitis virus' produced by the Expert Advisory Group on AIDS also recommends "endoscopes which will enter sterile body cavities must be immersed for a minimum of three hours".

8.48 While these times may be reduced if the items are processed in a validated automatic WD with appropriate routine monitoring, the exposure time should in all cases be at least that specified by the disinfectant manufacturer. More detailed information is provided in SHTM 2030, 'Validation and verification'.

8.49 Instructions for use supplied with the disinfectant should include:

a. the quality of water with which the product should be diluted;

b. the **storage life** – the life before dilution or activation (or before use if supplied at the required concentration for use);

c. the **use-life** – the storage life after dilution and storage under stated conditions within which the unused disinfectant will retain activity at, or above, the minimum specified by the manufacturer;

d. the **re-use life** – the extent to which the disinfectant may be re-used. This may be specified as time, the number of load items processed or the number of disinfection cycles.

NOTE: This is event related not time related but when a manufacturer specifies a "use-life" this should be based on simulated "worst case" use conditions. Whenever possible, a single use is preferred since it avoids the many problems associated with control of re-use.

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Materials compatibility

8.50 The disinfectant should not cause damage to either load items or the WD in which it is used. Damage which may occur with incompatible disinfectants includes corrosion, embrittlement or swelling of plastics, degradation of lens cement in optical systems etc. The potential for electrolytic attack to occur as a result of different metals in the load and the WD coming into contact, via a powerful electrolyte, should not be overlooked.

8.51 The material of construction of the WD and of the items in the load should not inhibit the disinfectant.

Safety of disinfectants

8.52 Many of the compounds which are most effective as disinfectants are potentially human health hazards. Employers are required by law to do everything that is reasonably practicable to protect the health of their workers. The safe use of these compounds is covered by the COSHH Regulations.

8.53 Glutaraldehyde has an occupational exposure standard of 0.2 ppm over a 15 minute reference period. This should not be regarded as a permissible limit but as a maximum which should not be exceeded. Further guidance is given in SHTM 2030 Part 3, ‘Validation and verification’.

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9. Washer-disinfectors for human-waste containers

Introduction

9.1 This chapter discusses specifications for WDs intended for emptying, cleaning and disinfecting human-waste containers.

9.2 WDs for human-waste containers are all Type 1 machines.

9.3 Human-waste containers include bed pans, urine bottles, commode bowls, enema and emesis containers, and suction bottles.

9.4 WDs currently available may be divided into two groups: flusher-disinfectors in which there is no detergent wash stage – all soil removal is accomplished by the physical action of water; and washer-disinfectors in which there is a wash stage after the initial flushing stage to remove gross soiling. While the former may be less expensive, the latter design may be used to process a wider range of items such as support frames for disposable bedpans, raised toilet seats, jugs and bowls etc.

Choice

9.5 WDs for human-waste containers are one of two available systems for providing for the needs of bed-dependent patients. The alternative system uses disposable containers, made of cellulose pulp, which are disposed of, complete with their contents, using a macerator. When properly installed, maintained and operated either system can provide a satisfactory solution for the provision of human-waste containers.

9.6 Factors to be considered in making the choice include:

a. the relative capital and running costs;

b. the storage space required for an appropriate working stock of disposables;

c. the peak throughput required;

d. the need to provide for the cleaning and disinfection of support frames used with disposable bedpans;

e. whether the flexibility to clean and decontaminate other sanitary items is required, and so on.

A review of these factors was published in 1991 (Rollnick) and should be consulted for further information.

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Load handling equipment

9.7 The load handling equipment may be specific for the containers to be processed or may be designed to accommodate a range of different containers without the need to change load carriers.

9.8 When a range of items is to be processed eg. raised toilet seats, jugs, bowls, disposable bedpan support frames, as well as bedpans and urine bottles, the load carrier should be designed to accept these without the need to change carriers or add accessories. This reduces the operator time, the storage space required and the risk of loading errors. When it is necessary to change carriers or add accessories this should be a simple operation not requiring the use of tools.

9.9 The loading capacities from currently available machines are either one bedpan/two urine bottles per cycle or two bedpans/four urine bottles per cycle. The higher capacity machine is the preferred option in most cases because of its increased capability to deal with peak demands. For certain applications (eg. GU wards) designs capable of carrying up to eight urine bottles per cycle are available.

Standard specifications

9.10 WDs for human-waste containers should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 2: 1993 and the safety specifications in BS EN 61010: Part 1.

Additional specifications

9.11 The WD should be equipped to provide automatic emptying of human-waste containers. Manual emptying prior to, or during, the loading of containers into the WD should not be required.

9.12 When a cold water rinse is used after the disinfection cycle, the water used shall not have been stored in a tank or cistern within the WD at a temperature above 20°C or below 60°C for more than four hours.

9.13 Consideration should be given to specifying an in-built condenser system to obviate the need for an external ventilation connection.

9.14 When required for connection to a hard water supply, a dispensing system should be specified to add detergent-descaler to the water during the washing stage of the process.

9.15 The WD should flush the residual soil from the emptied containers with a discharge volume of no less than 15 litres to ensure adequate clearance of solids from the drainage system. The total volume of water used per cycle may be significantly greater than this value and the volume of water required per load item processed should be a consideration when choosing a WD.

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Operating cycle

9.16 The WD should perform the following operational stages in each cycle:

a. emptying – this should take place automatically and is usually effected and controlled by closing the door; Some WDs are provided with two chemical additive dispensing systems as standard giving the option to add a detergent wash stage for processing specific items;

b. flushing – removing residual soil from the containers with water at no more than 35°C;

c. washing – removing any remaining soil by washing with water, water and detergent, or water and detergent/descaler;

d. rinsing – removing any residual detergent or detergent/descaler;

e. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time.

The following stages may be included if required by the user:

a. cooling – rinsing the hot load with cold water to reduce the temperature of the load;

b. drying – purging the load and chamber with heated air to remove residual moisture.

Disinfection requirements

9.17 Thermal disinfection using moist heat is the preferred method; none of the equipment intended to be processed in this type of WD is unable to withstand thermal disinfection within the specified temperature range and there is no justification for the use of chemical disinfection.

9.18 The WD should be programmable to provide a thermal disinfection process within the temperature range 65-90°C for disinfection times between 10 minutes and one second respectively. The preferred disinfection process is 80°C for one minute.

9.19 A post-disinfection cold water rinse is available on some WDs. This is intended to cool the load so that it can be handled, and/or used, immediately at the end of the cycle. However, the advantage in shortening the time before the item can be re-used is minimal and, since the final product is wet, it has to be dried manually – eg. using paper towels.

9.20 When thermal disinfection is the final stage of the cycle, the hot load at the end of the cycle dries rapidly as the water evaporates from the surface – cooling the load at the same time.

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Drying stage

9.21 Although a hot air drying stage is available on many current models, drying by evaporation after the hot disinfection/rinse stage is sufficient in most cases.

9.22 A hot air drying stage should be specified if the WD is to be used to process a range of other items.

Instrumentation/recorders

9.23 The WD should be fitted with a chamber temperature indicating instrument to show the temperature attained during the disinfection stage.

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10. Washer-disinfectors for surgical instruments and associated equipment

Introduction

10.1 This chapter discusses specifications for WDs intended to be used for cleaning and disinfecting surgical instruments and associated equipment including instrument trays (eg.: Edinburgh trays), bowls and hollowware.

10.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

10.3 WDs for this purpose may be Type 1 or Type 2 machines.

Type 1 machines

10.4 Single chamber cabinet washers for surgical instruments and associated equipment may be either:

a. simple “deluge” washers primarily intended for bowls and hollowware but also suitable for dealing with simple easy to clean instruments;

b. designed to accept inter-changeable load carriers, typically with rotating spray arms or other devices to ensure a uniform wash action with several layers of load items.

The spacing between layers should be designed to accommodate a number of wire mesh baskets full of instruments or should be more widely spaced to accept and correctly position large bowls, instrument trays, re-usable rigid containers and similar items. Spacing should also allow for anaesthetic accessories to be located and processed, as well as specialist carriers with connections for particular instruments such as rigid endoscopes and MAT instruments.

10.5 Since all stages of the cycle take place in the same chamber, it is not possible to get physical separation between the dirty and clean stages of the cycle. Assurance that the load will not be recontaminated is dependent upon the efficacy of the cleaning and disinfecting stages in decontaminating the interior of the WD as well as the load.

Type 2 machines

10.6 Continuous process washers, other than those designed as automatic ultrasonic cleaners only, are usually designed to accept inter-changeable load carriers (see above).

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10.7 Compared with Type 1 machines they have a higher throughput and, for a similar process, achieve some decrease in overall cycle time.

10.8 Since the load is moved through the machine as the cleaning and disinfection cycles proceed it is possible to get excellent physical separation between dirty and clean load items.

10.9 There may be some loss of operational flexibility when this type of machine is used for several applications at a time, eg. if it is used to process anaesthetic accessories the increased drying time, necessary for this application, will slow the passage of other loads passing through the WD.

10.10 WDs of this type are large, expensive pieces of equipment and their use is only justified in centralised production units.

Standard specifications

10.11 WDs for surgical instruments and associated equipment should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

10.12 An EU standard is in preparation for WDs for surgical instruments and associated equipment and for specific safety requirements for WDs.

Additional specifications

10.13 The automatic controller of Type 2 machines should prevent initiation of any further operating cycles if there is an inadequate supply of the chemical additives required for the next cycle.

10.14 Whenever practicable the WD should be of the double-ended pass through type to facilitate physical segregation of dirty and decontaminated items.

10.15 The design should permit installation through the wall between the decontamination area and the clean area with effective sealing to prevent either passage of air from dirty to clean areas or excessive air loss from the clean area (normally maintained at a pressure above atmospheric).

Load handling equipment

10.16 A number of different types of carrier may be required to accommodate the range of items to be processed. The range of carriers required in an SSD may include:

a. a multi-layer carrier for instruments in wire mesh baskets (wire mesh baskets to include a number with retaining systems for small instruments);

b. a two layer carrier for small hollowware and instrument trays;

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c. a single layer carrier for large bowls, Edinburgh trays etc;

d. a rigid endoscope/MAT instrument carrier;

e. an anaesthetic accessories carrier.

10.17 The load carriers must protect instruments from mechanical damage during the wash process and must also orientate the instruments to facilitate proper cleaning providing, when necessary, a direct connection between the water flow and the lumen of the load item.

10.18 The specification for load handling equipment should include the provision of appropriate tabling to permit sorting of instruments and loading of load carriers and, after processing, the unloading of load carriers.

10.19 When double-ended WDs are specified a conveyor will normally be required to return load carriers from the unloading to the loading end. Where this passes through the wall between the packing room and decontamination room there should be a pass through hatch with interlocked doors.

Operating cycle

10.20 The WD should perform the following operational stages in each cycle:

a. flushing – removing gross contamination from the items in the load with water at a temperature not exceeding 35°C;

b. washing – removing any remaining soil by washing with water, water and detergent, or water and enzymic cleaner. Several sub-stages may be used consecutively to provide a combination of treatments; physical removal of the soil may be by the impingement of water jets or by ultrasonication or both consecutively;

c. rinsing – removing any residual detergent or enzymic cleaner. This stage may be combined with the thermal disinfection stage which follows;

d. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time;

e. drying – purging the load and chamber with heated air to remove residual moisture.

Disinfection requirements

10.21 The load, the load carriers and the internal surfaces of the WD chamber should be subjected to a thermal disinfection cycle. This should ensure that all surfaces to be disinfected are exposed to moist heat for a period and at a temperature not less than specified in Table 2.

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Drying stage

10.22 The drying of the load is greatly facilitated by the thermal disinfection/hot rinse stage. In Type 1 machines with a low throughput drying by flash evaporation from the hot load may be sufficient. Individual items for which drying is more critical may be transferred to a separate drying cabinet.

10.23 For more critical applications and in Type 2 machines it is normal practice to include a hot air drying stage.

10.24 Thorough drying is of great importance. Products which are to be sterilized must be thoroughly dry as should products which are to be used without further treatment if there is not to be a significant risk of recontamination by, and growth of, micro-organisms.

The drying stage may be omitted on Type 1 machines particularly for small “table-top” machines. Additional chemical treatments may also be included if required by the user.

The addition of “rinse-aids” may be required to assist drying and to minimise “spotting” (deposits of waterborne salts) if purified water is not used for the final rinse.

The addition of instrument lubricants during the final rinse should be avoided whenever possible.

Instrumentation/recorders

10.25 The extent of necessary monitoring depends on the particular application. As a minimum for the thermal disinfection stage the attainment of the required temperature should be monitored independently of the cycle controller, displayed on a temperature indicator or recorder, and recorded.

10.26 When the WD is to be used to decontaminate medical devices – and the technical Standards described in the essential requirements of the EU Directives discussed in Chapter 1 must be met – additional monitoring facilities will be required.

10.27 The WD should be equipped with monitoring and recording devices to monitor the critical variables which affect the outcome of the cleaning and disinfection processes. This may include some, or all, of the following:

a. pump pressure, water flow and temperature at each process stage;
b. the flow or volume admitted of each chemical additive used (or, when applicable, by direct measurement of the concentration);
c. the chemical purity of the final rinse (by measurement of electrical conductivity);
d. the flow and temperature of the hot air used for drying.

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NOTE: Visual inspection following the decontamination process is not of itself sufficient to determine whether the process was successful. The decontamination process must be subject to validation and then routinely monitored to ensure that the process remains within the validated limits. Further guidance is given in SHTM 2030 Part 2, 'Operational management' and Part 3, 'Validation and verification'.

Test connections

10.28 Test connections should be provided to permit the connection of thermocouples to be used during validation and periodic testing.

10.29 When additional monitoring is provided (see above), a separate test connection should be provided for each sensor to permit periodic verification of the installed system by comparison with a calibrated test sensor.

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11. Washer-disinfectors for anaesthetic accessories

Introduction

11.1 This chapter discusses specifications for WDs intended for use in cleaning and disinfecting anaesthetic accessories. These items are often intended for use without further reprocessing.

11.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

11.3 Dedicated equipment for anaesthetic equipment would usually only be justified when there is a particularly heavy demand; most anaesthetic departments now use single use and/or filter protected patient circuitry.

11.4 Although dedicated WDs for anaesthetic equipment are commercially available their use is declining due to the changing pattern of equipment and accessories used in anaesthetic departments.

11.5 There is still a requirement for this type of equipment to be decontaminated because of its use in respiratory monitoring where the use of filters may not be practicable.

11.6 Dedicated anaesthetic WDs are usually Type 1 machines but when this facility is provided as an option with WDs for surgical instruments they may be Type 1 or Type 2 machines (see Chapter 10).

Load handling equipment

11.7 WDs for surgical instruments which can accept inter-changeable loading racks may be adapted to deal with anaesthetic accessories using a loading rack designed to hold anaesthetic breathing circuits, rebreathing bags and self-inflating resuscitator sets, face masks etc.

11.8 The design of load carrier should ensure that each hollow or tubular item can be connected to a spigot through which flushing, washing solutions and the water for rinsing and thermal disinfection can be directed into the lumen of the load item.

11.9 Whenever practicable the WD should be of the double-ended pass through type to facilitate physical segregation of dirty and decontaminated items.

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11.10 The design should permit installation through the wall between the decontamination area and the clean area with effective sealing to prevent either passage of air from dirty to clean areas or excessive air loss from the clean area (normally maintained at a pressure above atmospheric).

Standard specifications

11.11 WDs for anaesthetic accessories should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

11.12 An EU standard is in preparation for WDs for surgical instruments and associated equipment and for specific safety requirements for WDs.

Operating cycle

11.13 The WD should perform the following operational stages in each cycle:

a. flushing – removing gross contamination from the items in the load with water at less than 35°C;

b. washing – removing any remaining soil using water and detergent or water and enzymic cleaner. Several sub-stages may be used consecutively to provide a combination of treatments; physical removal of the soil should be by flushing through lumens and by the impingement of water jets on external surfaces of load items. Ultrasonication is not effective for items made from flexible rubber or plastic;

c. rinsing – removing any residual detergent. This stage may be combined with the thermal disinfection stage which follows;

d. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time;

e. drying – purging the load and chamber with heated air to remove residual moisture.

The drying stage may be omitted if a separate drying cabinet is to be provided. No additional chemical treatments should be necessary.

Disinfection requirements

11.14 Many anaesthetic accessories will be used without further decontamination treatment.

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11.15 The load, the load carriers and the internal surfaces of the WD chamber should be subjected to a thermal disinfection cycle. This should ensure that all surfaces to be disinfected are exposed to moist heat for a period and at a temperature not less than one of those specified in Table 2.

11.16 The use of chemical disinfection is particularly contra-indicated because of the possibility of residuals being absorbed into the polymeric materials, of which the anaesthetic accessories are made, and then being evolved as irritant or toxic gases during use.

Drying stage

11.17 Thorough drying of anaesthetic tubing and other accessories is essential whether or not they are to be subjected to a further decontamination process, eg. sterilization.

11.18 Because of the thermal characteristics of the materials and the structural complexity of the items, drying with a current of warm air is a relatively slow process and may take more than twice as long as an equivalent sized load carrier filled with steel instruments. It is, for example, very difficult to remove the residual water from inside long lengths of corrugated tubing.

11.19 When anaesthetic accessories are processed through a WD for surgical instruments the extended hot air drying stage required will significantly reduce the throughput; if significant quantities of anaesthetic accessories are to be decontaminated consideration may need to be given to the provision of a separate drying cabinet.

11.20 Whether within the machine, or within drying cabinet, the flow of warm dry air should be directed through and over the items to be dried.

Instrumentation/recorders

11.21 The extent of necessary monitoring depends on the particular application. As a minimum for the thermal disinfection stage the attainment of the required temperature should be monitored independently of the cycle controller, displayed on a temperature indicator or recorder, and recorded.

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12. Washer-disinfectors for endoscopes

Introduction

12.1 This chapter discusses specifications for WDs intended for cleaning and disinfection of flexible endoscopes (fibre-optic or video) and rigid endoscopes and their accessories.

12.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

12.3 WDs for flexible fibre-optic endoscopes are all Type 1 machines; the form of the chamber is often complex and sculpted to provide appropriate support to the endoscope(s) being processed. WDs for rigid endoscopes may be Type 1 or Type 2 machines.

12.4 Disinfection may be achieved:

a. for most rigid endoscopes and other items which are not heat sensitive, by direct contact of the load items with moist heat at a temperature in excess of 65°C and below 95°C. The preferred temperature is 80°C for no less than one minute;

b. for fibre-optic and other heat sensitive equipment, by direct contact of the load items with a chemical disinfectant.

NOTE: Users should seek advice from the manufacturer of the endoscope as to the most suitable method of disinfection and the limiting values of process variables (eg. temperature) for particular endoscopes.

12.5 Automated WDs for endoscopes are preferred to manual cleaning, whether followed by a manual or automated disinfection procedure. This is both for the safety of the user and also because it provides a more consistent, validated process with a higher level of assurance of attaining the required standards than can be achieved with manual cleaning.

Standard specifications

12.6 WDs for rigid endoscopes which can withstand thermal disinfection and steam sterilization are similar to WDs for surgical instruments and associated equipment and should conform to the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

12.7 An EU standard is in preparation for WDs for surgical instruments and associated equipment and for specific safety requirements for WDs.

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12.8 There are currently no British Standards for WDs intended for use with thermo-labile endoscopes. An EU standard for WDs for thermo-labile equipment including fibre-optic endoscopes and videoscopes is in preparation.

Additional specifications

12.9 WDs for endoscopes which employ a thermal disinfection stage should meet all the requirements specified for WDs for surgical instruments (see Chapter 10).

WDs with a chemical disinfection stage

12.10 The WD should be an enclosed system. It should be a requirement for the lid to be locked before it is possible to start a cycle, and it should not be possible for the operator to interrupt a cycle before completion.

12.11 The control system should permit regulation of pump pressure and inlet pressure to the various connections to allow the WD to be adjusted for particular types of instrument. It is desirable that this should be a programmable option on the automatic controller.

12.12 The WD should discharge solutions of cleaning agents to drain after each operating cycle unless the WD is equipped with means to verify the concentration of the chemical additive which remains active in the solution. (For some cleaning agents this may be achieved by continuous monitoring of in-use concentration using an appropriate ion selective electrode (ISE).)

12.13 The disinfectant solution should be used once and discarded. Alternatively, when systems which re-use disinfectant solutions for a number of cycles are employed, means should be incorporated to ensure that the automatic cycle will not start when the disinfectant concentration has fallen to, or below, the minimum recommended by the manufacturer or established by independent testing – eg. for a 2% solution of glutaraldehyde a limiting concentration of 1.5% would be recommended (Babb et al 1992).

NOTE: Re-use of the same disinfectant solutions for several operating cycles is often justified on grounds of economy. This may be a false economy if second and subsequent processes with the same batch of disinfectant solution are not subject to the same control as the initial use.

12.14 The rinsing stage should be carried out with water of a quality that does not lead to recontamination of the endoscope with micro-organisms coming from the incoming water supply reservoirs, including pipework within the machine.

12.15 The rinse water from one process should not be retained and used in subsequent cycles but should be discharged to drain.

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12.16 There should be no static water stored within the WD at a temperature above 10°C or below 55°C for more than four hours if it is intended to come into contact with the load. This should be controlled and monitored by the automatic controller of the WD.

12.17 WDs should be designed and constructed such that they are able to be drained and dried when not in use.

12.18 The available operating cycles on the automatic control system should provide for a WD decontamination cycle to ensure that all pipework, tanks, pumps, water filtration systems and other fittings which are used to carry aqueous solutions intended to come into direct contact with the product are cleaned and disinfected. The decontamination cycle shall be user selectable.

12.19 The automatic controller should control the temperature of the disinfectant solution or monitor the temperature to ensure that it is above a value previously determined during validation studies (see SHTM 2030, 'Validation and verification' for more information).

12.20 The WD should be equipped with a recorder or data logger to record the attainment of the specified value of critical cycle variables throughout the cycle.

12.21 The WD should be equipped with means to contain or vent fumes and gases from the disinfectant solution to ensure that operators are not exposed to hazardous concentrations of the chemicals used. The WD should be provided with means to vent fumes from the chamber before allowing access to the operator.

Load handling equipment

12.22 The loading system should be appropriate to the range of endoscopes which it is intended to process.

12.23 Some endoscopes are not designed to be completely immersed in liquid and the operating head must remain above the liquid level.

NOTE: Endoscopes of this type are being phased out of service.

Some endoscopes require protective caps to be fitted to sensitive components before they can be decontaminated in an automated WD, eg. videoscopes need a protective cap on the video plug.

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12.24 The load carrier needs to provide connection to the various channels within the endoscope to allow the cleaning and disinfection solutions to flow through the channels and may need to provide holders for disassembled components, valves etc.

Compatibility with items to be processed

12.25 Attention is drawn to the need to ensure that for any particular load item that all cleaning and decontamination processes are carried out in strict accordance with the manufacturer's instructions. All endoscopes, but particularly those incorporating fibre-optic systems, are easily damaged.

12.26 If the process conditions recommended by the manufacturer, including maximum temperatures, internal pressures, nature of any physical treatment such as ultrasonication, and limitations on the chemical additives which may be used, are ignored serious damage can be caused to these expensive instruments.

Disinfection requirements

12.27 The standard of disinfection required should be defined by the user in consultation with the control of infection officer.

12.28 In general:

a. endoscopes which, in use, are passed into sterile body cavities are considered to be invasive and must be sterilized;

b. endoscopes which, in use, come into contact with mucous membranes but do not invade sterile body cavities are non-invasive and can be decontaminated using high-level disinfection.

12.29 The choice of disinfectant should be based on the rigours of the disinfection procedure required, and on the compatibility with the endoscope and WD and the constructional materials of both.

NOTE: There is a potential for electrolytic action between different materials even when one material is part of the load and the other is part of the WD. This may result in corrosion of the load items and/or the WD.

Guidance on suitable disinfectants and exposure times is given in SHTM 2030 Part 3, 'Validation and verification' and in the MDA Bulletin on 'Decontamination of endoscopes and their accessories'.

Rinse water: quality requirements

12.30 For invasive endoscopes the final rinse water should be sterile and for non-invasive endoscopes it is preferable that it is sterile.

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12.31 The most reliable method of providing water of the quality required for the final rinse is to use sterile “bottled” water.

12.32 Alternatively it is possible to produce water of appropriate quality by treatment of the local piped water supply. This may be provided adjacent to, or within, the WD.

12.33 The nature and extent of treatment will depend in part on the quality of the local water supply but normally should include at least the following steps:

a. pre-filtration to remove suspended particulate matter (this may require one or two filtration stages but the final stage should be with a filter that will retain particles of 5 µm or larger);

b. filtration through a bacteria retentive filter (0.22 µm).

The operating system should include:

a. means to monitor the integrity of the filter or warn of failure;

b. means to disinfect or sterilize the filter and the downstream water distribution system between uses or at four hourly intervals. This should preferably be by exposure to moist heat but a chemical disinfection process may also be used. A demountable system which allows the filter and downstream distribution system to be removed, dried and steam sterilized between sessions provides an acceptable alternative;

c. means to maintain the filter with a constant flow of water (not left wet in static water);

d. means to inhibit microbial growth in water in the storage and distribution system downstream

e. of the filter. This may be achieved by recirculation through an appropriate UV light disinfection system or by maintaining the water at elevated temperature eg. >80°C.

12.34 The design of the pipework, tanks, valves and pumps to avoid dead legs and areas where microbial growth may proliferate is critical to the maintenance of the system from microbial contamination. All fittings and pipe connections should be pharmaceutical grade sanitary fittings.

NOTE: If heated storage is used it will be necessary to cool the water supplied to the WD to ensure that the endoscope(s) are not damaged by exposure to too high a temperature.

Operating cycle requirements

12.35 The following operating cycle presents a general specification which may need to be adapted for particular instruments. It assumes that immediately after use, and before transfer to decontamination, the insertion tube will have

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been wiped clean and that all channels will have been flushed through to remove gross contamination and ensure that they are free from blockages.

12.36 It is also assumed that any manual dismantling required (including removal of single use items, separation of accessories, removal of valves and covers, and disassembly) has taken place before the instruments are placed into the WD.

12.37 The operating cycle should include:

a. a **leak test** to verify that the endoscope is undamaged and will not suffer irreparable damage during exposure to the cleaning and disinfection process. (This should be a user selectable option);

b. **flushing** with water at a temperature not exceeding 35°C (this maximum temperature is necessary to minimise the coagulation of protein and consequent fixing of the soiling);

c. a **flow test** to ensure that all channels which should be irrigated with cleaning solution and disinfectant solutions are not blocked;

NOTE: Although this should have been verified before the instrument was placed in the WD, blockage can occur during processing when soiling dislodged from one place becomes trapped in a more restricted part of the instrument.

d. **washing** with an aqueous solution of detergent or an enzymic cleaner; when detergent solutions are used this may be at elevated temperature but should not exceed 60°C (see paragraphs 12.25 and 12.26).

The efficacy of chemical cleaning agents (detergents and enzymic cleaners) is affected by concentration, temperature, contact time and the presence or absence of materials/chemicals which will react with, and therefore inactivate, the chemical cleaning agent. The WD should provide means to control all these factors to the extent necessary to obtain satisfactory and reproducible cleaning.

For most rigid endoscopes ultrasonication may be used except for the telescope; ultrasonication generally is not suitable for use with optical or fibre-optic systems.

The pressure at which fluids are pumped through the internal channels of the endoscope should be controlled and maintained within the limits specified by the endoscope manufacturer;

e. **rinsing** to remove chemical additives used during the cleaning process;

NOTE: The rinse stage between cleaning and disinfection may be omitted if the disinfectant and cleaning agents are known to be compatible and the disinfectant preparation is used only for a single cycle.

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f. **drying** to remove excess water before transferring to the disinfection stage where residual water can cause serious dilution of the disinfectant. This stage may be optional unless the load has to be manually transferred to an automatic disinfector;

g. **disinfection**. For rigid endoscopes thermal disinfection may be practicable (see endoscope manufacturer's instructions) and if so should be used. For fibre-optic endoscopes there is usually an upper temperature limit of 60°C for processing conditions; thermal disinfection is impracticable and chemical disinfection should be used.

   The efficacy of chemical disinfectants is affected by concentration, temperature, contact time and the presence or absence of materials/chemicals which will react with, and therefore inactivate, the disinfectant. The WD should provide means to control all these factors to the extent necessary to obtain satisfactory and reproducible disinfection;

h. **rinsing** to remove disinfectant. After an effective cleaning and disinfection process the microbial quality of the final rinse water will determine the microbial contamination which may be present on the endoscope;

i. **drying**.

Drying stage

12.38 Drying may be achieved by purging with heated dry air; means should be provided to ensure that the temperature of the endoscope is not raised above the maximum specified by the endoscope manufacturer. The quality of air used should not contribute to physical, chemical or microbial recontamination of the decontaminated item.

12.39 Drying may also be accomplished by purging the decontaminated item with 70% alcohol and allowing this to evaporate. The quality of the alcohol used should not contribute to physical, chemical or microbial recontamination of the decontaminated item. In particular spore-free alcohol should be used.

NOTE: Most endoscope manufacturers advise that the lens system should not be exposed to alcohol for prolonged periods, although normally two to five minutes exposure will cause no damage.

Decontamination of the washer-disinfector

12.40 Automatic WDs for endoscopes may themselves act as a source of contamination for the decontaminated items.

12.41 The design, installation and operation of the WD, including the quality of connected services, may contribute to the problem.

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12.42 The WD should include a flushing stage for the WD pipework after each cleaning cycle to remove dislodged debris, biofilm etc. so that these cannot initiate a contamination problem.

12.43 All tanks used for the storage of water or aqueous solutions should be designed and constructed to ensure that they are free draining and cleanable.

NOTE: The use of hard water, water of inadequate microbiological quality or water stored in tanks at ambient temperatures for prolonged periods will promote contamination and the formation of biofilms within the machine.

12.44 The use of soft water can help alleviate this problem but it should be noted that base exchange softeners, and also de-ionisers, may themselves be a source of microbial contamination and can lead to high microbial counts of water borne organisms. These organisms are typically of species adapted to develop biofilms and the extracellular layers present in these biofilms provide good protection against microbicides.

12.45 Microbial colonisation of pipework may occur if the system is not disinfected regularly or if there is inappropriate cleaning and maintenance of the machine.

12.46 The WD manufacturer should provide information on cleaning and disinfection procedures and compatible chemicals for these purposes.

Requirements for control of the disinfection stage

12.47 The chemical disinfection system must:

a. ensure that the disinfectant solution temperature is either controlled at a pre-set temperature or is above a specified minimum temperature on which the exposure time was based;

b. ensure that all parts of load items to be disinfected are in contact with the disinfectant. This should include means to ensure the elimination of air bubbles etc;

c. avoid the risk of recontamination with micro-organisms from the WD, other load items or the connected services.

NOTE: Some disinfectant formulations have an upper temperature limit beyond which the disinfectant or its adjuvants in the formulation are decomposed or inactive.

Recontamination could lead to transfer of infection or inaccurate diagnosis if the contaminant is erroneously assumed to have come from the patient.

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Instrumentation/recorders

12.48 The extent of necessary monitoring depends on the particular application. As a minimum for the thermal disinfection stage the attainment of the required temperature should be monitored independently of the cycle controller, displayed on a temperature indicator or recorder, and recorded.

12.49 When the WD is to be used to decontaminate medical devices and the technical Standards described in the essential requirements of the EU Directives discussed in Chapter 1 must be met additional monitoring facilities will be required.

12.50 The WD should be equipped with monitoring and recording devices to monitor the pump pressure (or water flow) and temperature at each process stage, the flow or volume admitted of each chemical additive used (or, when applicable, by direct measurement of the concentration), the chemical purity of the final rinse (by measurement of electrical conductivity), and the flow and temperature of the hot air used for drying.

Test connections

12.51 Test connections should be provided to permit the connection of thermocouples to be used during validation and periodic testing.

12.52 When additional monitoring is provided (see above) a separate test connection should be provided for each sensor to permit periodic verification of calibration of the installed system by comparison with a calibrated test sensor.

NOTE: Visual inspection following the decontamination process is not of itself sufficient to determine whether the process was successful. The decontamination process must be subject to validation and then routinely monitored to ensure that the process remains within the validated limits. Further guidance is given in SHTM 2030 Part 2, ‘Operational management’ and Part 3, ‘Validation and verification’.

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13. Laboratory washer-disinfectors

Introduction

13.1 This chapter discusses specifications for laboratory WDs.

13.2 Laboratory WDs may be used to process components or equipment for use in the manufacture of medical devices or medicinal products or they may be used to process apparatus and equipment for use in clinical, or other, laboratories.

13.3 When used to process components or equipment for use in the manufacture of medical devices or medicinal products the design, construction, validation, operation and maintenance of these WDs will need to meet the requirements of the relevant EU Directives for medical devices or medicinal products (see Chapter 1).

13.4 WDs for both these applications may be machines of Type 1 or Type 2.

13.5 Commercially available machines offer a similar range of options to those WDs intended for the decontamination of surgical instruments and associated equipment (see Chapter 10).

Load handling equipment

13.6 The load handling equipment must be specific for the load items to be processed to ensure both that the load items are retained in the load carrier and that the external and any internal surfaces of the load items are reached effectively by the cleaning and disinfecting liquids throughout the cycle.

Standard specifications

13.7 There are no standard performance specifications specifically for laboratory WDs. For most applications the WD should conform to the relevant parts of the specifications in BS 2745: Part 1: 1993 and BS 2745: Part 3: 1993 which includes, for example, specific requirements for WDs used for the decontamination of glassware.

13.8 Laboratory WDs should conform to the safety specifications given in BS EN 61010: Part 1.

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Operating cycle

13.9 The WD should perform the following stages in each cycle:

a. flushing – removing gross contamination from the items in the load with water at a temperature not exceeding 35°C;

b. washing – removing any remaining soil by washing with water, water and detergent, or water and enzymic cleaner. Several sub-stages may be used consecutively to provide a combination of treatments; physical removal of the soil may be by the impingement of water jets or by ultrasonication or both consecutively;

c. rinsing – removing any residual detergent or enzymic cleaner. This stage may be combined with the thermal disinfection stage which follows and normally requires the use of purified (DI, RO or distilled) water;

d. thermal disinfection – raising the temperature of the load to the preset temperature (using hot water or steam) and maintaining the temperature for the required disinfection holding time;

e. drying – purging the load and chamber with heated air to remove residual moisture.

For many applications in laboratories the drying stage may be omitted.

NOTE: Laboratory WDs incorporating a solvent wash stage are also available but are beyond the scope of this SHTM.

Choice of detergent/cleaning agent

13.10 The cleaning agent(s) to be used should be chosen to be appropriate to the materials of the load items, the soiling to be removed, the intended end use of the load items and compatible with the WD. In many cases there are highly specific requirements and a specific formulation is required.

13.11 The use of detergent and other chemical additives may not be appropriate in all cases. For example in the preparation of single-use glass containers for pharmaceutical applications the process is required to remove dust and similar debris which have contaminated the containers during distribution and storage, rather than strongly adherent soiling, and vigorous washing with water alone may be sufficient. Furthermore, if detergents and/or other chemical additives are to be used the process must be designed and operated to ensure that the concentration of residual detergent is reduced to a level where it will not have an adverse effect on the product.

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Disinfection requirements

13.12 Disinfection is achieved by direct contact of the load items with moist heat at a temperature in excess of 65°C and below 95°C (see Table 2). The preferred temperature is 80°C for not less than one minute.

Drying stage

13.13 Drying is greatly facilitated by the final hot rinse. In general laboratory applications drying by flash evaporation from the hot load may be sufficient with individual items for which drying is more critical being transferred to a separate drying cabinet. For more critical applications, eg. containers for parenteral products where residual moisture may permit recontamination and unacceptable microbial growth, drying is important. Drying is also important for those products which are to be sterilized subsequently since this will require that the item is thoroughly dry.

Instrumentation/recorders

13.14 The extent of necessary monitoring depends on the particular application. As a minimum when thermal disinfection is required the attainment of the required temperature should be monitored independently of the cycle controller and displayed on a temperature indicator or recorder.

13.15 For critical applications, eg. the preparation of pharmaceutical containers for parenteral products, all key variables of the process should be independently monitored. The WD should be equipped with monitoring and recording devices to monitor the pump pressure, water flow and temperature at each process stage, the flow or volume admitted of each chemical additive used (or, when applicable, by direct measurement of the concentration), the chemical purity of the final rinse (by measurement of electrical conductivity), and the flow and temperature of the hot air used for drying.

NOTE: Visual inspection following the decontamination process is not of itself sufficient to determine whether the process was successful. The decontamination process must be subject to validation and then routinely monitored to ensure that the process remains within the validated limits. Further guidance is given in SHTM 2030 Part 2, ‘Operational management’ and Part 3, ‘Validation and verification’.

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Test connections

13.16 Test connections should be provided to permit the connection of thermocouples to be used during validation and periodic testing.

13.17 When additional monitoring is provided (see above) a separate test connection should be provided for each sensor to permit periodic verification of calibration of the installed system by comparison with a calibrated test sensor.

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14. Ultrasonic cleaners

Introduction

14.1 This chapter discusses specifications for ultrasonic cleaners.

14.2 The guidance given here assumes that the WD is to be used to decontaminate medical devices and that the essential requirements of the EU Directives discussed in Chapter 1 must be met.

14.3 Ultrasonic cleaners may be Type 1 or Type 2 machines.

14.4 Ultrasonic cleaners work by exposing the items to be cleaned to high frequency sound waves in the liquid cleaning medium.

14.5 The high frequency sound waves are generated within the liquid by the vibration of one or more surfaces of the bath; the surface(s) of the bath being caused to vibrate by one or more transducers bonded to the outer surface(s). The transducers convert electrical energy into vibrations of the required frequency and amplitude.

14.6 The highly effective cleaning action occurs as a result of the penetrative agitation caused by cavitation; the rapid formation and collapse of tiny bubbles within the liquid which are generated by the high frequency sound waves.

Applications

14.7 Ultrasonic cleaners are used in a wide range of industries including engineering, jewellery etc.

14.8 Ultrasonic treatment is particularly suitable for cleaning instruments of high grade steel. Delicate instruments such as micro-surgery instruments and dental instruments can be effectively cleaned with little risk of damage.

14.9 Ultrasonic treatment is also particularly effective for cleaning instruments that have deep interstices that may be contaminated with body tissues, eg. reamers, drills and burrs.

14.10 When combined with appropriate connection to an irrigation or flushing system ultrasonicators are also effective for cleaning cannulated instruments.

14.11 Ultrasonic cleaners are less effective when used to clean plastic and similar readily compressible materials since they absorb much of the ultrasonic energy.

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Standard specifications

14.12 Ultrasonic cleaners, whether designed as stand alone units or incorporated into continuous process machines, should comply with the requirements of BS 2745: Part 3: 1993 and the safety specifications in BS EN 61010: Part 1.

Additional specifications

14.13 The ultrasonic cleaner should be fitted with means to drain the tank with the cleaner in situ. The tank should be free draining so that no pools of water are left in the tank after draining.

14.14 The tank should be heated electrically and the heaters should be thermostatically controlled.

14.15 The ultrasonic cleaner should be fitted with a timer to control the duration of exposure.

14.16 The ultrasonic cleaner should have a lid; the lid should be interlocked with the operating system to prevent normal operation if the lid is open and should fit securely to prevent the emission of aerosols when the cleaner is in operation.

NOTE: The lid interlock should ensure that no part of the operator's body can be immersed in the ultrasonic cleaner during operation; long term direct exposure to ultrasound is suspected of causing arthritic conditions.

14.17 The ultrasonic cleaner should be effectively insulated to prevent high frequency sound transmission at a power which could cause a health hazard. (Note: High frequency sound is suspected of causing damage to hearing). The casing and lid should provide adequate sound proofing so that harmonic frequencies within the audible range are not obtrusive.

14.18 The manufacturer should specify the chemical additives (detergents and/or enzymic cleaners) which are required and which are compatible with the process.

NOTE: Low foaming detergents are required; liquid detergents used for washing dishes ("washing-up liquid") are generally not suitable. Although an ultrasonicator will work without detergent/cleaner the cleaning action is much less effective.

14.19 The manufacturer should specify the means by which the cleaner may be disinfected. This may be by the provision of a high-temperature, eg. 80°C cycle option, or by means of a suitable disinfectant solution. In the absence of guidance the microbiologist should be asked to advise on a suitable procedure.

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14.20 The manufacturer should specify the de-gassing time(s) which should be used on start-up and, when necessary, between each load of instruments processed.

Wash cycle

14.21 The ultrasonic frequency used is typically within the range 35 ± 5 kHz and the energy input used may range from 5.0 to 20.0 Watts/litre.

14.22 Ultrasonic cleaners may be designed to operate at a single frequency, across a frequency range, or with a feedback control system claimed to adjust the frequency in response to the loading conditions.

14.23 For medical applications aqueous solutions are used. Although ultrasonic cleaners containing aqueous solutions may be effective at temperatures up to 90°C it is normal practice to operate those for medical applications at temperatures between ambient and 40°C. This minimises the rate of coagulation of proteinaceous material in the soiling and is compatible with the use of enzymatic cleaners, many of which are rapidly destroyed at higher temperatures.

Type 1 ultrasonicators

Load handling equipment

14.24 A mechanical lifting device should be specified when the ultrasonicator is intended to process heavy sets of instruments.

14.25 The load container, usually a wire mesh basket, should be of appropriate size for the longest instrument to be processed.

14.26 When it is intended to process micro-surgical instruments or instruments with fine points the load handling equipment should provide means of retaining these in position so that the points are not blunted by the impacts resulting from fine mechanical shaking.

Type 2 (continuous process) ultrasonicators

14.27 Continuous process WDs may incorporate an ultrasonic cleaning stage within the cycle programme.

14.28 Ultrasonic cleaners are also available in continuous process format with a thermal disinfection stage and with the option to provide a hot air drying stage.

14.29 Ultrasonic cleaners with a solvent drying stage are no longer commercially available since the solvents used were CFCs which are now prohibited under the Montreal Protocol.

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Load handling equipment

14.30 If complex tabling or conveyors are required these should be specified, and preferably illustrated with a sketch plan, when seeking tenders.

14.31 When it is intended to process micro-surgical instruments or instruments with fine points the load handling equipment should provide means of retaining these in position so that the points are not blunted by the impacts resulting from fine mechanical shaking.

Instrumentation/recorders

14.32 The ultrasonic cleaner should be fitted with a temperature indicator; provision should be made for a recorder to be fitted if requested by the purchaser.

14.33 The ultrasonic cleaner should be fitted with an indicator to show the power consumption (in Watts), or electrical demand (in Amps) of the ultrasonic transducers; provision should be made for a recorder to be fitted if requested by the purchaser.

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Appendix 1: Glossary of terms

Automatic controller: Device that, in response to pre-determined cycle variables, operates the WD sequentially through the required stages of the cycle(s)/process.

Biological indicator: See BS EN 866-1:1997 ‘ Biological systems for testing sterilizers and sterilization processes: General requirements’.

Calibration: The set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by Standards.

Calorifier: A closed vessel in which water is indirectly heated under a pressure greater than atmospheric.

Chamber: That part of the WD in which the load is processed.

NOTE: The chamber does not include steam generators, pipework and fittings from which it can be isolated.

Chemical disinfection: Disinfection achieved by the action of one or more chemicals; the primary purpose of which is to be microbicidal.

Continuous process machine: A machine which automatically transports the load through each stage of the operating cycle.

Chemical additive: A formulation of chemical compounds intended for use in a WD.

Cycle complete: Indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber.

Cycle variables: The physical and chemical properties (eg. times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of the washing and processes.

Decontamination: The combination of processes, including cleaning and disinfection and/or sterilization, used to render a re-usable item safe for further use.

Disinfection: The reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

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Disinfection temperature: The minimum temperature of the disinfection temperature band.

Disinfection temperature band: The range of temperatures, expressed as the disinfection temperature and the maximum allowable temperature which may prevail throughout the load during the disinfection time.

Disinfection time: The time period at which the cycle variable (eg. temperature of the load, disinfectant concentration in the chamber) is maintained at or above the value specified for disinfection.

NOTE: This includes detergents, surfactants, rinse aids, disinfectants, and enzymatic cleaners.

Door: Device provided as a means of closing and sealing the chamber.

Double-ended washer-disinfector: A WD incorporating separate doors for loading and unloading.

Fail safe: Attribute of WD design, component or its associated services that minimises a possible safety hazard.

Fault: Recognition by the automatic controller that the pre-set cycle variables for the WD cycle have not been attained.

Holding time: the time period for which the cycle variables are maintained at or above the value specified for disinfection.

Hysteresis: The lagging of effect behind cause.

Inoculated carrier: See BS EN 866-1:1997 ‘ Biological systems for testing sterilizers and sterilization processes: General requirements’.

Installation test: Series of checks and tests performed after installation of the WD in the place of use.

Load: A collective term used to describe all the goods equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle.

Loading door: Door in a double-ended WD through which the load is put into the WD prior to processing.

Loading height: The minimum height to which the underside of the load or load container has to be raised for it to enter the loading door.

Medical device: See BS EN 46001: 1997 ‘Specification for applications of EN ISO 9001 to the manufacture of medical devices’.

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Monitoring: The measurement of physical variables, such as the function of the automatic controller to check the attainment, or otherwise, of the pre-set cycle variables essential to the efficacy of the operating cycle.

Operating cycle: The complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller.

Operating pressure: The gauge pressure at which the vessel is operated during normal use.

Override: The system by which the operating cycle can be interrupted or modified as necessary.

Safety hazard: Potential detrimental effect on persons arising from the load.

Steam generator: Vessel designed to contain water and a heating system (eg. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state.

Sterile: See BS EN 556 ‘Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled ‘Sterile’’.

Sterilization: Process used to render a product sterile (35).

Tank: A process vessel, integral to the WD, designed to hold solutions during processing.

Test organism: See BS EN 866-1:1997 ‘ Biological systems for testing sterilizers and sterilization processes: General requirements’.

Test soil: Substance used to test the washing efficacy of a WD.

Thermal disinfection: Disinfection achieved by the action of moist or dry heat.

Type test: Series of tests to establish the working data for a WD type.

Unloading door: Door in a double ended WD through which the load is removed after an operating cycle.

Usable space: Space inside the chamber which is not restricted by fixed parts and which is consequently available to accept the load.

Validation: See BS EN 554 ‘Sterilization of medical devices. Validation of and routine control of sterilization by moist heat’.

Viable micro-organism: Micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

Warning pipe: Overflow pipe so fitted that its outlet, whether inside or outside the building, is in a conspicuous position, where the discharge of water can be readily seen.

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Washer-disinfector (WD): Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

NOTE: This type of machine does not include those designed specifically to wash linen or clothing.

Waste outlet: The point from which the chamber discharges the waste fluids.

Works test: Series of tests performed at the manufacturer's works to demonstrate compliance of each WD with its specification.

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Appendix 2: Abbreviations

A	Amperes
a.c.	Alternating Current
A & E	Accident and Emergency
AP(s)	Authorised Person (Sterilizers)
BS	British Standard
°C	Degrees Celsius
$CaCO_3$	Calcium Carbonate
CE	Council of Europe
CEN	Committee European de Normalisation
CFCs	Chlorofluorocarbons (refrigerants)
Cl	Chlorine
COSHH	Control of Substances Hazardous to Health
d.c.	Direct current
D.I.	De-ionised (referring to water)
EEC	European Economic Community
EMC	Electro magnetic compatibility
EN	European Norm
EU	European Union
	Endotoxin unit
EU/ml	Endotoxin units/millilitre
GGMP	Guide to Good Manufacturing Practice…….etc.
GU	Genito Urinary
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
HMSO	Her Majesty's Stationary Office
HSE	Health and Safety Executive
IEC	International Electro Technical Commission
IEE	Institution of Electrical Engineers
ISE	Ion selective electrode
ISO	International Standards Organisation
Jm^2	Joules/square metre
kg	Kilogram
kHz	Kilo Hertz
kVA	Kilo Volt amp
kW	Kilo Watt
m	metre
MAT	Minimum access therapy
mbar	Millibar
MCA	Medical Control Agency
MDA	Medical Devices Agency
mg	Milligram
mg/l	Milligram/litre
ml	millilitre
mm	millimetre

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MP	Maintenance person
m/s	metre/second
m^3/hr	cubic metres/hour
N	Newton
NHS	National Health Service
nm	nanometre
No.	number
OEL	Occupational exposure limit
PA	Pascal
P&EF	Property and Environment Forum
P&EFEx	Property and Environment Forum Executive
PES	Programmable electronic system
pH	measure of acidity or alkalinity of a solution
ppm	parts per million
QAC	Quaterrary ammonium compound
RO	Reverse osmosis – a method of water treatment
Sec	Second
SHTM	Scottish Health Technical Memorandum
SHPN	Scottish Health Planning Note
SSD	Sterile services department
SSM	Standard sterilization modules (600 mm x 300 mm x 300 mm)
TC	Technical committee
TP	Test person
TSSU	Theatre sterile supplies unit
UK	United Kingdom
UV	Ultra violet
uPVC	Unplasticised polyvinyl chloride (plastic)
V	Volts
WC	water closet
WD	Washer disinfector
µm	micron (a unit of length equal to one millionth of a metre)
<	less than
>	greater than

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Appendix 3: Useful addresses

UK health agencies

NHSScotland
Property and Environment Forum Executive
4th Floor, St Andrew House
141 West Nile Street
Glasgow G1 2RN

NHS Estates
1 Trevelyan Square
Boar Lane
Leeds, LS1 6AE
Tel. 0113 254 7000

Medical Devices Agency (MDA)
Hannibal House,
Elephant and Castle, London, SE1 6TQ
Tel. 0171 972 8000

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
Edinburgh
EH4 2RQ
Tel. 0131 552 6255

Medicines Control Agency (MCA)
Market Towers,
1 Nine Elms Lane, London SW8 5NQ
Tel. 0171 273 3000

Scottish Executive Health Department,
St Andrews House,
Edinburgh EH1 3DG
Tel. 0131 556 8400

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Health and Safety

Health and Safety Executive
375 West George Street
Glasgow
G2 4LW
Tel. 0141 275 3000

Belford House
59 Belford Road
Edinburgh
EH4 3UE
Tel. 0131 247 2000

Standards organisations

British Standards Institution
British Standards House,
389 Chiswick High Road,
London W4 4AL
Tel 0181 996 9000

European Committee for Standardisation rue de Stassart 36, B-1050 Brussels

Other organisations

Institute of Healthcare Engineering and Estates Management.
2 Abingdon House,
Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1DS.
Tel. 02392 823 186

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Appendix 4: Information to be supplied by the manufacturer

A2.1 The following information should be supplied by the manufacturer of the WD at or before the time the WD is delivered.

Standards

A2.2 Statements of, and documentary evidence to substantiate, compliance with relevant British and EU Standards.

Instruction manual

A2.3 The manual should contain complete instructions including:

a. simplified operating instructions in a durable form suitable for fixing next to the WD;

b. guidance on the types of load that may be processed in the WD and the recommended loading patterns/load carriers to be used;

c. operational limits including the maximum working temperature which may be attained within the WD chamber or chambers, and the maximum pressure that may be applied to the lumen of cannulated instruments.

A2.4 When the WD incorporates a pressure vessel (eg. an integral steam generator) the operational limits of the pressure vessel including design pressure, maximum permissible working pressure and maximum permissible working temperature in accordance with the ‘Pressure systems regulations’. A valid test certificate should be provided by the manufacturer for all pressure vessels supplied.

Instruments and controls

A2.5 The manual should include a description of each instrument and control fitted to the WD including:

a. the scale ranges of each and the limits of accuracy;

b. evidence that the calibration of each instrument has been verified and that the instrument is reading correctly within its limits of accuracy.

Operating cycles

A2.6 The manual should give a description of each operating cycle available on the sterilizer.

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Services

A2.7 The manual should give a description of all the engineering services required by the WD, specifying:

a. values of the fluctuating demands placed on each service during the course of a normal operating cycle;

b. the maximum and minimum safe supply pressures, temperatures and voltages.

This should also include specification of the minimum acceptable water quality for each stage in the process (defined as pH, total dissolved solids, redox potential, electrical conductivity).

Safety

A2.8 Safety information should include:

a. description of any safety hazard that may arise in the normal operation of the WD and recommended precautions to avoid them;

b. description of all safety devices including their recommended settings and any means provided to override and reset them;

c. description of the chemical additives with which the WD is intended to be used.

Machine characteristics

A2.9 The manual should include a description of the machine, specifying the total volume of the chamber: This should include the following information:

a. dimensions of the usable space and its capacity expressed either as an integral number of load baskets based on the standard sterilization module (SSM) or as a specific number of identified load items eg. the number of bed pans;

b. parts of the usable chamber space which are fastest and slowest to attain the disinfection temperature, and those parts which are hottest and coolest during the disinfection holding time.

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Maintenance manual

A2.10 Two copies should be provided. The manual should include:

a. a planned preventive maintenance programme, consistent with the principles outlined in SHTM 2030 Part 2, ‘Operational management’, together with detailed instructions for the procedures contained within it;

b. a list of any special tools and equipment required for periodic maintenance and testing;

c. diagrams of all electrical, steam, compressed air, water, chemical additive dosing systems, and ventilation and drainage connections;

d. a complete list of all spare parts, indicating all parts which should be held in stock and that may require replacement during the normal working life of the WD together with their usage rates;

e. guidance on tracing and correcting likely causes of malfunction;

f. method of adjusting and calibrating the pressure, temperature and flow rate indicating or recording systems;

g. Specification and source of supply for suitable flexible ducting to enable extracts from WDs to be conveyed to atmosphere.

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Medicines Act	HMSO	1988	
	Health and Safety at Work Act	HMSO	1974	
	Public Health (Scotland) Act	HMSO	1988	
	The Water (Scotland) Act	HMSO	1980	
SI 2179	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd. 1994)	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health and Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health and Safety (Information for Employees) Regulations	HMSO	1989	

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Publication ID	Title	Publisher	Date	Notes
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1994	
SI 2037	Lifting Operations and Lifting Equipment Regulations	HMSO	1998	
SI 2865	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulation	HMSO	1994	
SI 2169	Medicines (Standard Provisions of Licences and Certificates) Amendment (No 3) Regulations	HMSO	1977 1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 201	Public supply contracts regulations	HMSO	1995	
SI 2023	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 853	**Specification for vessels for use in heating systems** **Part 1:** Calorifiers and storage vessels for central heating and hot water supply **Part 2:** Tubular heat exchangers and storage vessels for building and industrial services	BSI Standards	1996 1996	
BS 1427	**Guide to field and on-site test methods for the analysis of waters**	BSI Standards	1993	

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Publication ID	Title	Publisher	Date	Notes
BS 1752	**Specification for laboratory sintered or fritted filters including porosity grading**	BSI Standards	1983	
BS 2745	**Washer disinfectors for medical purposes** **Part 1:** Specification for general requirements **Part 2:** Specification for human-waste container washer-disinfectors **Part 3:** Specification for washer-disinfectors except those used for processing human-waste containers and laundry	BSI Standards	 1993 1993 1993	
BS 3218	**Specification for test tubes and boiling tubes**	BSI Standards	1982	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**	BSI Standards	1992	
BS 3849-4	**Concial connectors for anaesthetic and respiratory equipment. Specification for 8.5 mm cones and sockets**	BSI Standards	1990	
BS 3928	**Method for sodium flame test for air filters (other than air supply to IC engines and compressors)**	BSI Standards	1969	
BS 5164	**Specification for indirect-acting electrical indicating and recording instruments and their accessories**	BSI Standards	1975	
BS 5295	**Environmental cleanliness in enclosed spaces**	BSI Standards	1989	
BS 5452	**Specification for hospital hollow-ware made of plastics material**	BSI Standards	1977	
BS 5500	**Specification for unfired fusion welded pressure vessels**	BSI Standards	2000	
BS 5728	**Measurement of flow of cold potable water in closed conduits** **Parts 2, 3, 5, 6,and 7**	BSI Standards	1980 - 1987	
BS 6253	**Specification for glass beakers for laboratory use**	BSI Standards	1984	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**	BSI Standards	1984	
BS 7320	**Specification for sharps containers**	BSI Standards	1990	
BS EN 285	**Sterilisation. Steam sterilizers. Large sterilizer**	BSI Standards	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 554	**Sterilization of medical devices. Validation of and routine control of sterilization by moist heat**	BSI Standards	1994	
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 837	**Pressure gauges** **Part 1:** Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing **Part 2:** Pressure gauges. Selection and installation recommendations for pressure gauges **Part 3:** Diaphragm and capsule pressure gauges. Dimensions, metrology, requirements and testing	BSI Standards	1998 1998 1998	
BS EN 866	**Biological systems for testing sterilizers and sterilisation processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterlizers **Part 3:** Particular systems for use in moist heat sterlizers	BSI Standards	1997 1998 1997	
BS EN 1281	**Anaesthetic and Respiratory equipment** **Part 1:** Conical connectors	BSI Standards	1997	
BS EN 1282	**Anaesthetic and respiratory equipment** **Part 1:** Tracheostomy tubes: Tubes for use in adults	BSI Standards	1997	
BS EN 1782	**Tracheal tubes and connectors**	BSI Standards	1998	
BS EN 1820	**Anaesthetic reservoir bags**	BSI Standards	1997	
BS EN 6001	**Application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 6002	**Application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 12342	**Breathing tubes intended for use with anaesthetic apparatus and ventilators**	BSI Standards	1998	
BS EN 46001	**Specification for application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1998 1995	
BS EN 50103	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry**	BSI Standards	1996	
BS EN 60584	**Thermocouples** **Part 1:** Reference tables	BSI Standards	1996	
BS EN 60751	**Industrial platinum resistance thermometer sensors**	BSI Standards	1996	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **Part 1:** General requirements	BSI Standards	1993	
BS EN ISO 14644-1	**Cleanrooms and associated controlled environments. Classification of air cleanliness**	BSI Standards	1999	
BS EN ISO 9000	**Quality management and quality assurance standards.**	BSI Standards	2000	
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing.**	BSI Standards	1994/ 2000	
BS EN ISO 9002	**Quality assurance. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
PD 5304	**Safe use of machinery**	BSI Standards	2000	
European Union (EC) Directives				
90/385/EEC	Active Implantable Medical Devices Directive Note: the Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992	Official Journal of the European Communities (OJEC)		
91/356/EEC	Council Directive laying down the principle and guidelines of good manufacturing practice for medicinal products for human use	Official Journal of the European Communities (OJEC), L193, 17.7.91, p30		
93/42/EEC	Council Directive concerning medical devices	Official Journal of the European Communities (OJEC), L169, 12.7.93, p1		
80/778/EEC	Council Directive relating to the quality of water intended for human consumption	Official Journal of the European Communities (OJEC)		
93/94/EEC	Medical Devices Directive. Note: The Directive was adopted by the EC Council of Ministers on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations	Official Journal of the European Communities (OJEC), L319, 17.11.81, p19		
Scottish Health Technical Guidance				
SHTM 2007	Electrical Services Supply & Distribution	P&EFEx	2001	CD-ROM
SHTM 2010	Sterilization	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems Supplement 1: Dental compressed air and vacuum systems Supplement 2: Piped medical gases in ambulance vehicles	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilization	P&EFEx	2001	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	Scottish Office	1994	
SHPN 15	Accommodation for pathology service	Scottish Office	1994	
SHPN 26	Operating department	Scottish Office	1992	
SHPN 26 Supp.1	Operating department activity space data sheets	Scottish Office	1993	
HBN 13 Supp 1	Oxide sterilization section			
	NHS in Scotland PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1998	CD-ROM
Health and Safety Publications				
(MDA SN 9619)	Compatibility of medical devices and their accessories and reprocessing units with cleaning, disinfecting and sterilizing agents. Medical Devices Agency	Dept. of Health	1996	

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Publication ID	Title	Publisher	Date	Notes
(L5)	Control and substances hazardous to health and control of carcinogenic substances: Control of substances hazardous to health regulations 1999: approved code of practice. Health and Safety Executive	HSE Books	1999	3rd Edition
(HC(79)3)	Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms	Dept of Health	1979	
(H(91)33)	Decontamination of equipment, linen or other surfaces contaminated with hepatitis B and/or human immunodeficiency viruses	Dept. of Health	1991	
(SAB(93)32)	Endoscope washer/disinfectors: recontamination of equipment	Dept of Health	1993	
	Microbiological safety cabinets: recommendations concerning their choice, installation, routine maintenance and use (Health Equipment Information No 86) Medical Devices Agency	Dept. of Health	1980	
	Scottish Infection Manual 1998 – guidance on core Standards for the Control of Infection in Hospitals, Healthcare premises and at the Community Interface	Scottish Office	1998	
	Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Directorate. Microbiology Advisory Committee	Dept. of Health	1993	
(L23)	Manual handling: Manual handling operations regulations 1992: guidance on regulations. Health and Safety Executive	HSE Books	1992	
(EH40)	Occupational exposure limits. Health and Safety Executive	HSE Books		Issued annually
	Programmable electronic systems in safety related applications: an introductory guide. Health and Safety Executive	HSE Books	1987	
MDA DB 9501	Re-use of medical devices supplied for single use only	HMSO	1995	
	Safety in health service laboratories: safe working and the prevention of infection in clinical laboratories. Advisory Committee/Health and Safety Executive	HSE Books	1991	

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Publication ID	Title	Publisher	Date	Notes
	Safe working and the prevention of infection in the mortuary and post-mortem room. Health and Safety Executive			
(L22)	Work equipment. Provision and use of work equipment regulations 1998. Guidance on regulations. Health and Safety Executive	HSE Books	1998	
(L24)	Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992: approved code of practice and guidance. Health and Safety Commission	HSE Books	1992	
Miscellaneous References				
	Babb J R, Bradley C R, Barnes A R, *Question and Answer*	Journal of Hospital Infection	1992	Vol 20, p51-54
	Rollnick M, *How You Spend Your Pennies*	Health Estate Journal	1991	May, p12-15
	Dawson M, Novitsky T J, Gould M J. *Microbes, endotoxin and water*	Pharm Eng	1988	Mar/Apr vol 8, no2
	Twohy C W, Nierman ML, Duran A P *et al*, *Comparison of limulus amoebocyte lysates from different manufacturers*	Journal of Parent Science & Tech	1983	May/Jun vol 37, no3, p93-96
	Bacterial endotoxin test USP 8th Supp. Pharmacopoeial Convention		1993	Mar XXII NF XVII, p3349-3350
	Chloride in waters, sewage and effluent. Methods for the examination of waters and associated materials	DOE/Nat. Water St. Committee	1981	
	Determination of pH in low ionic strength waters	DOE/Nat Water St Committee	1988	
	Determination of alkalinity and acidity in water	DOE/Nat Water St Committee	1981	
	Deprygogenation by dry heat. Technical report no 7. Parental Drug Association			Ch12, p101-108
	Dry heat destruction of lipo-polysaccharide. Applied Environmental Microbiology		1997	Vol 36 p715

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Publication ID	Title	Publisher	Date	Notes
	General principles of sampling and accuracy of results	DOE/Nat Water St Committee		
	Guidelines on the validation of the Limulus Amoebocyte Lysate test as an end product Endotoxin test for human and animal parenteal drugs, biological products and medical devices	US Food and Drug Administration	1987	
	Guide to contract procedures	NHS Estates	1998	
	International standards for drinking water	WHO	1971	
	Iron in raw and potable waters by spectrophotometry. Methods for the examination of waters and associated materials	DOE/Nat Water St. Committee	1977	
	Measurements of Electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters	DOE/Nat Water St Committee	1981	
	Model Engineering Specifications	NHS Estates, HMSO	1998	Issued in 4 volumes
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Ninhydrin test	Analytical Bio-chemistry	1993	Vol 211, p240-242
	Phosphorus and silicon in waters, effluent and sludges	DOE/Nat Water St Committee	1992	
	Rules governing medicinal products in the European Community. Vol IV Good manufacturing practice for medicinal products. Commissions of the European Communities		1992	
	Scottish Capital Investment Manual	Scottish Office		
	Sterilization and disinfection of heat-labile equipment: report of a working Party on sterilization and disinfection of heat-labile equipment. Hospital Infection Research Laboratory		1986	

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Publication ID	Title	Publisher	Date	Notes
	Total hardness, calcium hardness and magnesium hardness in raw and potable waters	DOE/Nat Water St Committee	1981	
	Water Supply Byelaws Guide. Water Byelaws Advisory Service Water Research Centre		1989	2nd Edition

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Scottish Health Technical Memorandum 2030

(Part 2 of 3)

Operational management

Washer-disinfectors

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Version 2
NHSScotland, Property and Environment Forum Executive, October 2001

Executive summary

SHTM 2030 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer-disinfectors (WDs) in use in the National Health Service for processing medical devices, laboratory ware and sanitary products.

No guidance is given on WDs intended for use in processing textiles or for dishwashers in general catering applications.

This part, 'Operational management', is intended as a guide for management, technical personnel with appropriate training and experience and also for users responsible for the day to day running of WDs. It will also be of interest to architects, planners, estates managers, supplies officers, and others.

Detailed information on the planning and design of a sterile services department including the provision of WDs is given in Scottish Hospital Planning Note 13, *Sterile services department*. Guidance for laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services.*

Although this edition of SHTM 2030 reflects current WD technology it is recognised that considerable scope exists for improvements in the operational and management standards used with WDs.

NOTE: The term washer-disinfector is abbreviated to 'WD' throughout this publication.

The current British Standards for WDs are expected to be replaced by European Standards within the next two to three years. These Standards include consideration of the requirements arising as a result of European Union Directives on medical devices, which are of concern for WDs in two ways. Firstly, some WDs will themselves be considered to be medical devices and therefore must meet the relevant requirements of the Medical Devices Directive and secondly, the manufacturer of a medical device which is intended to be reprocessed is required to specify the method to be used for reprocessing which will include any necessary washing and disinfecting stage.

When practicable the information in this SHTM has been aligned with existing or anticipated standards and advice is offered when no standard has yet been formulated.

The WDs described in this SHTM may not be suitable, without modification, for safely processing articles contaminated with either Hazard Group 4 pathogens or with agents which are unusually resistant to disinfection.

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The guidance previously given in HTM 2030 ‘Management policy’ has been incorporated into SHTM 2030 ‘Operational management’. HTM 2030 is superseded.

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1. Disinfection in healthcare: an overview

1.1 Decontamination by washing and disinfection is a complex and subtle process. The testing, maintenance and reporting procedures described in this SHTM may seem excessive, but they are based upon good practice in both the UK and Europe, as formalised in European Standards designed to support the EC Directives.

1.2 The main purpose of washing and disinfection is to eliminate the hazard of contamination and infection.

1.3 Disinfection is the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

1.4 The lethality of the process is less than that of sterilization but eliminates virtually all recognised pathogenic organisms, although not necessarily all microbial forms, for example bacterial endospores. Disinfection is adequate for the preparation of many items intended for use in patient care, but should not be used as a substitute for sterilization.

1.5 The hospital infection committee should prepare and implement a disinfection policy. This requires consultation between the microbiologist, infection control officer, engineer, pharmacist, supplies officer and representatives of medical, nursing and domestic staff.

1.6 The use of chemical disinfectants should be avoided when heat can be reasonably used as an alternative, for example in thermal disinfection or sterilization.

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2. Washer-disinfectors and the role of management

Introduction

2.1 This part of SHTM 2030 covers the maintenance and operation of the various types of WDs used in hospitals, laboratories and other healthcare facilities.

2.2 Terminology used in washing and disinfection has long been inconsistent and this has often led to ambiguities. This SHTM introduces a set of terms which, it is hoped, will provide workers in this field with a standard vocabulary and will also be consistent with the EU Standards. The glossary contains defined terms referred to in this part of SHTM 2030.

2.3 Full references for all the documents referred to in this part and also for selected documents providing additional information of which the reader should be aware are listed at the end of the publication.

2.4 The NHS is no longer protected by Crown immunity and is now subject to the full force of the law, notably in health and safety, medicinal products and consumer legislation. Tighter statutory control, brought in by new European Union Directives, will extend to almost every aspect of disinfection, and practices which were common a few years ago will no longer be acceptable.

2.5 The test, maintenance and reporting procedures described in this SHTM are based upon good practice in both the United Kingdom and the rest of Europe, as formalised in new European Standards designed to support the new EU Directives, and are designed to prevent the possibility of gross failure and serious incident.

2.6 Good staff morale is important. Anomalous behaviour which may foreshadow a malfunction of a WD is often first noticed by an alert operator or other relatively junior employee. It is vital that staff feel free to report such observations promptly, and that appropriate remedial action is taken. “Untiring vigilance” demands no less.

Legal framework for washing and disinfection

2.7 WDs are used in relation to both medical devices and medicinal products as well as for sanitary equipment, laboratory equipment and cutlery/crockery.

2.8 They may be used for reprocessing, within their intended use, medical devices, sanitary equipment, laboratory equipment, manufacturing equipment and components (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery.

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2.9 Users must be clear as to whether the load items they intend to process in a WD are classified as medicinal products or medical devices. While the practical requirements are very similar their implementation is covered by different legislation.

2.10 For the guidance given in this SHTM the various types of WDs are presumed to be used primarily as follows:

a. for medicinal products – laboratory WDs;

b. for medical devices, WDs for human-waste containers, surgical instruments and utensils, for anaesthetic equipment, for heat labile medical equipment eg. endoscopes.

2.11 When a WD is purchased with the intention of processing both medicinal products and medical devices purchasers should ensure that the requirements for both types of product are met.

Medicinal products

2.12 The manufacture and supply of medicinal products are controlled by extensive legislation based on EU Directives for medicinal products. These are enacted in the UK by the Medicines Act and a number of Regulations.

2.13 The requirements for the manufacture and supply of medicinal products are set out in the 'Guide to good manufacturing practice for medicinal products' (GGMP) published in Part IV of the 'The rules governing medicinal products in the European Community'.

2.14 The GGMP contains guidance on cleaning of components and manufacturing equipment which has implications for the operation of WDs. When a WD is to be installed for processing containers, components or manufacturing equipment for use with medicinal products the GGMP should be consulted at an early stage.

2.15 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) when necessary.

Medical devices

2.16 This part refers to three EU Directives on the manufacture and supply of medical devices and in-vitro diagnostics:

a. the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC) covers all powered implants or partial implants that are left in the human body. (Heart pacemakers are the most common example of powered implants.) The Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992 (see paragraph 4.29);

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b. the Medical Devices Directive (Council Directive 93/94/EEC) covers most other medical devices ranging from first aid bandages and tongue depressors through to hip prostheses and will therefore have a wide impact on disinfection. The Directive was adopted by the EU Council on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations;

c. the In-Vitro Diagnostic Medical Devices Directive will cover any medical device, reagent product, kit, instrument, apparatus or system which is intended to be used in vitro for the examination of substances derived from the human body. Some examples of in-vitro diagnostic devices are blood grouping reagents, pregnancy test kits, and hepatitis B test kits.

2.17 Whether, and if so in what circumstances, the Medical Devices Directive (93/42/EEC) applies to medical devices which are being reprocessed for further use – either within a particular healthcare facility or externally under a service contract – is a complex issue beyond the scope of this SHTM. Guidance is given in the MDA Directives Bulletin 18. If necessary advice should be sought from the Medical Devices Agency (MDA).

2.18 The relevant essential requirements of the Medical Devices Directive are:

a. that devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Appendix 1, paragraph 8.1);

b. that devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (Appendix 1, paragraph 7.2).

2.19 There is no direct equivalent of the GGMP for medical devices. The same role is fulfilled by general quality system Standards (the BS EN ISO 9000 series), supplemented by Standards tailoring the requirements specified in the general Standards for medical devices (BS EN 46001 and BS EN 46002) and Standards providing guidance on compliance with these Standards (BS EN 724 and BS EN 50103).

2.20 These are mandated Standards and as such compliance with them affords the presumption of conformance with relevant essential requirements of the Directive.

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Published Standards

2.21 British Standard 2745: 1993 specifies requirements for WDs for medical purposes. The standard is in three parts: Part 1: 'Specification for general requirements'; Part 2: 'Specification for human-waste container washer-disinfectors' and Part 3: 'Specification for washer-disinfectors except those used for processing human-waste containers and laundry'.

2.22 There are no European Standards, as yet, for WDs. CEN Technical Committee TC102 is developing a series of mandated, Standards relevant to the Medical Devices Directive, for WDs. There are four parts with the working titles 'General Requirements', 'Washer-disinfectors for human-waste containers', 'Washer-disinfectors for medical devices and surgical instruments' and 'Washer-disinfectors for thermo-labile medical devices (for example endoscopes)'.

2.23 IEC Technical Committee TC66 is developing Standards for 'Safety requirements for washer-disinfectors'.

2.24 When published, compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.

2.25 This edition of SHTM 2030 has been written while the new Standards are in the course of development. The guidance given here is designed to be broadly consistent with the emerging Standards but SHTM 2030 should not be regarded as a substitute for the Standards themselves when ascertaining compliance with the EU Directives and the UK Regulations that implement them.

2.26 If the WD is purchased with the intention of processing both medical devices and components or equipment for use in the manufacture of medical products purchasers should ensure that the requirements for both types of load are met.

Washer-disinfectors as medical devices

2.27 The Medical Devices Directive (93/42/EEC) Annex IX, Classification Criteria, Rule 15 classifies as medical devices "all devices intended specifically to be used for disinfecting medical devices" and places them in Class IIa for conformity assessment purposes. It specifically excludes products that are intended to clean medical devices, other than contact lenses, by means of physical action.

2.28 WDs for cleaning and disinfecting medical devices are thus covered by the medical devices legislation and those supplied on or after 14 June 1998 will have to bear the CE marking in accordance with the provisions of the

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Medical Devices Directive. This will apply to many of the WDs described in this SHTM.

2.29 Detailed guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency.

Water supply

2.30 All organisations responsible for water supply have the statutory power to make and enforce bye-laws to prevent waste, excessive consumption, misuse or contamination of the water supply. The Model Water Bye-laws form the basis of such bye-laws. WDs must be designed, constructed, installed, operated and maintained in accordance with requirements of the relevant bye-laws.

Safety

2.31 Extensive guidance on the safe operation of various types of WDs is given within this SHTM (Chapters 5 to 11), while guidance on safety practice of testing WDs in given in SHTM 2030 Part 3, 'Validation and verification'.

2.32 Many of the chemical additives used in WDs and their associated ancillary equipment, eg. water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.

2.33 The 'Control of Substances Hazardous to Health (COSHH) Regulations' 1999 place an obligation upon management to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a special ventilation system.

2.34 Some of the substances that may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH 40 published annually by the Health and Safety Executive. These limits are a statutory maxima and should not be regarded as representing a safe working exposure. Employers have a legal obligation to ensure that exposure is reduced as far as reasonably practicable.

2.35 The WD, including any special ventilation equipment necessary for its safe operation, will be subject to the COSHH Regulations. These Regulations also include control of biological agents. This is of particular relevance to the operation of WDs which are commonly used to process items that may be heavily contaminated with pathogenic micro-organisms.

NOTE: Detailed guidance on ventilation systems is provided in SHTM 2025.

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Summary of management responsibilities

2.36 SHTM 2030 will assist managers and other personnel to ensure that WDs are operated safely and effectively and in compliance with existing and anticipated legislation and standards. To this end, the major responsibilities of management can be summarised as follows:

a. to ensure that washing and disinfection are carried out in compliance with the law and with the policy of the UK health departments;

b. to ensure that all personnel connected with washing and disinfection, whether NHS employees or contract personnel, are suitably qualified and trained for their responsibilities;

c. to ensure that purchased WDs conform to legal requirements, the minimum specifications set out in British and European Standards and any additional requirements of the UK health departments;

d. to ensure that WDs are installed correctly and safely with regard to proper functioning, safety of personnel and environmental protection;

e. to ensure that newly installed WDs are subject to a documented scheme of validation comprising installation checks and tests, commissioning tests and performance qualification tests before they are put into services;

f. to ensure that WDs are subject to a documented scheme of periodic tests at yearly, quarterly, weekly and (in some cases) daily intervals;

g. to ensure that WDs are subject to a documented scheme of preventative maintenance;

h. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice;

i. to ensure that procedures for dealing with malfunctions, accidents and dangerous occurrences are documented and adhered to.

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3. Statutory Requirements

Introduction

3.1 So far as washing and disinfection are concerned, the chief areas of legislation with which managers should be familiar are health and safety, medicinal products and consumer protection including the medical devices regulations.

Health and safety

3.2 The largest body of law with which managers need to be familiar concerns health and safety, in particular the Health and Safety at Work etc Act 1974 (the HSW Act) and its various Regulations.

3.3 The HSW Act and its Regulations require employers to assess the risks to their employees. Attention is drawn to the following hazards which are implicit in the practice of washing and disinfection:

a. the hazard of scalding from escaping steam or water vapour;

b. the high temperatures (up to 100ºC) at which WDs are operated;

c. the toxic properties of chemicals used in certain WDs;

d. the infection hazard associated with the microbial pathogens that may be handled by personnel using certain laboratory WDs;

e. the hazard of infection to patients and staff by the inadvertent release of an infected load due to the failure of a disinfection and quality control process;

f. the hazards associated with the handling of heavy and hot loads while loading and unloading WDs;

g. the hazards associated with high pressure leaks from piping used for transfer of water or chemical agents.

3.4 The guidance given throughout this SHTM is designed to ensure that these hazards are minimised and that washing and disinfection procedures comply with the relevant legislation and established good practice.

Health and Safety at Work etc Act 1974

3.5 The HSW Act sets out the basic legal responsibilities of employers and employees with regard to health and safety at work.

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Management of Health and Safety at Work Regulations 1999

3.6 The Management of Health and Safety at Work Regulations 1999 expand upon the principles of the HSW Act.

3.7 The core of the Regulations is a requirement of employers to make a systematic assessment of the risks to health and safety of their employees and others arising from work activities.

Workplace (Health, Safety and Welfare) Regulations 1992

3.8 The Workplace (Health, Safety and Welfare) Regulations 1992 are designed to ensure that workplaces meet the health, safety and welfare needs of each member of the workforce, including people with disabilities.

3.9 Most of the Regulations deal with the physical requirements of the workplace. Managers concerned with the operation of WDs should pay particular attention to the Regulations on maintenance, ventilation, temperature, lighting, cleanliness, room dimensions and space, floors, doors, and traffic routes.

Provision and Use of Work Equipment Regulations 1998

3.10 The Provision and Use of Work Equipment Regulations 1998 (PUWER) aim to ensure the provision of safe work equipment and its safe use.

3.11 PUWER 1998 replaces the existing Provision and Use of Work Equipment Regulations 1992 and applies to all equipment (including lifting equipment) used at work. PUWER 1992's requirements are carried forward in full but there are important new additions, including a requirement to inspect work equipment where significant risk could result from incorrect installation or relocation; deterioration, or as a result of exceptional circumstances; and to record the results of those inspections (Regulation 6).

Pressure Systems Safety Regulations 2000

3.12 These Regulations apply to steam and compressed air services supplying WDs and to those WDs with a pressurised chamber.

3.13 The Regulations define the duties of the competent person: a person or organisation responsible in law for advising on the scope of a written scheme of examination of a pressure system, drawing up the scheme, certifying the scheme as being suitable, and carrying out examination under the scheme.

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Control of Substances Hazardous to Health Regulations 1999

3.14 The Control of Substances Hazardous to Health (COSHH) Regulations 1999 list a number of substances hazardous to health and specify a maximum exposure limit for inhalation, eg. glutaraldehyde.

3.15 The Health and Safety Executive (HSE) publishes an annually updated guidance note on current exposure limits – 'Occupational Exposure Limits (EH40)'.

Until January 1998 an occupational exposure limit for glutaraldehyde had been in force. It has been cancelled and to replace it a Maximum exposure limit (MEL) has been set.

This is in the form of a concentration in air. It is illegal to expose people to concentrations of glutaraldehyde in air above this level.

Source: HSE Guidance EH40 Feb 1999.

3.16 Users of WDs should note that a "substance hazardous to health" may include a micro-organism which creates a hazard to the health of any person. Suitable precautions are required when handling items that may be contaminated with pathogenic micro-organisms.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995

3.17 Commonly known as RIDDOR, these Regulations impose duties on persons responsible for the activities of persons at work, and on self-employed persons, to report accidents resulting in death or major injury arising out of or in connection with work, and to report specified dangerous occurrences. They also require certain particulars of accidents at work to be reported both to the Department of Health and also to the Health and Safety Executive, and require records to be kept.

3.18 Some WDs may contain pressure vessels as defined under Part 1 of Schedule 1 (see paragraph 3.12).

3.19 Poisoning by chemical agents, eg. disinfectants, is a reportable disease listed under Schedule 2.

Manual Handling Operations Regulations 1992

3.20 These Regulations require employers to make an ergonomic assessment of all manual handling operations which involve a risk of injury and to reduce the risk as far as is reasonably practicable. Factors to be assessed include the nature of the task, the load, the working environment and individual capability. Reference should also be made to the 'Lifting Operations and Lifting Equipment Regulations' 1998

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3.21 Managers should assess the risks associated with loading and unloading WDs, whether by loading trolleys or by hand. Top-loading WDs can be especially hazardous if lifting equipment is not available. The mass of the load is not the only source of risk; the temperature and other factors should be taken into account. Risks associated with maintenance and overhauling should also be assessed.

Personal Protective Equipment at Work Regulations 1992

3.22 Managers should assess whether the risks associated with washing and disinfection require the use of personal protective equipment (PPE). Some examples include heat-resistant gloves for use when hot loads are removed from WDs, protective gloves for use when loading contaminated material into WDs, eye or face protection when testing WDs containing pumped fluids and chemical agents, and foot protection for operators loading and unloading WDs.

Consumer protection

3.23 In recent years new legislation has been introduced affording protection to persons who may be harmed by unsafe goods supplied to them. In certain circumstances this may include products from WDs.

Consumer Protection Act 1987

3.24 Part 1 implements EU Council Directive 85/374/EEC (the Product Liability Directive) providing for compensation to be paid to persons injured by a defective product. Under the Act a product is defective “if the safety of the products is not such as persons generally are entitled to expect”, taking the circumstances into account. It is likely that civil action for damages could be taken against a hospital for supplying, for example, “disinfected” products that were not in fact disinfected and caused the infection of a patient.

3.25 The Active Implantable Medical Devices Regulations 1992 (SI 1992/3146) and the Medical Devices Regulations 1994 (SI 1994/301) are both issued under the Consumer Protection Act.

Electromagnetic Compatibility Regulations 1992

3.26 The Electromagnetic Compatibility Regulations (SI 1992/2372) (the EMC Regulations) impose requirements concerning the electromagnetic compatibility of most types of electrical and electronic apparatus which must be complied with when such apparatus is to be supplied or taken into service.

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3.27 A WD (and any ancillary equipment) is a “relevant apparatus” within the terms of the Regulations, and will have to meet Standards for emission of and immunity to electromagnetic disturbance. Note that it is an offence not only to supply but also to “take into service” a WD that does not conform to the Regulations.

3.28 The Regulations do not apply to any WD supplied or taken into service in the EU before 28 October 1992. A WD supplied or taken into service in the UK on or before 31 December 1995 is not required to comply with the Regulations provided it complies with the requirements of the Wireless Telegraphy Acts listed in Schedule 1 of the Regulations.

NOTE: Detailed guidance on the application of the EMC Regulations in healthcare premises may be found in SHTM 2014, *Abatement of electrical interference*.

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4. Personnel

Introduction

4.1 This chapter introduces the personnel who share the responsibility for the safe and efficient operation of WDs. It gives guidance on qualifications and training and summarises areas of responsibility.

Training

4.2 It is essential that personnel at all levels should have a sound general knowledge of the principles, design and functions of WDs. They should be trained on those types and models of WD with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, safety of others and general safety. Training given to individuals should be recorded and reviewed regularly.

4.3 Users working in relative isolation should take care to ensure not only that they are trained in the use of WDs in their charge, but also that they are aware of the changing requirements of the law and good practice as outlined in this SHTM.

4.4 Further information is available from the Property Environment Forum Executive and the Authorised Person (Sterilizers).

4.5 Detailed training on a particular model of WD is usually available from the manufacturer, either on site (such as during validation) or by courses at their premises.

Functional responsibility

4.6 There have been profound changes in the management philosophy of the NHS over recent years. With the wide range of circumstances in which a WD may be employed, from a busy sterile services department in a major general hospital to a small clinic, it is not possible to prescribe a universally applicable management structure for washing and disinfection.

4.7 The approach chosen for this SHTM is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual's role in connection with washing and disinfection but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with

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washing and disinfection and in some cases the same individual may take on more than one role.

4.8 In every case, however, it is possible to identify a user who is responsible for the day-to-day management of the WD. The philosophy of this SHTM is to invest the user with the responsibility for seeing that the WD is operated safely and efficiently.

4.9 In cases where steam is generated in a pressure vessel within the WD, the law requires that a competent person (pressure vessels), who is not the user, be designated to exercise certain responsibilities of inspection (see paragraph 4.17).

4.10 For small installations where the user is qualified to perform all required test and maintenance functions, no other personnel may be necessary. However, it is strongly recommended that in all cases the user receives professional advice from a microbiologist, and that maintenance be carried out by a suitable qualified person and a maintenance person with assistance from the microbiologist when microbiological testing is required.

Key personnel

4.11 The following personnel are referred to in this part of SHTM 2030. Further information including qualifications and areas of responsibility can be found in Part 1 of SHTM 2010.

Management

4.12 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the operation of the premises.

4.13 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small autonomous units the user may take on this function.

User

4.14 The user is defined as the person designated by management to be responsible for the management of a WD.

4.15 In a hospital the user could be a sterile services manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager; in primary care he/she could be a general practitioner, dentist or other health professional. When a WD is used to process equipment or containers for use in the preparation of medicinal products the user is normally the production manager in charge of the manufacturing process.

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4.16 The principal responsibilities of the user are as follows:

a. to certify that the WD is fit for use;

b. to hold all documentation relating to the WD;

c. to ensure that the WD is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records.

Competent Person (Pressure vessels)

4.17 The competent person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the 'Pressure Systems Safety Regulations 2000'. The shorter term "competent person" is used in this SHTM.

4.18 The following guidance on the qualifications for the competent person is based on the HSC Approved Code of Practice, Safety of Pressure Systems:

a. where required to draw up or certify schemes of examination, the competent person should be qualified at least to technician engineer level, with adequate relevant experience and knowledge of the law, codes of practice, examination and inspection techniques and understanding of the effects of operation of the pressure vessel concerned. He or she must have established access to basic design and plant operation advice, materials engineering and non-destructive testing (NDT) facilities. The competent person must have sufficient organisation to ensure a reasonable data storage and retrieval system with ready access to relevant laws, technical standards and codes;

b. where required to carry out examinations, the competent person should have sufficient practical and theoretical knowledge and actual experience of the type of pressure vessel which is to be examined to enable defects or weaknesses to be detected and their importance in relation to the integrity and safety of the WD to be assessed.

4.19 The principal duties of the competent person under the Regulations are as follows (they need not all be exercised by the same individual):

a. advising on the scope of the written scheme of examination;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

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4.20 Most insurance companies maintain a technical division able to advise on appointing a competent person. Advice may also be obtained from Scottish Healthcare Supplies, Trinity Park House, Edinburgh.

Test Person (Washer-disinfectors)

4.21 The test person (washer-disinfectors) is defined as a person designated by management to carry out validation of washer-disinfectors and to provide advice on testing, maintenance and procedures. The shorter terms test person or TP are used in this SHTM. The test person should either:

a. be a Test Person (Sterilizers) (see SHTM 2010 for a definition of this role);

b. be qualified to at least HNC level in engineering or relevant sciences and have at least two years experience in the validation of washer-disinfector processes; or

c. should have received appropriate documented training, and been assessed as technically competent to act as test person (washer-disinfectors). This person will normally have at least three years experience in the maintenance of washer-disinfectors processes.

4.22 The principal responsibilities of the TP are as follows:

a. to advise on programmes of periodic testing and periodic maintenance of WDs;

b. to advise on operational procedures for routine production;

c. to conduct the validation test specified in SHTM 2030 Part 3, ‘Validation and verification’ and to prepare the validation report;

d. to conduct the periodic tests specified in SHTM 2030 Part 3, ‘Validation and verification’ and to prepare reports as required by the user;

e. to conduct any additional tests at the request of the user.

Maintenance Person (Washer-disinfectors)

4.23 The Maintenance Person (washer-disinfectors) is defined as a person designated by management to carry out maintenance duties on washer-disinfectors. The shorter terms maintenance person or MP are used in this SHTM.

4.24 The Maintenance Person should be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of washer-disinfector. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.

4.25 The principle responsibilities of the Maintenance Person are as follows:

a. to carry out the maintenance tasks outlined in this part of SHTM 2030;

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b. to carry out additional maintenance and repair work at the request of the user.

4.26 A Maintenance Person who has a minimum of 5 years experience in the maintenance of washer-disinfectors may, by agreement, perform the duties of the Test Person for the daily, weekly and quarterly tests described in SHTM 2030 Part 3, 'Validation and verification'.

Microbiologist

4.27 The microbiologist is defined as a person designated by management to be responsible for advising the user on microbiological aspects of disinfection.

4.28 The microbiologist should have a degree in microbiology and will normally be a member of the hospital staff.

4.29 The principle responsibilities of the microbiologist are as follows:

a. to provide general and impartial advice on all matters concerned with washing and disinfection;

b. to advise the user on the microbiological aspects of all disinfection procedures;

c. to arrange for the culturing of biological indicators used in microbiological tests;

d. to audit the documentation from all washer-disinfectors which have been tested by microbiological methods.

Control of Infection Officer

4.30 The Control of Infection Officer is defined as the person designated by management to be responsible for advising the user on all infection control aspects.

Production Manager

4.31 The Production Manager is defined as a person designated by management to be responsible for production of medicinal products and medical devices.

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Quality Controller

4.32 The Quality Controller is defined as a person designated by management to be responsible for quality control of medicinal products and/or medical devices with the authority to establish, verify and implement all quality control and quality assurance procedures.

Laboratory Safety Officer

4.33 The Laboratory Safety Officer is defined as a person designated by management to be responsible for all aspects of laboratory safety in respect of equipment, maintenance, personnel and training relating to safety issues, and to ensure compliance with safety legislation and guidelines.

Operator

4.34 An operator is defined as a person, designated by management, with the authority to operate a WD. Their duties may include the noting of WD instrument readings, replenishment of consumable items, such as detergent, and simple housekeeping duties.

Manufacturer

4.35 The manufacturer is defined as a person or organisation responsible for the manufacture of a WD.

Contractor

4.36 The contractor is defined as a person or organisation designated by management to be responsible for the supply and installation of the WD, and for carrying out the installation checks and tests. The contractor is usually the manufacturer of the WD.

Purchaser

4.37 The purchaser is defined as the person or organisation who orders the WD and is responsible for paying for it.

Independent Advisor

4.38 The Independent Advisor is defined as a person who may or may not be registered as an AP(sterilizers), but can demonstrate to the satisfaction of management previous training and experience appropriate to carry out the designated tasks in respect of WDs as the AP(S) would carry out in respect of sterilizers. AP(S) is a suitable person to carry out the functions of an independent advisor. The principle responsibilities of the Independent Advisor are, independent advice on WDs and audit review of WD documentation.

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5. Operational management: an overview

Introduction

5.1 It is important that all WDs are effective in achieving the performance required to produce clean and disinfected products, and that they are safe in operation.

5.2 Failure to achieve the required standard of cleanliness may also impair the capability of the process to achieve disinfection and/or subsequent sterilization.

5.3 The cleanliness and microbial safety of all products processed in a WD is ultimately dependent upon the care taken by the personnel responsible for its design, manufacture, installation, operation, test and maintenance.

5.4 Washing and disinfection may appear to be relatively simple processes, but considerable care is needed to consistently achieve satisfactory results. The quality and safety of the product obtained from a WD ultimately depends upon the vigilance of skilful personnel fully trained in the operation of WDs.

5.5 Responsibility for assurance on these points rests variously with the TP, the MP, the microbiologist, the control of infection officer, and the user.

Maintenance

5.6 Decontamination processes are among those processes which have to be validated before use. In consequence the performance of the process has to be routinely monitored (see SHTM 2030 Part 3, ‘Validation and verification’) and the equipment has to be maintained in good working order.

5.7 The maintenance of WDs should, therefore, meet the following requirements:

a. preventive maintenance should be planned and performed in accordance with documented procedures;

b. the procedure for each planned task, and the frequency at which it is carried out, should be specified and documented;

c. the WD should not be used to process contaminated loads until all maintenance tasks have been satisfactorily completed and recorded;

d. records of maintenance should be retained as specified in BS EN ISO 9001: 1994 or BS EN ISO 9002: 1994;

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e. the maintenance scheme, maintenance procedures and maintenance records should be reviewed periodically by a designated person who should be appropriately qualified and experienced.

Safety precautions

5.8 Whether products which have been processed in a WD are safe to handle and/or use, as appropriate, is ultimately dependent on the vigilance of all personnel responsible for its operation.

5.9 Effective decontamination necessitates, in many cases, complex operating cycles. Protection is provided, in the first instance, by fail-safe design principles some of which also serve to protect the product by indicating when an ineffective operating cycle has occurred.

5.10 However fool-proof the design, any safety device can be defeated ultimately, either wantonly or accidentally. To ensure that this does not occur requires the continuing vigilance of skilful personnel fully trained in the operation of WDs.

5.11 Some WDs are only intended to perform an initial step in the reprocessing of soiled re-usable items. Care should be taken to ensure that items which have been cleaned and disinfected in a WD are, when necessary, subjected to terminal sterilization prior to their use on patients.

5.12 To prevent the hazard of burning or scalding the door should be interlocked to prevent it being opened in mid-cycle. In the event of a fault there may be an escape of hot water vapour when the door is opened or hot water (up to 93°C) may be retained within the chamber and load.

5.13 Washing is a wet process and water dropping on to the floor can create a serious hazard of slipping and falling for personnel. Any leaks should receive urgent attention from maintenance staff and any spillages should be cleaned up as soon as possible.

Management should have a safety policy to deal with spillages which considers both the chemical and microbiological hazards that may be posed.

A copy of the documented procedures to deal with spillages should be available in the vicinity of each WD. The user, and all operators who may use the WD, should be trained in the implementation of these procedures.

5.14 Overloading load baskets, and/or load carriers, can cause a hazard and will also impair the efficacy of the disinfection process. Operators and maintenance personnel should ensure that the loading does not exceed the manufacturer’s stated capacity for the loading accessories in use.

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5.15 Detergents and other additives are, or may be, caustic and can cause adverse effects to exposed tissues; operators and maintenance personnel should wear protective gloves, a face shield and water-proof clothing whenever handling chemical additives or servicing the injection pumps or pipework. Contact with the eyes and skin or ingestion of chemical additives should be avoided.

5.16 Operators and maintenance personnel should read and follow the precautions and instructions given in the material safety data sheet and on the label prior to handling any chemical additive, refilling the container or servicing the injection pump and pipework.

All staff who may be exposed to contamination by any chemical additive should be trained in the action they should take to minimise harm to themselves and others in the vicinity. This will include: first aid; alerting emergency services if necessary; methods for cleaning and decontaminating the affected area; and the correct disposal of the materials used. There should be a written procedure detailing the actions to be taken in the event of spillages and contamination of personnel.

NOTE: The training should be part of a documented programme and should include periodic assessment and retraining.

5.17 Any equipment issued to operators should comply with the 'Provision and Use of Work Equipment Regulations (1998)'.

5.18 Operators and maintenance personnel should be issued with appropriate personal protective equipment (PPE) complying with the 'Personal Protective Equipment at Work Regulations (1992)'. In providing protection against, or minimising the risks from, hazards to health and safety priority should be given to engineering controls and safe systems of work; PPE should always be regarded as a last resort.

Equipment damage

5.19 The user should ensure that chemical additives used in the decontamination process are compatible with the materials of which the WD is constructed and also with the items to be processed.

5.20 Most WDs are made partly or wholly of stainless steel; the water supplied to the chamber, and the detergent and other chemical additives used, should have a low chloride content to minimise the risk of corrosion.

5.21 Lubricants for squeeze tubes on peristaltic pumps and other dispensing devices should be chosen and used in accordance with the manufacturer's instructions.

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NOTE: In the absence of specific instructions silicone-based lubricants should always be used since petroleum-based lubricants can cause serious damage to many types of plastic tube.

5.22 Care should be taken to ensure that the walls of ultrasonic tanks are not scratched as this can cause serious cavitation erosion.

5.23 Operators should be instructed never to drop or rest load items directly on the bottom of an ultrasonic tank.

Performance qualification

5.24 New load items should not be processed until:

a. performance qualification (PQ) tests as specified in SHTM 2030 Part 3, 'Validation and verification' have been conducted by the TP to the satisfaction of the user and the independent advisor; or

b. the user is satisfied that the new load item is represented by one of the existing loading conditions/process cycles for which a PQ report exists; or

c. the instructions from the manufacturer of the item are sufficiently detailed and specific that the appropriateness of the proposed treatment is readily apparent.

5.25 The user, in consultation with the manufacturer(s) of the load items, the Independent Advisor and the control of infection officer as necessary, should ensure that the load is suitable for the process to which it is to be exposed. This should include consideration of the compatibility of all process chemicals used.

5.26 The process selected will depend on the nature of the load and its ability to withstand the environmental conditions present during the operating cycle. The rates of change of cycle variables, such as temperature and pressure, may also need to be considered.

5.27 Before selecting a process it may be necessary to carry out preliminary tests on the product, or on a surrogate product, to determine both the levels and rates of change of the cycle variables necessary to achieve the required result and to determine which can be tolerated by the product without causing unacceptable changes in its performance.

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Loading

5.28 The user should ensure that each load is presented to the process in accordance with documented procedures established and tested during PQ.

5.29 Overloaded baskets or load carriers will result in inefficient cleaning and disinfection.

5.30 Cannulated load items, which are intended to be connected to spigots on the load carrier to ensure flushing of the lumen, will not be adequately cleaned and disinfected if they are not properly connected.

5.31 Small and light items should be secured with a hold-down screen or by other means; if they are free to move around there is a serious risk of damage to the instruments. Small sharp instruments which have moved within the load may also represent a hazard to staff who have to subsequently handle the load.

5.32 Load carriers should only be used with the items for which they were intended.

Documentation

5.33 When the WD is used to process medical devices, other than sanitary appliances, intended for use on a patient without further processing, eg. sterilization, each production cycle should be fully documented. The user should ensure that the records are kept securely.

Cycles which were aborted, for whatever reason, should also be noted along with the remedial action taken.

NOTE: Further guidance is given in subsequent chapters on WDs for particular applications.

5.34 Operators should be encouraged to note and report any indication that the WD may not be working as expected.

5.35 A process log should be kept for those products, other than human-waste containers, which will be used without being subjected to further processing (eg. sterilization). This will include items such as anaesthetic accessories and some fibre-optic endoscopes.

5.36 If in doubt as to whether records are required, and if so which records are necessary, the user should consult the Independent Advisor.

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Post-decontamination inspection and release for further processing

5.37 The user in consultation with the Independent Advisor should establish and document procedures to ensure that loads are not released for use or further processing, eg. sterilization, until the user is satisfied:

a. that the disinfection stage of the process has been reproduced within the permitted tolerances established during commissioning and PQ; and

b. that the cleaning stage of the process has been reproduced within the permitted tolerances established; and/or

c. that visual inspection of the load shows that an acceptable standard of cleanliness has been obtained.

5.38 The procedures should ensure that:

a. the load has been correctly positioned in the loading basket and/or on the load carrier;

b. that the settings for the operating cycle are in accordance with the specification for that load type;

c. that the instrument/indicator readings and/or chart record for the cycle conforms with the data established during validation within the permitted tolerances;

d. that the decontaminated load shows no obvious defects – such as damage, residual soiling or staining – which may suggest a faulty operating cycle.

5.39 Whenever an operator has cause to suspect that the load may not have been properly disinfected the load must not be released. The user should be informed immediately.

5.40 A small percentage of load items which remain soiled after processing may not be sufficient cause to reject the entire load. The rejected items should be returned for reprocessing. However, the cause of the failure to clean all the items in the load should be investigated.

NOTE: This may be due to improper loading or items which were exceptionally heavily soiled or for which decontamination was unavoidably delayed.

5.41 Documented procedures for reprocessing rejected loads should be agreed between the user and the Independent Advisor. The method by which rejected loads are returned for reprocessing should be chosen to ensure that product flow in a controlled environment is not compromised.

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5.42 For loads which are to be used in connection with the manufacture of medicinal products the quality controller will establish the procedures for product release.

5.43 After decontamination and before release of the product for use or further processing, as appropriate, the conditions for storage and handling should not compromise the cleanliness or freedom from microbial contamination of the product.

5.44 When a single-door WD is in use a system to clearly differentiate between processed and unprocessed loads may be required.

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6. Maintenance

Introduction

6.1 Disinfection, and to a great extent, cleaning are processes whose efficacy cannot be verified retrospectively by inspection or testing of the product before use. For this reason decontamination processes (cleaning and disinfection and/or sterilization) have to be validated before use, the performance of the process routinely monitored, and the equipment maintained.

6.2 Means of ensuring that a WD is fit for its intended purpose will include the validation and testing programme specified in SHTM 2030 Part 3, 'Validation and verification', and also the programme of planned maintenance as described in this chapter.

6.3 The philosophy of maintenance and testing embodies two main principles to ensure that the required standards of performance and safety are met and maintained:

a. all WDs are subject to a carefully planned programme of tests to monitor their performance;

b. all WDs are subjected to a planned programme of preventive maintenance.

Expertise on the maintenance of WDs is available at two levels, the MP/TP and the Independent Advisor.

Testing of WDs is dealt with in SHTM 2030 Part 3, 'Validation and verification'.

Planned maintenance (PM) programme

Design of a PM programme

6.4 The PM programme recommended by the manufacturer should be used when it is available. The maintenance programme may be modified subsequently to take account of equipment use, equipment history and local conditions after a suitable period of operational experience.

If no PM programme is available from the manufacturer a maintenance programme should be drawn up in consultation with the Independent Advisor and MP/TP.

6.5 A set of procedures should be developed for each model of WD, each containing full instructions for a particular maintenance task.

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6.6 The frequency with which each task will need to be carried out will depend, in part, on the usage level for the WD and also on the quality of the water supplied to the WD. It may be necessary to adjust the programme so that work is carried out more frequently on WDs which are heavily used and/or are supplied with hard water.

6.7 It is important that maintenance is planned so that the WD is out of service as little as possible.

6.8 Systematic records should be kept of all maintenance work undertaken both to demonstrate that the work has been carried out and also to facilitate periodic review of the PM programme.

Maintenance and facilities management software packages (eg. WIMS) may be used to maintain a full technical and financial history of the equipment.

Warranty period

6.9 After the purchase of a new WD the manufacturer may carry out certain inspection and maintenance procedures under the terms of the warranty. This may not be a full PM programme. The user should ensure that the complete PM programme is carried out by the MP during the warranty period.

6.10 The user should also comply with any reasonable instructions from the manufacturer during the warranty period.

Review of a PM programme

6.11 The PM programme should be reviewed at least annually to ensure that the equipment is being fully maintained but without any unnecessary maintenance activity.

6.12 The review should aim to identify:

a. the adequacy of maintenance records and compliance with the PM programme;
b. any emerging defects;
c. any changes required to the PM programme;
d. any changes required to any maintenance procedure;
e. any additional training required by maintenance personnel.

6.13 Proposed changes to the PM programme should be made in consultation with the WD manufacturer whenever possible.

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Routine housekeeping

6.14 Certain maintenance tasks may be carried out by the user, or by the operator under the user's supervision, and should be recorded in the WD log.

6.15 Examples of such tasks include:

a. checking that the rotating spray arms are free to rotate;

b. checking that nozzles are not blocked;

c. removal and cleaning of strainers and filters;

d. checking that the supply of chemical additives is sufficient for the day's use and replenishing if necessary;

e. cleaning the inside of the chamber;

f. cleaning the external surfaces of the WD and washing of loading side conveyors and trolleys;

g. for WDs with a built-in water softener, checking the level of salt in the regeneration tank and replenishing if necessary.

Overhauls

6.16 The user should arrange for each WD to receive periodic overhauls. For WDs which incorporate a pressure vessel this should be timed to precede the examination of the pressure vessel by the competent person and the yearly tests.

6.17 Improvements and modifications recommended by the WD manufacturer should be reviewed and considered for implementation before each overhaul.

6.18 The overhauls, and any necessary inspections, should be scheduled so that in any particular installation only one machine needs to be withdrawn from service at a time.

Inspection of pressure vessels

6.19 Under the 'Pressure Systems Safety Regulations 2000' all WDs which incorporate pressure vessels are subject to a periodic inspection by a competent person (see paragraph 3.13).

6.20 The Independent Advisor will advise on the application of the Regulations to any particular installation.

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6.21 The competent person has five principal duties under the Regulations:

a. advising on the scope of the written scheme of examination;
b. drawing up the written scheme of examination or certifying the scheme as being suitable;
c. carrying out examinations in accordance with the written scheme;
d. assessing the results of the examinations;
e. reviewing the written scheme of examination for its suitability.

6.22 The user should liaise closely with the competent person to ensure that the written scheme of examination is accommodated within the maintenance and testing programmes.

6.23 The competent person may require certain examinations to be carried out more frequently than recommended by the manufacturer.

6.24 Each written scheme of examination should specify detailed procedures for, and the frequency of, examination and should be regularly reviewed and updated.

Features requiring special attention

Steam generators

6.25 Steam generators, provided as an integral part of some WDs, are steam boilers and they should be subject to a written scheme of examination for pressure vessels.

6.26 Steam generators constructed from stainless steel will be subject to the risk of stress corrosion cracking. To minimize the risk the manufacturer's guidance on feedwater quality should be followed.

Stainless steel chambers

6.27 Stainless steel is used in the manufacture of many WD chambers. Over a wide range of specifications, stainless steels are susceptible to cracking from crevice corrosion and from stress corrosion initiated by chemical attack.

Leak tightness of doors

6.28 The door(s) of the WD are intended to prevent the escape of fluids into the surrounding environment, ie. to ensure freedom from aerosols which may be potentially infectious in the work place.

6.29 Damaged door seals are the major potential source of leaks and should receive careful attention as advised by the manufacturer.

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6.30 The working life of door seals may be prolonged by regular cleaning.

6.31 Door seals should be renewed with spares provided, or approved, by the manufacturer at recommended intervals or when there is any sign of damage/deterioration.

Door interlocks

6.32 The interlocks on door(s) of the WD are intended to:

a. prevent the operator gaining access to the load during processing;

b. prevent both the loading and unloading doors being open at the same time on “pass-through” WDs;

c. prevent the operator gaining direct access to a load that has not been satisfactorily processed.

6.33 Maintenance and inspection of door safety devices and door interlocks should be carried out in accordance with the WD manufacturer’s written instructions.

6.34 Security and settings of door safety switches and interlocks should be checked at least monthly. The setting should be within the limits specified by the manufacturer.

Chemical dosing systems

6.35 Admission of the correct amount of chemical additive at the right time in the operating cycle is essential to the correct functioning of a WD. The chemical additive dosing system should be subjected to regular (at least monthly) inspection, maintenance and test. This should include:

a. visual inspection of all piping to ensure freedom from leaks;

b. visual inspection and/or testing to determine whether the delivery or pick-up piping is blocked by coagulated or hardened chemical additive (many of the chemical additives used are a viscous suspension) – and cleaning or replacing piping as necessary;

c. lubrication of the pinch tubing on peristaltic pumps in accordance with the manufacturer’s instructions;

d. verification that the volume dispensed is within the specified limits.

Water sprays and jets

6.36 The correct flow and distribution of water and aqueous solutions throughout the chamber and load are essential to the correct functioning of a WD. The spray system should be checked on a daily basis as part of the routine housekeeping tasks carried out by the user.

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In addition maintenance staff should also check the system at least weekly; this should include:

a. checking that the rotating spray arms, both installed within the chamber and located on load carriers, are free to rotate;

b. checking that nozzles are not blocked – clean and/or replace if necessary;

c. checking for wear in bearings of rotating parts – replace any worn parts as necessary;

d. checking the mating of any necessary connection between the load carrier and the water supply in the chamber.

Ultrasonic transducers

6.37 Many ultrasonic cleaners are not fitted with means to provide continuous monitoring of performance. Transducers can fail or become detached from the ultrasonic tank without being noticed by the operator (other than by the deterioration in the cleaning performance).

6.38 Periodic functional testing of ultrasonic cleaners is described in SHTM 2030 Part 3, ‘Validation and verification’.

6.39 The tank of the ultrasonic cleaner should be cleaned with a suitable neutral detergent and soft brush at least weekly.

Instruments

6.40 Each instrument fitted to WDs should be maintained and calibrated in accordance with the manufacturer’s instructions. Any instrument which is reading incorrectly or inconsistently should be repaired by the manufacturer, or scrapped if it is not economical to repair.

6.41 Instruments which are consistent in their readings but are slightly inaccurate compared with a reference instrument should be checked for zero and span and then adjusted to work correctly at the value of interest, eg. at the normal working temperature.

6.42 An instrument case should never be left open and any broken glass should be replaced promptly.

6.43 Temperature measuring systems are subject to both inherent errors and to loss of calibration with use. Temperatures read from an indicator or recorder should be treated with caution and interpreted in the light of the established characteristics of the particular measuring system, the load and data from previous cycles.

6.44 Temperature recorders should be used to record the attainment of thermal disinfection conditions for all critical applications.

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6.45 The absolute minimum intervention should be made to recording systems which are functioning correctly. Any adjustments should be strictly in accordance with the manufacturer's instructions.

6.46 Persons who change charts, print rolls and other consumables on recording instruments should be authorised to do so by the user. They should be fully trained and should be aware of the delicate nature of the instruments.

Water treatment plant

6.47 The correct functioning of water treatment plant incorporated in, or otherwise supplying, a WD is essential to maintaining the required cleaning performance.

6.48 The system should be inspected periodically to ensure that it is free from leaks.

6.49 The quality of water supplied should be verified by testing at weekly intervals for a period of three months following commissioning or major repair/overhaul of the water treatment system. At the discretion of the Independent Advisor and the microbiologist, the frequency of testing may be reduced to monthly intervals after three months of satisfactory weekly test results.

6.50 For water supplied from a de-ioniser or reverse osmosis plant this should include checking the pH and the conductivity to verify that these remain within specified limits.

6.51 When a water softener is used the water supply should be tested for hardness to ensure it remains below the specified maximum concentration of calcium salts.

6.52 Water intended for use as the final rinse water on items to be used invasively on patients or in the production of parenteral medicinal products should be tested for the presence of bacterial endotoxins.

6.53 Water intended for use as the final rinse water after a chemical disinfection process for load items which will not then be sterilized should be tested both for the presence of bacterial endotoxins and for total viable microbial count.

Ventilation plant

6.54 Correct operation of ventilation plant is essential to ensure:

a. the safe operation of WDs which include a chemical disinfection stage;
b. the efficient operation of the drying stage (where this is included);
c. the maintenance of a comfortable working environment.

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6.55 All ventilation systems associated with a WD should be inspected, serviced and maintained at least every six months. Guidance on maintenance is given in SHTM 2025.

6.56 WDs which include a chemical disinfection stage should have the associated ventilation system examined and tested annually.

6.57 Before undertaking maintenance work on the cabinet, or its associated ventilation system, it may need to be decontaminated and the advice of the designated safety officer should be sought. A permit-to-work system should be in operation.

Returning a washer-disinfector to service

6.58 Whenever any work has been carried out on a WD, whether or not this was part of the PM programme, the user should be satisfied that it is fit for use. Following major repairs, overhauls etc. which may affect the performance of the WD the user and Independent Advisor should draw up a schedule of checks and tests to be carried out before the WD is returned to service. This should include some or all of the recommissioning (yearly) tests specified in SHTM 2030 Part 3, ‘Validation and verification’.

Trouble-shooting

6.59 A failure to clean all the items processed in a load through a WD is the most frequently observed fault. The most common causes of this type of failure, and thus those which should be considered first in any investigation, are:

a. Incorrect loading:
   (i) items which are not correctly located in an appropriate load carrier will not be subjected to the intended washing process;
   (ii) overloaded baskets and load carriers will allow some load items to shield others from spray jets etc;
   (iii) hinged instruments which are not opened prior to washing will not be effectively cleaned.

b. Blocked spray jets, spray arms that are not free to rotate, or a blocked strainer in the chamber base.

c. Soiled instruments which have been stored for prolonged periods before decontamination – blood and protein will coagulate if stored for more than eight hours making this hard to remove.

d. Soiled instruments subjected to heat treatment before decontamination – this will lead to coagulation of blood and protein making this hard to remove.

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e. Incorrect choice or quantity of detergent:

   (i) the detergent chosen must be compatible with the loads to be processed, the soil to be removed and the quality of water supplied;

   (ii) malfunction of the dosing system may cause the wrong quantity of chemical additive to be used – too little will not provide the detergency required but too much may also impair cleaning by causing excessive foaming etc.

f. Inappropriate water quality:

   (i) initial flush with water which is too hot will lead to coagulation of blood and protein making this hard to remove;

   (ii) the hardness of water used during washing must be compatible with the detergent chosen;

   (iii) hard water used in the final rinse will leave deposits on the surface of instruments.

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7. Water disinfectors for human-waste containers

Introduction

7.1 This type of WD is used to empty, clean and disinfect human-waste containers (eg. bedpans, urine bottles, suction jars); both those which are not required to be sterile, eg. bedpans (but are required to be disinfected), as well as those which subsequently may be subjected to sterilization, eg. suction bottles.

7.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

7.3 The key requirement for WDs of this type is the safe emptying of the human waste (faeces, urine, blood etc.) and the effective cleaning and disinfection of the items for re-use.

7.4 Two distinctly separate types of WD are used for this purpose: a flusher-disinfector in which cleaning is achieved by the physical action of jets of water and no detergent is used (although a de-scaling agent may be used); and a WD which incorporates a detergent washing stage.

Safety precautions

7.5 The area in which the WD is located should be provided with appropriate equipment to deal with spillage from the containers during transfer to the WD (see paragraph 5.13).

7.6 At the end of the operating cycle the washed and disinfected containers may be too hot to handle without protective gloves; containers may also retain significant volumes of hot water with the attendant risks of scalding. Operators should be trained in the use of the WD and should be provided with appropriate protective clothing.

7.7 Many of the chemical additives used as anti-scaling agents are toxic, irritant and corrosive. They are potentially hazardous and require careful handling and secure storage (see paragraphs 5.15 and 5.16).

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Load handling/presentation

7.8 Load carriers are designed for particular types of containers; if it is intended to process a different container the manufacturer's advice on an appropriate load carrier should be sought.

7.9 The use of an inappropriate load carrier may prevent safe emptying of the container and may not permit effective cleaning and disinfection to take place.

7.10 Most WDs for human-waste containers are single-door machines; the area in which they are located should provide facilities for the segregation of containers awaiting processing and those that have been processed. These areas should be maintained in a good state of repair to facilitate the frequent cleaning which is required.

Selection of cycle variables and chemical agents

7.11 WDs which are connected to a hard water supply may need to include the use of a de-scaling agent to prevent the build-up of lime-scale on the containers being processed.

NOTE: A lime-scale deposit on the containers is not only unsightly but also makes the container more difficult to clean.

7.12 WDs for human-waste containers may be provided with a drying stage but this is rarely used for ward installations.

7.13 The operating cycle may combine the disinfection stage with the final rinse leaving the containers at high temperature at the end of the cycle. The operator should be provided with insulated gloves to allow safe removal of these hot items; being hot any residual moisture evaporates very quickly.

7.14 An option to use a cold final rinse, after disinfection, may be employed to facilitate the safe removal of the containers which will usually then require manual drying before use.

Cycle monitoring

7.15 The WD should be provided with either a temperature recorder to monitor and record the temperature attained during the disinfection stage or an indication from the automatic controller that the specified temperature was maintained for the specified time during the disinfection stage.

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Product release

7.16 Before a product is released for re-use the operator should verify the successful completion of the disinfection stage and visually inspect each load item for cleanliness.

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8. Washer-disinfectors for anaesthetic accessories

Introduction

8.1 This type of WD is used to process anaesthetic and respiratory accessories; both those which are not required to be sterile (but are required to be disinfected) as well as those which will be subject to further processing, eg. sterilization.

8.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

8.3 The key requirement for WDs of this type is the circulation of water (and/or other aqueous solutions), used for washing, and hot air, used for drying, through the lumen of hollow items.

8.4 The facility to process anaesthetic accessories may be provided by a dedicated load carrier using a WD for instruments (see Chapter 9). A separate drying cabinet is often advantageous when a dedicated load carrier is used in a WD for instruments. Drying times for anaesthetic accessories are much greater than for instruments and the use of a separate drying cabinet improves the overall throughput of the WD.

8.5 WDs for anaesthetic accessories may incorporate a drying stage in the automatic process or there may be a separate drying cabinet.

Product compatibility

8.6 The instructions of the manufacturers of the anaesthetic accessories should be followed regarding the suitability of the various items for processing in a WD for anaesthetic accessories.

8.7 A neutral detergent or washing without a detergent may be necessary for some products, eg. laryngeal masks made of silicone rubber.

8.8 The maximum temperature attained during disinfection and drying may need to be controlled to minimise the oxidative degradation of rubber materials.

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Load handling/presentation

8.9 The use of a load carrier specifically intended for anaesthetic accessories is essential.

8.10 Items with a lumen should be placed over, or connected to, the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumen during processing.

8.11 Items such as breathing bags and sets and self-inflating resuscitator sets (including valves) may need to be dismantled before being placed in an appropriate load carrier.

8.12 Other items such as Magill forceps and tubing clamps can be decontaminated in a WD for instruments (see Chapter 9).

Selection of cycle variables and chemical agents

8.13 An initial flush (pre-rinse) assists the removal of mucous, blood and other body fluids before washing commences. The water should be at a low temperature to avoid coagulation of proteinaceous material. Organic matter not loosened by the flushing stage may become coagulated during, and not be removed by, the wash cycle.

8.14 Anaesthetic accessories made from plastic may need to be washed, disinfected and dried at temperatures lower than those normally used for instruments and utensils.

8.15 The operating temperature for the drier is a balance between the speed of drying and the longevity of anaesthetic accessories made of rubber.

8.16 The importance of an effective drying stage cannot be over emphasised. Items which are left wet or damp will rapidly become re-colonised with micro-organisms.

8.17 The compatibility of all materials and items to be processed should be established by reference to the manufacturer's instructions, or when necessary by appropriate performance qualification testing.

Cycle monitoring

8.18 WDs used to disinfect anaesthetic accessories intended for re-use without further processing should be equipped with a temperature recorder, independent of the automatic controller, to monitor and record the temperature attained during the disinfection stage.

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8.19 It is desirable that they should be equipped with means of monitoring, directly or indirectly, the flow of water during the flushing and washing stages and the flow of air during the drying stage.

Product release

8.20 Before anaesthetic accessories intended for re-use without further processing are released the recorded cycle variables should be checked to ensure that they are within acceptable limits for the process.

8.21 The load items should be inspected for cleanliness and dryness and to ensure that there are no signs of physical deterioration. For complex items, eg. valves, consideration should be given to function testing using a medical grade compressed air supply.

8.22 Items for use without further re-processing should be packaged to protect them from adventitious contamination.

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9. Washer-disinfectors for instruments and utensils

Introduction

9.1 This type of WD is used to process surgical instruments, instrument trays and re-usable containers and hollowware.

9.2 Disinfection is achieved by direct contact of the load with water, or steam at a pressure near to atmospheric pressure, to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

Safety precautions

9.3 At the end of the operating cycle the washed and disinfected load may be too hot to handle without using protective gloves; bowls and receivers (particularly those made of polypropylene) may also retain significant volumes of hot water with the attendant risks of scalding. Operators should be trained in the use of the WD and provided with appropriate protective clothing (see paragraph 5.18).

9.4 Many of the chemical additives used are toxic, irritant and corrosive. They may be hazardous and will require careful handling and secure storage (see paragraphs 5.15 and 5.16).

9.5 A written procedure should be available for the filling or connection of all chemical additive containers. Staff whose duties include this task should receive formal training.

9.6 Adequate protective clothing, washing and eye washing facilities should be provided. Appropriate hazard labels should be displayed in the vicinity of use.

9.7 When the chemical additive(s) used has a volatile component the measurement of environmental concentrations may be necessary both during commissioning and as periodic routine checks.

9.8 During loading there should be minimal handling of contaminated instruments and equipment. Staff should be trained in the appropriate procedures and provided with suitable protective equipment including gloves and eye protection.

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9.9 Before transferring instruments to the WD operators should carefully check the returned instrument trays for hazardous items, eg. scalpel handles with the blade left attached. When present, hazardous items should be carefully removed using, if necessary, handling equipment such as forceps or cheatals.

9.10 Operators should dispose of any sharps found into a sharps disposal container complying with BS 7320:1990.

Product compatibility

9.11 The compatibility of all materials and items to be processed should be established by reference to the manufacturers' instructions, or when necessary by appropriate performance qualification testing.

9.12 Factors to be considered in determining the compatibility of the load to the WD process include, but are not necessarily limited to:

a. whether or not the load can be immersed in water;

b. the availability of an appropriate load carrier;

c. the maximum operating temperature (this will usually occur during the thermal disinfection or drying stages);

d. the internal pressure to which the lumen of a cannulated instrument may be subjected;

e. the mechanical damage which may occur from the impact of water jets or other items in the load;

f. the compatibility of chemical additives used – both with the instrument itself and in combination with other load items (when acidic chemical additives are used metal items of different composition in the same load may be subject to electrolytic corrosion).

Load handling/presentation

9.13 Load carriers specific to the type of load should be used to ensure that all surfaces to be cleaned and disinfected will be exposed to the action of the water jets, will not be dislodged by the water jets and will drain freely.

9.14 For single-door machines facilities to allow segregation of the handling equipment, eg. trolleys used for clean and dirty items, is required.

Selection of cycle variables and chemical agents

9.15 A flushing (pre-rinse) stage assists the removal of blood and other body fluids before washing commences. The water used for flushing should be at a low enough temperature to avoid coagulation of proteinaceous material.

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Organic matter not loosened by the flushing stage may become coagulated during, and not be removed by, the wash cycle.

9.16 The choice of detergent will be based upon a number of factors. These include:

a. the quality of water available;

b. the nature of the soiling to be removed;

c. the nature of the washing process.

Advice should be sought from both the WD and detergent manufacturers.

NOTE: For most applications mild alkaline detergents, up to pH 10.5, are preferred. The alkalinity contributes to the detergent action by the saponification and emulsification of fats and oils, by the peptidisation of proteins and by softening the water. The presence of alkaline builders also has a synergistic effect with surfactants present in the formulation.

9.17 A low foaming detergent will be required for most WDs since foaming will impair the wash action.

9.18 The use of enzymic detergents may be considered. These are most effective when used for soaking instruments since the contact time is of importance. Many enzymic cleaners are inactivated at the high temperatures used in wash cycles with non-enzymic detergent.

9.19 The quality of water used for the final rinse stage is important in ensuring freedom from scaling, process residuals etc.

9.20 The rinse stage may include a neutralising agent to counteract the detergent and/or minimise the effect of hard water which otherwise would cause “spotting” on the instruments.

9.21 The rinse may include an additive to facilitate free draining of water (rinse aid). Additives intended to lubricate hinged instruments (instrument milk) are also available. The use of these lubricants is generally contra-indicated. Instruments requiring lubrication may be identified on inspection after washing and disinfection and individually lubricated.

9.22 The final hot rinse may be combined with the disinfection stage.

9.23 Water purified by de-ionisation or reverse osmosis is preferred for the final rinse stage since this gives the lowest levels of process residuals and minimises the requirement for rinse additives.

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Cycle monitoring

9.24 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.

9.25 The following variables may need to be monitored for each of the listed stages – together with the duration of each stage:

a. Flushing stage:
   (i) pump pressure or flow rate for water;
   (ii) temperature of water.
b. Washing stage:
   (i) pump pressure or flow rate for water and/or aqueous solutions;
   (ii) temperature of water and/or aqueous solutions;
   (iii) volume(s) of chemical additives injected.
c. Rinsing stage:
   (i) pump pressure or flow rate for water and/or aqueous solutions;
   (ii) temperature of water and/or aqueous solutions;
   (iii) volume(s) of any chemical additives injected.
d. Disinfecting stage (moist heat):
   (i) pump pressure or flow rate for water;
   (ii) temperature of water.

9.26 WDs equipped to monitor all these variables have become commercially available only in the past two to three years.

9.27 As a minimum, WDs used to process surgical instruments should monitor the temperature during the disinfection stage and the time during which the temperature met or exceeded the specified minimum. There should also be means of ensuring an adequate flow of water within the chamber and load.

9.28 WDs that do not have independent monitoring of the time for which the specified temperature was maintained do not provide adequate assurance that the load was disinfected; a load that has not been disinfected may not be safe for staff to handle or for re-use.

Product release

9.29 Before a product is released for use or further processing it should be visually inspected for cleanliness and dryness. The attainment of the required temperature for the required time during the disinfection stage should be verified.

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10. Washer-disinfectors for thermo-labile endoscopes

Introduction

10.1 This type of WD is used to process endoscopes which are thermo-labile and cannot withstand thermal disinfection. They are typically of the flexible fibre-optic or video-endoscope type.

NOTE: Rigid endoscopes capable of withstanding a thermal disinfection process may be decontaminated in WDs for instruments and utensils equipped with an appropriate load carrier designed to provide flushing of the lumen.

10.2 Disinfection is achieved by direct contact of the load with a chemical disinfectant solution at a specified concentration for a specified time either at a specified temperature or within a previously validated temperature range.

10.3 The disinfection facility may be provided as part of the automatic process or as a separate machine intended to disinfect items which have been cleaned. For this reason equipment for chemical disinfection is considered separately (see Chapter 12).

Product compatibility

10.4 Endoscopes may be harmed by some chemical additives or the use of an inappropriate operating cycle in the WD. The reprocessing instructions supplied by the manufacturer of the endoscope should be followed carefully.

Load handling/presentation

10.5 Few, if any, WDs for thermo-labile endoscopes are capable of cleaning the endoscope without any pre-treatment. As soon as the endoscope is removed from the patient, the channels should be flushed in accordance with the endoscope manufacturer's instructions. The outside of the instrument should then be wiped with a swab soaked in an aqueous solution of a suitable detergent.

Instrument/biopsy channels should be brushed through several times with a cleaning brush designed for the instrument in accordance with the endoscope manufacturer's instructions.

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10.6 The use of a load carrier specifically intended for the endoscope(s) to be processed is essential.

10.7 The channels of the endoscope should be connected to the appropriate nozzle on the load carrier to ensure the free passage of fluids through the lumens during processing.

Selection of cycle variables

10.8 The cleaning stage should terminate with a rinse stage to remove any chemical agents used in cleaning which may be incompatible with the disinfectant to be subsequently used.

10.9 The automatic process should include means to ensure the removal of residual water which might dilute disinfectants.

Cycle monitoring

10.10 The WD should be equipped with means to provide independent monitoring of all critical cycle variables (see paragraph 9.25).

10.11 This should include means to verify that all channels to be irrigated with cleaning solution are not blocked.

Product release

10.12 Before a product is released for use or further processing it should be visually inspected for cleanliness and dryness. When the process includes a chemical disinfection stage the attainment of the required conditions should be verified (see Chapter 12).

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11. Manually-loaded ultrasonic washers

Introduction

11.1 This type of washer is used to process metal instruments with complex interstices. It may be used as a pre-cleaning method before processing through a WD for instruments and utensils.

11.2 Ultrasonic cleaners work by subjecting the load to a high intensity of high frequency sound waves which causes cavitation at the surface of the instruments, loosening the soiling.

11.3 Ultrasonic cleaning is not a disinfection process and loads cleaned by ultrasonication must be subjected to a subsequent disinfection or sterilization process as appropriate.

11.4 The guidance offered in this chapter is, when relevant, equally applicable to ultrasonic cleaning processes included in a WD for instruments and utensils.

Safety precautions

11.5 Ultrasonic cleaners should only be operated in accordance with the manufacturers' instructions. They should only be operated when the lid is in place to avoid the dispersion of aerosols and to protect operators from the noise that may be generated.

11.6 Ear protection may be necessary for operators if the ultrasonic cleaner produces significant audible noise during operation.

11.7 Operators should be instructed not to put their hands, or any other parts of their body, into the ultrasonic tank while it is operating.

11.8 Items washed in an ultrasonic cleaner will only have been cleaned, not disinfected, and should therefore be handled with appropriate precautions.

11.9 Ultrasonic cleaners should never be operated with the tank empty since this can seriously damage the transducers.

Product compatibility

11.10 Ultrasonic cleaners are used to assist in cleaning jointed and serrated stainless steel instruments. Plastics and other similar materials which absorb the ultrasonic energy are not successfully cleaned by this method.

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11.11 Cannulated instruments can be cleaned by ultrasonication but this is generally successful only when means are provided to ensure that the cannula is also flushed with cleaning solution during the process.

11.12 Cemented glass syringes and optical systems will be damaged if they are subjected repeatedly to ultrasonication.

11.13 The compatibility of all materials and items to be processed should be established by reference to the manufacturer's instructions, or by appropriate performance qualification testing when necessary.

Load handling/presentation

11.14 Instruments should be placed in the basket provided with the machine.

11.15 The cleaner should be located at a convenient height for loading and unloading. When heavy sets of instruments are to be processed the cleaner should be equipped with a mechanical lifting device.

11.16 Cannulated instruments should be connected to the appropriate nozzle on the load carrier to ensure that the cleaning solution can be pumped through the lumen during processing.

11.17 Hinged instruments should be opened before being placed in the cleaner.

11.18 Gross contamination, such as blood and other visible soil, should be rinsed off instruments before they are immersed in the ultrasonic tank.

Selection of cycle variables and chemical agents

11.19 The only variables selectable are the operating temperature (on some machines), the concentration of chemical additives and the exposure time.

11.20 The efficacy of ultrasonic cleaning is improved by the use of a low foaming surfactant or detergent. The choice of detergent and control of the in-use concentration of detergent have a significant effect on cleaning performance. Advice should be sought from both the WD and detergent manufacturers.

Routine operation

11.21 The tank should be filled with the volume of clean cold water recommended in the manufacturer's instructions and the required volume of detergent added. The ultrasonic cleaner should then be brought up to operating temperature (if it is of the thermostatically controlled type) and operated for a period of not less than five minutes to de-gas the solution.

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11.22 After de-gassing, the instruments to be cleaned should be loaded into the ultrasonic cleaner using the basket provided and, when the lid is in place, the cleaner operated.

11.23 After the specified time the instrument basket should be removed, the instruments removed and either transferred to a WD for instruments and utensils or thoroughly rinsed in clean hot water (60°C or hotter) before drying prior to sterilization or chemical disinfection.

11.24 The tank should be emptied and refilled with clean solution when the solution has become visibly soiled or every four hours, whichever is the sooner. De-gassing is necessary after each fill, before instruments are processed.

Cycle monitoring

11.25 The user should carry out a daily test to verify the activity of the transducers (see SHTM 2030 Part 3, ‘Validation and verification’).

Product release

11.26 Before a product is released for use or further processing it should be visually inspected for cleanliness.

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12. Liquid chemical disinfectors

Introduction

12.1 Machines for the automatic disinfection of items by liquid chemical disinfectants are intended for use only on items previously subjected to a cleaning process.

12.2 The guidance offered in this chapter is equally applicable when the disinfection process is included in a single machine with the cleaning process.

Safety precautions

12.3 Chemical disinfectants are potentially hazardous. Depending on the formulation they may cause irritation to the skin, eyes, respiratory tract and mucous membranes and may be volatile, flammable and corrosive. A risk assessment should be undertaken in accordance with the COSHH Regulations (see paragraph 3.14).

12.4 Staff training should include specific instruction on the procedures to be adopted in the event of equipment malfunction.

Product compatibility

12.5 The compatibility of all materials and items to be processed should be established by reference to the manufacturer's instructions, or when necessary by appropriate testing.

12.6 Factors to be considered in determining the compatibility of the load to the WD process include, but are not necessarily limited to:

a. whether or not it can be immersed in aqueous solutions;

b. the availability of an appropriate load carrier providing the necessary connection to all channels which require disinfection;

c. the maximum operating temperature;

d. the internal pressure to which the channels may be subjected;

e. the compatibility with the chemical disinfectants used.

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Load handling/presentation

12.7 Items to be processed should be:

a. clean, to ensure that all internal channels are clear and that the activity of the disinfectant is not compromised by residual soiling;

b. free from process residues from the cleaning process, eg. detergent, which may inactivate the disinfectant;

c. dry or free from significant surface moisture which would cause dilution of the disinfectant solution;

d. verified as undamaged, eg. by means of a leak test;

e. dismantled to the extent necessary, eg. with valves opened or demounted as recommended by the manufacturer;

f. protected with any necessary closure to prevent the ingress of aqueous solutions into the wrong part of the equipment, eg. videoscopes which are only immersible if the protective cap is in place;

g. connected to the disinfector so as to ensure the passage of disinfectant through all channels.

Selection of cycle variables and chemical agents

12.8 The activity of chemical disinfectants is time and temperature dependent. The temperature of the disinfectant solution should, therefore, be either thermostatically controlled or monitored during each cycle to ensure that it is within the temperature range validated during commissioning.

12.9 The exposure time should be controlled to ensure that the predetermined minimum exposure time has been attained.

12.10 As the various disinfectant formulations differ considerably in their properties, the choice of disinfectant should be made in consultation with the manufacturers of the equipment to be disinfected, the disinfector and the disinfectant. Guidance on the properties of commonly used disinfectants is given in ‘Sterilization, disinfection and cleaning of medical equipment, guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Agency’.

12.11 The operating cycle must provide adequate rinsing after the chemical disinfection stage to ensure that residues of the disinfectant have been reduced to a level at which they do not present a hazard to patients.

12.12 The quality of the final rinse water, especially microbial quality, and the means of ensuring that quality are important characteristics of the process if recontamination of disinfected items is to be avoided. The manufacturer’s instructions should be followed precisely.

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Cycle monitoring

12.13 For disinfectant solutions which are formulated for multiple or prolonged use the date of preparation and/or activation and the number of operating cycles run should be recorded. Whenever practicable the concentration of disinfectants intended for re-use should be monitored on a daily basis.

12.14 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.

12.15 This should include means to verify that all channels to be irrigated with disinfectant solution are not blocked.

12.16 The disinfectant temperature and exposure time should be monitored for each cycle.

12.17 The means employed to maintain the quality of the final rinse water should be monitored in accordance with the manufacturer's instructions.

Product release

12.18 Before a product is released for use or further processing it should be verified that the chemical disinfection stage was within the limits previously determined during commissioning.

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13. Laboratory washer-disinfectors

Introduction

13.1 This type of WD is used to process laboratory equipment and glassware and may also be used to process containers and equipment for use in the preparation of medicinal products.

13.2 Disinfection is achieved by direct contact of the load with water to raise the temperature of the surface of the load to a specified temperature for not less than a specified time, or a combination of conditions providing equivalent lethality.

Safety precautions

13.3 At the end of the operating cycle the load may be too hot to handle without protective gloves. Operators should be trained in the use of the WD and provided with appropriate protective clothing.

13.4 Many of the chemical agents used are toxic, irritant and corrosive. They are potentially hazardous and require careful handling and secure storage.

13.5 A written procedure should be available for the filling or connection of all chemical additive containers. Staff whose duties include this task should receive formal training.

Product compatibility

13.6 The compatibility of all materials and items to be processed should be established by reference to the manufacturers' instructions, or when necessary by appropriate performance qualification testing.

Load handling/presentation

13.7 Load carriers specific to the type of load should be used to ensure that all surfaces to be cleaned and disinfected will be exposed to the action of the water jets, will not be dislodged by the water jets and will drain freely.

13.8 For single-door machines facilities to allow segregation of the handling equipment, eg. trolleys used for clean and dirty items, is required.

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Selection of cycle variables and chemical agents

13.9 A flushing (pre-rinse) stage assists the removal of gross soiling and proteinaceous material before washing commences. The water used for flushing should be at a low enough temperature to avoid coagulation of proteinaceous material.

13.10 The choice of detergent will be based upon a number of factors. These include:

a. the quality of water available;

b. the nature of the load;

c. the nature of the soiling to be removed;

d. the nature of the washing process.

Advice should be sought from both the WD and detergent manufacturers.

NOTE: For some applications, particularly where detergent residues would be a significant problem for the intended use of the load, washing without detergent may be used.

13.11 The quality of water used for the final rinse stage is important in ensuring freedom from scaling, process residuals etc.

13.12 Water purified by de-ionisation, distillation or reverse osmosis is preferred for the final rinse stage since this gives the lowest levels of process residuals.

13.13 When the WD does not include a separate drying stage the use of a high temperature final rinse will facilitate the rapid natural drying of the load on removal from the WD.

Cycle monitoring

13.14 The WD should be equipped with means to provide independent monitoring of all critical cycle variables.

13.15 The variables which may need to be monitored include those identified for WDs for instruments and utensils (paragraph 7.25).

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Product release

13.16 Before a product is released for use or further processing it should be visually inspected for cleanliness. When disinfection is required the attainment of the required temperature for the required time during the disinfection stage should be verified.

13.17 For loads which are to be used in connection with the manufacture of medicinal products the quality controller will establish the procedures for product release.

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Appendix 1: Glossary of terms

Automatic controller: Device that, in response to pre-determined cycle variables, operates the WD sequentially through the required stages of the cycle(s)/process.

Biological indicator: See BS EN 866-1:1997 'Biological systems for testing sterilizers and sterilization processes: General requirements'.

Calibration: The set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by Standards.

Calorifier: A closed vessel in which water is indirectly heated under a pressure greater than atmospheric.

Chamber: That part of the WD in which the load is processed.

NOTE: The chamber does not include steam generators, pipework and fittings from which it can be isolated.

Chemical disinfection: Disinfection achieved by the action of one or more chemicals; the primary purpose of which is to be microbicidal.

Continuous process machine: A machine which automatically transports the load through each stage of the operating cycle.

Chemical additive: A formulation of chemical compounds intended for use in a WD.

Cycle complete: Indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber.

Cycle variables: The physical and chemical properties (eg. times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of the washing and processes.

Decontamination: The combination of processes, including cleaning and disinfection and/or sterilization, used to render a re-usable item safe for further use.

Disinfection: the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

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Disinfection temperature: The minimum temperature of the disinfection temperature band.

Disinfection temperature band: The range of temperatures, expressed as the disinfection temperature and the maximum allowable temperature which may prevail throughout the load during the disinfection time.

Disinfection time: The time period at which the cycle variable (eg. temperature of the load, disinfectant concentration in the chamber) is maintained at or above the value specified for disinfection.

NOTE: This includes detergents, surfactants, rinse aids, disinfectants, and enzymatic cleaners.

Door: Device provided as a means of closing and sealing the chamber.

Double-ended washer-disinfector: A WD incorporating separate doors for loading and unloading.

Fail safe: Attribute of WD design, component or its associated services that minimises a possible safety hazard.

Fault: Recognition by the automatic controller that the pre-set cycle variables for the WD cycle have not been attained.

Holding time: the time period for which the cycle variables are maintained at or above the value specified for disinfection.

Hysteresis: The lagging of effect behind cause.

Inoculated carrier: See BS EN 866-1:1997 ‘Biological systems for testing sterilizers and sterilization processes: General requirements’.

Installation test: Series of checks and tests performed after installation of the WD in the place of use.

Load: A collective term used to describe all the goods equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle.

Loading door: Door in a double-ended WD through which the load is put into the WD prior to processing.

Loading height: The minimum height to which the underside of the load or load container has to be raised for it to enter the loading door.

Medical device: See BS EN 46001: 1997 ‘Specification for application of EN ISO 9002 to the manufacture of medical devices’.

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Monitoring: The measurement of physical variables, such as the function of the automatic controller to check the attainment, or otherwise, of the pre-set cycle variables essential to the efficacy of the operating cycle.

Operating cycle: The complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller.

Operating pressure: The gauge pressure at which the vessel is operated during normal use.

Override: The system by which the operating cycle can be interrupted or modified as necessary.

Safety hazard: Potential detrimental effect on persons arising from the load.

Steam generator: Vessel designed to contain water and a heating system (eg. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state.

Sterile: See BS EN 556 ‘Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled ‘Sterilie’’.

Sterilization: Process used to render a product sterile.

Tank: A process vessel, integral to the WD, designed to hold solutions during processing.

Test organism: See BS EN 866-1:1997 ‘Biological systems for testing sterilizers and sterilization processes: General requirements’.

Test soil: Substance used to test the washing efficacy of a WD.

Thermal disinfection: Disinfection achieved by the action of moist or dry heat.

Type test: Series of tests to establish the working data for a WD type.

Unloading door: Door in a double ended WD through which the load is removed after an operating cycle.

Usable space: Space inside the chamber which is not restricted by fixed parts and which is consequently available to accept the load.

Validation: See BS EN 554 ‘Sterilization of medical devices. Validation of and routine control of sterilization by moist heat’.

Viable micro-organism: Micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

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Warning pipe: Overflow pipe so fitted that its outlet, whether inside or outside the building, is in a conspicuous position, where the discharge of water can be readily seen.

Washer-disinfector (WD): Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

NOTE: This type of machine does not include those designed specifically to wash linen or clothing.

Waste outlet: The point from which the chamber discharges the waste fluids.

Works test: Series of tests performed at the manufacturer's works to demonstrate compliance of each WD with its specification.

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Appendix 2: Abbreviations

AP(S)	Authorised Person (Sterilizers)
BS	British Standard
°C	degrees Celsius
CE	Council of Europe
CEN	Committee European de Normalisation
COSHH	Control of Substances Hazardous to Health
DC	Direct Current
DI	De-Ionised (referring to water)
EEC	European Economic Community
EMC	Electro-Magnetic Compatibility
EN	European Norm
EU	Endotoxin Unit
GGMP	'Guide to Good Manufacturing Practice for Medicinal Products'(GGMP) published in Part IV of 'The Rules Governing Medicinal Products in the European Community'
HSE	Health and Safety Executive
HSW	Health and Safety at Work
MCA	Medicines Control Agency
MDA	Medical Devices Agency
MP	Maintenance Person (Sterilizers)
NDT	Non-destructive testing
NHS	National Health Service
OEL	Occupational Exposure Limit
P&EF	Property and Environment Forum
P&EFEx	Property and Environment Forum Executive
PM	Planned maintenance
PQ	Performance qualification
PPE	Personal protective equipment
SHPN	Scottish Health Planning Note
SHTM	Scottish Health Technical Memorandum
TC	Technical Committee
TP	Test Person
WD	Washer-Disinfector
WIMS	Works Information and Management Systems

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Appendix 3: Useful addresses

UK health agencies

NHSScotland
Property and Environment Forum Executive
4th Floor, St Andrew House,
141 West Nile Street,
Glasgow G1 2RN

Medical Devices Agency (MDA)
Hannibal House, Elephant and Castle,
London, SE1 6TQ
Tel 0171 972 8000

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
Edinburgh
0131 552 3255

Medicines Control Agency (MCA)
Market Towers, 1 Nine Elms Lane,
London SW8 5NQ
Tel 0171 273 3000

Scottish Executive Health Department
St Andrews House,
Edinburgh EH1 3DG
Tel 0131 556 8400

Health and Safety

Health and Safety Executive
375 West George Street
Glasgow
G2 4LW
0141 275 3000

Belford House
59 Belford Road
Edinburgh
EH4 3UE
0131 247 2000

Health and Safety Executive Information Line
0870 154 5500

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Standards organisations

British Standards Institution
British Standards House,
389 Chiswick High Road,
London
W4 4AL
Tel 0181 996 9000

European Committee for Standardisation
Rue de Stassart 36,
B-1050
Brussels

Other organisations

Institute of Healthcare Engineering and Estates Management.
2 Abingdon House,
Cumberland Business Centre.
Northumberland Road,
Portsmouth,
PO5 1DS
Tel 02392 823186

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Medicines Act	HMSO	1988	
	Health and Safety at Work Act	HMSO	1974	
	Public Health (Scotland) Act	HMSO	1988	
	The Water (Scotland) Act	HMSO	1980	
SI 2179	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd. 1994	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health and Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health and Safety (Information for Employees) Regulations	HMSO	1989	

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Publication ID	Title	Publisher	Date	Notes
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1994	
SI 2037	Lifting Operations and Lifting Equipment Regulations	HMSO	1998	
SI 2865	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulation	HMSO	1994	
SI 2169	Medicines (Standard Provisions of Licences and Certificates) Amendment (No 3) Regulations	HMSO	1977 1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 201	Public supply contracts regulations	HMSO	1995	
SI 2023	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 853	**Specification for vessels for use in heating systems** **Part 1:** Calorifiers and storage vessels for central heating and hot water supply **Part 2:** Tubular heat exchangers and storage vessels for building and industrial services	BSI Standards	 1996 1996	
BS 1427	**Guide to field and on-site test methods for the analysis of waters**	BSI Standards	1993	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 1752	**Specification for laboratory sintered or fritted filters including porosity grading**	BSI Standards	1983	
BS 2745	**Washer disinfectors for medical purposes** **Part 1:** Specification for general requirements **Part 2:** Specification for human-waste container washer-disinfectors **Part 3:** Specification for washer-disinfectors except those used for processing human-waste containers and laundry	BSI Standards	 1993 1993 1993	
BS 3218	**Specification for test tubes and boiling tubes**	BSI Standards	1982	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**	BSI Standards	1992	
BS 3849-4	**Concial connectors for anaesthetic and respiratory equipment. Specification for 8.5 mm cones and sockets**	BSI Standards	1990	
BS 3928	**Method for sodium flame test for air filters (other than air supply to IC engines and compressors)**	BSI Standards	1969	
BS 5164	**Specification for indirect-acting electrical indicating and recording instruments and their accessories**	BSI Standards	1975	
BS 5295	**Environmental cleanliness in enclosed spaces**	BSI Standards	1989	
BS 5452	**Specification for hospital hollow-ware made of plastics material**	BSI Standards	1977	
BS 5500	**Specification for unfired fusion welded pressure vessels**	BSI Standards	2000	
BS 5728	**Measurement of flow of cold potable water in closed conduits** **Parts 2, 3, 5, 6,and 7**	BSI Standards	1980 - 1987	
BS 6253	**Specification for glass beakers for laboratory use**	BSI Standards	1984	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**	BSI Standards	1984	
BS 7320	**Specification for sharps containers**	BSI Standards	1990	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 285	**Sterilisation. Steam sterilizers. Large sterilizer**	BSI Standards	1997	
BS EN 554	**Sterilization of medical devices. Validation of and routine control of sterilization by moist heat**	BSI Standards	1994	
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 837	**Pressure gauges** **Part 1:** Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing **Part 2:** Pressure gauges. Selection and installation recommendations for pressure gauges **Part 3:** Diaphragm and capsule pressure gauges. Dimensions, metrology, requirements and testing	BSI Standards	1998 1998 1998	
BS EN 866	**Biological systems for testing sterilizers and sterilisation processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterlizers **Part 3:** Particular systems for use in moist heat sterlizers	BSI Standards	1997 1998 1997	
BS EN 1281	**Anaesthetic and Respiratory equipment** **Part 1:** Conical connectors	BSI Standards	1997	
BS EN 1282	**Anaesthetic and respiratory equipment** **Part 1:** Tracheostomy tubes: Tubes for use in adults	BSI Standards	1997	
BS EN 1782	**Tracheal tubes and connectors**	BSI Standards	1998	
BS EN 1820	**Anaesthetic reservoir bags**	BSI Standards	1997	
BS EN 6001	**Application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 6002	**Application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 12342	**Breathing tubes intended for use with anaesthetic apparatus and ventilators**	BSI Standards	1998	
BS EN 46001	**Specification for application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1998 1995	
BS EN 50103	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry**	BSI Standards	1996	
BS EN 60584	**Thermocouples** **Part 1:** Reference tables	BSI Standards	1996	
BS EN 60751	**Industrial platinum resistance thermometer sensors**	BSI Standards	1996	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **Part 1:** General requirements	BSI Standards	1993	
BS EN ISO 14644-1	**Cleanrooms and associated controlled environments. Classification for air cleanliness**	BSI Standards	1999	
BS EN ISO 9000	**Quality management and quality assurance standards.**	BSI Standards	2000	
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing.**	BSI Standards	1994/ 2000	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN ISO 9002	**Quality assurance. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	
PD 5304	**Safe use of machinery**	BSI Standards	2000	
European Union (EC) Directives				
90/385/EEC	Active Implantable Medical Devices Directive Note: the Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992	Official Journal of the European Communities (OJEC)		
91/356/EEC	Council Directive laying down the principle and guidelines of good manufacturing practice for medicinal products for human use	Official Journal of the European Communities (OJEC), L193, 17.7.91, p30		
93/42/EEC	Council Directive concerning medical devices	Official Journal of the European Communities (OJEC), L169, 12.7.93, p1		
80/778/EEC	Council Directive relating to the quality of water intended for human consumption	Official Journal of the European Communities (OJEC)		
93/94/EEC	Medical Devices Directive. Note: The Directive was adopted by the EC Council of Ministers on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations	Official Journal of the European Communities (OJEC), L319, 17.11.81, p19		
Scottish Health Technical Guidance				
SHTM 2007	Electrical Services Supply & Distribution	P&EFEx	2001	CD-ROM
SHTM 2010	Sterilization	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems Supplement 1: Dental compressed air and vacuum systems Supplement 2: Piped medical gases in ambulance vehicles	P&EFEx	2001	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilization	P&EFEx	2001	CD-ROM
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	Scottish Office	1994	
SHPN 15	Accommodation for pathology service	Scottish Office	1994	
SHPN 26	Operating department	Scottish Office	1992	
SHPN 26 Supp.1	Operating department activity space data sheets	Scottish Office	1993	
HBN 13 Supp 1	Oxide sterilization section			
	NHS in Scotland PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1998	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
Health and Safety Publications				
(MDA SN 9619)	Compatibility of medical devices and their accessories and reprocessing units with cleaning, disinfecting and sterilizing agents. Medical Devices Agency	Dept. of Health	1996	
(L5)	Control and substances hazardous to health and control of carcinogenic substances: Control of substances hazardous to health regulations 1999: approved code of practice. Health and Safety Executive	HSE Books	1999	3rd Edition
(HC(79)3)	Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms	Dept of Health	1979	
(H(91)33)	Decontamination of equipment, linen or other surfaces contaminated with hepatitis B and/or human immunodeficiency viruses	Dept. of Health	1991	
(SAB(93)32)	Endoscope washer/disinfectors: recontamination of equipment	Dept of Health	1993	
	Microbiological safety cabinets: recommendations concerning their choice, installation, routine maintenance and use (Health Equipment Information No 86) Medical Devices Agency	Dept. of Health	1980	
	Scottish Infection Manual 1998 – guidance on core Standards for the Control of Infection in Hospitals, Healthcare premises and at the Community Interface	Scottish Office	1998	
	Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Directorate. Microbiology Advisory Committee	Dept. of Health	1993	
(L23)	Manual handling: Manual handling operations regulations 1992: guidance on regulations. Health and Safety Executive	HSE Books	1992	
(EH40)	Occupational exposure limits. Health and Safety Executive	HSE Books		Issued annually
	Programmable electronic systems in safety related applications: an introductory guide. Health and Safety Executive	HSE Books	1987	

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Publication ID	Title	Publisher	Date	Notes
MDA DB 9501	Re-use of medical devices supplied for single use only	HMSO	1995	
	Safety in health service laboratories: safe working and the prevention of infection in clinical laboratories. Advisory Committee/Health and Safety Executive	HSE Books	1991	
	Safe working and the prevention of infection in the mortuary and post-mortem room. Health and Safety Executive			
(L22)	Work equipment. Provision and use of work equipment regulations 1998. Guidance on regulations. Health and Safety Executive	HSE Books	1998	
(L24)	Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992: approved code of practice and guidance. Health and Safety Commission	HSE Books	1992	
Miscellaneous References				
	Babb J R, Bradley C R, Barnes A R, *Question and Answer*	Journal of Hospital Infection	1992	Vol 20, p51-54
	Rollnick M, *How You Spend Your Pennies*	Health Estate Journal	1991	May, p12-15
	Dawson M, Novitsky T J, Gould M J. *Microbes, endotoxin and water*	Pharm Eng	1988	Mar/Apr vol 8, no2
	Twohy C W, Nierman ML, Duran A P *et al*, *Comparison of limulus amoebocyte lysates from different manufacturers*	Journal of Parent Science & Tech	1983	May/Jun vol 37, no3, p93-96
	Bacterial endotoxin test USP 8th Supp. Pharmacopoeial Convention		1993	Mar XXII NF XVII, p3349-3350
	Chloride in waters, sewage and effluent. Methods for the examination of waters and associated materials	DOE/Nat. Water St. Committee	1981	
	Determination of pH in low ionic strength waters	DOE/Nat Water St Committee	1988	

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Publication ID	Title	Publisher	Date	Notes
	Determination of alkalinity and acidity in water	DOE/Nat Water St Committee	1981	
	Deprygogenation by dry heat. Technical report no 7. Parental Drug Association			Ch12, p101-108
	Dry heat destruction of lipo-polysaccharide. Applied Environmental Microbiology		1997	Vol 36 p715
	General principles of sampling and accuracy of results	DOE/Nat Water St Committee		
	Guidelines on the validation of the Limulus Amoebocyte Lysate test as an end product Endotoxin test for human and animal parenteal drugs, biological products and medical devices	US Food and Drug Administration	1987	
	Guide to contract procedures	NHS Estates	1998	
	International standards for drinking water	WHO	1971	
	Iron in raw and potable waters by spectrophotometry. Methods for the examination of waters and associated materials	DOE/Nat Water St. Committee	1977	
	Measurements of Electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters	DOE/Nat Water St Committee	1981	
	Model Engineering Specifications	NHS Estates, HMSO	1998	Issued in 4 volumes
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Ninhydrin test	Analytical Bio-chemistry	1993	Vol 211, p240-242
	Phosphorus and silicon in waters, effluent and sludges	DOE/Nat Water St Committee	1992	
	Rules governing medicinal products in the European Community. Vol IV Good manufacturing practice for medicinal products. Commissions of the European Communities		1992	

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Publication ID	Title	Publisher	Date	Notes
	Scottish Capital Investment Manual	Scottish Office		
	Sterilization and disinfection of heat-labile equipment: report of a working Party on sterilization and disinfection of heat-labile equipment. Hospital Infection Research Laboratory		1986	
	Total hardness, calcium hardness and magnesium hardness in raw and potable waters	DOE/Nat Water St Committee	1981	
	Water Supply Byelaws Guide. Water Byelaws Advisory Service Water Research Centre		1989	2nd Edition

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Scottish Health Technical Memorandum 2030

(Part 3 of 3)

Validation and verification

Washer-disinfectors

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Version 2
NHSScotland, Property and Environment Forum Executive, October 2001

Executive summary

SHTM 2030 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer-disinfectors (WDs) in use in NHSScotland for processing medical devices, laboratory ware and sanitary products. No guidance is given on WDs intended for use in processing textiles or for dishwashers in general catering applications.

This part is intended as a guide for technical personnel with appropriate training and experience and also for users responsible for the day to day running of WDs. It will also be of interest to architects, planners, estates managers, supplies officers, and others.

Detailed information on the planning and design of a sterile services department, including the provision of WDs, is given in Scottish Hospital Planning Note 13; *Sterile Services Department* and Health Building Note 13 Supplement 1 *'Ethylene oxide sterilization'* section. Guidance for Laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

Although this version of SHTM 2030 reflects current WD technology it is recognised that considerable scope exists for improvements in the operational and management technology used with WDs.

The current British Standards for WDs, although only in force since 1993, are expected to be replaced by European Standards within the next two to three years. These Standards include consideration of the requirements arising as a result of European Union Directives on medical devices which are of concern for WDs in two ways; firstly, some WDs will themselves be considered to be medical devices and therefore must meet the relevant requirements of the Medical Devices Directive and secondly, the manufacturer of a medical device which is intended to be reprocessed is required to specify the method to be used for reprocessing which will include any necessary washing and disinfecting stage.

When practicable the information in this SHTM has been aligned with existing or anticipated Standards and advice is offered where no Standard has yet been formulated.

The WDs described in this SHTM may not be suitable, without modification, for safely processing articles contaminated with either Hazard Group 4 pathogens or with agents which are unusually resistant to disinfection.

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1. General

Introduction

1.1 This part of SHTM 2030 covers the validation and periodic testing of the various types of washer-disinfectors (WDs) used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in washing and disinfection has long been inconsistent and this has often led to ambiguities. This SHTM introduces a set of terms which, it is hoped, will provide workers in the field with a vocabulary that will be consistent with the European Union (EU) standards that are to be introduced in the near future. The glossary provides a definition of terms referred to in this part of SHTM 2030.

1.3 References for all the documents referred to in this part and other selected documents that provide additional information of which the reader should be aware are contained at the end of this part.

Legal framework for washing and disinfection

1.4 WDs are used in relation to both medical devices and medicinal products as well as for sanitary equipment, laboratory equipment and cutlery/crockery.

1.5 WDs may be used for reprocessing medical devices, sanitary equipment, laboratory equipment, manufacturing equipment (for use in the manufacture of medicinal products or medical devices) or cutlery and crockery, within their intended use.

1.6 WDs may also be used as part of the manufacturing process for medical devices, medicinal products, in-vitro diagnostics or laboratory products in processing ‘single-use’ products or components such as bottles and vials.

Medicinal products

1.7 The manufacture and supply of medicinal products are controlled by extensive legislation based on EU Directives for medicinal products. These are enacted in the UK by the Medicines Act and a number of Regulations.

1.8 The requirements for the manufacture and supply of medicinal products are set out in the ‘Guide to good manufacturing practice for medicinal products’ (GGMP) published in Volume IV of ‘The rules governing medicinal products in the European Community’.

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1.9 The GGMP contains guidance on cleaning of components and manufacturing equipment which have implications for the design, installation and operation of WDs. When a WD is to be installed for processing containers, components or manufacturing equipment for use with medicinal products the GGMP should be consulted at an early stage.

1.10 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) when necessary.

Medical devices

1.11 SHTM 2030 Part 2, 'Operational management', refers to the three European Directives on the manufacture and supply of medical devices and in-vitro diagnostics.

1.12 Whether, and if so in what circumstances, the Medical Devices Directive applies to medical devices which are being reprocessed for further use, either within a particular healthcare facility or externally under a service contract, is a complex issue beyond the scope of this SHTM. If necessary, further guidance is given in the MDA Directives Bulletin 18.

1.13 The essential requirements of the Medical Devices Directive require inter alia:

a. that devices and manufacturing processes be designed to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties (Annex I, paragraph 8.1);

b. that devices must be designed manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (Annex I, paragraph 7.2).

1.14 There is no direct equivalent of the GGMP for medical devices. The same role is fulfilled by general Quality System standards (the BS EN ISO 9000 series), supplemented by standards tailoring the requirements specified in the general standards for medical devices (BS EN 46001 and BS EN 46002), standards providing guidance on compliance with these standards (BS EN 724 and BS EN 50103) and the Institute of Sterile Services Management (ISSM) guidance document 'Standards & Practice'.

1.15 Other than the ISSM guidance these are mandated Standards and as such compliance with them affords the presumption of conformance with the relevant essential requirements of the Directive.

Published Standards

1.16 British Standard 2745: 1993 specifies requirements for WDs for medical purposes. The Standard is in 3 parts; Part 1: 'Specification for General

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Requirements', Part 2: 'Specification for washer-disinfectors for human-waste containers' and Part 3: 'Specification for washer-disinfectors except those used for processing human-waste containers and laundry'.

1.17 There are no European Standards, as yet, for WDs. CEN Technical Committee TC102 is developing a series of mandated Standards relevant to the Medical Devices Directive for WDs. There are four parts with the working titles 'General Requirements', 'Washer-disinfectors for human-waste containers', 'Washer-disinfectors for medical devices and surgical instruments' and 'Washer-disinfectors for thermo-labile medical devices (for example endoscopes)'.

1.18 IEC Technical Committee TC66 is developing Standards for 'Safety requirements for washer-disinfectors'.

1.19 When published, compliance with these Standards may be used to give a presumption of conformance to the relevant requirements of the Medical Devices Directive.

1.20 This edition of SHTM 2030 has been written while the new Standards are in the course of development. The guidance given here is designed to be broadly consistent with the emerging Standards but SHTM 2030 should not be regarded as a substitute for the Standards themselves when ascertaining compliance with the EU Directives and the UK Regulations that implement them.

1.21 If the WD is purchased with the intention of processing both medical devices and components, or equipment for use in the manufacture of medical products, purchasers should ensure that the requirements for both types of load are met.

Key personnel

1.22 The following personnel are referred to in this part of SHTM 2030.

Management

1.23 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the operation of the premises.

1.24 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small autonomous units the user may take on this function.

User

1.25 The user is defined as the person designated by management to be

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responsible for the management of a WD.

1.26 In a hospital the user could be a sterile services manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager; in primary care he/she could be a general practitioner, dentist or other health professional. When a WD is used to process equipment or containers for use in the preparation of medicinal products, the user is normally the production manager in charge of the manufacturing process.

1.27 The principal responsibilities of the user are as follows:

a. to certify that the WD is fit for use;

b. to hold all documentation relating to the WD;

c. to ensure that the WD is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records.

Competent Person (Pressure vessels)

1.28 The competent person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a WD described in the Pressure Systems Safety Regulations 2000. The shorter term “competent person” is used in this SHTM.

1.29 The following guidance on the qualifications for the competent person is based on the HSC Approved Code of Practice, Safety of Pressure Systems:

a. where required to draw up or certify schemes of examination, the competent person should be qualified at least to technician engineer level, with adequate relevant experience and knowledge of the law, codes of practice, examination and inspection techniques and understanding of the effects of operation of the pressure vessel concerned. He or she must have established access to basic design and plant operation advice, materials engineering and non-destructive testing (NDT) facilities. The competent person must have sufficient organisation to ensure a reasonable data storage and retrieval system with ready access to relevant laws, technical standards and codes;

b. where required to carry out examinations, the competent person should have sufficient practical and theoretical knowledge and actual experience of the type of pressure vessel which is to be examined to enable defects or weaknesses to be detected and their importance in relation to the integrity and safety of the WD to be assessed.

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1.30 The principal duties of the competent person under the Regulations are as follows (they need not all be exercised by the same individual):

a. advising on the scope of the written scheme of examination;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

1.31 Most insurance companies maintain a technical division able to advise on appointing a competent person. Advice may also be obtained from Scottish Healthcare Supplies, Trinity Park House, Edinburgh.

Test Person (Washer-disinfectors)

1.32 The test person (washer-disinfectors) is defined as a person designated by management to carry out validation of washer-disinfectors and to provide advice on testing, maintenance and procedures. The shorter terms 'test person' or TP are used in this SHTM. The test person should either:

a. be a test person (Sterilizers) (see SHTM 2010 for a definition of this role);

b. qualified to at least HNC level in engineering or relevant sciences and have at least two years experience in the validation of washer-disinfector processes; or

c. have at least five years experience in the testing of washer-disinfector processes.

1.33 The principal responsibilities of the TP are as follows:

a. to advise on programmes of periodic testing and periodic maintenance of WDs;

b. to advise on operational procedures for routine production;

c. to conduct the validation test specified in SHTM 2030 Part 3, ‘Validation and verification’ and to prepare the validation report;

d. to conduct the periodic tests specified in SHTM 2030 Part 3, ‘Validation and verification’ and to prepare reports as required by the user;

e. to conduct any additional tests at the request of the user.

Maintenance Person (Washer-disinfectors)

1.34 The Maintenance Person (washer-disinfectors) is defined as a person designated by management to carry out maintenance duties on washer-

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disinfectors. The shorter terms maintenance person or MP are used in this SHTM.

1.35 The maintenance person should be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of washer-disinfector. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.

1.36 The principle responsibilities of the Maintenance Person are as follows:

a. to carry out the maintenance tasks outlined in SHTM 2030 Part 2, 'Operational management';

b. to carry out additional maintenance and repair work at the request of the user.

1.37 A Maintenance Person who has a minimum of 5 years experience in the maintenance of washer-disinfectors may, by agreement, perform the duties of the Test Person for the daily, weekly, quarterly and yearly tests described in this SHTM 2030.

Microbiologist

1.38 The microbiologist is defined as a person designated by management to be responsible for advising the user on microbiological aspects of disinfection.

1.39 The microbiologist should have a degree in microbiology and will normally be a member of the hospital staff.

1.40 The principle responsibilities of the microbiologist are as follows:

a. to provide general and impartial advice on all matters concerned with washing and disinfection;

b. to advise the user on the microbiological aspects of all disinfection procedures;

c. to arrange for the culturing of biological indicators used in microbiological tests;

d. to audit the documentation from all washer-disinfectors which have been tested by microbiological methods.

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Control of Infection Officer

1.41 The Control of Infection Officer is defined as the person designated by management to be responsible for advising the user on all infection control aspects.

Production Manager

1.42 The Production Manager is defined as a person designated by management to be responsible for production of medicinal products and medical devices.

Quality Controller

1.43 The Quality Controller is defined as a person designated by management to be responsible for quality control of medicinal products and/or medical devices with the authority to establish, verify and implement all quality control and quality assurance procedures.

Laboratory Safety Officer

1.44 The Laboratory Safety Officer is defined as a person designated by management to be responsible for all aspects of laboratory safety in respect of equipment, maintenance, personnel and training relating to safety issues, and to ensure compliance with safety legislation and guidelines.

Operator

1.45 An operator is defined as any person with the authority to operate a WD. Their duties may include the noting of WD instrument readings, replenishment of consumable items, such as detergent, and simple housekeeping duties.

Manufacturer

1.46 The manufacturer is defined as a person or organisation responsible for the manufacture of a WD.

Contractor

1.47 The contractor is defined as a person or organisation designated by management to be responsible for the supply and installation of the WD, and for carrying out the installation checks and tests. The contractor is usually the manufacturer of the WD.

Purchaser

1.48 The purchaser is defined as the person or organisation who orders the WD and is responsible for paying for it.

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Independent Advisor

1.49 The Independent Advisor is defined as a person who may or may not be registered as an AP (Sterilizers), but can demonstrate to the satisfaction of management previous training and experience appropriate to carry out the designated tasks in respect of WDs as the AP(S) would carry out in respect of sterilizers. AP(S) is a suitable person to carry out the functions of an Independent Advisor.

Water supply

1.50 All the organisations responsible for water supply have the statutory power to make and enforce byelaws to prevent waste, excessive consumption, misuse or contamination of the water supply. The Model Water Byelaws form the basis of such byelaws. WDs must be designed, constructed, installed, operated and maintained in accordance with the requirements of the relevant byelaws.

Safety

1.51 Guidance on the safe operation of the various types of WD is given in SHTM 2030 Part 2; 'Operational management'. As far as testing is concerned, normal safety precautions are adequate except in the case of WDs using liquid chemical germicides. In this case users are recommended to operate a permit-to-work system to ensure that such WDs are declared safe to work on, and that personnel working on them have documented authority to do so.

Chemical additives

1.52 Many of the chemical additives used in WDs and their associated ancillary equipment, for example water treatment plant, are corrosive, toxic or otherwise hazardous and require special provision for their storage and use.

1.53 The 'Control of Substances Hazardous to Health (COSHH) Regulations 1999' place upon management an obligation to ensure that suitable measures are adopted to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a special ventilation system.

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1.54 Some of the substances which may be used in WDs, in particular those employing chemical disinfection or sterilization, have Occupational Exposure Limits (OEL) set out in Guidance Note EH40 published annually by the Health and Safety Executive. These limits are statutory maxima but should not be regarded as representing a safe working exposure. Employers have a legal obligation to ensure that exposure is reduced as far as reasonably practicable.

1.55 The WD, including any special ventilation equipment necessary for its safe operation, will be subject to the COSHH Regulations. These Regulations introduced controls on biological agents which are of relevance to purchasers of WDs. Detailed guidance on ventilation systems is provided in SHTM 2025.

Infectious materials

1.56 All WDs have the potential to process infectious materials. The user should therefore ensure that personnel working on WDs wear appropriate protective clothing and are fully informed of any hazards that may be present. In case of doubt the microbiologist should be consulted.

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2. Testing of washer-disinfectors

Introduction

2.1 WDs are used to carry out the processes of cleaning and disinfection consecutively.

2.2 In some instances a visual inspection for residual contamination may be considered sufficient for monitoring the adequacy of the cleaning process before use. However, this is not true in all cases; for example, visual inspection will not detect soiling on the internal surfaces of instruments with lumens and will not detect low, but potentially significant, concentrations of soiling (for example proteins) or residual chemical additives from the WD remaining on load items.

2.3 There is no simple method to verify by inspection or test the efficacy of the disinfection process on a product prior to use.

2.4 In consequence, cleaning and disinfection processes have to be validated before use, the performance of the process monitored during routine use, the calibration of controls and instrumentation verified, and the equipment subjected to a suitable maintenance programme.

2.5 The control protocols described in this part of SHTM 2030 provide the means for ensuring that the WD is fit for its intended purpose and includes tests and checks carried out during manufacture, after delivery, during validation and periodically thereafter. Tests are also required before a WD is returned to service after repairs that affect one or more components which influence the attainment of critical process control variables or after modification.

2.6 The control protocol is based on four key aspects to ensure that the required standards of performance and safety are met and sustained:

a. all WDs are subjected to a planned programme of tests to validate their performance, that is, to provide experimental evidence that, when operated under the specified conditions, the WD will reliably produce cleaned and disinfected items to the standard required;

b. all WDs are subjected to a planned programme of tests to monitor their performance;

c. all WDs are operated in accordance with an agreed procedure by staff trained in the use of the WD;

d. all WDs are subjected to a planned programme of preventative maintenance irrespective of whether a preventive maintenance scheme is operated on the premises.

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2.7 Expertise on all aspects of the operation and testing of WDs should be available on three levels; the Independent Advisor, Test Person (WD), and Maintenance Person (WD).

2.8 The scheduled test programmes include simple tasks to be undertaken by the user as well as more complex tests undertaken by the MP/TP.

2.9 Schedules for pre-delivery works tests (when necessary), installation checks, validation tests and periodic tests are presented in Chapters 3, 4, 5 and 6 of this document, and discussed below. When appropriate, the schedules refer to detailed test procedures described in later chapters.

2.10 Maintenance of WDs is dealt with in SHTM 2030 Part 2; 'Operational management'.

Responsibilities

2.11 WDs should be subjected to a planned programme of testing both before delivery and on-site. The on-site testing should be carried out using the procedures described in this SHTM and should include installation qualification, operational qualification and process qualification. The purchaser, manufacturer and contractor have distinct responsibilities.

Management

2.12 Management should nominate, when necessary, an Independent Advisor to provide advice on validation and a MP/TP to carry out the checks and tests required.

2.13 The Independent Advisor should review the results of pre-delivery works tests carried out by the manufacturer, and review the test instruments provided by either or both the contractor (see paragraph 1.37) and the MP/TP to ensure that their accuracy, calibration and condition meet the standards for test instruments described in Chapter 8.

2.14 The MP/TP should witness the installation checks and tests carried out by the contractor, including ensuring that the calibration of each test instrument provided by the contractor has been checked on site and is satisfactory and arrange for test loads to be supplied as required.

2.15. The TP should carry out the initial operational qualification and performance qualification tests.

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Manufacturer

2.16 The manufacturer should ensure that the WD is designed, manufactured and tested within a quality system complying with the requirements of BS EN ISO 9001 or BS EN ISO 9002.

2.17 The manufacturer should carry out pre-delivery works testing. The extent of testing will depend on whether the product is in serial production or a 'one off' and, for machines in serial production, whether the manufacturer has obtained a certificate of compliance to a relevant British or European Standard by means of a type test for the particular type and size of WD.

Contractor

2.18 The contractor, who may also be the manufacturer, should complete the installation checks and tests specified in Chapter 4 to the satisfaction of the MP/TP before the WD can be accepted for use in accordance with the contract.

2.19 The contractor should provide the test instruments and equipment (but, unless otherwise specified in the contract, should not be expected to provide the test loads). The test instruments provided should meet the standards for test instruments described in Chapter 8.

Validation

2.20 Validation is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a pre-determined specification. Validation is a total process beginning with a review of the specification against which the equipment is purchased. This is to ensure that it will meet the user's specified production needs including installation qualification, operational qualification and performance qualification. Installation qualification and operational qualification are sometimes referred to jointly as 'commissioning'.

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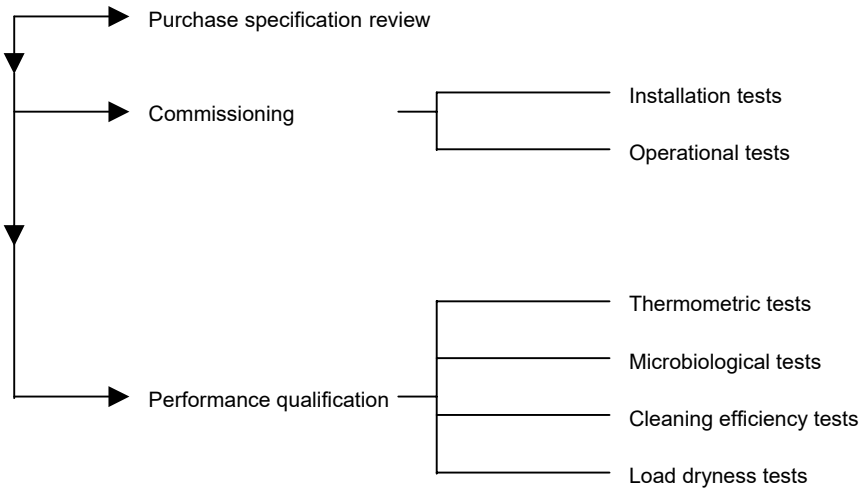
Figure 1: The validation process



Works tests

2.21 Before delivery of the WD, the manufacturer should subject the machine to a programme of factory tests. The extent of these tests will depend on whether the WD is in serial production or is a unique design (a 'one-off'). For machines in serial production the works tests are intended to verify that, in respect of various critical attributes, the WD performs in conformity with the results obtained from type testing. It is rarely necessary to attend the factory to witness works tests but the manufacturer should make the results of these tests available on or before delivery of the WD.

2.22 For 'one-off' designs a more extensive programme of works tests, similar to the programme of type tests for machines in serial production, is required and the purchaser may wish to arrange for their representative (either the Independent Advisor or MP/TP) to attend the factory to witness these tests before accepting delivery of the WD.

2.23 The schedule for type test and works tests is set out in Chapter 3.

Commissioning

2.24 Commissioning is defined as the process of obtaining and documenting evidence that the equipment has been provided and installed within the agreed purchase specification, and that it functions within pre-determined limits when operated in accordance with the manufacturer's instructions.

2.25 Commissioning consists of a series of installation tests to be carried out by the contractor and operational tests to be carried out by the MP/TP.

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Pre-Installation checks

2.26 The contractor should verify that the site services are adequate for the operation and performance of the WD before it is delivered.

2.27 The contractor should verify the condition of the water supply and set chemical dosing levels as appropriate.

Installation tests

2.28 The contractor should carry out the required installation checks on delivery of the WD to ensure that the WD has been supplied and installed correctly and is safe to operate.

2.29 Ventilation systems should be checked by the contractor responsible for their installation.

2.30 When these checks have been completed and found satisfactory the contractor should carry out the installation tests necessary to demonstrate that the WD is working satisfactorily. The contractor is not required to carry out any thermometric tests unless these were specified in the purchase contract. Any assistance required from the purchaser should be agreed as part of the purchase contract.

2.31 If any modification, maintenance or repair work is carried out on the steam, water, compressed air ventilation or drainage systems after the installation tests have been completed, the relevant installation tests should be repeated before the operational tests are undertaken.

2.32 The schedule for installation checks and tests is set out in Chapter 4.

Operational tests

2.33 When the WD has been installed and accepted the MP/TP should carry out a sequence of operational performance tests to evaluate the basic performance and safety of the WD. Some of these tests are identical to those specified as installation tests and need not be repeated if operational testing follows within ten working days of the completion of the installation tests.

2.34 For operational tests see Chapter 5.

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Performance qualification

2.35 Performance qualification is defined as the process of obtaining documented evidence that the equipment, as commissioned, will produce an acceptable product when operated in accordance with the specification.

2.36 Performance qualification consists of tests designed to show that:

a. soil removal and cleaning have been effective throughout the load and the WD chamber, and the products are of the required standard of cleanliness, free from process residues (when applicable);

b. disinfection conditions have been attained throughout the load and the WD chamber, and to the required standard for the type of load being processed. A thermometric test is sufficient for WDs employing a thermal disinfection process. Additional microbiological tests will be required for WDs that use chemical disinfectants and may be necessary for WDs where the nature of the load or loading conditions do not permit thermometric monitoring which accurately reflects the conditions pertaining in the load.

2.37 In principle, it might be argued that a performance qualification test is required for each loading condition that a WD is required to process. In practice, it is possible to identify reference loads and reference loading conditions which present an equal or greater challenge to the process than the loads which may be encountered in normal use.

Documentation

2.38 Accurate and efficient record keeping is an essential part of the management of a WD. The extent and nature of the records that are necessary varies with the type of WD and the use to which it is put. Guidance is given in SHTM 2030 Part 2, ‘Operational management’.

Summary sheets

2.39 On completion of the validation process the MP/TP should immediately prepare a summary report containing the results of the commissioning and performance qualification tests and essential working data.

2.40 The summary report should be signed by the MP/TP and countersigned by the user to certify that the WD is fit for use.

2.41 Summary reports should be securely retained by the user and be available for ready reference.

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Validation report

2.42 Within one month of the completion of the validation process the MP/TP should prepare a full validation report which should include:

a. all the data supplied by the contractor, collected during the installation checks and tests, with written confirmation that they meet the manufacturer's specification;

b. written confirmation that the calibrations of all measuring instruments fitted to the WD have been verified;

c. all the data collected during the commissioning tests, with written confirmation that they meet the specified requirements;

d. data showing the correlation between the performance of the measuring instruments fitted to the WD and the test instruments used;

e. reports containing all the data collected during the performance qualification tests with written confirmation from the MP/TP and the user of the loading conditions and types of load (including when necessary reference to specific individual items) which may be satisfactorily processed in the WD.

2.43 When data is in the form of electronic data files, the report should include copies of disks or tapes containing the data in a format agreed with the user and a printout of the directory of each, annotated to show where the data for each test is to be found.

2.44 The MP/TP should certify that all necessary tests have been carried out and that the results are satisfactory.

2.45 The records of any microbiological tests should be signed by the microbiologist.

2.46 The Independent Advisor should review and countersign the completed validation report.

2.47 The validation report should be retained by the user. Copies may be retained as necessary by the MP/TP, the Independent Advisor, the Microbiologist, Estates Dept. and, where applicable, the Quality Controller.

Periodic tests

2.48 After validation and when the WD is passed into service, it should be subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals, refer to (Table 5).

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2.49 The user, Microbiologist and the MP/TP are responsible for the periodic tests.

2.50 The daily, weekly and quarterly test schedules provide evidence that the WD continues to operate within the limits established during commissioning.

2.51 The yearly test schedule is a revalidation procedure and provides a more comprehensive test programme than the other periodic tests; it serves to demonstrate that data collected during commissioning and the performance qualification remain valid.

Revalidation

2.52 In addition to annual revalidation (Table 5), further revalidation is required in the following circumstances:

a. when the WD is to be returned to service after repair or component replacement of part of the systems which affect satisfactory attainment of the pre-set variables of the operating cycle;

b. when the pre-set values of the cycle variables have been modified;

c. when the software in a programmable electronic system (PES), used for control of the process, has been modified;

d. whenever the user or Independent Advisor advises that revalidation is necessary;

e. whenever it is required by an authorised inspectorate or licensing authority.

2.53 The full revalidation procedure is identical to that specified for the yearly test. See Chapter 7.

2.54 It will not always be necessary to carry out a full revalidation and the advice of the Independent Advisor, Microbiologist or the Control of Infection Officer should be sought on which tests are required following any particular event.

Repeat validation

2.55 Revalidation and periodic tests are designed to establish the continued conformance of the equipment and its performance with data established during the original validation study.

2.56 There are occasions when it may be necessary to repeat the full set of tests carried out during the initial validation in order to obtain a new set of data.

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2.57 Repeat validation will be necessary:

a. when the WD is modified to such an extent that it must be presumed that the original data is no longer valid;

b. when a WD, other than a table top machine, has been moved and installed at a new site;

c. when the WD has been dismantled or extensively overhauled;

d. whenever the user or Independent Advisor advises that repeat validation is necessary;

e. whenever it is required by an authorised inspectorate or licensing authority;

f. whenever revalidation fails to confirm compliance with the original data and no cause for the discrepancy can be found.

2.58 It will not always be necessary to carry out a full repeat validation and the advice of the Independent Advisor should be sought as to which tests are required following any particular event.

Types of test

2.59 The tests should fall into the following categories:

a. **Automatic control tests** which are designed to verify the correct functioning of the operating cycle from the readings obtained from the instruments fitted to the WD;

b. **Thermometric tests** which are designed to provide assurance that the temperature requirements for disinfection are met by using accurate measuring equipment, independent of the instruments fitted to the WD to monitor the temperatures attained within the chamber and reference loads;

c. **Microbiological tests** which are designed to show that disinfection conditions are attained when thermometric methods alone are inadequate for this purpose;

d. **Cleaning efficacy tests** which are designed to show, by monitoring the removal of a test soil, that the process will effectively clean products of the type to be processed.

2.60 Other performance tests specific to certain types of WD are designed to provide assurance that the WD will perform correctly under the anticipated conditions of use.

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Procedure on failure of a test

2.61 There should be no difficulty in ensuring that a correctly installed and maintained WD will comply with both the validation tests and periodic tests described.

2.62 Failure of a test generally indicates that a WD is not working to specification and it should be withdrawn from service and the failure investigated.

2.63 In practice, the action to be taken is a matter of judgement and will depend on the nature of the failure and the use to which the WD is being put. It may be acceptable for the WD to continue operating under carefully defined restrictions until the cause of the failure can be established and rectified.

2.64 The Independent Advisor and the user should agree the course of action to be taken.

2.65 The user has the ultimate responsibility for certifying that the WD is fit for use.

Inter-relationship of test programmes

2.66 The tests described in this part of SHTM 2030 are intended for use in type tests, works tests, commissioning (installation and operational tests), and performance qualification (thermometric tests, microbiological tests, cleaning efficacy tests and load dryness tests), and routine periodic tests.

2.67 The inter-relationship of the various test programmes, the place where they would usually be conducted and the responsibility for conducting the tests are shown in Figure 2.

2.68 The circumstances under which each of the test schedules should be applied is given in Table 1: ‘Summary of manufacturer's test programmes for WDs'.

2.69 The programmes of tests should be applied to all WDs where relevant. Details are given under the test schedules for particular types of WD.

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Figure 2: Inter-relation of test programmes

Location	Serial Production	'One-off' WD Production	Responsibility
Factory	Type Test ➜ Works Test	Type Test	Manufacturer

Location	Tests	Responsibility
On-site	INSTALLATION	Manufacturer/TP(s)
	OPERATIONAL	Manufacturer/TP(s)
	PERFORMANCE QUALIFICATION	User/MP(s)/TP(s)
	PERIODIC ROUTINE TEST	TP(s)
	ANNUAL REVALIDATION TESTS	User/MP(s)/TP(s)

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3. Schedule of type tests and works tests

Introduction

3.1 The manufacturer carries out type tests on representative samples of WDs in serial production to demonstrate compliance of the WD design with its specification and/or published Standards as appropriate.

3.2 The manufacturer carries out works tests on each WD before it leaves the manufacturing site to ensure that each WD meets specification.

3.3 For WDs in serial production the programme of tests required for the works test is usually a reduced set of the tests in the schedule for type testing.

3.4 For WDs of 'one-off' design the schedule of works tests would necessarily be the same as the schedule for type testing.

3.5 Type tests, and more rarely works tests on one-off designs, may be carried out or witnessed by a third party to allow certification of the product to a relevant standard e.g. BS 2745 Part 2 or Part 3. The product certification scheme run by BSI leads to the award of the 'kitemark' for certified products. A similar scheme is operated through CEN for products complying with European Standards and compliant products may carry the CEN 'keymark'. Those clinical WDs which are classified as medical devices and are supplied on, or after, 14 June 1998 will be required to bear the CEN marking.

3.6 The manufacturer should make available to the purchaser the results of type tests and works tests on or before delivery of the WD.

3.7 It will rarely be necessary for the purchaser, or their representative, to visit the manufacturer's works to witness works testing except, perhaps, in the case of 'one-off' machines. The advice of the Independent Advisor should be sought.

3.8 A summary of the tests which should be included in a programme of type tests and works tests is shown in Table 1.

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Table 1: Summary of manufacturer's test programmes for WDs

	Type Test	Works Test
1. Cleaning efficacy		
Chamber	✓	
Load	✓	
Load carrier	✓	
2. Thermometric		
Thermal disinfection	✓	✓
Temperature control	✓	✓
Over-temperature cut-outs	✓	✓
Chemical disinfection	✓	✓
Thermal insulation	✓	
3. Microbiological		
Disinfection	✓	
4. Load dryness	✓	✓
5. Fluid emission		
Chamber leak proof	✓	✓
Door seal	✓	✓
Vapour emission	✓	✓
6. Sound power	✓	
7. Electromagnetic interference	✓	
8. Doors & interlocks		
Cycle start	✓	✓
Loading/unloading	✓	✓
With services	✓	
On fault condition	✓	✓
9. Process residuals	✓	
10. Chemical dosing		
Accuracy and repeatability	✓	✓
Low level indicator	✓	✓
11. Water quality		
Rinse water	✓	
In relation to performance testing	✓	
Water volume	✓	
12. Air quality	✓	
13. Pipework		
Dead volume	✓	
Free draining	✓	
Overflow	✓	✓
Venting system	✓	
14. Instrumentation		
Legibility	✓	
Calibration	✓	✓
15. Load carriers		
Fitting	✓	✓
Stability	✓	✓
Alignment	✓	✓
Force to move	✓	✓
Effect in cycle	✓	
16. Operating cycle		
Spray system	✓	✓
Reproducibility	✓	✓
Fault indication	✓	✓

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4. Schedule of installation tests

Introduction

4.1 On delivery of the WD the contractor should carry out the installation checks included in the contract and as set out in this chapter to establish that:

a. the WD has been provided and installed correctly;

b. the WD is safe to operate;

c. the WD does not interfere with other equipment;

d. all connected services are satisfactory and do not prevent attainment of the designed cleaning and disinfection performance of the WD.

4.2 The contractor responsible for installing the WD should carry out installation checks on services and other ancillary equipment. These checks should be completed and all services and ancillary equipment found to be satisfactory before carrying out installation checks on the WD itself.

4.3 The contractor responsible for installing the WD should carry out any additional checks specified by the manufacturer.

4.4 The MP/TP should carry out any checks specified in this chapter which were not included in the purchase contract for the WD.

4.5 As a safety precaution, checks on chemical dosing systems (for chemical additives such as detergents, disinfectants etc.) should be carried out using water. Checks on fume extract systems designed to eliminate personnel exposure to hazardous chemicals (for example gluteraldehyde) should be carried out using a non-hazardous substitute or a smoke test.

Checks on ancillary equipment

4.6 Ancillary equipment should, whenever practicable, be installed and commissioned before validation of the WD begins.

4.7 When the checks on ancillary equipment require the WD to be in operation, the MP/TP should carry them out in co-operation with the contractor for the WD.

4.8 The contractor for the WD is not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.

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Engineering services

4.9 Check that the following requirements are met:

a. the engineering services have been installed correctly, they are adequate to meet the demands of the WD, they do not leak and all necessary isolating valves/switches and test points have been installed;

b. drains remove effluent effectively when all plant in the vicinity, including the WD, is connected and operating;

c. the water treatment plant (if fitted) operates correctly and the quality of water supplied for each stage of the process is in accordance with the specification;

d. the provision for storage, handling and connection to the WD for all process chemicals, meets the requirements for safe handling of potentially hazardous chemicals;

e. the exhaust ventilation and/or condenser unit fitted to the WD is adequate to remove the hot, humid air evolved from the washing, thermal disinfection and drying and unloading processes;

f. for WDs employing volatile process chemicals, the exhaust ventilation maintains the environmental concentration below any limit specified for occupational exposure and that the discharge is to a safe place.

NOTE: The maximum permitted concentration and the method of detection and analysis will depend on the chemical being used.

Additional checks for WDs using a chemical disinfectant

4.10 WDs using chemical disinfectants require further tests to the ventilation and safety systems because of the possible emission of toxic gases or vapours.

4.11 For WDs using a chemical disinfectant, check that the ventilation system within the loading (or unloading) area of the WD, the plant room (if applicable) and the storage area for the disinfectant meet the specified requirements. Particular attention should be paid to the following:

a. the installation meets the manufacturer's specifications;

b. air flow is from the operator towards the WD and air does not flow from the plant room (if applicable) or disinfectant storage area into the loading (or unloading) area;

c. exhaust systems are non-recirculating and their discharges comply with relevant safety Regulations.

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4.12 Check that local exhaust ventilation incorporated in the WD or installed as a dedicated accessory meets the specified requirements. Particular attention should be paid to the following:

a. air flow is from the operator towards the WD;

b. the rate of flow complies with the specified requirements;

c. The exhaust discharge complies with safety Regulations.

4.13 When the disinfectant solution is intended to be discharged to drain ensure that the drainage system is trapped, sealed and vented to a safe position. The drainage system should be checked to ensure that it is not possible for toxic materials to be vented into any other part of the building.

Checks on the WD

Preliminary checks

4.14 Check that the electrical equipment on the WD is correctly connected to the electrical service. Carry out the following electrical tests:

a. insulation resistance;

b. phase sequence (for 3 phase installations);

c. polarity;

d. bonding and earth continuity;

e. emergency stop.

4.15 After the WD has been installed, check that the following requirements are met:

a. the manufacturer has supplied all the documents specified in the contract;

b. the WD has been supplied and installed in accordance with the contract;

c. calibration verification certificates for the measuring instruments and controller(s) on the WD have been supplied;

d. no defects are apparent from a visual inspection of the WD;

e. all supports, bases and fixings are secure and without imposed strain from service connections;

f. thermal insulation is in good condition and securely attached;

g. security and settings of door safety switches are in compliance with data

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supplied by the manufacturer;

h. keys, codes or tools required to operate locked controls and control over-rides have been supplied, operate correctly and only operate the control for which it is intended;

i. loading conveyors and trolleys, load carriers and load baskets are effective and safe in use.

Functional checks

4.16 During an operating cycle, with an empty chamber, check that the following requirements are met (several cycles may be necessary to complete all the checks):

a. the selection of automatic or manual control is by key, code or tool. The selection of one control mode inactivates the other control modes;

b. under automatic control, water, steam, compressed air or chemical additives cannot be admitted into the chamber, and the operating cycle cannot start until the door is closed;

c. under manual control, the operator can advance the cycle only sequentially through each stage. Any stages designed to remove chemical additives from the chamber and load cannot be circumvented;

d. throughout the cycle, the indicated and recorded values of cycle variables are within the limits specified by the manufacturer;

e. throughout the cycle, there are no leaks of water, steam aerosols, toxics chemicals or effluent;

f. there is no evidence of interference to or from other equipment connected to the same services;

g. there is no evidence of electromagnetic interference to or from other equipment;

h. operation and reading of all instruments appear to be satisfactory;

i. the temperature of surfaces routinely handled by the operator does not exceed those specified in SHTM 2030 Part 2, ‘Design considerations’;

j. the effluent temperature does not exceed that specified in SHTM 2030 Part 1, ‘Design considerations’.

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4.17 At the end of the cycle check that the following requirements are met:

a. the door opening system cannot be opened until the cycle has been completed, that is, the automatic controller has operated in accordance with its specification;

b. for systems incorporating one or more cycle stages at pressures 200 mbar above or below atmospheric pressure:

(i) the door opening system cannot be operated until the chamber has been vented to atmosphere and the chamber pressure is within 200 mbar of atmospheric pressure;

(ii) the door retaining parts cannot be released until the seal between the door and chamber has been broken, and the chamber is effectively vented to atmospheric pressure.

Response to external faults

4.18 It is necessary to check that the WD reacts correctly and safely when exposed to a number of external fault conditions; that is, a safety hazard is not created and a false indication of satisfactory completion of a cycle is not obtained.

4.19 During an operating cycle, check the response of the WD to the following simulated faults (as appropriate to the type of WD):

a. operation of the emergency stop button;

b. power failure;

c. failure of the disinfection process;

d. failure of extract ventilation (chemical disinfection).

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TABLE 2

Machines being put into service for the first time
TESTING SCHEDULE

Type of WD	Pre Installation Checks			Installation Checks						Commissioning Tests			
						Drainage							Water System
Para Ref.		(9.37)	(9.49)	(9.54)	(9.55)	(11.4)	(9.17)				(11.4)	(9.95)	
	Design Specification. Use and services	Water Quality (Hardness)	Water Supply Temperature	Water Supply Pressure	Verification of WD instrument calibration	Automatic Control Test	Blocked Drain Protection	Estimation of dead volume of Drainage pipework	Efficacy of Drainage Discharge	Safety Checks	Automatic Control Test (each cycle)	Verification of WD instrument calibration	Chemical Purity
Human Waste	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Surgical Instruments	U/M/A	U/A/C	U/A/C	U/A/C/	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Holloware	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Anaesthetic Accessories	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Endoscopes	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Laboratory	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP
Utensils & Crockery	U/M/A	U/A/C	U/A/C	U/A/C	C	C	C	C	C	TP/C	TP/C	TP/C	C/TP

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TABLE 2 (continued)

TESTING SCHEDULE

Type of WD	Commissioning Tests								
	Doors and Interlocks				Chemical Dosing				
Para Ref	(9.69)	(9.73)	(9.76)	(9.8)	(9.88)	(9.9)	(18.9)	(18.3)	(17.3)
	Cycle Start	In Cycle	Double ended WD	Fault indication	Reproducibility of Volume	Low Level Detection	Channel Patency	Self Disinfection	Ultrasonic Activity
Human Waste	TP/C	TP/C	TP/C	TP/C	C	TP/C			
Surgical Instruments	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U		TP/C
Holloware	TP/C	TP/C	TP/C	TP/C	C	TP/C			
Anaesthetic Accessories	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U		
Endoscopes	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U	TP/C	
Laboratory	TP/C	TP/C	TP/C	TP/C	C	TP/C	TP/C/U		
Utensils and Crockery	TP/C	TP/C	TP/C	TP/C	C	TP/C			

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TABLE 2 (Continued)

TESTING SCHEDULE

Type of WD	Commissioning Tests								
		Cleaning Efficacy Test (6.23)							
Para Ref.	(9.115)					(9.101)	(9.108)	(10.3)	(9.113)
	Test for air quality	Test Soil (6.28)	Reference Load	General Instruments	Endoscopic/ MAT instruments	Load carrier temperature test	Over temperature protection test (if fitted)	Thermometric test for thermal disinfection	Load dryness test
Human Waste		U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Surgical Instruments	U/M/C	U/M/C	U/M/C	U/M/C	U/M/C	TP/C	TP/C	TP/C	TP/C/U
Holloware	U/M/C	U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Anaesthetic Accessories	U/M/C	U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Endoscopes	U/M/C	U/M/C	U/M/C	U/M/C	U/M/C				TP/C/U
Laboratory	U/M/C	U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U
Utensils and Crockery		U/M/C	U/M/C	U/M/C		TP/C	TP/C	TP/C	TP/C/U

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5. Schedule of operational tests

Introduction

5.1 To demonstrate compliance with specifications the contractor should carry out installation checks and tests before operational tests are carried out (see Chapter 4); these may be repeated by the MP/TP if required.

5.2 Operational tests and performance qualification (see Chapters 5 and 6) tests are carried out by the MP/TP.

5.3 Unless otherwise specified in Chapter 8 the tests should be carried out with the WD at normal working temperature, which may require a 'warm-up' run to be carried out before commencement of testing.

5.4 A number of the tests required can be carried out concurrently on the same operating cycle and this is also indicated in Chapter 8.

5.5 The calibration of test equipment should be checked before and after use as described in Chapter 8.

5.6 In principle, performance qualification tests should be carried out after operational tests have been completed. However, for WDs employing a thermal disinfection stage, the performance qualification tests may be performed while the temperature sensors used in the commissioning tests are still in place.

5.7 Although dishwashers generally are excluded from this SHTM, there may be instances where, due to local needs, dishwashers should be tested to verify compliance with current disinfection standards (especially in the case of patients who are immunologically compromised).

5.8 The responsibility for microbiological tests rests with the user, microbiologist and control of infection officer. The scope and contents of any tests will be incorporated in local protocols agreed between the above persons and will take account of local circumstances.

5.9 During the commission of WDs for endoscopes, the Occupational Health Officer should carry out tests on and around the machine for traces of disinfectant vapour, particularly in the vicinity of the door or lid when opening at the end of a process. The frequency of testing will be determined by the local Occupational Health Officer.

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6. Schedule of performance qualification tests

Introduction

6.1 Performance qualification (PQ) is the procedure for obtaining documented evidence that the WD, as commissioned, will produce cleaned and/or disinfected goods of the standard required when operated in accordance with the operational instructions.

6.2 PQ tests are performed as part of the initial validation procedure, as part of any repeat validation procedure and whenever the user, acting on the advice of the Independent Advisor, judges that new loading or operating conditions require a new PQ test.

6.3 Circumstances that may lead to new PQ tests would include changes to the quality of the water supply, changes to the chemical additives used in the cleaning and disinfection process, changes to the loading system or the requirement to process a new type of product.

6.4 Performance qualification should not be undertaken on any WD until the requirements of the installation and operational tests specified in Chapters 4 and 5 have been met.

6.5 Soil removal efficacy tests are required for all WDs as part of the performance qualification (see Para 6.24).

6.6 Performance qualification tests are carried out by the MP/TP.

6.7 Tests should be carried out with the WD at normal working temperature which may require a ‘warm-up’ run to be carried out before commencement of the tests.

6.8 Test data obtained from the PQ tests should be recorded in a written PQ report which clearly identifies the loading conditions, the operating cycles, the chemical additives and the water quality used at each stage of the cycle.

6.9 The user should employ the PQ report to confirm the suitability of the process for loads which are to be processed. It should be used by the MP/TP and Independent Advisor as the basis for comparison with subsequent performance requalification tests.

6.10 Performance requalification (PRQ) is the process of confirming that the WD continues to meet the performance standards established during PQ and that the working data established during PQ tests remain valid.

6.11 Performance requalification is carried out annually as part of the yearly test schedule, as part of any revalidation or repeat validation study, or whenever the user requests such confirmation.

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6.12 Before undertaking performance requalification tests the MP/TP should confirm, either by testing or by reference to current test records, that the WD meets the requirements of the installation and operational tests.

Loading conditions

6.13 A **loading condition** is a specified combination of the nature and number of load items, the items of chamber furniture, and their distribution within the chamber. For example, a load placed on the topmost level of a four level load carrier constitutes a different loading condition from the same load placed on the lowest level.

6.14 In principle, validation is not complete until a PQ test has been performed for each loading condition that the WD is expected to process.

6.15 In practice, the loading conditions specified in the tests to be carried out during commissioning are designed to represent the nature of production loads and to present a greater challenge to the process than production loads. In these cases further PQ tests will not be required; the data obtained from the commissioning tests will be sufficient.

6.16 PQ tests are required under the following conditions:

a. when the proposed production loading condition presents a greater challenge to the process than that presented by the commissioning tests; for example, WDs for surgical instruments will require PQ tests if the mass of metal instruments to be processed exceeds that of the standard test load or if it is intended to process instruments with narrow lumens;

b. when the nature of the load is not represented by the commissioning tests; for example, WDs for surgical instruments will require PQ tests if it is intended to process instruments with narrow lumens such as endoscopes.

6.17 When PQ tests are required it is often possible to select a production load that is known to be a greater challenge to the process than any of the others. This **reference load** can then serve as a ‘worst case’ and allow one PQ test to be valid for a range of less demanding conditions.

Surrogate devices

6.18 Many of the devices that constitute the most difficult loads to process in a WD, which therefore require PQ, are difficult to monitor either thermometrically or microbiologically, are in short supply and are extremely expensive; examples include fibre-optic endoscopes, videoscopes, etc.

6.19 A **surrogate device** is a test piece designed and constructed to emulate the characteristics of a device to facilitate appropriate monitoring of the cleaning and disinfecting processes.

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6.20 An example of a surrogate device might be a rigid endoscope emulated by a similar length of stainless steel tube of appropriate diameter and bore. The surrogate device can be constructed to incorporate the appropriate temperature sensors so that it may be separated into sections to facilitate the evaluation of residual test soil or survivors from a microbial challenge.

6.21 The surrogate device should have similar geometry and thermal mass and, as far as may be practicable, should be constructed of the same materials and the same surface finishes as the device it is designed to emulate. There are several devices available for assessing the efficacy of WD processes, and these can be used in conjunction with the reference loads as part of the testing procedures. Their suitability to a particular process should be verified before use. Advice should be sought from the Independent Advisor.

6.22 When an instrument presents particular problems in validation the manufacturer of the instrument should be requested to provide details of the method by which they recommend that PQ studies should be performed.

Cleaning efficacy tests

Native soiling

6.23 Cleaning efficacy tests are intended to demonstrate the ability of the WD to remove or reduce to acceptable levels, soiling and contamination which occurs during normal use of re-usable items.

6.24 Naturally occurring contamination shows considerable variation both in the nature and proportion of constituents and also in the extent of soiling which may occur during use.

NOTE: These tests should be carried out by the user in conjunction with the Microbiologist.

6.25 Test methods based on the detection of naturally occurring soiling are difficult to standardise and show poor reproducibility due to:

a. the variation in the composition of the soiling which may affect the ease with which soiling is removed;

b. the changes in sensitivity of detection which may occur due to variation in composition of the soiling;

c. the variation in the extent of soiling.

6.26 A number of methods exist for estimating (both qualitatively and quantitatively) the residual levels of some important soils or components of soils. These include detection of blood (Hydrogen peroxide test, Kastle-Meyer test), protein (Ninhydrin test, Biuret test) or bacterial endotoxins (LAL test).

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6.27 Common practice in the past has been to rely solely upon visual inspection to detect unacceptable levels of residual soiling. This method has poor sensitivity, is very subjective and can be greatly influenced by a number of factors including the intensity and nature of the illumination in the inspection area.

Test soils

6.28 Artificial test soils are designed to simulate the nature of native soiling and to be equally, or more difficult to remove.

6.29 By incorporating appropriate marker substances, they can provide improved sensitivity of detection.

6.30 Test soils can be used to give a quantified loading level, quantified detection and hence a quantified estimate of the soil removal which has occurred.

6.31 Test soils avoid any hazard which may be associated with native soiling (for example blood borne viruses) which may be of particular concern with the more extensive handling necessary for test work.

6.32 Worldwide, many different test soils have been specified for testing WDs but they generally fail to meet the key criteria necessary for a test soil.

NOTE: These tests should be specified by the Independent Advisor.

Standard test soils

6.33 Current proposals for the European standard for WDs are to specify a test method for the validation of test soils. This would allow acceptance of the use of any test soil which meets the defined criteria and is validated as equivalent to a particular native soil, or soils.

6.34 Test soils are specified in BS 2745.

NOTE: These tests should be specified by the Independent Advisor.

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Process residues

6.35 The nature of process residues and the level of such residues that may be of concern depend on the chemical additives and quality of water used during the process and the intended use of the washed and disinfected product.

6.36 The water used for the process may give rise to a number of chemical residues on processed items. The most obvious of these is the presence of limescale from the use of hard water.

6.37 The water used for the process may give rise also to contaminants of microbial origin. Bacterial endotoxins, primarily derived from the cell wall of Gram negative bacteria, may give rise to adverse (pyrogenic) reactions when introduced into the mammalian body. Items not autoclaved and intended for surgically invasive use or for the preparation or administration of parenteral fluids should be free from, or have acceptably low levels of, bacterial endotoxins.

NOTE: These tests should be carried out by the user in conjunction with the Microbiologist.

6.38 The chemical additives used during the process (detergents, rinse aids etc.) may not be completely removed by the rinsing process. The residual level which may be tolerated will depend upon the nature of the chemical and the intended use of the product. The supplier of any chemical agent used should provide data on the chemical composition of the chemical agent and the biocompatibility of the components of the chemical agent. The supplier should also provide details of the method of detection, which may be used to determine whether processed items are free from residuals at the specified levels.

Disinfection

Thermometric tests

6.39 Thermometric tests are required for both thermal disinfection processes and chemical disinfection processes.

6.40 For thermal disinfection processes the time temperature relationships which are generally regarded as acceptable are shown in Table 3.

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Table 3: Thermal disinfection temperature bands

Disinfection temperature (°C)[a]	Minimum exposure time (minutes)	Maximum allowable temperature (°C)
65	10	70
73	3	78
80	2	85
90	1[b]	95
93[c]	10	98

Note:

a. The disinfection temperature is measured at the surface to be disinfected.

b. The exposure time of 1 second (as specified in BS 2745 Part 1) is too short for reliable measurement and a minimum time of 1 minute should be used.

c. This time/temperature relationship is only used for items known to be contaminated with large amounts of pathogenic organisms, for example in laboratories.

Microbiological tests

6.41 A microbiological PQ test is required, in addition to the thermometric test, for WDs in which disinfection is carried out using a chemical germicidal agent (see Chapter 10).

6.42 Normally, microbiological testing is not required for thermal disinfection processes. If particular circumstances make such testing necessary or desirable the advice of the microbiologist should be sought. Direct evaluation of microbial efficacy within the WD is difficult. Whenever practicable, microbiological testing should be carried out by:

a. undertaking a laboratory investigation of the inactivation characteristics of the micro-organisms of interest (that is, by determination of the D value and Z value over the range 65ºC to 95ºC);

b. calculating from these data the exposure conditions necessary to give the required assurance of disinfection;

c. determining attainment of the required exposure conditions in the WD by physical measurement (temperature, time etc.).

NOTE: Advice of the microbiologist should be sought for these tests.

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Load dryness tests

6.43 The presence of residual water on cleaned and disinfected items is undesirable since it may interfere with the correct functioning of the item, promote re-contamination and microbial growth, or prevent attainment of sterilizing conditions. In many cases these data will already be available from the published literature.

6.44 The ability of the WD to dry the load may be evaluated either visually, when appropriate, or by drying to constant weight and determining the mass of residual water present at the end of the WD process cycle.

PQ report

6.45 All the data collected during PQ tests should be filed in a PQ report, a copy of which should be kept with the plant history file.

6.46 The PQ report should contain or refer to the complete specification for the washing/disinfection process. The specification should be sufficiently detailed to allow the loading condition and the operating cycle (including the type and volume of all chemical additives and the water quality) to be replicated on any future occasion.

6.47 The report should include the following:

a. a specification of the loading condition defined by the nature and number of the load items, items of chamber furniture and their distribution within the chamber; photographs taken of the load are valuable for future reference and can minimise the need for extensive descriptive text;

b. a specification of the operating cycle, defined by the settings for the cycle variables; for microprocessor based control systems a copy of the program held independently on electro-magnetic storage media is suitable also;

c. a specification of the service supply, defined by reference to the nature and volume of all chemical additives and the quality of the water service(s);

d. a specification of any pre-test operation of the WD, for example a warm-up cycle;

e. a specification of any pre-treatment of the test load, for example manual cleaning, ultrasonic cleaning etc;

f. all the indicated, recorded and measured data from the test; these should be annotated with the target values and permitted tolerances of elapsed time and other cycle variables at all significant points of the operating cycle, for example at the beginning and end of each stage or sub-stage;

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g. for WDs equipped with process recording, the original of the process record derived from the test should also form part of the record.

Master process record

6.48 A master process record (MPR) is a record of the values and permitted tolerances of cycle variables for a correctly functioning operational cycle against which test and production cycles can be checked.

6.49 It is derived from the process records obtained during a PQ test, or during commissioning when no PQ test was required.

6.50 The MPR may be a 1:1 copy of the process record from a chart recorder, a template derived from the process record or data stored in a computer system and compared automatically with the data from each production run.

6.51 An MPR is intended to facilitate production control on WDs when the attainment of the validated standards of cleanliness and disinfection are critical to the safe subsequent use of the product.

6.52 When a number of different processes and different loading conditions are to be used for production it will be necessary to prepare an MPR for each operational condition.

Tests for performance requalification

6.53 Performance requalification (PRQ) tests are performed once a year to ensure that the established criteria for cleaning and disinfection are still being met. The PRQ tests should follow the yearly schedule of tests and checks listed in Chapter 7.

6.54 For a given operating cycle it is necessary to perform the PRQ tests only for those reference loads for which a PQ test was performed and reported.

6.55 The need for additional PQ tests in the light of changes in the nature of loads being processed should be agreed between the user and the TP.

6.56 The procedure for the PRQ test is essentially the same as that used for the corresponding PQ test. The operating cycle and the loading conditions used should be identical with those used previously for the PQ test.

6.57 The PRQ test should be considered satisfactory if the values of the measured variables are within the tolerances stated in the PQ report.

6.58 The results of the PRQ tests should be linked with the relevant PQ report and retained securely.

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6.59 The PRQ test should meet the specified requirements without difficulty for a WD which has passed the yearly test programme. If the PRQ test is not satisfactory the advice of the Independent Advisor and/or the WD manufacturer should be sought.

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TABLE 4

Tests carried out following commissioning and at any time a machine is subjected to change or major service

TESTING SCHEDULE

Type of WD	Performance Qualification					
	Installation Checks	Cleaning Efficacy Test		Operational Tests		
Para Ref.	(10.3)	(6.35)	(9.113)	(7.8)	(11.4)	(9.95)
	Thermometric Test	Process Residues	Load dryness test	Safety Checks	Automatic Control Test (each cycle)	Verification of WD Instrument Calibration
Human Waste	MP/TP		U/M	MP/TP	MP/TP	MP/TP
Surgical Instruments	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Holloware	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Anaesthetic Accessories	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Endoscopes	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Laboratory	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP
Utensils & Crockery	MP/TP	U/M	U/M	MP/TP	MP/TP	MP/TP

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7. Schedule of periodic tests

Introduction

7.1 Periodic tests are carried out at daily, weekly, quarterly and yearly intervals. They are the shared responsibility of the MP/TP, microbiologist and the user.

7.2 The yearly test schedule is identical to that required for revalidation. It contains the tests required for re-commissioning and for re-qualification of the performance of the WD.

7.3 Tests should only be undertaken after completion of the planned maintenance tasks described in SHTM 2030 Part 2; 'Operational management'.

7.4 Unless otherwise specified in Chapter 9 the tests should be carried out with the WD at normal working temperature, which may require a 'warm-up' run to be carried out before commencement of testing.

7.5 A number of the tests required can be carried out concurrently on the same operating cycle and this is also indicated in Chapter 9.

7.6 The results of periodic tests, whether carried out by the MP/TP, microbiologist or the user, should be filed securely, for example in the plant history file.

7.7 Although dishwashers generally are excluded from this SHTM, there may be instances where due to local needs, dishwashers should be tested to verify compliance with current disinfection standards (especially in the case of patients who are immunologically compromised).

Weekly safety tests

7.8 The user should examine the door seals as a safety check before starting the sequence of weekly tests.

7.9 For WDs which include a pressure vessel or pressure system (for example steam or compressed air), make any check required by the competent person in connection with the written scheme of examination for the pressure vessel.

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Yearly safety tests

7.10 In order to ensure the continued safe functioning of the WD the MP/TP should conduct a series of safety tests before starting the yearly tests.

7.11 The Independent Advisor should draw up a documented programme of the yearly safety tests necessary for a particular installation.

7.12 The original installation checks and tests may be used as a basis for the yearly safety test paying particular attention to those factors which affect safety and especially to those which may have changed since the previous annual safety test (or installation test).

7.13 The adequacy and safe connection of all engineering services should be verified.

7.14 The responsibility for microbiological tests rests with the user, microbiologist and control of infection officer. The scope and contents of any tests will be incorporated in local protocols agreed between the above persons and will take account of local circumstances.

7.15 During the commission of WDs for endoscopes, the Occupational Health Officer should carry out tests on and around the machine for traces of disinfectant vapour, particularly in the vicinity of the door or lid when opening at the end of a process. The frequency of testing will be determined by the local Occupational Health Officer.

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TABLE 5

SCHEDULE OF PERIODIC TESTS

Type of WD	Daily Test				Weekly Test			Quarterly Tests								
Para Ref.	(11.4)	(9.101)				(13.5)	(6.27)		(7.8)		(10.3)	(9.31)	(9.69)	(9.73)	(9.76)	(9.80)
	Automatic Control Test (Roate cycles)	Check Spray Arm for Rotation & Blockages	Remove & Clean Strainers /Filters	Check Spray Nozzles for Blockage	Carry out Daily Test	Monitor final rinse water quality	Cleaning Efficacy	Carry out Daily and Weekly Tests	Safety Checks	Basic Function of Engineering Services	Thermo-metric Tests for Disinfection	Water system Chemical Purity	Doors & Interlocks			
													Cycle start	In Cycle	Double ended WD	Fault indication
Human Waste	U	IF FITTED	U	U	U/MP		U/M	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP	MP/TP	MP/TP	MP/TP
Surgical Instruments	U	U	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Holloware	U	U	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP	MP/TP	MP/TP	MP/TP
Anaesthetic Accessories	U	IF FITTED	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Endoscopes	U	IF FITTED	U	U	U/MP	U/M	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Laboratory	U	U	U	U	U/MP		U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP
Utensils & Crockery	U	U	U	U	U	U/MP	U/M	MP/TP	MP/TP	MP/TP	MP/TP	From Local Water Authority	MP/TP	MP/TP	MP/TP	MP/TP

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TABLE 5

SCHEDULE OF PERIODIC TESTS

Type of WD	Yearly and Revaliation										(Weekly, Quarterly, Yearly) Cleaning Efficacy Test	
Para Ref.		(11.4)	(8.29)	(9.88)	(9.90)	(18.9)	(18.3)	(17.3)	(9.101)	(9.108)		
	Carry out Daily, Weekly and Quarterly Tests	Automatic Control Test (each cycle)	Verification of WD instrument calibration	Chemical Dosing		Channel Patency	Self Disinfection	Ultrasonic Activity	Load carrier temperature test	Over temperature protection test (if fitted)	Reference Load	Endoscopic /MAT instruments
				Reprod-ucibility	Low Level Detection							
Human Waste	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP				MP/TP	MP/TP IF FITTED	U/M	U/M
Surgical Instruments	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP/U	MP/TP	MP/TP IF FITTED	U/M	U/M
Holloware	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP				MP/TP	MP/TP IF FITTED	U/M	U/M
Anaesthetic Accessories	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP			MP/TP	MP/TP IF FITTED	U/M	U/M
Endoscopes	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP		MP/TP		U/M	U/M
Laboratory	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP			MP/TP	MP/TP IF FITTED	U/M	U/M
Utensils and Crockery	MP/TP	MP/TP	MP/TP	MP/TP	MP/TP				MP/TP	MP/TP IF FITTED	U/M	U/M

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M = Microbiologist or Control of Infection Officer

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Schedule of typical periodic tests

Daily Test (where applicable)
- automatic control test
- check spray arm for rotation (if fitted)
- check spray nozzles for blockage
- remove and clean strainers/filters

Weekly Test (where applicable)
- carry out daily test
- cleaning efficacy

Quarterly Tests (where applicable)
- daily and weekly tests
- safety checks
- basic function of engineering services
- thermometric tests for disinfection
- chemical purity (water system)
- doors and interlocks (start, in cycle etc)

Yearly Tests and Revalidation (where applicable)
- daily, weekly and quarterly tests
- automatic control test (each cycle)
- verification of WD instrument calibration
- water system purity
- chemical dosing (reproducibility/low level detection)
- channel patency
- self disinfection
- ultrasonic activity
- load carrier temperature
- over temperature protection
- cleaning efficacy (consult Microbiologist/Independent Advisor)

The precise schedule of periodic tests should be agreed with the independent advisor, microbiologist and the control of infection officer, recognising the manufacturer's recommendations.

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8. Test equipment and materials

Introduction

8.1 This chapter reviews the major items of portable test equipment necessary to carry out the test procedures described in this SHTM.

8.2 Instrumentation technology continues to advance rapidly making it increasingly difficult and undesirable to provide detailed specifications for the equipment to be used in testing WDs. There is a trend towards computer controlled data loggers with software which enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated and/or graphed data. Although these new systems may offer advantages, the traditional instruments, such as chart recorders, remain the accepted standard.

8.3 The objectives of this chapter are both to ensure that traditional measurement methods are supported adequately and to define clearly the essential requirements that apply to the test equipment whether it is a traditional system or the latest technology.

8.4 When it is proposed to use measurement and/or recording techniques that are not covered in this SHTM the advice of the Independent Advisor should be sought.

8.5 It has been assumed also that there will be ready access to standard laboratory equipment and supplies.

Calibration and sources of error

8.6 The integrity of the measuring system is essential in order to obtain meaningful results. Significant errors can arise through improper use of calibration instruments and it is therefore important that staff are trained and skilled in their use. Two types of errors exist: Intrinsic and Introduced. Intrinsic errors relate mainly to the instruments best capability and usually cannot be improved upon without modification. Introduced errors may be very small or great, depending upon the skill used in the process.

Careful attention to detail including the location of the test instruments, effective maintenance and the skill of personnel trained in the application, handling and use of the instruments are required to eliminate or minimize errors. Systematic errors can be reduced by careful calibration.

8.7 Instruments should be subjected to a planned maintenance and calibration programme in accordance with the instrument manufacturer's recommendations. The drift status of instruments should be monitored to ensure that they remain within their intrinsic specification. Each instrument

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should be labeled with a unique reference number, a calibration date, date due and a reference to a UKAS/NAMAS laboratory reference from which its current calibration status may be traced. If being transported, a suitable protective carrying case should be used.

8.8 The calibration of all test instruments should be verified at a frequency defined by the stability of the equipment. In the first instance the period should be at least yearly. Calibration should be carried out against reference instruments with a valid certificate of calibration provided within a NAMAS or ISO/EN17025 scheme of accreditation. A written procedure that describes the calibration method should be prepared and made available for the Independent Advisor to review. A history record should be kept for each instrument.

8.9 All test instruments should be located in a position protected from draughts and not subjected to rapid temperature variations. Test instruments should be allowed a period of time to stabilize within the environment of the test site prior to use. The instrument manufacturer's instructions should be followed.

Recorders

8.10 Test recorders are required to measure temperature in all types of WD and may also be required for the measurement of pressure, flow rates and humidity. They should be designed for use with the appropriate sensors, independent of those fitted to the WD. Most of the tests described in this SHTM may be conducted with a single recorder combining both temperature and pressure functions showing both records on the same chart or printout. For WDs incorporating humidity control or humidity monitoring of a hot air drying stage, the measurement of humidity is desirable but not essential.

8.11 Analogue recorders should comply with the display requirements of BS 3693. Recorders using a potentiometric system should comply with BS 5164.

8.12 Digital recorders (data loggers) have many advantages over traditional pen recorders. Data may be presented graphically or as a listing of numerical values or as a combination of both. In many cases parts of the operating cycle can be expanded and replotted for closer examination.

8.13 Digital recorders should have the facility to copy data onto tape or disk which can then be removed for secure storage. Software used with digital recorders should be developed under a quality system (such as BS EN ISO 9001).

8.14 The accuracies quoted by recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. Temperature measurement errors due to ambient temperature changes should not exceed 0.04°C per °C rise.

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Temperature measurement

Temperature sensors

8.15 Temperature sensors should be used to sense the temperature in locations specified in the tests described in this SHTM. The sensors should be either platinum resistance elements complying with BS EN 60751 or thermocouples complying with BS EN 60584.

8.16 The performance characteristics of the temperature sensor should not be adversely affected by the environment in which it is placed, e.g. pressure, hot detergent solution etc.

8.17 In order to avoid undue disturbance of the system being measured, the major diameter of the temperature sensors and their connecting leads which will be located within the WD should not exceed 2 mm.

Thermometric recording instrument(s)

8.18 One or more thermometric recording instruments should be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described in this SHTM. They may also be used to verify the readings obtained from instruments fitted to the WD.

8.19 The recording instrument(s) should record the temperature from a minimum of eight temperature sensors. The channels may be multiplexed or independent of one another. The data recording rate for each channel should not exceed 1.0 s. All data sampled should be used for the interpretation of results.

8.20 The scale range should include the expected maximum and minimum values of the cycle variables throughout the operating cycle with sufficient allowance for any deviations resulting from a malfunctioning WD. This should normally include at least the range 10°C to 110°C. Instruments determined as suitable for testing sterilizers according to SHTM 2010 will normally be suitable for most systems except tunnel washers.

8.21 In some WDs the air temperature close to the heater bank during the drying stage may considerably exceed the upper limit of the air drying temperature.

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8.22 The most critical stage of the WD operating cycle is the disinfection stage. It is during this period that the values of the cycle variables are at their most critical and the recorder should be capable of measuring them to sufficient accuracy to confirm that the disinfection conditions have been attained. The criteria are as follows:

a. For digital recorders, the sampling interval should be short enough for the holding time to contain at least five independent measurements in each recording channel;

b. The response time of the recorder should be short enough to enable the output to follow significant fluctuations in the cycle variables and to ensure that successive measurements are independent of each other. It should not be longer than the sampling interval;

c. The recorder must be accurate enough to show clearly whether the measured temperatures are within the disinfection temperature band. The intrinsic repeatability of the recorder should be ± 0.25°C or better and the uncertainty of measurement of the complete measurement system including sensors should be no more than ± 0.5°C taking all component errors into consideration. The additional error due to changes in environmental temperature should not exceed 0.04°C per °C;

d. For analogue instruments the minor mark interval should not exceed 0.5°C and the chart speed should be not less than 10 mm per minute/600 mm per hour. The resolution should be not less than 0.5°C. Digital instruments should register and record in increments of not more than 0.1°C.

NOTE: For the shortest holding time recommended (1 second at 90°C) this would correspond to a sampling interval of 0.2 second. However it is suggested that the minimum exposure time set should be not less than 12 seconds for which a sampling interval of 1 second is then appropriate. For pen recorders the chart speed should be fast enough to allow fluctuations on that scale to be clearly resolved. The duration of the holding time should be measurable to within ± 10%.

Use of sensors

8.23 WDs conforming to BS 2745 are equipped with thermocouple entry glands.

8.24 In older machines, having no dedicated entry port, sensors can be introduced through a door seal, with care. If possible, sensors should be distributed across the point of entry so that the integrity of the seal is not compromised, i.e. it is not good practice to introduce 8 thermocouples into a chamber via a door seal all at the one point since this will invariably compromise the seal.

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8.25 Many of the tests require a sensor to be placed at the reference point specified by the manufacturer as representative of the conditions prevailing throughout the chamber and load. This will usually be in the drain or sump of the chamber and will often be adjacent to the sensor used for the automatic controller.

8.26 The sensors may often be placed in positions where they are submerged for most of the cycle. Under these conditions water may migrate along the wire between the cores and the outer insulation sheath. To prevent damage to the recorder the outer sheath should either be punctured or stripped back a few centimetres from the end connected to the recorder to allow droplets of water to fall clear of the recorder.

8.27 Sensors used to monitor the temperature of load items and the chamber walls should be held securely in good thermal contact with the region to be monitored using high temperature masking tape or autoclave indicator tape.

Calibration

8.28 Calibration should be carried out in accordance with the instrument manufacturer's instructions by a validated method using a working or reference standard which is traceable to a UKAS/NAMAS laboratory reference.

8.29 It is normal practice to use a recorder which is routinely calibrated against an independent thermometer prior to measurement work on the WD being carried out. The independent thermometer is usually placed in a heat source or bath as are the recorder sensors. A comparison calibration is then carried out. The heat source should be of a design that meets the recommendation of publication EA-10.13 Feb 2000 'Guidelines on the calibration of temperature block calibrators'. Procedures used when applying comparison calibrations should also be in accordance with these guidelines. Comparison calibration is carried out before and after each series of tests on a WD. The heat source should be of a design that meets the recommendation of publication EA-10.13 Feb 2000 'Guidelines on the calibration of temperature block calibrators'. Procedures used when applying comparison calibrations should also be in accordance with these guidelines, and at a temperature within the disinfection temperature band.

8.30 Adjustment may be carried out to the recorder prior to testing to ensure the best results are obtainable. Following any adjustment, the temperature measured by all temperature sensors when immersed in a temperature source at a temperature within the disinfection temperature band should not differ by more than ±0.25 Deg ºC.

8.31 The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within ± 0.1°C and within the disinfection temperature band should not differ by more than 0.5°C after calibration and adjustment.

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Self contained systems

8.32 Temperature measuring systems involving the use of leads from the sensing point within the load to an external measuring instrument are difficult or impractical to use within several designs of WD, for example continuous process machines consisting of several interconnecting cabins which are separated by intermediate doors during processing.

8.33 Single channel data loggers should only be used as a complementary test and trend of the full process. Full temperature mapping by traditional means remains the standard.

8.34 A number of different designs of small self-contained single channel data loggers for the measurement of temperature are commercially available. They are independently powered, may be programmed to take readings at the required rate for the required duration and are downloaded onto a personal computer on completion of the data logging period. Those housed in protective cases rated at IP68 are suitable for inclusion in washing machines.

8.35 Care needs to be taken in selecting units which are capable of withstanding the high temperature which may be found during the thermal disinfection stage (90°C) and drying stage (105°C) of the cycle since many of these devices are powered by batteries which will not withstand temperatures above approximately 75°C.

8.36 Data loggers with an external probe may be housed in an insulated waterproof container through which the lead to the sensor passes by means of a leak tight gland. A 25 mm thick layer of mineral wool insulation on all surfaces of a data logger contained within a 1000 ml screw top polypropylene jar has proved suitable. The waterproof container should protect the device from elevated temperatures.

8.37 The accuracy obtainable from these units is rarely to the standard specified for conventional temperature recorders but the limit of error should not exceed ± 0.8°C when tested over the range 0°C to 100°C at an ambient temperature of 20°C ± 3°C. Rapidly changing environmental temperatures, which can cause thermoelectric currents to alter measurement stability, are the most likely reasons for the greatest errors. The additional error due to changes in environmental temperature should not exceed 0.04°C per minute. Instruments should register and record in increments of not more than 1°C.

8.38 The device should be capable of recording the sensed temperature at least every 1 second and should be capable of storing not less than 1800 records.

8.39 For continuous process WDs, not less than three such devices will be needed together with a conventional temperature recorder.

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Pressure measurement

8.40 Pressure may be required to be measured over the range from atmospheric to 10 bar (for example for the water supply pressure). Differential pressure of 1 –100 hectoPascals may be required to be measured (for example for the determination of the pressure drop across filters).

Transducers

8.41 Transducers for use with pressure recorders should conform with BS 6447, be suitable for the purpose and be of an accuracy equal to, or better than, the gauges specified below. The natural frequency of the sensor and connected tubing should be not less than 10Hz and the time constant for rising pressure (0–63%) should be not greater than 0.04 seconds.

Gauges

8.42 Pressure gauges are required when the pressure recorder is unsuitable or for verifying the calibration of pressure instruments fitted to the WD.

8.43 Three pressure gauge ranges will normally cover the whole pressure range for all WDs.

8.44 Pressure gauges should be temperature compensated and except for the differential pressure gauge be Bourdon-tube gauges conforming to BS EN 837 of nominal size 150 mm and accuracy class 0.25 (that is, the air should not exceed 0.25% FSD).

8.45 Gauges should be tested yearly by a recognised testing laboratory as described in BS EN 837-1, 1998.

8.46 The measurement of differential pressure across air filters may be made with an inclined water manometer.

8.47 The recorder for pressure measurement should have an overall limit of error no more than 1% of the maximum specified operating pressure.

Flow measurement

Water

8.48 The volume of water used for each stage of the operating cycle may be measured using a water meter complying with BS 5728.

8.49 The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 16 bar.

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NOTE: When the meter is connected in the pipe there will be a noticeable pressure drop across the meter. Although this should be less than 1 bar it may interfere with the normal operation of the WD and therefore should not be used during tests for other characteristics than the volume of water used.

8.50 The meter should have a minimum scale division of 0.1 litres or less and be designed to measure flow rates over the range 1 litre per minute to 25 litres per minute.

8.51 A single jet turbine system is sufficiently accurate for the purpose. Other systems such as multi-jet turbine or semi-positive displacement systems complying with BS 5728 Class D, may also be used.

Chemical additives

8.52 The volume of chemical additive used for each stage of the operating cycle may be measured using a flow meter. There are a number of commercially available flow sensors designed to monitor flows in the range 0 to 2 litres/minute which are suitable for interfacing to a recorder or datalogger.

8.53 The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 10 bar.

8.54 The system should have an accuracy of ± 2.5% of full scale deflections or better.

8.55 The calibration of the meter should be verified by determining the indicated volume flowing, using a graduated measuring cylinder.

Gas monitoring equipment

8.56 A gas monitoring instrument is required for tests on WDs using chemical additives which have a significant vapour pressure and are a potential risk.

8.57 The nature of the instrument will depend on the substance to be monitored. In case of doubt, advice should be sought from the manufacturer of the chemical additive or the Independent advisor.

8.58 The scale range of the measuring instrument should include the appropriate short term exposure limit or occupational exposure limit and extend to at least ten times that exposure limit.

Aerosol generator

8.59 An aerosol generator is required for tests on WDs incorporating air filters intended to deliver air free from micro-organisms.

8.60 The device should be capable of generating a polydisperse aerosol with

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particles having the size distribution shown in Table 6.

Particle counting photometer

8.61 A particle counter is required for tests on WDs incorporating air filters intended to deliver air free from micro-organisms. The device should be suitable for estimation for comparison of mass concentration of airborne particles as defined in Table 6.

8.62 It should have an accuracy of better than ± 5% over the range of a five-expandable, six-decade resolution (that is 0.01% to 100% of the test cloud) as specified in Appendix C of BS 5295: Part 1.

8.63 The photometer should have a minimum threshold sensitivity of 0.0001 μgl^{-1} and should be capable of measuring aerosol concentration in the range 80-120 μgl^{-1}.

8.64 The sampling flow rate should be 0.40 ± 0.05 ls^{-1} and sampling should be via a suitable probe.

Table 6: Particle size distribution for aerosol generator

Particle size µm	Fraction % by mass
<0.5	>20
<0.7	>50
<1.0	>75

Source: BS 5295: Part 1

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9. Testing methods

Introduction

9.1 This chapter discusses general principles and methods that are used in the tests described in this SHTM.

Terminology

9.2 For the purposes of this SHTM the following definitions have been adopted.

Cycle variables

9.3 The **cycle variables** are the physical and chemical properties such as time, temperature, pressure, flow rate, concentration and chemical composition that influence the efficacy of the cleaning and disinfection processes. Many of the tests described in this SHTM require the values of cycle variables to be determined experimentally and then compared with specified or standard values.

9.4 An **indicated value** is that shown by a visual display fitted to the WD.

9.5 A **recorded value** is that shown on the output of a recording instrument fitted permanently to the WD.

9.6 A **measured value** is that shown on a test instrument, for example a temperature recorder attached to the WD for test purposes.

9.7 A **noted value** is that written down following personal observation of an indicated, recorded or measured value.

Disinfection conditions

9.8 Most operating cycles have a stage in which the load is exposed to the disinfection conditions for a specified length of time. This period is known as the **holding time**.

9.9 The **disinfection conditions** are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

9.10 The holding time is preceded by a period in which the disinfection conditions are present in the chamber but have yet to be attained throughout the load. This is known as the **equilibration time**.

9.11 Together the equilibration time and the holding time constitute the **plateau period**. The plateau period can always be determined from the indicated or recorded temperature in the chamber during each cycle. The equilibration

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and holding times cannot be ascertained unless the temperature in that part of the load which is slowest to reach temperature is also being measured.

9.12 For thermal (moist heat) disinfection, the disinfection conditions are specified by a **disinfection temperature band**, defined by a minimum acceptable temperature, known as the **disinfection temperature**, and a **maximum allowable temperature**.

9.13 The higher the disinfection temperature the shorter the holding time which will be required to achieve the same level of disinfection (see Table 3).

9.14 For liquid chemical disinfection, the disinfection conditions are specified by a **disinfection temperature band** and a **disinfectant contact concentration range**. The disinfection temperature band is defined by a minimum acceptable temperature, known as the disinfection temperature and a maximum allowable temperature. The disinfectant contact concentration is specified by the minimum acceptable concentration in contact with the load to be disinfected and the maximum allowable concentration.

9.15 For those WDs in which the chemical disinfection stage is thermostatically controlled at elevated temperature, the duration of the exposure to chemical germicide may be determined thermometrically. In most cases, investigation of the performance of chemical disinfection processes can only be carried out successfully using microbiological test methods in conjunction with physical testing.

9.16 The disinfection temperature band may also be quoted for liquid chemical disinfection/sterilization processes but is not a complete specification of the disinfection conditions since the efficacy of such processes depends also on the concentration of the chemical agent.

Blocked drain protection (Commissioning Test)

Introduction

9.17 In the event that the drain from the chamber of the WD become blocked, continued operation of the WD must not allow water and suspended soil to be discharged either during the operating cycle or, for cabinet type WDs with sealed door(s), by sudden discharge when the door is opened at the end of the cycle.

9.18 The purpose of blocked drain protection is to prevent spillage and minimise the risk of cross-infection.

9.19 In the test, the drain is deliberately blocked and successive operating cycles are run until the water level is above the level of the door seal. The test is intended for use both as a type test (and as such is a requirement of BS 2745: Part 2 1993) and as an installation test.

9.20 The manufacturer should be consulted to detail a suitable test method.

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Estimation of dead volume of pipework (Manufacturers Type Test)

Introduction

9.21 Residual water that does not drain from the internal pipework of the WD may provide an environment for microbial growth; these micro-organisms may then be available to re-contaminate the disinfected load.

9.22 The test is intended primarily as a Type test but may also be of value as an operational test or when investigating microbial contamination occurring in a WD.

Equipment

9.23 Volumetric measuring vessels of appropriate size are necessary.

Method

9.24 The pipework of the WD which is known to be dry (either following dismantling and re-assembly or purging with dry compressed air for not less than 30 minutes) is flushed with a known volume of water (simulating the flow that would occur in normal use).

9.25 The volume of water flushed through the system should be twice that determined as the volume used per operating cycle. The volume of water discharged is measured and the dead volume, estimated as the volume retained, calculated from the difference between the two values.

9.26 When the WD has two or more pipework systems which are entirely separate (for example for flushing water, wash water, rinse water, chemical disinfectant solution) each system may be tested separately.

Results

9.27 The volume of retained water should be less than 1% of the volume of water used.

For WDs with chemical disinfection systems, the retained volume in the pipework providing the final rinse volume should be, as nearly as possible, zero.

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Water system

Introduction

9.28 A continuous supply of water of the specified chemical and microbiological quality is essential to the correct functioning of all WDs. Water which is too hard or has too high a concentration of dissolved solids may impair the activity of detergents (or require the use of increased quantities of chemical additives) and cause deposits, scaling or corrosion of items being processed.

9.29 Water containing high numbers of micro-organisms may recontaminate disinfected items. For all these tests the water should be sampled from the water supply pipe to each WD. Additional samples may need to be taken from any water treatment plant when trying to identify the cause of a non-conformity.

9.30 Testing of water should be carried out by the microbiologist. The following is a typical example of sampling and testing method.

Water samples

9.31 Water samples should be obtained from draw-off points installed at convenient locations within the system.

9.32 The sampling procedure should be suitable for all the physical, chemical, and biological determinands of interest. It may be used for water samples throughout the water distribution system.

9.33 The sampling containers used should be specific for the determinants of interest. This should include, as appropriate:

a. 330 ml sterile single use plastic containers containing sodium thiosulphate for testing of microbiological quality of water (total coliform, faecal coliforms, and total viable count at 37^{o}C);

b. 250 ml sterile, pyrogen free, single use containers (for determination of bacterial endotoxin levels and/or total viable count);

c. 1 litre acid washed, borosilicate bottles, (for determination of cations);

d. 1 litre polypropylene bottles, (for determination of anions, total dissolved solids);

e. 100 ml high density polyethylene bottles (for determination of pH, conductivity).

9.34 The first 50 ml of sample taken at each sampling point should be run to waste.

9.35 All samples should be taken in duplicate.

9.36 Samples should be tested within four hours of collection or stored at 2°C to

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5°C and tested within 48 hours of collection.

Water quality tests

9.37 The following sections describe analytical methods which may be used to determine the various biological, physical and chemical properties of water samples for the various qualities of feedwater to the WD.

9.38 The methods of analysis required to detect chemical contaminants at low concentrations with a high level of accuracy require the use of a laboratory with appropriate expertise, facilities and experience. Other tests can be carried out on-site or with very simple laboratory facilities; these lack the precision and sensitivity of the laboratory tests but are sufficient for most purposes.

NOTE: Advice on the testing of sterile water for final rinsing, should be sought from the microbiologist.

9.39 This SHTM contains detailed procedures for tests which may be carried out on-site or with very simple laboratory equipment at, or shortly after, the time of sampling.

9.40 The precision, accuracy, sensitivity and limits of detection of these methods are usually inferior to those of laboratory methods. They are useful, however, in that they provide evidence of any gross failure and the results are available straightaway making them of diagnostic value during a fault finding exercise. They are generally economical compared with more sophisticated laboratory analysis and can be carried out by non-specialist personnel after thorough, but limited, training. The results should not however be used as evidence in cases of dispute.

Choice of method

9.41 For any given determinant there will usually be several methods which are suitable and cover the range of concentrations of interest. The methods given below are intended to be representative of those which may be suitable. They are chosen as examples of tests which may conveniently be carried out on site.

9.42 A number of test systems are available commercially. Before adopting one of these methods care should be taken to ensure that the test(s) provides results of sufficient accuracy and sensitivity.

9.43 It is not necessary to use experienced chemical analysts to undertake the on-site analysis of water samples described. It is, however, essential that personnel receive appropriate training before attempting to carry out this work.

9.44 It is apparent that many contaminants will be detected by two or more of the determinations normally carried out for laboratory analysis. For example, an

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increase in one or other of the ionic species present will cause an increase in electrical conductivity and an increase in the evaporative residue as well as showing an increase in the concentration of that particular ion.

9.45 Further guidance on appropriate test methods may be obtained from BS 1427: 1993.

9.46 Tests suitable for use on-site fall into three main categories:

a. **instrumental tests** using portable instruments designed for on-site use for example portable pH meters, ion selective electrodes etc.;

b. **spectrophotometric tests** based on measurement of the absorbance of a coloured reaction product; measurement may be visual or photometric and may be against a precalibrated coloured disc or against standard reference solutions;

c. **titrimetric tests** these may be carried out using standard laboratory equipment or with commercially available apparatus designed for field use; the latter is usually much simpler to use.

9.47 For all the instrumental methods described there is commercially available equipment specifically intended for field use. All the variables for which instrumental methods are described are temperature dependent. The equipment used should be temperature compensated. Also the equipment should be allowed sufficient time on site, before it is put into use, to equilibrate to the local ambient temperature.

9.48 Commercially available test kits based on visual or photometric comparison with coloured discs have become an accepted standard for on site analysis. Manufacturers usually supply a complete test system, including kits of reagents. To ensure compatibility, and maintenance of the manufacturers claimed sensitivity and accuracy for the method, the kit specified by the manufacturer should not be substituted.

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Water supply temperature

Introduction

9.49 The water supplied to the various stages of the WD operating cycle should be at an appropriate temperature. If the temperature of the water supplied to the flushing stage is too high (> 45°C) there is a risk of coagulating proteinaceous soiling and inhibiting the cleaning process. If the temperature of water supplied to the washing, rinsing and disinfection stages is too low the WD cycle may be greatly extended, with a significant reduction in throughput, while the water is heated to the required temperature within the WD. Water supplied in the temperature range 25°C to 40°C presents a serious risk of microbial contamination of the system.

Equipment

9.50 An indicating or recording thermometer is necessary.

Method

9.51 The temperature of the water supply should be measured from a sampling point as close to the WD as possible. Place the temperature sensor in the middle of the flowing stream as close as practicable to the sampling point. Allow the water to flow for at least a minute before the temperature is read.

Alternative method (for periodic testing)

9.52 When it is not convenient, or practicable, to run the water to waste from a sampling point close to the WD the water temperature may be estimated by measurement of the temperature of the outer surface of the supply pipe. When it is intended to use this method the correlation between the temperature of the water flowing out of the pipe and the surface temperature of the pipe at a particular point should be established during installation testing. The surface temperature should be measured using a sensor designed for the purpose and the manufacturer's instructions for ensuring good thermal contact with the surface should be followed. The temperature should be noted or recorded during a normal operating cycle not less than 30 seconds after the start of water flow through the pipe to the WD.

Results

9.53 The noted value should be within the temperature range specified for the installation.

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Water supply pressure

Introduction

9.54 If the pressure of the water supply to the WD is below the minimum pressure specified by the manufacturer, the performance and productivity of the WD will be affected adversely.

9.55 If the pressure of the water supply to the WD is above the maximum pressure specified by the manufacturer, the capacity of overflow devices may be inadequate, the designed performance characteristics of valves etc. may be exceeded and in extreme cases there may be the risk of damage to components of the WD or to products being processed. (For example many flexible endoscopes are likely to be damaged if subjected to internal pressures greater than 35 kPa.)

9.56 The test should be carried out as an installation and/or operational test. The test should be repeated when any change is made to the water services supplying the WD (including the connection or removal of other machines).

Equipment

9.57 Pressure indicator or recorder 0–10 bar is necessary.

Method

9.58 The pressure sensor should be connected to each of the water supply pipes to the WD, as close to the WD as may be practicable, on the supply side of the WD isolating valve for that supply. The static pressure when the valve is closed and the pressure indicated throughout a normal operating cycle should be recorded or observed and noted. When the water service also supplies other equipment on the same supply line, the test should be run both with the other equipment operating throughout the test (or their operation simulated by an appropriate discharge to waste) and with no other equipment operating.

Results

9.59 The water pressure should remain within the supply pressure limits specified by the WD manufacturer.

Overflow test

Introduction

9.60 For WDs which incorporate one or more water storage tanks within the WD the capacity of the overflow(s) to discharge all excess water, as intended, without spillage into the WD or working area should be verified.

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Method a: Type test or Works test

9.61 The WD should be connected to all necessary services and the water supply pressure adjusted to not less than 6 bar under the conditions of flow which prevail with the supply valve(s) fully open.

9.62 Fully open the supply valve(s).

9.63 Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 minutes.

Method b: Installation test

9.64 The WD should be connected to all necessary services.

9.65 Fully open the supply valve(s).

9.66 Observe the level of water in each tank or cistern until this has been unchanged for not less than 2 minutes.

Results

9.67 The WD and installation should be regarded as satisfactory when equilibrium conditions have been attained within the tank(s) without discharge of water other than by the intended (piped) overflow.

Volume of water used per stage

9.68 During type testing, the manufacturer should be required to determine the volume of water used during each stage of the cycle. These data are used in calculations of the service requirement (see SHTM 2030 Part 1; 'Design considerations'). The volume of water used for each stage of the cycle should be within ± 5% of the volume specified by the manufacturer.

Doors and door interlocks

Cycle start interlock

Introduction

9.69 The interlock should prevent a cycle being started with the door open.

Method

9.70 Testing should be carried out as follows. The doors should be left open and unlocked. All services should be connected. An attempt should be made to initiate an operating cycle.

9.71 The doors should then be closed and locked and a further attempt made to initiate an operating cycle.

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Results

9.72 It should not be possible to initiate a cycle with the door(s) left open. With the door(s) closed it should be possible to initiate an operating cycle.

In-cycle interlock

Introduction

9.73 An interlock is required to ensure that the door(s) cannot be deliberately or inadvertently opened while the WD is in operation.

NOTE: When practicable, the interlocks should be visually inspected to verify engagement before attempting to open the door.

Method

9.74 The door(s) should be closed and locked and the operating cycle started. While the operating cycle is in progress an attempt should be made to unlock each of the doors.

Results

9.75 In these circumstances it should not be possible to unlock any of the doors.

Double-ended WDs

Method

9.76 Both during and between cycles, attempts should be made to open either or both the loading door and unloading door of the double ended WD.

Results

9.77 It should not be possible to open the unloading door after initiation of a cycle until a cycle has been completed satisfactorily.

9.78 It should not be possible for both doors to be opened at the same time.

9.79 It should not be possible to open the loading door until a cycle has been satisfactorily completed and the unloading door has been opened and closed.

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Failed cycle interlock

Introduction

9.80 The interlock should prevent an operator from removing a load in the normal manner at the end of a cycle which failed.

Method

9.81 During an operating cycle one, or more, of the services to the WD should be interrupted sufficiently to cause a cycle failure.

Results

9.82 A ‘fault’ should be indicated. It should not be possible to open the unloading door (if fitted); it should only be possible to open the loading and/or unloading door by means of a special key, code or tool.

Fault indication on sensor failure

Introduction

9.83 A failure of any sensor used as part of the control system of the WD should cause a fault to be indicated by the automatic controller.

Method

9.84 Each sensor providing information to the automatic controller is disabled in turn to establish that a fault is indicated.

9.85 Testing of each sensor should be carried out as follows. An operating cycle should be started. During, or before, the stage of the cycle at which the sensor is intended to provide data used to determine the control of the cycle the sensor should be disabled.

9.86 Each sensor should be tested in both ‘open circuit’ and ‘short circuit’ failure modes.

Result

9.87 A fault should be indicated during or at the end of the cycle. It should not be possible to open the door on a single-ended WD or the unloading door of a double-ended WD.

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Chemical dosing

Reproducibility of volume admitted

Introduction

9.88 The test is intended to verify the setting for the dispensed volume of chemical additive(s) and to ensure that it is reproducible within defined limits. The test should be carried out for each chemical dosing system on the WD.

Equipment

9.89 A flow meter of appropriate range may be used.

A measuring cylinder to BS 604: 1982 (1993) is necessary [or BS 5404: Part 2: 1977 (1994) when compatibility with the chemical additive to be measured has been established].The size of measuring cylinder should be appropriate to the volume of chemical additive to be dispensed.

Method

9.90 Testing should be carried out as follows:

a. Disconnect the supply line to the chamber as close as possible to its discharge point into the chamber or water circulation system;

b. Actuate the dosing system and collect the discharged volume of the chemical solution in the measuring cylinder;

c. Repeat the test three more times. Record the volume dispensed on each test.

Results

9.91 The mean collected volume from the final three tests should be within ± 10% of the nominal dispensed volume.

Care is required since many of the concentrates used are irritant or corrosive. Water may not be an acceptable substitute because, for many dosing systems, differences in viscosity can affect the dispensed volume.

Indication of insufficient chemical additives

Introduction

9.92 The use of the correct volume of chemical additive(s) is necessary for the correct functioning of the WD. The WD should be equipped with means to ensure that a cycle is not initiated when there is insufficient chemical additive remaining in the reservoir to complete a cycle.

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9.93 The test should be carried out for each chemical dosing system on the WD.

Method

9.94 A low level of additives is placed in the dispenser reservoir and repeated cycles are run. Care is required since many of the concentrates used are irritant or corrosive. Water may not be an acceptable substitute because, for many dosing systems, differences in viscosity can affect the dispensed volume.

9.95 Fill an otherwise empty container with sufficient chemical for more than 2 but less than 4 operational cycles. Run the WD on 3 consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or weight).

Results

9.96 The WD should indicate at the beginning of the third or fourth cycle that there is insufficient chemical remaining to complete a cycle.

Instrumentation fitted to WD

Verification of calibration

9.97 Specifications for instruments fitted permanently to WDs are given in the relevant British Standards and will be included in the forthcoming European Standards; they are discussed in SHTM 2030 Part 2; ‘Design Considerations’.

9.98 The calibration of instrumentation fitted to the WD should be verified by comparison with calibrated test instruments during steady state conditions e.g. the temperature during the disinfection hold period. A reference channel should be identified on the recording equipment and placed in the same position as the indicating sensor to ensure that the measurement probe is in the same position as the indicating probe.

9.99 This may be carried out concurrently with other testing, for example during the automatic control test during quarterly periodic testing.

Load carriers

Introduction

9.100 Load carriers come in a variety of forms including trolleys, carriages and baskets. Their correct functioning is essential to the successful outcome of a WD operating cycle. It is important that they cannot easily be misaligned, that they function correctly and that, when applicable, they make good connection with service supply points in the chamber and with load items (when necessary).

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Method

9.101 The alignment of load carriers, their connection to water, air or chemical additive supply in the chamber (when applicable) and their connection to load items e.g. cannulated instruments (when applicable) should be verified by visual observation.

9.102 Load carriers with rotary spray arms should be checked to ensure that the spray arms are free to rotate, both when the load carrier is empty and when fully loaded.

Thermometric tests

9.103 Thermometric tests are carried out to verify the attainment of the specified conditions throughout the chamber and load during the operating cycle. Continuous process WDs and multi-chamber WDs in which the use of recorders with fixed sensors is impractical should be tested using single channel data loggers that can be processed through the WD. The use of biological indicators as a substitute for thermometric testing is not acceptable.

Load carrier temperature (Validation Tests, Yearly Tests & Re-validation)

Equipment and materials

9.104 A temperature recorder complying with the requirements specified in Chapter 8 and having not fewer than six sensors is necessary.

NOTE: Three independent data loggers and a temperature recorder having at least one sensor may be used as an alternative.

Method

9.105 Temperature sensors should be located at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature and one on each door of cabinet washer.

9.106 The temperature attained should be measured throughout three operating cycles (3 tests for validation, 1 test for yearly), the first of which should be at least 60 minutes since the machine was last used (a ‘cold start’) and the final three with not more than a 15 minute interval between cycles (a ‘hot start’). The WD should be operated empty except for chamber furniture (for example load carriers).

9.107 The load carrier should be replaced between cycles with a load carrier at ambient temperature.

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9.108 Multi-chamber WDs may be tested with each chamber tested consecutively using independent data loggers to record the temperature of the load carrier. A temperature recorder with fixed sensors may be used to record the temperature adjacent to the reference sensor.

9.109 This test may be run simultaneously with the chamber wall temperature test.

NOTE: When the length of cycle and/or the number of data-loggers available precludes re-use of the data-loggers with not more than 15 minutes between cycles the WD should be kept in continuous operation so that when the second and subsequent tests are initiated not more than 15 minutes has elapsed since the first chamber completed a cycle.

Results

9.110 The results should be the following:

a. The temperatures recorded on the surface of the load carrier should be within the range 0°C to 5°C of the disinfection temperature throughout the holding period for the disinfection stage;

b. The temperatures recorded on the surface of the load carrier should be within ± 5°C of the set temperature for the relevant stage throughout the holding period for each of the other stages;

c. The temperature indicated/recorded by the WD instruments should be within ± 2°C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage;

d. The temperature profile obtained for the operating cycle should be consistent within ± 2°C for the last three test cycles.

Over-temperature protection

Introduction

9.111 The WD is fitted with over-temperature protection (i.e. 5°C above the operating temperature) to ensure that, in the event of the automatic control failing to control the temperature in the WD, the temperature will not rise to a level which would damage the load in the WD.

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Equipment and materials

9.112 A temperature recorder complying with the requirements specified in Chapter 8 and having not less than 4 sensors is necessary.

Method

9.113 Temperature sensors should be located at two diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature.

9.114 The WD, empty except for the load carrier, should be operated on a normal operating cycle. For multi-cycle machines the two cycles that have the highest and lowest operating temperatures should be tested.

Results

9.115 The over-temperature protection should operate at a temperature not more than 5°C higher than that provided by any temperature control or temperature limiting device.

Load dryness

Introduction

9.116 The presence of residual water on cleaned and disinfected items may interfere with the correct functioning of the item, promote re-contamination and microbial growth or prevent attainment of sterilizing conditions.

9.117 The dryness of most items may be evaluated visually. The dryness of the internal surface of lengths of tubing may be tested by blowing through with dry compressed air onto a mirror; misting of the mirror will indicate residual internal moisture.

Air quality

Introduction

9.118 Many WDs are fitted with air filters to remove particulate material from the air supplied to the drying stage. These filters are often HEPA filters (for example EU 12/13) of the type used to remove bacterial contamination from the air supply. When they are used as general particulate filters, performance tests will not normally be required for the filter or the filter housing. The filter and filter housing should be tested when the intention is to provide air free from bacterial contamination when the load is intended for use without further processing (for example sterilization).

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9.119 Microbial sampling will not normally be required for either system unless otherwise specified.

Method

9.120 The complete installation should be tested using the method described in BS 5295: Part 1 Appendix C: ‘Method of testing for the determination of filter installation leaks’. A challenge aerosol of inert particles of the type produced by a dispersed oil particle generator should be introduced into the air upstream of the filter. The downstream face of the filter and its housing should then be scanned for leakage using a photometer.

Results

9.121 The reading on the photometer should be steady and repeatable and should not exceed 0.01% of the upstream reading.

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10. Disinfection efficacy tests

Introduction

10.1 Thermometric tests are required for both thermal disinfection processes and chemical disinfection processes. For thermal disinfection processes, the time temperature relationships which are generally regarded as acceptable are shown in Table 2. Microbiological testing is only required for chemical disinfection processes.

10.2 Temperature monitoring of the load should be used to determine the attainment of the required time-temperature conditions.

Thermometric test for disinfection

10.3 This test is suitable for all WDs and should be used to establish the adequacy of temperature control during chemical disinfection as well as for verifying attainment of thermal disinfection conditions.

10.4 The load under test will consist of a reference load (see Chapters 12 to 18) or a performance qualification load of discrete items of the type which the WD under test is intended to process, or of surrogate devices used to simulate such load items.

Equipment

10.5 The following equipment is necessary.

10.6 A temperature chart recorder calibrated 0°C–120°C in accordance with UKAS/NAMAS traceability.

NOTE: For type 1 machines and type 2 machines without physical separation of compartments (Conveyor WDs) sensors may be passed into the chamber through the thermocouple entry port into the chamber.

10.7 **Method**

Temperature sensors should be placed in the following positions:

a. sensors on product items at each level in the load carrier;

b. one on an item in the region known to be slowest to attain the disinfection temperature;*

c. one on an item in the region known to be fastest to attain the disinfection temperature;*

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d. one adjacent to the automatic control temperature sensor;

e. one adjacent to the process recorder sensor (if fitted) in each chamber or compartment;

f. one on each door of double door cabinet WD.

NOTE: *These positions should be specified by the manufacturer and supported by data type tests. If these data are not available from the manufacturer, preliminary tests to map the temperature throughout the load will be necessary.

10.8 The sensors should be in good thermal contact with the item or installed sensor which they are monitoring and placed, if possible, in or on the part of the item which will be slowest to heat up.

10.9 The test should be performed in triplicate.

Results

10.10 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test;

b. the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that specified for the appropriate disinfection temperature band in Table 3;

c. during the holding time the measured temperatures are within the disinfection temperature band specified for the operating cycle; the indicated and recorded chamber temperatures are within 2°C of the temperature measured at the automatic control sensor; the temperature measured on the surface of each load item does not fluctuate by more than ± 2°C and does not differ from that in other load items by more than 4°C;

d. at the end of the cycle: the temperature sensors have remained in position.

10.11 If having completed the commissioning tests based on a reference load the WD fails to meet the above requirements for the specific performance qualification load then it is possible that the WD is not capable of processing loads of the type intended. Advice should be sought from the Independent advisor.

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11. Automatic control test

Introduction

11.1 The automatic control test is designed to show that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the WD.

11.2 It is carried out once a week on most WDs and is the main test for ensuring that the WD continues to function correctly.

11.3 During the commissioning, yearly and quarterly test programmes the temperature sensors for subsequent thermometric tests will be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments the calibration of these instruments may be checked during periods of stable temperature in the automatic control test.

Test procedure

11.4 Place the test load appropriate to the type of WD, contained within any load furniture normally used, in the chamber.

11.5 For WDs equipped with multiple cycle capability select the operating cycle to be tested. Start the cycle.

11.6 Ensure that a batch process record is made by the recording instrument fitted to the WD. If the WD does not have a recorder, observe and note the elapsed time indicated chamber temperatures and pressures at all significant points of the operating cycle, for example the beginning and ending of each stage or sub-stage, and the maximum values during the holding time.

11.7 At the approximate mid-point of the disinfection hold time, note the elapsed time and the indicated chamber temperature.

11.8 The test should be considered satisfactory if the following requirements are met:

a. a visual display indicating ‘cycle complete’ occurs;

b. during the whole of the operational cycle the values of the cycle variables as indicated by the instruments on the WD or shown on the batch process record are within the limits established as giving satisfactory results either by the manufacturer or during performance qualification;

c. during the disinfection hold period determined from the indicated and/or recorded chamber temperature:

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(i) the indicated and recorded chamber temperatures are within the appropriate disinfection temperature band specified in Table 2;

(ii) the time for which the disinfection temperature is maintained is not less than that previously established, by either the manufacturer or performance qualification tests, as necessary to ensure that the load is maintained at temperatures within the disinfection temperature band for the time specified in Table 3;

d. the door cannot be opened until the cycle is complete;

e. the person conducting the test does not observe any mechanical or other anomaly.

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12. Specific tests for WDs for human-waste containers

Introduction

12.1 WDs for human-waste containers are used to process bedpans, commode bowls, vomitus bowls, urine bottles, suction bottles, kidney dishes and sputum cups etc. The WD is usually a dedicated machine intended solely for human-waste containers.

12.2 WDs for human-waste containers (Bedpan WDs) are Type 1 (single or double door) machines only. The following tests are specific to WDs for human-waste containers.

12.3 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Test for safety of loading and/or emptying of containers

Introduction

12.4 The test is intended to ensure that containers can be emptied without spillage or splashing which would cause a hazard to the operator. The WD should be tested for either manual or automatic emptying.

Equipment and materials

12.5 A full load of each type of container which the WD is intended to process is necessary.

Method: manual emptying

12.6 Each type of container which the WD is designed to process should be tested. Fill each container to not less than 75% of its brim full capacity and empty it and locate it in the load carrier in accordance with the manufacturer's instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid is spilled or splashed. Carry out the test in triplicate on each type of container.

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Method: automatic emptying

12.7 Each type of container which the WD is designed to process should be tested. Fill each container to 75% ± 5% of its brim full capacity and locate it in the load carrier in accordance with the manufacturer's instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid is spilled or splashed. Carry out the test in triplicate on each type of container.

Results

12.8 There should be no spillage or splashing of the contents of the containers during the emptying process.

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13. Specific tests for WDs for surgical instruments

Introduction

13.1 WDs for surgical instruments may be Type 1 (double or single door) or Type 2 (multiple cabinet or conveyor).

13.2 'WDs for surgical instruments' is a description often given to a WD for general purposes which is used for other specific applications by using suitable load carriers (for example hollowware, anaesthetic accessories, laboratory ware). The tests described for WDs for each of these specific purposes (see Chapters 14, 15 and 16) should be carried out in addition to the test described in this Chapter, when relevant.

13.3 WDs for surgical instruments are used also to process those rigid endoscopes which are able to withstand thermal disinfection. Specific tests for WDs used for this purpose are considered in this category.

13.4 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Water quality

13.5 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

13.6 Water which is too hard or has too high a concentration of dissolved solids may impair the activity of detergents (or require the use of increased quantities of chemical additives) and cause deposits, scaling or corrosion of items being processed. Water for washing and subsequent stages of the process should be tested to ensure that it is not.

13.7 Trace elements in the water supply may cause corrosion of surgical instruments. The water supplied for the final rinse stage should be of high purity and this should be confirmed by testing.

13.8 It is necessary for the user and microbiologist to establish microbiological quality of the water, particularly final rinse water, and ensure that the quality is maintained. This should include discussions on microbiological testing, including the advisability of monitoring bacterial endotoxin levels.

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Reference test loads

13.9 The following general equipment is suggested:

a. 3 cuscoe speculae;

b. 3 artery forceps (Crile, Kelly or Spencer Wells) with box joints;

c. 3 No 3 scalpel handles;

d. 3 Yankauers or Pooles suction tubes;

e. sufficient additional instruments to make up a full load;

f. dissecting forceps;

And where appropriate the following endoscope/MAT instruments are required:

g. 2 Trochar and Cannulae;

h. 2 MAT forceps;

i. 2 surrogate endoscopes (see below);

j. sufficient additional instruments to make up a full load.

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14. Specific tests for WDs for hollowware

Introduction

14.1 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

14.2 WDs for hollowware are used to process bowls, receivers, instrument trays, containers and lids etc. The WD may be a dedicated machine intended solely for hollowware or a WD for surgical instruments with an appropriate load carrier and operating cycle. In the latter case, the tests and reference loads described in this Chapter should also be applied to the WD for surgical instruments (see Chapter 13).

14.3 WDs for hollowware may be Type 1 (single or double door) or Type 2 (multiple chamber or conveyor).

14.4 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Reference test loads

14.5 Metal and plastic hollowware has significantly different drying characteristics and may also have different carrier requirements since plastic containers are easily ‘flipped over’ and may then become filled with water. When this happens, not only are the containers impossible to dry but also, there may be a serious risk of scalding when unloading the WD. Plastic items are usually more difficult to dry and are therefore chosen for the standard test load.

14.6 The suggested standard test load for hollowware should consist of items conforming to BS 5452: 1977 (1989) as follows:

a. instrument tray 200 mm x 150 mm;

b. instrument tray 300 mm x 250 mm;

c. compartmented instrument tray 270 mm x 180 mm;

d. kidney dish of 150 mm x 300 mm;

e. wash bowl of 350 mm x 135 mm;

f. lotion bowl of 100 mm x 45 mm;

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g. lotion bowl of 250 mm x 110 mm;

h. gallipot of 40 mm (30 ml to 60 ml);

i. gallipot of 80 mm (250 ml to 280 ml);

j. sufficient additional items of the same type to form a full load.

Performance qualification tests

14.7 Additional tests are unlikely to be required for particular load items other than for WDs which are used to clean and disinfect re-usable containers for sterile products (see EN 868 Part 8 – Yet to be formally published).

14.8 A test load consisting of the following should be used:

- full size container (600 mm x 300 mm x 300 mm);
- 1 half height container (600 mm x 300 mm x 150 mm);
- 2 half-size half-height containers (300 mm x 300 mm x 150 mm).

14.9 Further tests may be necessary also for particular loading configurations. When load carriers are heavily loaded there may be ‘shadowing’ of some parts of the load causing inefficient cleaning and/or failure to achieve disinfection conditions throughout the load.

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15. Specific tests for WDs for anaesthetic accessories

Introduction

15.1 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

15.2 WDs for anaesthetic accessories are used to process breathing tubes, reservoir bags, connectors, endotracheal tubes, tracheostomy tubes, face masks and similar items. The WD may be a dedicated machine intended solely for anaesthetic accessories or a WD for surgical instruments with an appropriate load carrier and operating cycle. In the latter case the tests and reference loads described in this chapter should be applied also to the WD for surgical instruments (see Chapter 13).

15.3 WDs for anaesthetic accessories may be Type 1 (single or double door) or Type 2 (multiple chamber or conveyor).

15.4 Long lengths of tubing are difficult to clean internally and the attainment of cleanliness is difficult to verify. Anaesthetic tubing is also difficult to dry; this is particularly the case for plastic tubing which cannot withstand high (100°C+) drying temperatures.

15.5 Thermal disinfection should be verified by thermometric measurement; the use of biological indicators for assessment of thermal disinfection is not a satisfactory alternative.

Reference test loads

15.6 A suggested test load consisting of the following should be used:

a. Breathing tubes > 600 mm in length (conforming to BS EN 12342: 1998) (transparent/translucent tubing should be used);

b. anaesthetic reservoir bag of 15 mm, 1.5 litre capacity (conforming to BS 1820:1970);

c. anaesthetic reservoir bag of 22 mm, 1.5 litre capacity (conforming to BS 1820:1970);

d. dis-assembled conical connectors of 15 mm, screw threaded with cone and socket joints (conforming to BS 3849-4);

e. dis-assembled conical connectors of 22 mm, screw threaded with cone

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and socket joints (conforming to BS 3849-4);

f. tracheostomy tube and connector of 11mm size (conforming to BS EN 1282-1:1997);

g. endotracheal tube connector of 11 mm size (conforming to BS EN 1782:1998); face masks.

Performance qualification tests

Cleaning and disinfection

15.7 The inner surfaces of anaesthetic accessories are often those for which successful cleaning and disinfection are most critical. Some items may be used after disinfection without further decontamination (for example sterilization). Performance qualification tests, in addition to the operational tests specified may be required for all aspects of the process. The use of surrogate devices may be advantageous.

Drying

15.8 Items which are left warm and damp after an ineffective drying stage will rapidly become recontaminated with micro-organisms.

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16. Specific tests for WDs for laboratory glassware

Introduction

16.1 WDs for laboratory use are generally of Type 1 (single or double door) only. Their major use is for cleaning laboratory glassware and this is reflected in the reference load specified. However, there is a wide range of possible loads and load carriers adapted for particular purposes and specific performance qualification tests may therefore be required.

16.2 The disinfection stage may not be required for many laboratory applications.

Reference test loads

16.3 The suggested reference test load to be used in tests for cleaning efficacy, thermal disinfection efficacy and (when applicable) load dryness consists of a full load of glassware. This should contain:

a. rimless test tubes of 16 mm x 150 mm with 1.2 mm wall thickness(conforming to BS 3218: 1982);

b. low form beakers, 1000 ml volume, 106 mm diameter by 145 mm high (conforming to BS 6523: 1984);

c. additional items as may be required to fully load the chamber of the WD.

Performance qualification tests

Load items

16.4 For laboratory items other than general purpose glassware of the type included in the reference load, or of other items (for example hollowware) for which standard reference loads have been defined, it will be necessary to review how well they are represented by the items of which the reference loads are composed. If the reference loads do not adequately represent the loads which will be used further tests should be carried out using loads composed of items which will be in normal production loads.

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Nature of soiling

16.5 Laboratory items may be subjected to soiling of a variety of types many of which are very difficult to remove. The test soil for operational testing is chosen to represent biological fluids which may be present. If other types of soiling will be encountered, tests should be conducted using items soiled in the manner which will occur for normal production loads.

Process residue tests

16.6 In many cases there will be a need for laboratory items to be free from residues of chemical additives used during the cycle since these may interfere with the subsequent use of the load items. The manufacturer(s) of the chemical additives which it is intended to use should be asked to provide appropriate test methods for the determination of residual levels.

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17. Specific tests for ultrasonic cleaners

Introduction

17.1 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

17.2 Ultrasonic cleaners may be of the 'stand-alone' ultrasonic bath type or may be WDs of Type 1 or Type 2 (multiple chamber or conveyor) or they may be one stage of a Type 2 WD. Many Type 1 ultrasonic cleaners do not incorporate a disinfection stage and are intended for use as a pre-cleaning process before final cleaning and disinfection in a WD for surgical instruments (see Chapter 13).

17.3 Some ultrasonic cleaners are equipped with means to irrigate hollow instruments such as endoscopes. These WDs should be tested both with the general reference load and the endoscope/MAT reference load (see below).

Test for ultrasonic activity

Introduction

17.4 The activity of an ultrasonic cleaner may be investigated by the erosion pattern which is created on aluminium foil exposed in the bath for a short period. The activity will not be uniform throughout the ultrasonic bath. Tests carried out during commissioning are intended to establish the variation in activity at different positions and levels within the bath and the time required to obtain a characteristic erosion pattern.

17.5 The exposure time will depend on the thickness of the foil, the hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.

Equipment and materials

17.6 The following equipment and materials are necessary:

a. aluminium foil of nominal thickness 0.015 mm to 0.025 mm (sold as an aluminium foil wrap for cooking);

b. autoclave indicator tape;

c. stopwatch, graduated in 0.2 s and with an accuracy over a period of 15

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min of ± 0.5 s, or better;

d. ruler/tape measure graduated in mm.

Method

17.7 Measure the depth of the bath from the level of the lid to the bottom of the bath. Let the depth be D mm.

17.8 Cut strips of aluminium foil 15 mm to 20 mm wide and {D + 120} mm.

17.9 Carry out the manufacturer's recommended start-up procedure; this will normally include a period of operation to eliminate dissolved gases from the solution in the bath (the de-gassing procedure).

17.10 Ensure that the water in the tank is at the required level, that the required amount of any chemical additive specified by the manufacturer has been added and that the water in the tank is at the specified operating temperature.

17.11 Using strips of autoclave indicator tape across the top of the bath suspend nine strips of the prepared foil in the bath in a 3 x 3 grid.

17.12 The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should be not more than 10 mm above, but not touching, the bottom of the bath.

17.13 Operate the bath for the predetermined exposure time. This may vary typically between 30 seconds for a watt density of 20 Wdm^{-3} and 10 minutes for a watt density of 5 Wdm^{-3}.

17.14 Remove the strips from the bath, blot dry and examine.

17.15 The strips may be filed conveniently by sticking them to an A4 sheet of plain paper using a transparent adhesive tape.

17.16 Drain the bath and clean to remove debris of eroded aluminium foil.

Results

17.17 The zones of maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent (by visual inspection).

17.18 On re-testing the extent of erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.

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NOTE: For precise evaluation the foils should be weighed before and after exposure to ultrasonication and the loss in weight recorded. The variation in loss of weight should be such that the weight of any one foil is within ± 20% of the mean loss of weight.

Reference test loads

17.19 The suggested test load should contain the following general equipment:

a. cuscoe speculae;

b. artery forceps (Crile, Kelly or Spencer Wells) with box joints;

c. no. 3 Scalpel handles;

d. Yankauers or Pooles suction tubes;

e. sufficient additional instruments to make up a full load.

17.20 The test load should contain the following endoscope/MAT instruments:

a. Trochar and Cannulae;

b. MAT forceps;

c. surrogate endoscopes (see below).

17.21 Sufficient additional instruments to make up a full load.

17.22 The surrogate endoscope should be constructed from 6 mm o.d./4 mm id stainless steel tubing. The overall length should be 450 mm. At the midpoint of the tube should be a 50 mm length of tubing connected to the tubing on either side with compression fittings.

17.23 The 50 mm demountable length may be used to provide a more readily visible section for determination of cleaning efficacy.

Performance qualification tests

Load items

17.24 For ‘difficult to clean’ laboratory items other than those of the type included in the reference load, or of other items (for example hollowware) for which standard reference loads have been defined, it will be necessary to review how well they are represented by the items of which the reference loads are composed. If the reference loads do not adequately represent the loads which will be used further tests should be carried out using loads composed

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of items which will be in normal production loads.

Nature of soiling

17.25 Ultrasonic cleaners are often used for items which are contaminated with soiling which is difficult to remove by other cleaning processes.

17.26 The test soil for operational testing is chosen to represent biological fluids which may be present. If other types of soiling will be encountered (for example orthopaedic bone cement) tests should be conducted using items soiled in the manner which will occur for normal production loads.

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18. Specific tests for WDs for endoscopes

Introduction

18.1 WDs for flexible thermolabile endoscopes are machines of Type 1 (single and double door) only. (Rigid endoscopes able to tolerate terminal steam sterilization are considered under WDs for surgical instruments).

18.2 These WDs are characterised by a chemical disinfection stage because the products which are intended to be processed will not withstand the high temperatures required for thermal disinfection. It is necessary to ensure that the disinfectant is removed from the endoscope before it is used on a patient; this is achieved by a post-disinfection rinsing stage. It is apparent that the microbiological control of this stage is of critical importance to the microbial status of the processed item. A number of additional tests are required to ensure that this aspect of the process is properly controlled.

WD self-disinfection test

Introduction

18.3 It is necessary to verify that the WD 'machine disinfection' mode will disinfect those parts of the WD which come into contact with fluids which are intended to, or may, contact the load.

18.4 The WD may be equipped with an auto or manually selected 'self-disinfect' mode; it may be thermal or chemical and in the latter case may be the same or a different germicide from that used for chemical disinfection of the load. The preferred method is thermal disinfection or, if this is not possible, the use of a different germicide. The use of the same germicide carries the risk of allowing organisms resistant to that particular germicide to proliferate.

18.5 The process is intended to deal with the situation where the WD has become contaminated. The piping used to convey rinse water to the endoscope, if contaminated, may easily develop a layer of biofilm containing many micro-organisms in a state which is highly resistant to chemical disinfection. This tubing should normally be replaced at the interval specified by the manufacturer. Normally this should not exceed 500 operating cycles or 3 months.

18.6 Thermal disinfection systems should be evaluated by thermometric monitoring of the system with sensors placed at the parts of the system most remote from the heat source. The entire system should attain the required disinfection temperature (see Table 3).

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NOTE: Advice on microbiological testing should be sought from the microbiologist.

Final rinse decontamination test

18.7 Precautions must be taken to ensure that the microbiological quality of the final rinse water will not compromise in any way the efficacy of the process. The final rinse water will require to be of high quality and shown to be free of mycobacteria. The microbiological quality of the final rinse water should be monitored weekly to ensure compliance.

18.8 Various methods are used to ensure that the final rinse water is decontaminated before use. The test should verify the performance of the particular system by the method specified by the manufacturer.

18.9 This may include:

a. verification of filter performance by a bubble point test or by measuring the differential pressure drop across the filter;

b. verification of thermal disinfection by thermometric testing;

c. verification of UV activity by confirmation that the illumination is at the wavelength and intensity specified by the manufacturer and that the residence time is also as specified.

NOTE: Advice should be sought from the microbiologist.

Channel patency detection test

18.10 WDs for endoscopes should be fitted with means to ensure that each of the channels is patent so that germicidal and rinse solutions will flow through each channel.

18.11 A surrogate device should be used to demonstrate that the system for determining the patency of each channel is functioning correctly. The surrogate device may be constructed by using a 1.5 metre length of 1mm ID PTFE tubing.

18.12 For each channel (air/water, biopsy, elevator as relevant) connect a 1.5 metre length of tubing of the appropriate diameter and run a operating cycle. On completion of the cycle replace one of the tubes with a similar tube which has a 100 mm long 1.1 mm OD 0.5 mm ID melting point tube (Borosilicate glass) inserted and secured in the distal end and run another operating cycle. Repeat the test changing the position of the partially obstructed tube on each test.

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18.13 The WD should indicate a fault for any channel to which the partially obstructed surrogate device is fitted.

Disinfectant concentration test

18.14 WDs employing a chemical disinfection stage may re-use the chemical germicide a number of times.

18.15 When such a system is employed the WD should be equipped with means to establish that the concentration of the active ingredient(s) in the germicide is above the concentration specified as the minimum acceptable. This may be in the form of a test kit to be employed by the user.

18.16 The disinfectant concentration test is carried out to establish that the means provided is effective.

18.17 The full strength solution, unused (and if necessary freshly prepared or activated), should be prepared according to the manufacturer's instructions. When this requires the addition of water, only distilled or purified water should be used.

18.18 A dilution series should be prepared using distilled or purified water.

NOTE: Handling of disinfectant solutions may need to be carried out in a laboratory with appropriate safety precautions. Seek advice from the Microbiologist or Independent Advisor.

Reference test loads and soil tests

18.19 For advice on reference test loads and test soil, consult the microbiologist/ Independent Advisor.

Microbiological tests for disinfection efficacy and performance qualification test

18.20 For advice on the above tests, consult the Microbiologist/Independent Advisor.

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Appendix 1: Glossary

Automatic controller: device that, in response to pre-determined cycle variables, operates the WD sequentially through the required stages of the cycle(s)/process.

Calibration: the set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.

Chamber: that part of the WD in which the load is processed.

Chemical additive: one or more chemicals added to the chamber and load of a WD during one or more stages of the process.

NOTE: The chamber does not include steam generators, pipework and fittings from which it can be isolated.

Chemical disinfection: disinfection achieved by the action of one or more chemicals the primary purpose of which is to be microbiocidal.

Commissioning: obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within pre-determined limits when operated in accordance with operational instructions.

Cycle variables: the physical and chemical properties (e.g. times, temperatures, disinfectant concentration, pressures and flows) that influence the efficacy of the washing and processes.

D value: for a microbiological process the extent of exposure under defined conditions which cause a 90% decrease in the viable population of a specified micro-organism.

Decontamination: the combination of processes, including cleaning and disinfection and/or sterilization, used to render a re-usable item safe for further use.

Disinfection: the reduction of the number of viable micro-organisms on a product to a level previously specified as appropriate for its intended further handling or use.

Door: device provided as a means of closing and sealing the chamber.

Fail safe: attribute of WD design, component or its associated services that minimises a possible safety hazard.

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Fault: recognition by the automatic controller that the pre-set cycle variables for the WD cycle have not been attained.

Installation qualification: see commissioning.

Installation test: series of checks and tests performed after installation of the WD in the place of use.

Load: a collective term used to describe all the goods equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle.

Medical device: see BS EN 46001: 1997 'Specification for application of EN ISO 9001 to the manufacture of medical devices'.

Monitoring: the measurement of physical variables, such as the function of the automatic controller to check the attainment, or otherwise, of the pre-set cycle variables essential to the efficacy of the operating cycle.

Operating cycle: the complete set of stages of the process that is carried out in the sequence as regulated by the automatic controller.

Performance qualification: obtaining and documenting evidence that the equipment as commissioned will produce acceptable product when operated in accordance with the process specification.

Product compatibility: ability of the WD operational cycle to achieve the intended results without detrimental effect on the product or its intended use.

Reference load: specified load made up to represent the most difficult combination of items to be processed in a particular WD operational cycle.

Routine test: series of tests intended to be performed by the user, or their representative, at various pre-determined intervals to demonstrate that the performance of the WD remains within the limits established during type/works/installation and validation testing.

Steam generator: vessel designed to contain water and a heating system (e.g. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state.

Sterile: see BS EN 556, 'Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile''.

Sterilization: the killing or removal of all micro-organisms including bacterial spores.

Surrogate device: a test piece designed and constructed to emulate those characteristics of a device which influence the facility with which it may be cleaned and disinfected.

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Tank: a process vessel, integral to the WD, designed to hold solutions during processing.

Test soil: substance used to test the washing efficacy of WDs.

Thermal disinfection: disinfection achieved by the action of moist or dry heat.

Type test: series of tests to establish the working data for a WD type.

Validation: documented procedure for obtaining, recording and interpreting data to show that a process will consistently produce product complying with pre-determined specifications.

Viable micro-organism: micro-organisms, including viruses, which are capable of multiplication under specified culture conditions.

Washer-disinfector (WD): machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

NOTE: This type of machine does not include those deigned specifically to wash linen or clothing.

Works test: series of tests performed at the manufacturer's works to demonstrate compliance of each WD with its specification.

Z value: for a thermal microbicidal process the change in temperature required to cause a tenfold change in D value.

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Appendix 2: Abbreviations

AP(S)	Authorised Person (Sterilizers)
BS	British Standard
°C	degrees Celsius
CEN	Committee European de Normalisation
COSHH	Control of Substances Hazardous to Health
DOE	Department of the Environment
EN	European Norm
EU	European Union or Endotoxin Unit
FSD	Full scale deflection
GGMP	'Guide to good manufacturing practice for medicinal products' (GGMP) published in Volume IV of 'The rules governing medicinal products in the European Community'
HEPA	High Efficiency Particulate Arrestance
HMSO	Her Majesty's Stationery Office
HSE	Health and Safety Executive
HTM	Hospital Technical Memorandum
Hz	Hertz
ID	Internal Diameter
IEC	International Electrotechnical Commission
ISE	Iron selective electrodes
ISO	International Standards Organisation
ISSM	Institute of Sterile Services Management
kPa	kilo Pascal
LAL	Limulus Amoebocyte Lysate
l/s	litres/second
MAT	Minimal Access Therapy
mbar	milli bar
MCA	Medicines Control Agency
MDA	Medical Devices Agency
min	minute
ml	milli litre
mm	millimetre
MP	Maintenance Person
MPR	Master Process Record
NAMAS	National Measurement Accreditation Scheme
NDT	Non-destructive Testing
NHS	National Health Service
OD	Outside diameter
OEL	Occupational exposure limit
PES	Programmable Electronic System
P&EF	Property and Environment Forum
P&EFEx	Property and Environment Forum Executive
PQ	Performance qualification
PRQ	Performance re-qualification

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S	Second
SHPN	Scottish Hospital Planning Note
SHTM	Scottish Health Technical Memorandum
T.C.	Technical committee
TP	Test Person
UK	United Kingdom
UKAS	United Kingdom Accreditation Services
WD	Washer-disinfector
Wdm-3	Watts/cubic decimetre = Watts/litre
WHO	World Health Organisation
μ**gl**$^{-1}$	microgram/litre
<	less than
>	greater than

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Appendix 3: Useful addresses

UK health agencies

NHSScotland
Property and Environment Forum Executive,
4th Floor St Andrew House,
141 West Nile Street,
Glasgow, G1 2RN

Scottish Healthcare Supplies,
Trinity Park House, South Trinity Road,
Edinburgh, EH5 3SH
Tel 0131 552 6255

Medical Devices Agency (MDA)
Hannibal House, Elephant and Castle,
London, SE1 6TQ
Tel 0171 972 8000

Medicines Control Agency (MCA)
Market Towers,
1 Nine Elms Lane,
London, SW8 5NQ
Tel 0171 273 3000

Health and Safety

Health and Safety Executive
375 West George Street,
Glasgow
G2 4LW
Tel 0141 275 3000

Belford House,
59 Belford Road,
Edinburgh
EH4 3UE
Tel 0131 247 2000

Health and Safety Executive Information Line
Tel 0870 154 5500

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Standards organisations

British Standards Institution
British Standards House,
389 Chiswick High Road,
London W4 4AL
Tel 0181 996 9000

European Committee for Standardisation
Rue de Stassart 36,
B-1050 Brussels

Other organisations

Institute of Healthcare Engineering and Estates Management
2 Abingdon House,
Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1DS.
Tel. 02392 823 186

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Medicines Act	HMSO	1988	
	Health and Safety at Work Act	HMSO	1974	
	Public Health (Scotland) Act	HMSO	1988	
	The Water (Scotland) Act	HMSO	1980	
SI 2179	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd. 1994)	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health and Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health and Safety (Information for Employees) Regulations	HMSO	1989	

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Publication ID	Title	Publisher	Date	Notes
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1994	
SI 2037	Lifting Operations and Lifting Equipment Regulations	HMSO	1998	
SI 2865	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulation	HMSO	1994	
SI 2169	Medicines (Standard Provisions of Licences and Certificates) Amendment (No 3) Regulations	HMSO	1977 1992	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 201	Public supply contracts regulations	HMSO	1995	
SI 2023	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 853	**Specification for vessels for use in heating systems** **Part 1:** Calorifiers and storage vessels for central heating and hot water supply **Part 2:** Tubular heat exchangers and storage vessels for building and industrial services	BSI Standards	1996 1996	
BS 1427	**Guide to field and on-site test methods for the analysis of waters**	BSI Standards	1993	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 1752	**Specification for laboratory sintered or fritted filters including porosity grading**	BSI Standards	1983	
BS 2745	**Washer disinfectors for medical purposes** **Part 1:** Specification for general requirements	BSI Standards	1993	
	Part 2: Specification for human-waste container washer-disinfectors		1993	
	Part 3: Specification for washer-disinfectors except those used for processing human-waste containers and laundry		1993	
BS 3218	**Specification for test tubes and boiling tubes**	BSI Standards	1982	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**	BSI Standards	1992	
BS 3849-4	**Concial connectors for anaesthetic and respiratory equipment. Specification for 8.5 mm cones and sockets**	BSI Standards	1990	
BS 3928	**Method for sodium flame test for air filters (other than air supply to IC engines and compressors)**	BSI Standards	1969	
BS 5164	**Specification for indirect-acting electrical indicating and recording instruments and their accessories**	BSI Standards	1975	
BS 5295	**Environmental cleanliness in enclosed spaces**	BSI Standards	1989	
BS 5452	**Specification for hospital hollow-ware made of plastics material**	BSI Standards	1977	
BS 5500	**Specification for unfired fusion welded pressure vessels**	BSI Standards	2000	
BS 5728	**Measurement of flow of cold potable water in closed conduits** **Parts 2, 3, 5, 6,and 7**	BSI Standards	1980 - 1987	
BS 6253	**Specification for glass beakers for laboratory use**	BSI Standards	1984	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**	BSI Standards	1984	
BS 7320	**Specification for sharps containers**	BSI Standards	1990	
BS EN 285	**Sterilization. Steam sterilizers. Large sterilizer**	BSI Standards	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 554	**Sterilization of medical devices. Validation of and routine control of sterilization by moist heat**	BSI Standards	1994	
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized devices to be labelled 'Sterile'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 837	**Pressure gauges** **Part 1:** Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing **Part 2:** Pressure gauges. Selection and installation recommendations for pressure gauges **Part 3:** Diaphragm and capsule pressure gauges. Dimensions, metrology, requirements and testing	BSI Standards	1998 1998 1998	
BS EN 866	**Biological systems for testing sterilizers and sterilisation processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterlizers **Part 3:** Particular systems for use in moist heat sterlizers	BSI Standards	1997 1998 1997	
BS EN 1281	**Anaesthetic and Respiratory equipment** **Part 1:** Conical connectors	BSI Standards	1997	
BS EN 1282	**Anaesthetic and respiratory equipment** **Part 1:** Tracheostomy tubes: Tubes for use in adults	BSI Standards	1997	
BS EN 1782	**Tracheal tubes and connectors**	BSI Standards	1998	
BS EN 1820	**Anaesthetic reservoir bags**	BSI Standards	1997	
BS EN 6001	**Application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 6002	**Application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 12342	**Breathing tubes intended for use with anaesthetic apparatus and ventilators**	BSI Standards	1998	
BS EN 46001	**Specification for application of EN ISO 9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for application of EN ISO 9002 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1998 1995	
BS EN 50103	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry**	BSI Standards	1996	
BS EN 60584	**Thermocouples** **Part 1:** Reference tables	BSI Standards	1996	
BS EN 60751	**Industrial platinum resistance thermometer sensors**	BSI Standards	1996	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **Part 1:** General requirements	BSI Standards	1993	
BS EN ISO 14644-1	**Cleanrooms and associated controlled environments. Classification for air cleanliness**	BSI Standards	1999	
BS EN ISO 9000	**Quality management and quality assurance standards.**	BSI Standards	2000	
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing.**	BSI Standards	1994/ 2000	
BS EN ISO 9002	**Quality assurance. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
PD 5304	**Safe use of machinery**	BSI Standards	2000	
European Union (EC) Directives				
90/385/EEC	Active Implantable Medical Devices Directive Note: the Directive was adopted by the EC Council of Ministers on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992	Official Journal of the European Communities (OJEC)		
91/356/EEC	Council Directive laying down the principle and guidelines of good manufacturing practice for medicinal products for human use	Official Journal of the European Communities (OJEC), L193, 17.7.91, p30		
93/42/EEC	Council Directive concerning medical devices	Official Journal of the European Communities (OJEC), L169, 12.7.93, p1		
80/778/EEC	Council Directive relating to the quality of water intended for human consumption	Official Journal of the European Communities (OJEC)		
93/94/EEC	Medical Devices Directive. Note: The Directive was adopted by the EC Council of Ministers on 14 June 1993 and came into effect in the UK on 1 January 1995 as the Medical Devices Regulations	Official Journal of the European Communities (OJEC), L319, 17.11.81, p19		
Scottish Health Technical Guidance				
SHTM 2007	Electrical Services Supply & Distribution	P&EFEx	2001	CD-ROM
SHTM 2010	Sterilization	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems Supplement 1: Dental compressed air and vacuum systems Supplement 2: Piped medical gases in ambulance vehicles	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilization	P&EFEx	2001	CD-ROM

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SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	Scottish Office	1994	
SHPN 15	Accommodation for pathology service	Scottish Office	1994	
SHPN 26	Operating department	Scottish Office	1992	
SHPN 26 Supp.1	Operating department activity space data sheets	Scottish Office	1993	
HBN 13 Supp 1	Oxide sterilization section			
	NHS in Scotland PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1998	CD-ROM
Health and Safety Publications				
(MDA SN 9619)	Compatibility of medical devices and their accessories and reprocessing units with cleaning, disinfecting and sterilizing agents. Medical Devices Agency	Dept. of Health	1996	

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Publication ID	Title	Publisher	Date	Notes
(L5)	Control and substances hazardous to health and control of carcinogenic substances: Control of substances hazardous to health regulations 1999: approved code of practice. Health and Safety Executive	HSE Books	1999	3rd Edition
(HC(79)3)	Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms	Dept of Health	1979	
(H(91)33)	Decontamination of equipment, linen or other surfaces contaminated with hepatitis B and/or human immunodeficiency viruses	Dept. of Health	1991	
(SAB(93)32)	Endoscope washer/disinfectors: recontamination of equipment	Dept of Health	1993	
	Microbiological safety cabinets: recommendations concerning their choice, installation, routine maintenance and use (Health Equipment Information No 86) Medical Devices Agency	Dept. of Health	1980	
	Scottish Infection Manual 1998 – guidance on core Standards for the Control of Infection in Hospitals, Healthcare premises and at the Community Interface	Scottish Office	1998	
	Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Directorate. Microbiology Advisory Committee	Dept. of Health	1993	
(L23)	Manual handling: Manual handling operations regulations 1992: guidance on regulations. Health and Safety Executive	HSE Books	1992	
(EH40)	Occupational exposure limits. Health and Safety Executive	HSE Books		Issued annually
	Programmable electronic systems in safety related applications: an introductory guide. Health and Safety Executive	HSE Books	1987	
MDA DB 9501	Re-use of medical devices supplied for single use only	HMSO	1995	
	Safety in health service laboratories: safe working and the prevention of infection in clinical laboratories. Advisory Committee/Health and Safety Executive	HSE Books	1991	

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Publication ID	Title	Publisher	Date	Notes
	Safe working and the prevention of infection in the mortuary and post-mortem room. Health and Safety Executive			
(L22)	Work equipment. Provision and use of work equipment regulations 1998. Guidance on regulations. Health and Safety Executive	HSE Books	1998	
(L24)	Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992: approved code of practice and guidance. Health and Safety Commission	HSE Books	1992	
Miscellaneous References				
	Babb J R, Bradley C R, Barnes A R, *Question and Answer*	Journal of Hospital Infection	1992	Vol 20, p51-54
	Rollnick M, *How You Spend Your Pennies*	Health Estate Journal	1991	May, p12-15
	Dawson M, Novitsky T J, Gould M J. *Microbes, endotoxin and water*	Pharm Eng	1988	Mar/Apr vol 8, no2
	Twohy C W, Nierman ML, Duran A P *et al*, *Comparison of limulus amoebocyte lysates from different manufacturers*	Journal of Parent Science & Tech	1983	May/Jun vol 37, no3, p93-96
	Bacterial endotoxin test USP 8th Supp. Pharmacopoeial Convention		1993	Mar XXII NF XVII, p3349-3350
	Chloride in waters, sewage and effluent. Methods for the examination of waters and associated materials	DOE/Nat. Water St. Committee	1981	
	Determination of pH in low ionic strength waters	DOE/Nat Water St Committee	1988	
	Determination of alkalinity and acidity in water	DOE/Nat Water St Committee	1981	
	Deprygogenation by dry heat. Technical report no 7. Parental Drug Association			Ch12, p101-108
	Dry heat destruction of lipo-polysaccharide. Applied Environmental Microbiology		1997	Vol 36 p715

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Publication ID	Title	Publisher	Date	Notes
	General principles of sampling and accuracy of results	DOE/Nat Water St Committee		
	Guidelines on the validation of the Limulus Amoebocyte Lysate test as an end product Endotoxin test for human and animal parenteal drugs, biological products and medical devices	US Food and Drug Administration	1987	
	Guide to contract procedures	NHS Estates	1998	
	International standards for drinking water	WHO	1971	
	Iron in raw and potable waters by spectrophotometry. Methods for the examination of waters and associated materials	DOE/Nat Water St. Committee	1977	
	Measurements of Electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters	DOE/Nat Water St Committee	1981	
	Model Engineering Specifications	NHS Estates, HMSO	1998	Issued in 4 volumes
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Ninhydrin test	Analytical Bio-chemistry	1993	Vol 211, p240-242
	Phosphorus and silicon in waters, effluent and sludges	DOE/Nat Water St Committee	1992	
	Rules governing medicinal products in the European Community. Vol IV Good manufacturing practice for medicinal products. Commissions of the European Communities		1992	
	Scottish Capital Investment Manual	Scottish Office		
	Sterilization and disinfection of heat-labile equipment: report of a working Party on sterilization and disinfection of heat-labile equipment. Hospital Infection Research Laboratory		1986	

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Publication ID	Title	Publisher	Date	Notes
	Total hardness, calcium hardness and magnesium hardness in raw and potable waters	DOE/Nat Water St Committee	1981	
	Water Supply Byelaws Guide. Water Byelaws Advisory Service Water Research Centre		1989	2nd Edition

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Health Facilities Scotland

NHS National Services Scotland

STATUS IN NHSSCOTLAND

BEST PRACTICE GUIDANCE

Health Building Note 00-02
Core elements:
Sanitary spaces

For queries on the status of this document contact
nss.hfsenquiries@nhs.net or telephone 0141207 1600

Status Note v2 amended 24th March 2017

Health Building Note 00-02 – Sanitary spaces

This document must be read in conjunction with current Scottish Government Policy and NHSScotland Guidance, which take precedence. These include publications in both: www.sehd.scot.nhs.uk/ and www.hfs.scot.nhs.uk/publications-/ .

Specific updates for NHSScotand use:

This guidance must be read in conjunction with the public sector equality duty in the Equality Act 2010 and the Specific Duties (Scotland) Regulations 2012. These state named Scottish public authorities, including NHSScotland, must have 'due regard' to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. This requires an integrated response across services, facilities, training and communications to ensure the characteristics protected by the Act are appropriately served. An Equality Impact Assessment (EIA) is required for all proposed investments. Scottish Capital Investment Manual's NHSScotland Design Assessment Process will also support the implementation of this public sector equality duty at key business case stages of the facility design process.

Update since last issue: new section 5.74 Changing Places facility, and reference to detailed design and registration requirements, which are available from www.changing-places.org.

Changing Places facilities are primarily for public not clinical use, as are general accessible toilets, their functions should not normally be combined. The quantity and location for both should be considered for all new public investment under an Equality Impact Assessment (EIA). It is anticipated that the population of Scotland served by majority of NHSScotland campuses, would require a Changing Places facility, as well as general accessible toilets, baby changing, gender neutral facilities, together with inclusive, dementia and age appropriate design inside and out.

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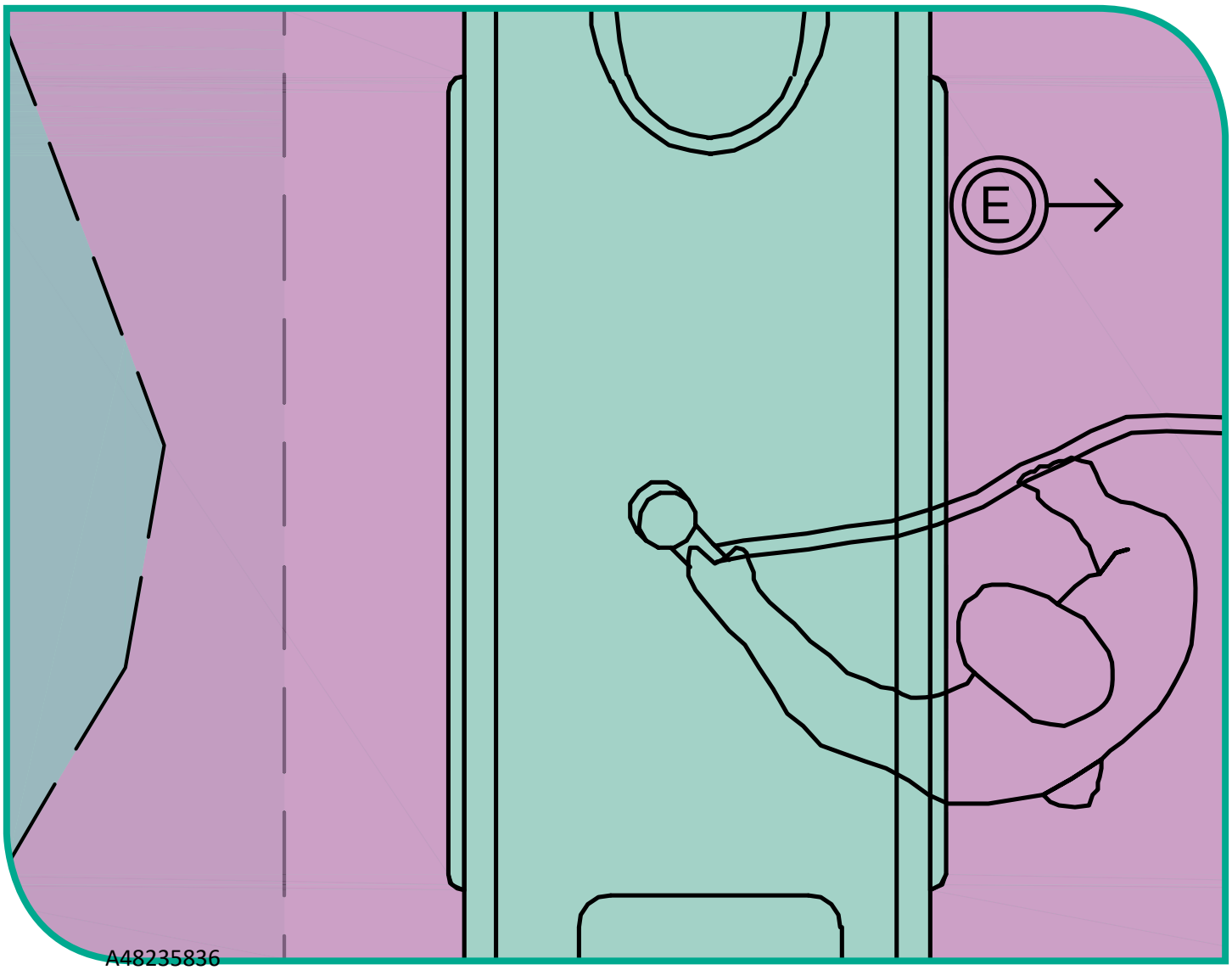
Department of Health

Core elements
Health Building Note 00-02: Sanitary spaces



Core elements
Health Building Note 00-02: Sanitary spaces

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This document is available from our website at https://www.gov.uk/government/collections/health-building-notes-core-elements

Preface

About Health Building Notes

Health Building Notes give "best practice" guidance on the design and planning of new healthcare buildings and on the adaptation/ extension of existing facilities.

They provide information to support the briefing and design processes for individual projects in the NHS building programme.

The Health Building Note suite

Healthcare delivery is constantly changing, and so too are the boundaries between primary, secondary and tertiary care. The focus now is on delivering healthcare closer to people's homes.

The Health Building Note framework (shown below) is based on the patient's experience across the spectrum of care from home to healthcare setting and back, using the national service frameworks (NSFs) as a model.

Health Building Note structure

The Health Building Notes have been organised into a suite of 17 core subjects.

Care-group-based Health Building Notes provide information about a specific care group or pathway but cross-refer to Health Building Notes on **generic (clinical) activities** or **support systems** as appropriate.

Core subjects are subdivided into specific topics and classified by a two-digit suffix (-01, -02 etc), and may be further subdivided into Supplements A, B etc.

All Health Building Notes are supported by the overarching Health Building Note 00 in which the key areas of design and building are dealt with.

Example

The Health Building Note on accommodation for adult in-patients is represented as follows:

> "Health Building Note 04-01: Adult in-patient facilities"

The supplement to Health Building Note 04-01 on isolation facilities is represented as follows:

> "Health Building Note 04-01: Supplement 1 – Isolation facilities for infectious patients in acute settings"

Health Building Note number and series title	Type of Health Building Note
Health Building Note 00 – Core elements	Support-system-based
Health Building Note 01 – Cardiac care	Care-group-based
Health Building Note 02 – Cancer care	Care-group-based
Health Building Note 03 – Mental health	Care-group-based
Health Building Note 04 – In-patient care	Generic-activity-based
Health Building Note 05 – Older people	Care-group-based
Health Building Note 06 – Diagnostics	Generic-activity-based
Health Building Note 07 – Renal care	Care-group-based
Health Building Note 08 – Long-term conditions/long-stay care	Care-group-based
Health Building Note 09 – Children, young people and maternity services	Care-group-based
Health Building Note 10 – Surgery	Generic-activity-based
Health Building Note 11 – Community care	Generic-activity-based
Health Building Note 12 – Out-patient care	Generic-activity-based
Health Building Note 13 – Decontamination	Support-system-based
Health Building Note 14 – Medicines management	Support-system-based
Health Building Note 15 – Emergency care	Care-group-based
Health Building Note 16 – Pathology	Support-system-based

Other resources in the DH Estates and Facilities knowledge series

Health Technical Memoranda

Health Technical Memoranda give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare (for example medical gas pipeline systems, and ventilation systems).

They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

All Health Building Notes should be read in conjunction with the relevant parts of the Health Technical Memorandum series.

Activity DataBase (ADB)

The Activity DataBase (ADB) data and software assists project teams with the briefing and design of the healthcare environment. Data is based on guidance given in the Health Building Notes, Health Technical Memoranda and Health Technical Memorandum Building Component series.

1. Room data sheets provide an activity-based approach to building design and include data on personnel, planning relationships, environmental considerations, design character, space requirements and graphical layouts.

2. Schedules of equipment/components are included for each room, which may be grouped into ergonomically arranged assemblies.

3. Schedules of equipment can also be obtained at department and project level.

4. Fully loaded drawings may be produced from the database.

5. Reference data is supplied with ADB that may be adapted and modified to suit the users' project-specific needs.

How to obtain publications

Health Building Notes are available from the UK Goverment's website at: https://www.gov.uk/government/collections/ health-building-notes-core-elements

Health Technical Memoranda are available from the same site at: https://www.gov.uk/government/collections/ health-technical-memorandum-disinfection-and-sterilization.

Executive Summary

Health Building Note 00-02 – 'Sanitary spaces' provides evidence-based best practice guidance on the design and layout of sanitary spaces for use in healthcare settings.

Room sizes have been standardised wherever possible. For areas where a standard room size is not appropriate, this document provides a sizing methodology suitable for briefing purposes. Most of the indicative room layouts are informed by one or more ergonomic drawings.

In places, the guidance differs from that provided in Approved Document M (2010) and BS 8300:2001 (2009 edition). Where this is the case, the reasons for the variations are discussed.

Contents

1 Introduction

1.1 Health Building Note 00-02 provides design guidance and indicative room layouts of sanitary spaces in healthcare buildings.

Purpose and scope of this document

1.2 Most of the layouts are informed by one or more ergonomic drawings (the colour-coding on the room layouts relates to ergonomic information). Both the ergonomic drawings and indicative room layouts aim to enable spaces to be designed that are fit for purpose, accessible, safe and secure.

1.3 The indicative room layouts represent example design solutions, not specific recommendations. Actual requirements should be determined on an individual project basis.

1.4 Although primarily applicable to new buildings, the recommendations contained within this guidance should also be applied, where practical, when existing facilities are being upgraded.

Principle of using generic rooms wherever possible

1.5 Generic rooms are designed to accommodate a range of activities rather than being tailored for a single function/specialty or narrow range of functions.

1.6 Sanitary spaces should be generic wherever possible to maximise flexibility in use. Generic rooms make up a high proportion of the sanitary spaces within healthcare buildings.

Standardised room sizes

1.7 The size (and dimensions) of the indicative room layouts have been standardised wherever possible. This may mean sizing up to some extent, but results in rooms that can be adapted (for alternative use) much more easily.

1.8 For areas where a standard room size is not appropriate, this document provides a sizing methodology suitable for briefing purposes.

1.9 Where special departmental requirements warrant a variation from the spaces described in this document, information is provided in the relevant guidance.

Evidence base

1.10 This document is based on the professional opinion of healthcare planning and design experts and ergonomic research (published and unpublished).

Grab rails

1.11 Grabrails are referenced extensively throughout this guidance. They are used to provide support and stability when transferring horizontally, sitting down and standing up, and while adjusting clothing. They should allow for a firm grip whether wet or dry.

1.12 Horizontal, vertical and hinged grabrails should be installed to allow users to choose the rail most appropriate for their needs. The grabrail positions on the drawings provided are generally in accordance with Approved Document M unless stated otherwise.

1.13 Hinged grabrails should lock in the vertical position, but be easy to unlock with one hand. Hinged grabrails should be capable of use with:

- vertical weight of 88 kg+50% = 132 kg; and
- a horizontal force of 155 Newtons (N) +50% = 233 N

1.14 Where appropriate grabrails may be used in place of (and to act as) towel rails.

Use of colour

1.15 Adequate colour contrast can help a visually impaired person identify features and appliances in toilets. The colour of the appliances themselves is unimportant, white being perfectly acceptable, providing they are set against a background which contrasts adequately.

1.16 When using toilets there is often a need to identify features more quickly than would be the case if undertaking a simple navigation task to get around. As such the differences in colour and tones used to contrast appliances with their backgrounds should be greater than for other circumstances.

1.17 Wherever possible the lighting to toilet areas should offer good overall illuminance and the use of highly reflective glazed tiles should be avoided.

1.18 Smaller items such as grabrails, soap dispensers and dryers should be provided against a background which affords them adequate contrast.

1.19 Wall mirrors which are placed inside the toilet, directly opposite the entrance door, can cause confusion for visually impaired people when understanding the space they have just entered or when trying to determine the layout and location of facilities. Therefore, they should be avoided.

2 Bathrooms

Bathroom with bidet: semi-ambulant

Room description and layout

2.1 See Figure 1. The following activities take place in semi-ambulant bathrooms with bidets:

- undressing and dressing;
- hanging/holding clothes;
- use of the toilet;
- use of the bidet;
- personal washing;
- use of the bath.

2.2 Semi-ambulant bathrooms should contain a bath, semi-ambulant toilet, bidet and ambulant wash-hand basin.

2.3 Bidets should be fitted with a sensor-operated over-rim supply.

2.4 Bidets are not considered appropriate for independent wheelchair users because of the difficulty in transferring between the wheelchair, toilet and bidet.

2.5 Semi-ambulant bathrooms with bidets are also suitable for ambulant users.

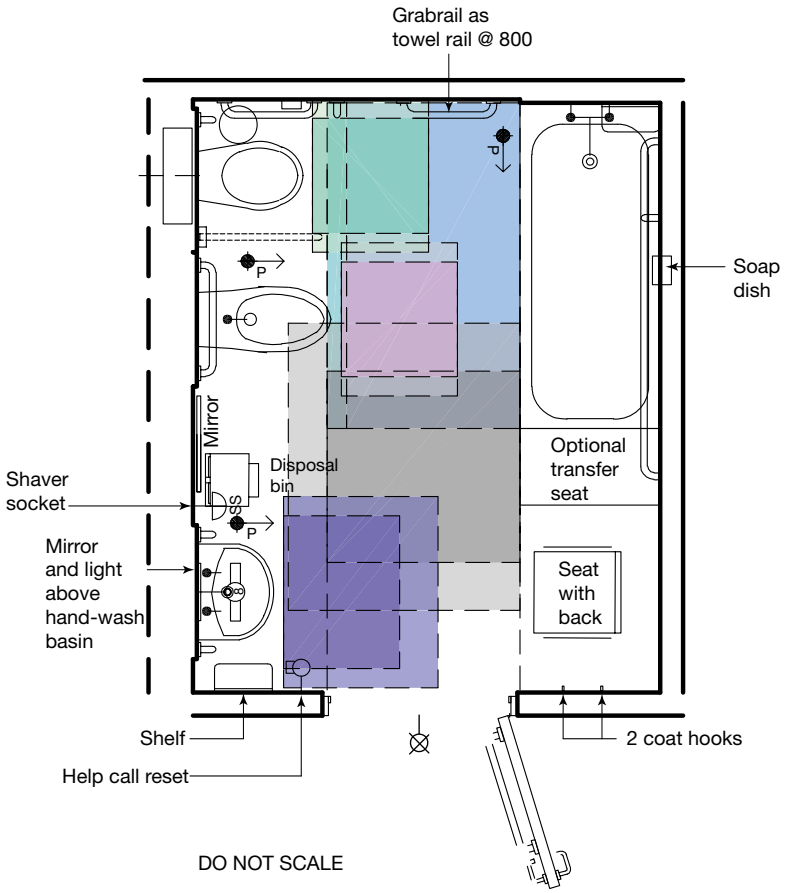


Figure 1 Space requirements for bidet: semi-ambulant

Ergonomic drawings

Bidet

2.6 This ergonomic drawing (see Figure 2) shows the space requirements for a bidet.

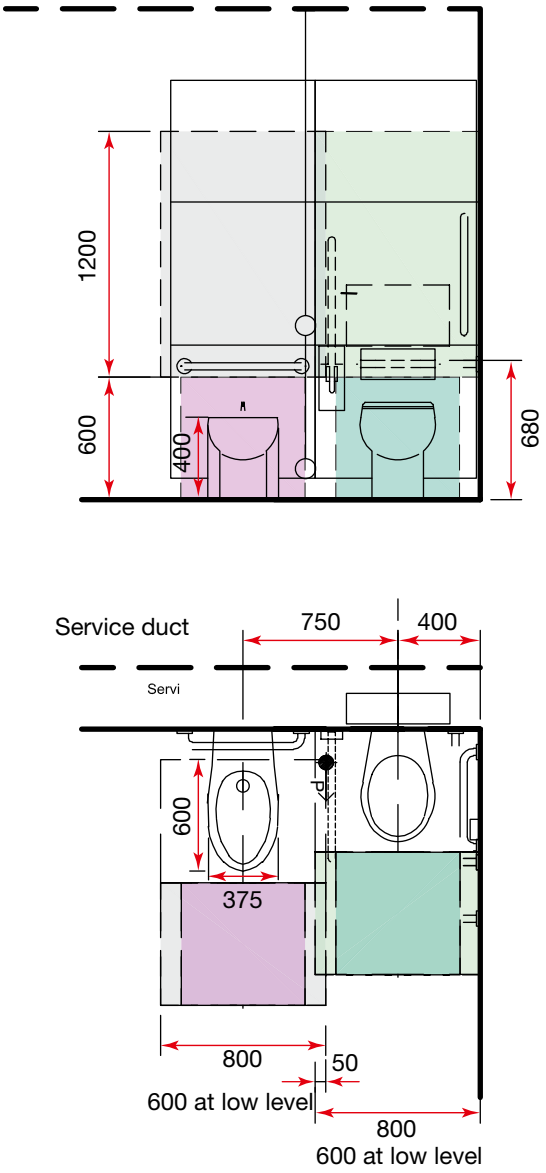


Figure 2 Space requirements for access to a bidet

Dressing and undressing: ambulant

2.7 These ergonomic drawings (see Figure 3) show the space requirements for ambulant dressing and undressing.

2.8 An identical space provision is suitable for semi-ambulant users though it should be located adjacent to a seating area.

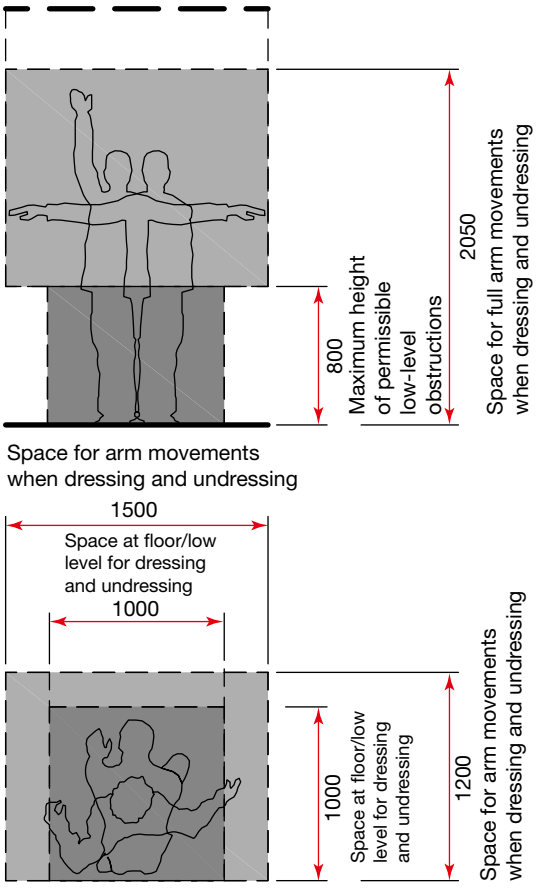


Figure 3 Space requirements for ambulant dressing and undressing

Toilet: semi-ambulant

2.9 This ergonomic drawing (see Figure 4) shows the space requirements for a semi-ambulant toilet.

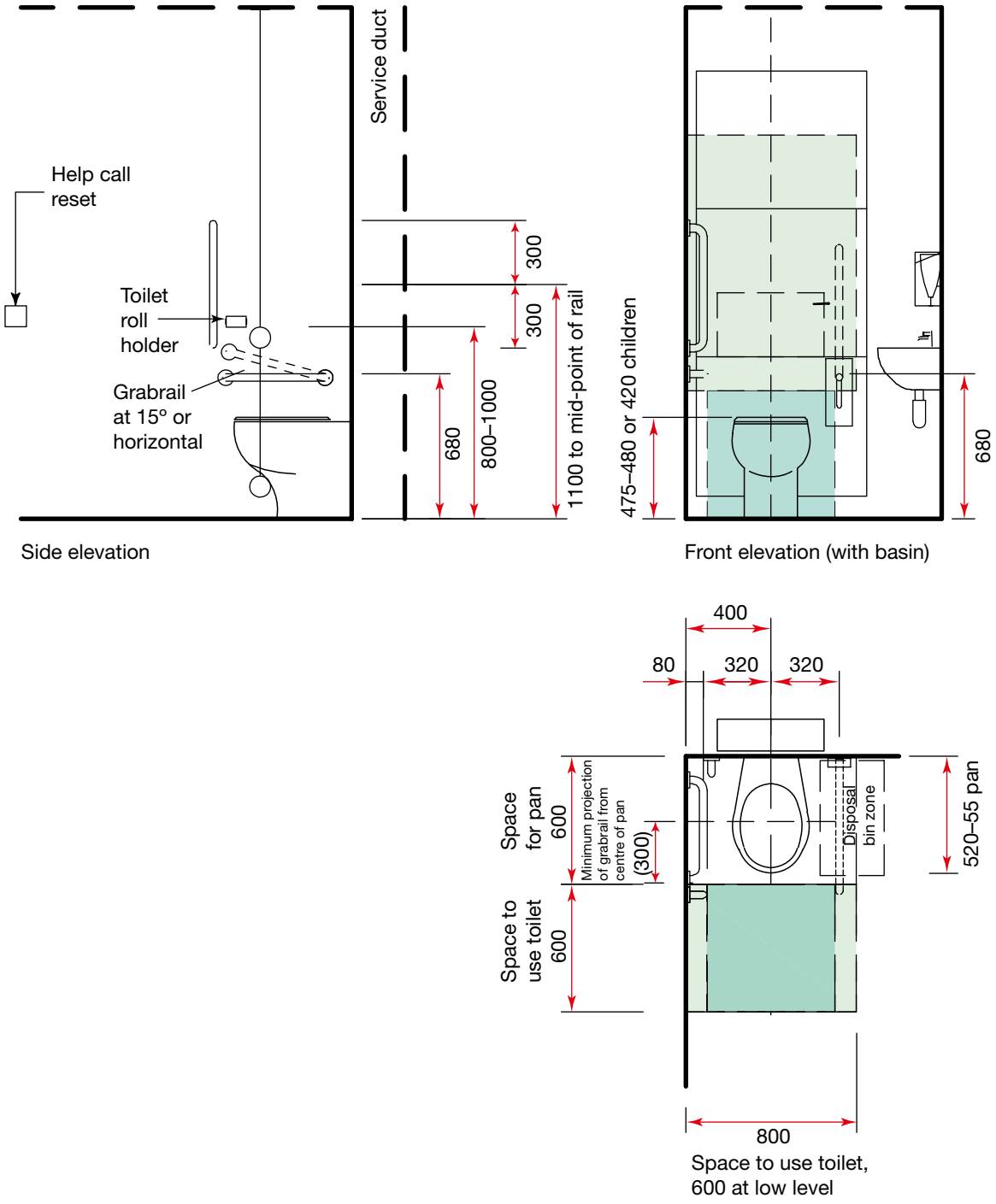


Figure 4 Space requirements to access a semi-ambulant toilet

Wash-hand basin: ambulant

2.10 Wash-hand basins may be used for personal washing activities.

2.11 This ergonomic drawing (see Figure 5) shows the space requirements for ambulant/ semi-ambulant use of a 400 mm deep × 500 mm wide wash-hand basin.

2.12 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

2.13 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

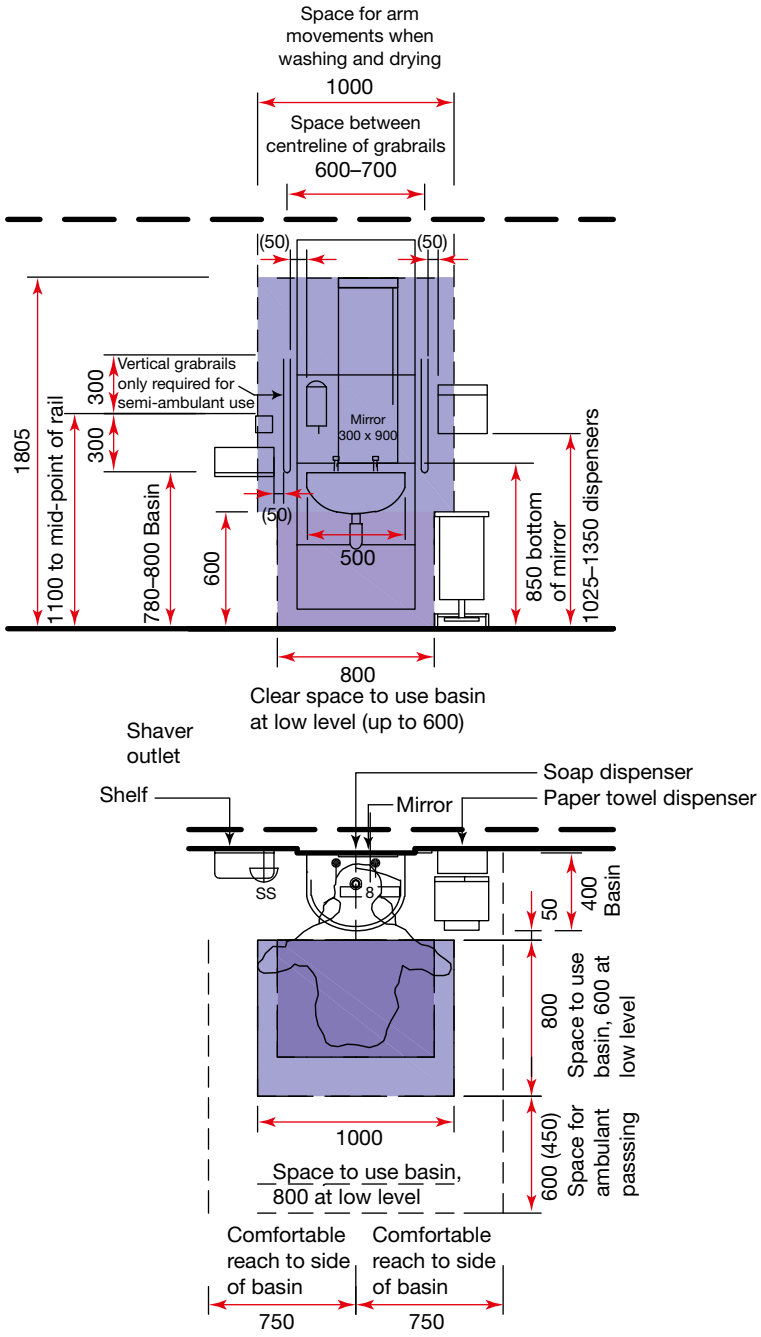


Figure 5 Space requirements for ambulant/semi-ambulant use of a 400 mm deep x 500 mm wide wash-hand basin

Full-length mirror: standing or seated users

2.14 This ergonomic drawing (see Figure 6) shows the space requirements for a full-length mirror for standing or seated users.

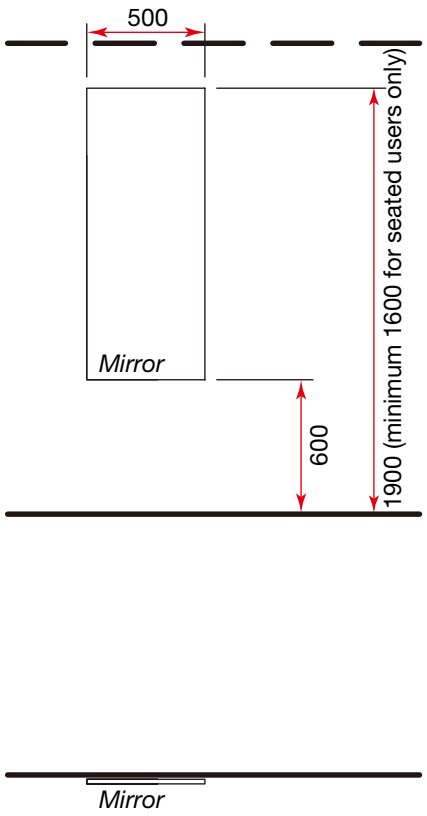


Figure 6 Space requirements to full-length mirror for standing or seated users

Bath: semi-ambulant

2.15 This ergonomic drawing (see Figure 7) shows the space requirements for a semi-ambulant bath.

2.16 Where a fixed transfer seat is not provided at the foot of the bath, an independent use bath hoist (chair) should be available, of the type that can be securely fixed to the bath rim when required. Manufacturers' advice should be sought regarding space requirements for such bath hoists.

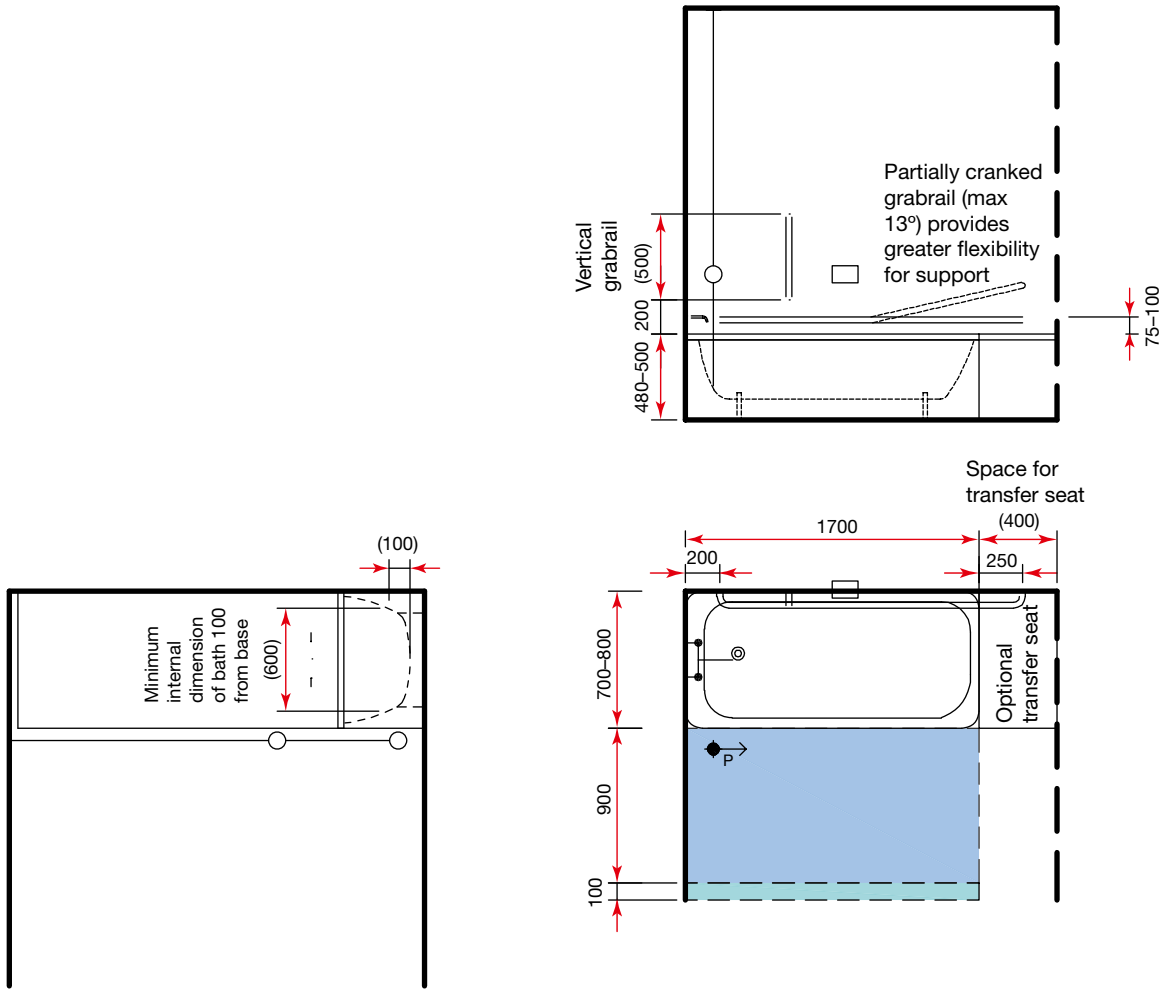


Figure 7 Space requirements to access a semi-ambulant bath

Bathroom: assisted

Bathroom: assisted

2.17 The following assisted activities take place in assisted bathrooms (end access to bath):

- undressing and dressing;
- hanging/holding clothes;
- wheelchair and sanitary chair access to the toilet and wash-hand basin;
- mobile hoist access to transfer a patient to the toilet or bath or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet (supervised only);
- use of the toilet;
- personal washing (whilst seated);
- use of the bath.

2.18 An assisted bathroom should contain an adjustable-height bath, assisted toilet and wheelchair wash-hand basin.

2.19 Assisted variable-height baths are available in a large variety of sizes and are not covered by 'Element 4: Sanitary assemblies'. The room layout provided is based on a variable height bath measuring 800 mm wide and 2400 mm long.

2.20 The bath should be positioned in the centre of the room to provide increased access for users and staff.

2.21 Assisted bathrooms are not suitable for independent wheelchair users, and are of limited use for ambulant and semi-ambulant use without due consideration of bath access requirements and the use of an adjustable-height wash-hand basin for standing users.

2.22 The room layout (see Figure 8) utilises the minimum clear space requirement to the side of the toilet for mobile hoist transfer (that is, 1150 mm from the centreline of the toilet to the nearest obstruction), on the bath side of the toilet only.

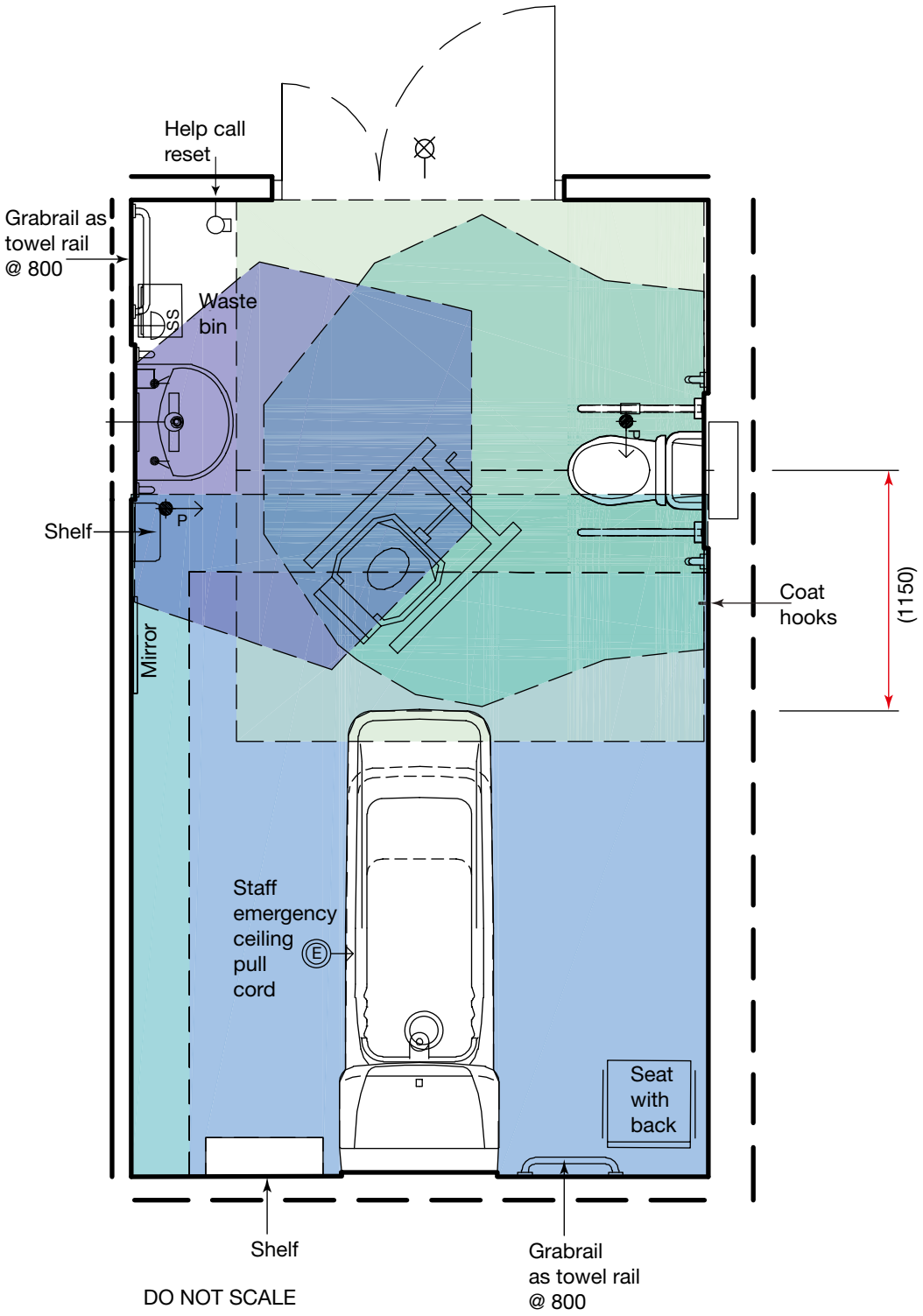


Figure 8 Space requirements for bathroom: assisted

Ergonomic drawings

Assisted bath

2.23 This ergonomic drawing (see Figure 9) shows the space requirements for an assisted bath.

2.24 Variable-height baths vary considerably in size and service requirements depending on the model and manufacturer. Specialist/ manufacturer advice should be sought at the earliest possible stage to clarify requirements.

2.25 Where used as a treatment bathroom, medical gases should be provided at the head of the bath, and the model of bath should allow for the use of a stretcher hoist.

2.26 This is generic briefing information, and manufacturers' advice should be sought on the specific requirements of baths and associated lifting aids.

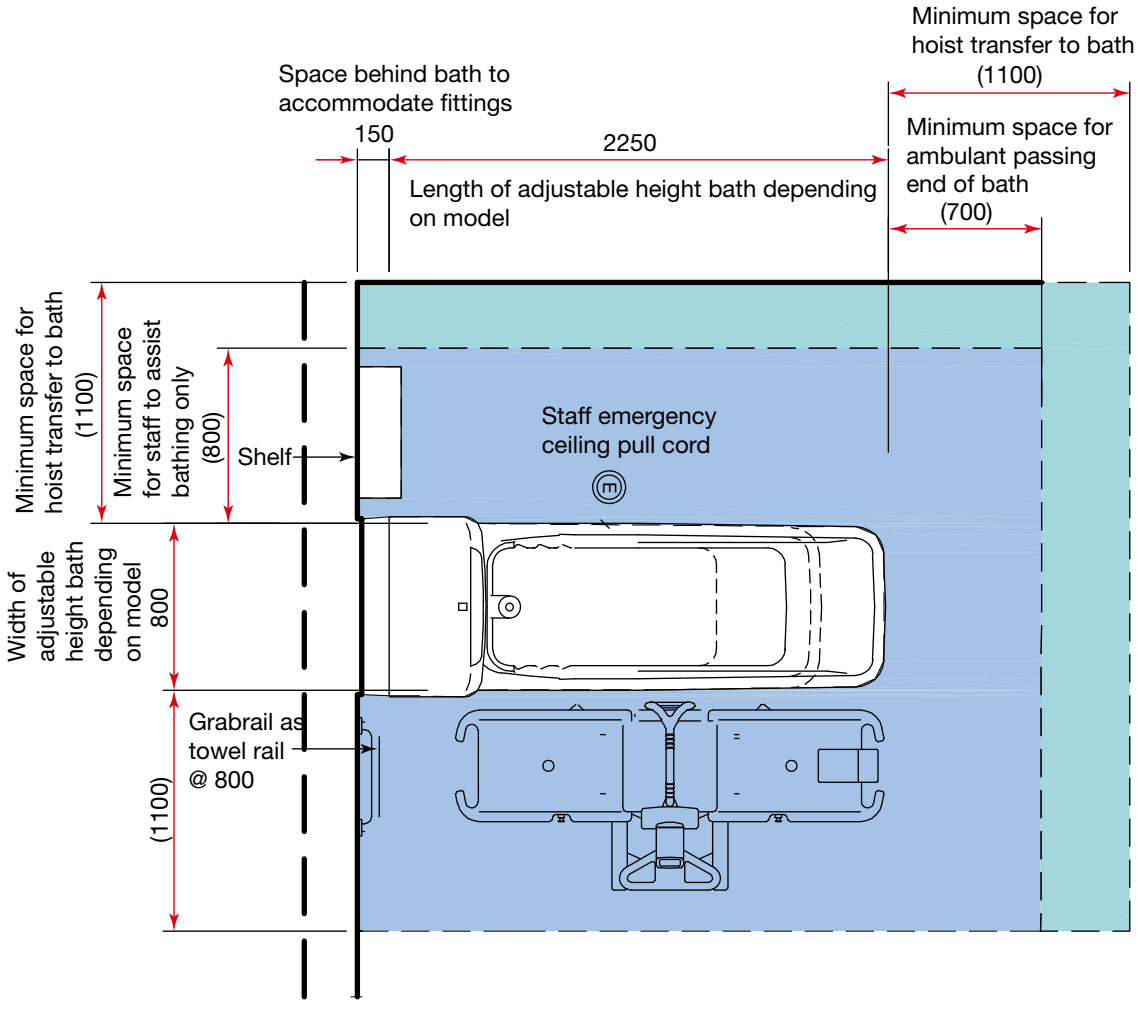


Figure 9 Space requirements to access an assisted bath

Toilet: assisted

2.27 This ergonomic drawing (see Figure 10) shows the space requirements for an assisted toilet.

2.28 The clear space on either side of the toilet for mobile hoist transfer is greater than that recommended in BS 8300 (Figure 55).

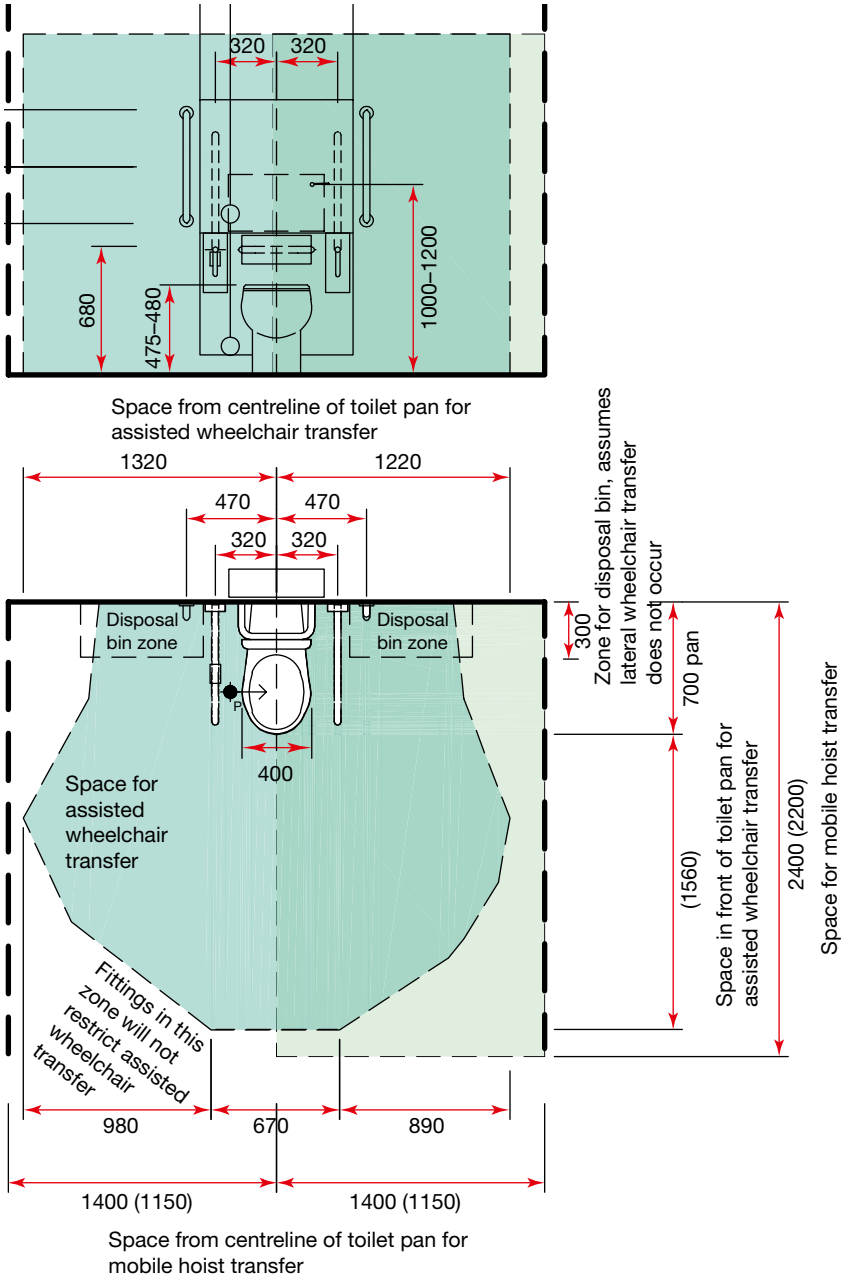


Figure 10 Space requirements to access an assisted toilet

Full-length mirror: standing or seated users

2.29 This ergonomic drawing (see Figure 11) shows the space requirements for a full-length mirror for standing or seated users.

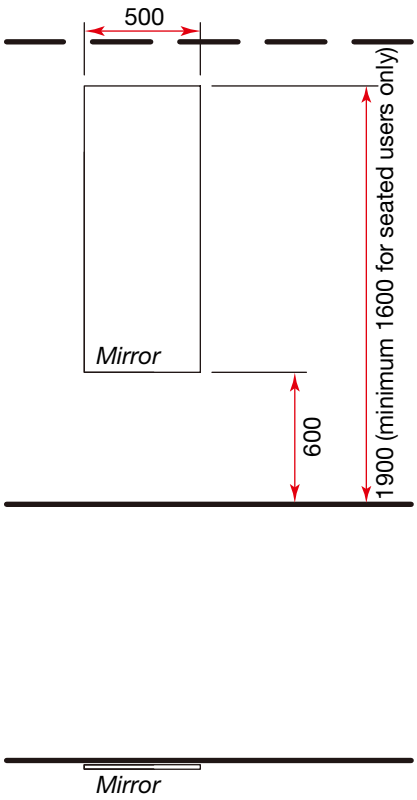


Figure 11 Space requirements for a full-length mirror for standing or seated users

Wash-hand basin: wheelchair

2.30 Wash-hand basins may be used for personal washing activities.

2.31 This ergonomic drawing (see Figure 12) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

2.32 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

2.33 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

2.34 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

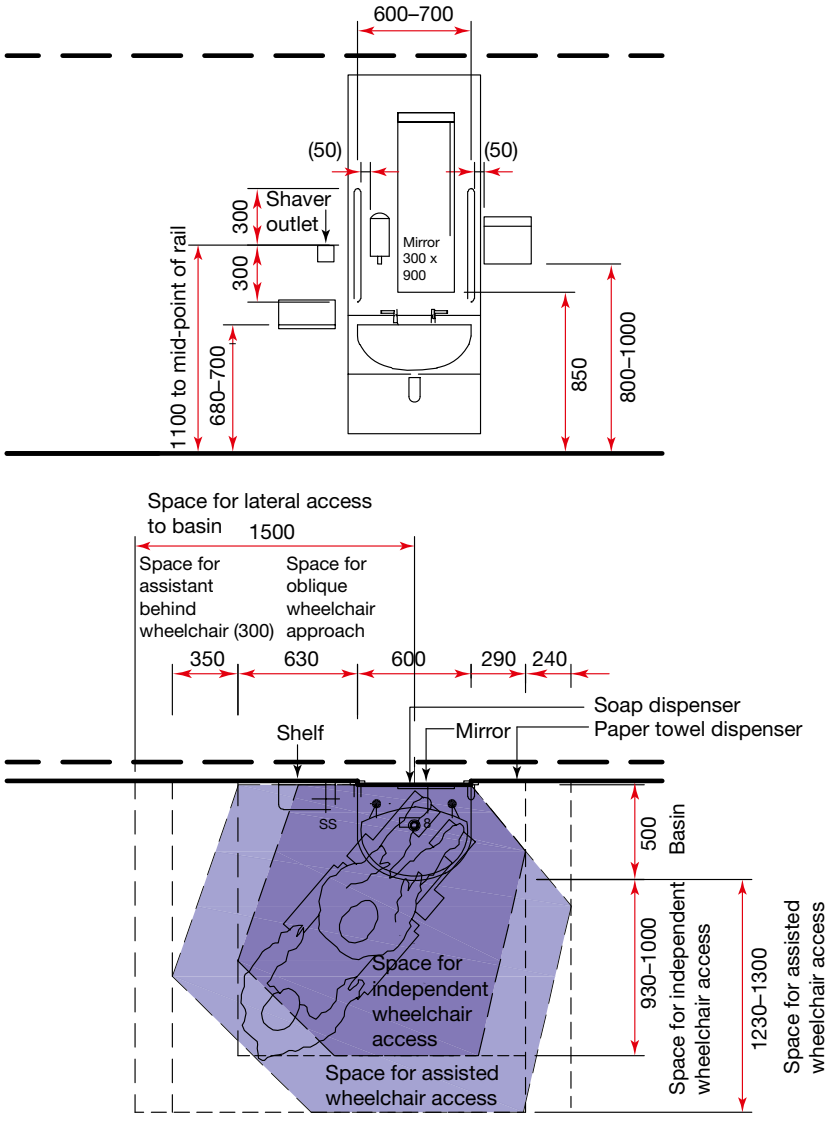


Figure 12 Space requirements for a wheelchair accessible wash-hand basin

Bathroom: independent wheelchair

Room description and layout

2.35 The following activities take place in independent wheelchair bathrooms:

- undressing and dressing;
- hanging/holding clothes;
- wheelchair access to the toilet, hand-rinse basin, wash-hand basin and bath;
- independent transfer from a wheelchair to the toilet or bath;
- use of the toilet;
- disposal of sanitary towels (optional);
- emptying of urine bottles and colostomy bags;
- hand-rinsing (whilst in a wheelchair facing the hand-rinse basin or seated on the toilet);
- personal washing (whilst seated);
- use of the bath.

2.36 Bathrooms for independent wheelchair use should contain an independent wheelchair toilet and adjacent hand-rinse basin, separate wheelchair wash-hand basin for personal washing and an independent wheelchair bath.

2.37 The example layout provided (see Figure 13) conflicts with the equivalent space in Approved Document M and BS 8300.

2.38 The layouts of independent wheelchair bathrooms in Approved Document M (Diagrams 24 and 25) and BS 8300 (Figure 45) show a wash-hand basin adjacent to the toilet. This is based on the assumption that users will fill the basin before sitting at the toilet (since the taps may be out of reach) to be able to wash their hands from a seated position on the toilet. This is not considered acceptable in healthcare premises, and hence a separate wash-hand basin has been included within the room (in addition to the hand-rinse basin adjacent to the toilet).

2.39 The example layout allows for right-hand independent wheelchair transfer to the toilet and bath.

2.40 To enable this space to be suitable for all unassisted use, an adjustable-height wash-hand basin may be provided in place of the wheelchair wash-hand basin.

2.41 Additional space may be required for special baths.

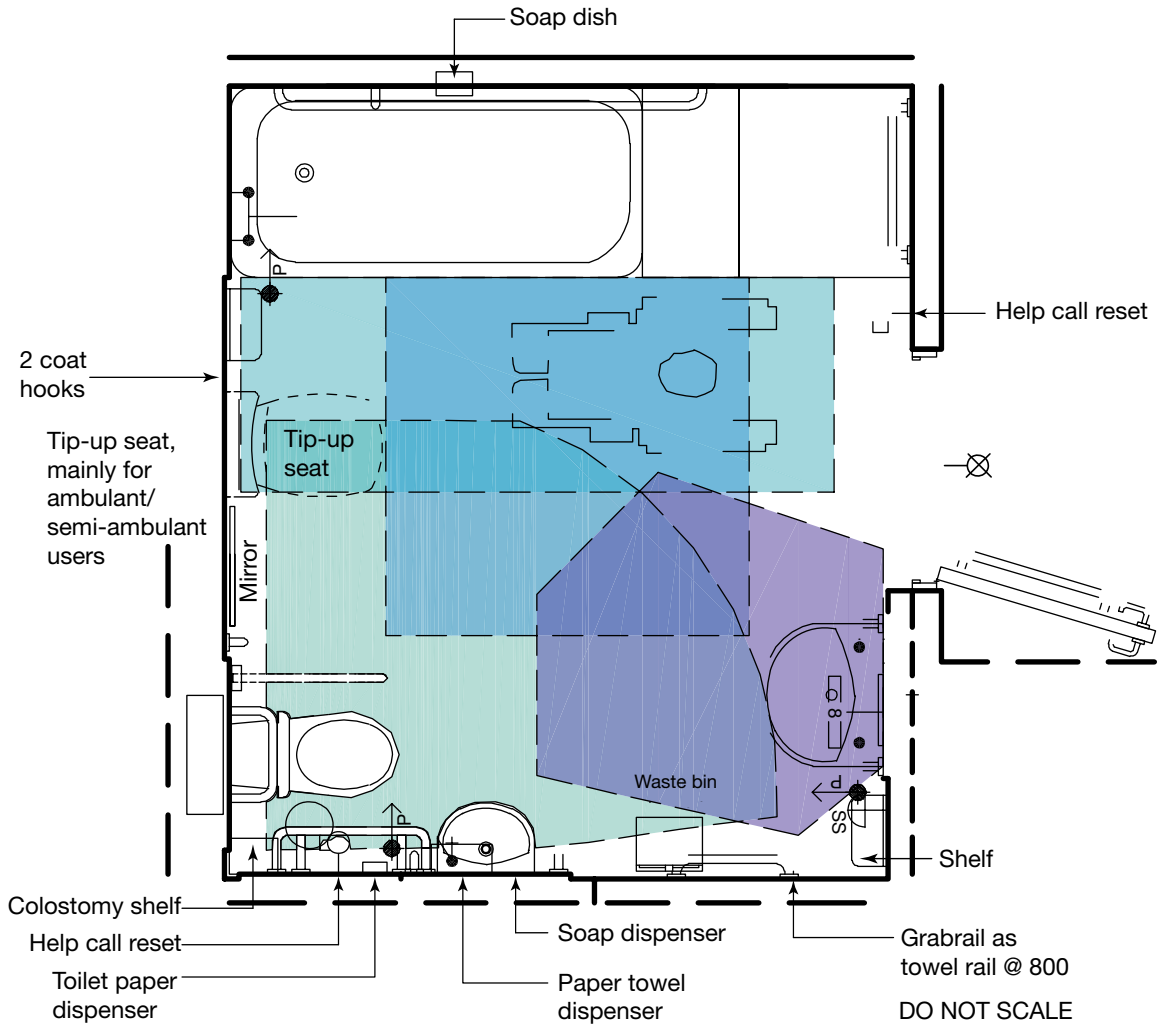


Figure 13 Space requirements to access bathroom: independent wheelchair

Ergonomic drawings

Bath: independent wheelchair

2.42 This ergonomic drawing (see Figure 14) shows the space requirements for an independent wheelchair bath.

2.43 Note the bath and fixings are similar to the bath for semi-ambulant use except for the tap location.

2.44 Wall-mounted taps (compliant with 'Health Building Note 00-10 Part C – Sanitary assemblies') should be provided for reasons of infection control (rather than the corner deck-mounted taps shown in BS 8300). The taps should be located close to the edge of the bath to allow access to the taps for a wheelchair user.

2.45 Where a fixed transfer seat is not provided at the foot of the bath, an independent use bath hoist (chair) should be available, of the type that can be securely fixed to the bath rim when required. Manufacturers' advice should be sought regarding space requirements for such bath hoists.

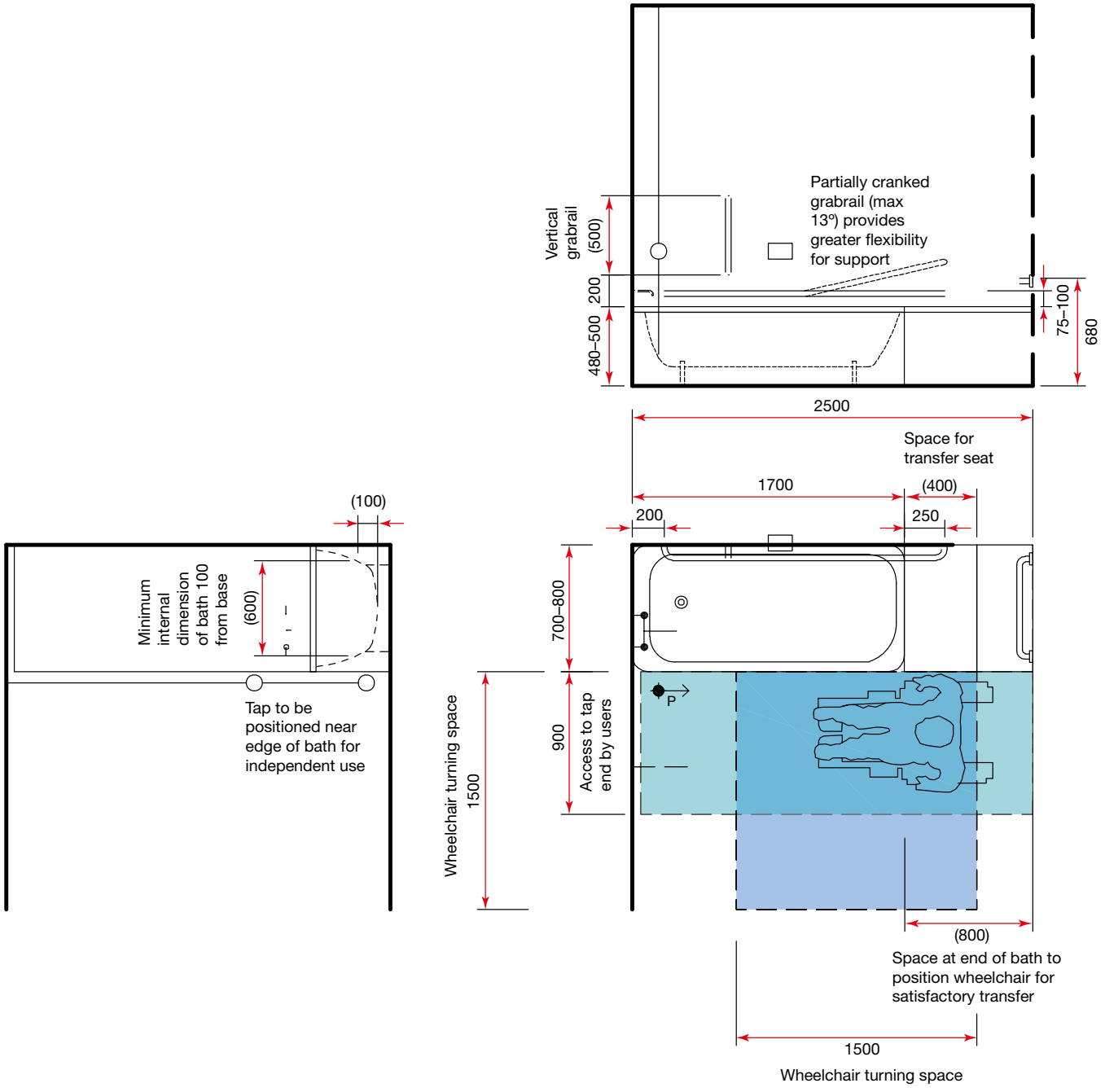


Figure 14 Space requirements for an independent wheelchair bath

Toilet and adjacent hand-rinse basin: independent wheelchair: grabrail options

2.46 These ergonomic drawings (see Figure 15) show the fixing position of grabrails for an independent wheelchair toilet and adjacent hand-rinse basin.

2.47 Grabrails should be provided symmetrically on either side of the toilet at 320 mm from the centreline of the toilet pan. This conflicts with the recommendations in Approved Document M and BS 8300.

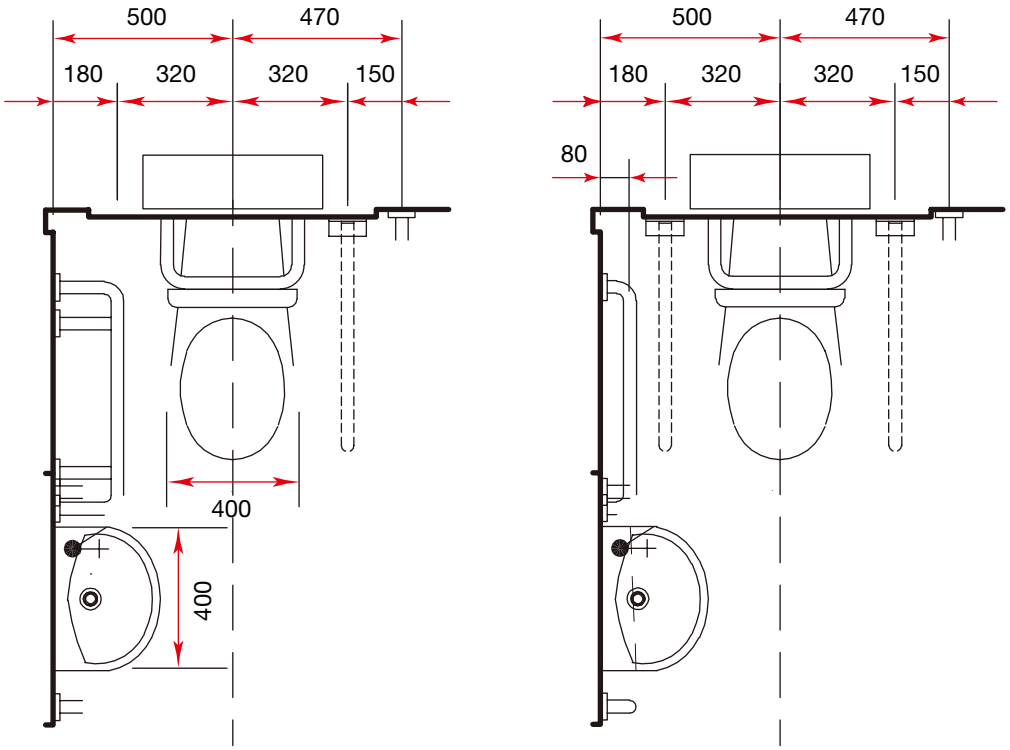
2.48 Approved Document M (paragraph 5.10j) states: "where the horizontal support rail on the wall adjacent to the toilet is set with the minimum spacing from the wall, an additional dropdown rail should be provided on the wall side at a distance of 320 mm from the centreline of the toilet."

Note

Where the maximum spacing defined in Approved Document M, 85 mm, is used, this positions the grabrail approximately 390 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

2.49 BS 8300 (paragraph 12.6.3.5 b) states: "A fixed horizontal rail should be located on the side wall with a 50 mm to 60 mm clearance between the rail and the wall." This places the rail approximately 420 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

2.50 The ergonomic drawings provided illustrate two options for the provision of grabrails. The room layouts on this website are based on option one.



Fixed grabrail between toilet and wall

Alternative fixed and hinged grabrail between toilet and wall

Figure 15 Space requirements showing the fixing position of grabrails for an independent wheelchair toilet and adjacent hand-rinse basin

Toilet and adjacent hand-rinse basin: independent wheelchair

2.51 This ergonomic drawing (see Figure 16) shows the space requirements for an independent wheelchair toilet and adjacent hand-rinse basin.

2.52 The recommended clear space in front and to the open side of the toilet (for independent wheelchair transfer) is greater than the recommendations in Approved Document M and BS 8300.

2.53 Approved Document M and BS 8300 recommend a minimum clear distance of 1000 mm to the open side of the centreline of the toilet for independent wheelchair transfer. Robert Feeney Associates (RFA) research for BS 8300 indicates that this will allow just over 60% of wheelchair users to comfortably transfer onto the toilet. The same research indicates that a clear space of 1400 mm accommodates 90% of wheelchair users and this is, therefore, recommended.

2.54 Approved Document M and BS 8300 recommend a 750 mm long toilet pan for independent wheelchair transfer. However, RFA research indicated that a 700 mm long toilet pan allows independent wheelchair transfer. For maximum space efficiency a 700 mm pan is recommended.

2.55 As a consequence of the reduction in pan length, the hand-rinse basin is located closer to the corner of the room than the position given in Approved Document M and BS 8300, to allow hand-rinsing from a seated position on the toilet.

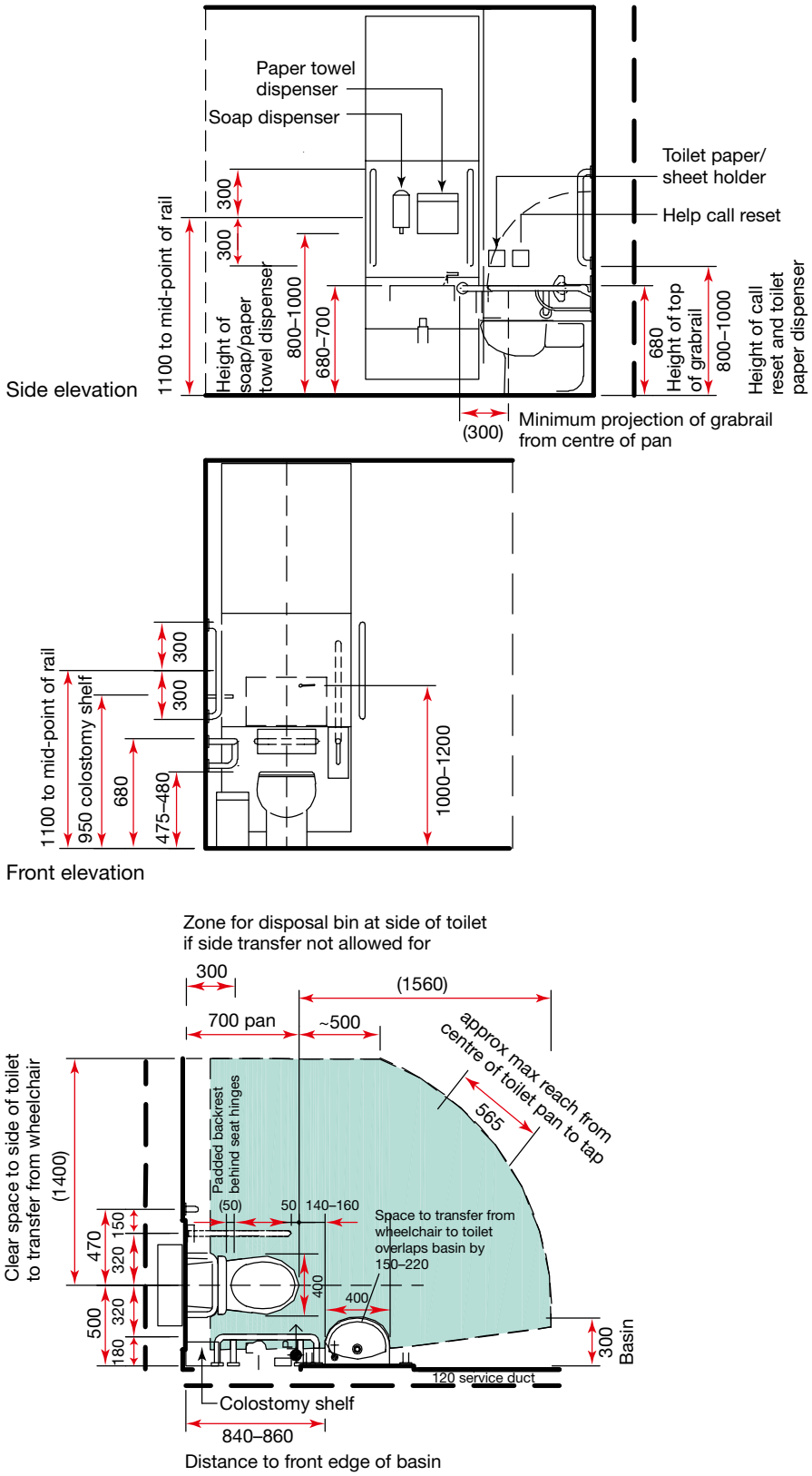


Figure 16 Space requirements for an independent wheelchair toilet and adjacent hand-rinse basin

Wash-hand basin: wheelchair

2.56 Wash-hand basins may be used for personal washing activities.

2.57 This ergonomic drawing (see Figure 17) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

2.58 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

2.59 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

2.60 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

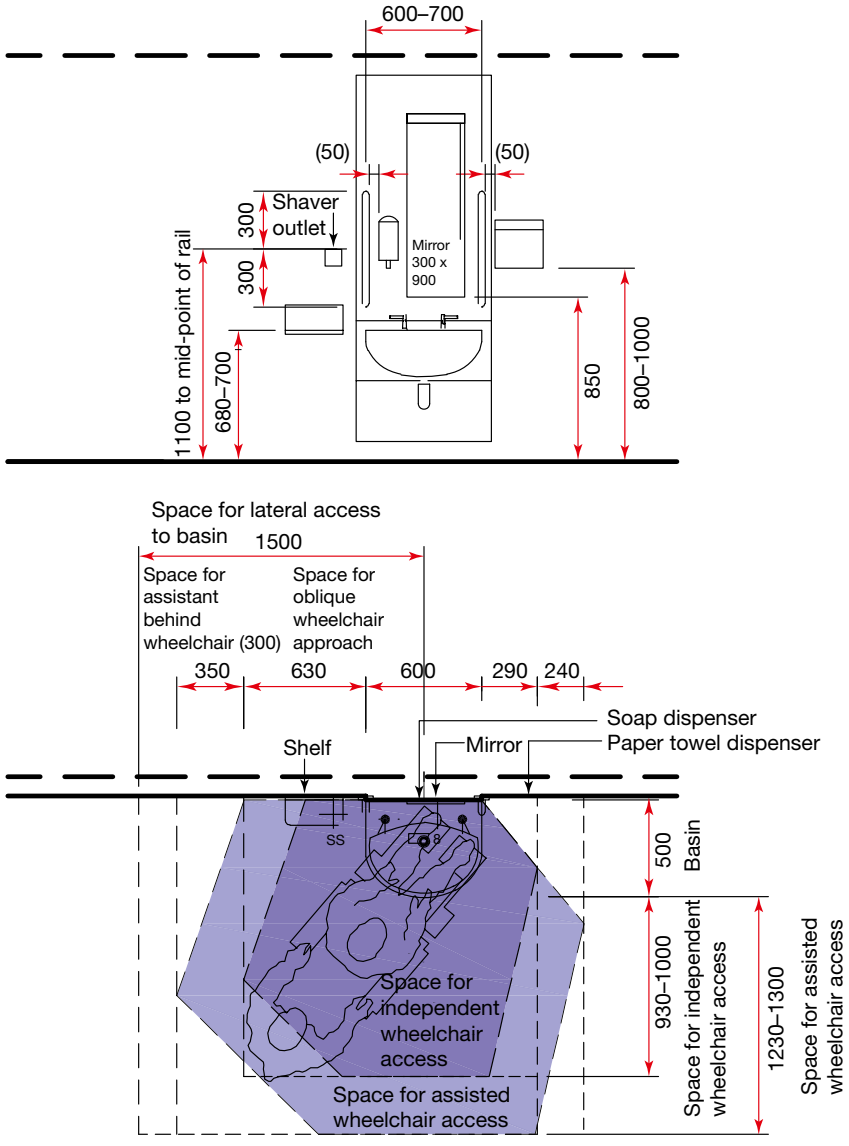


Figure 17 Space requirements for a wheelchair accessible wash-hand basin

Full-length mirror: standing or seated users

2.61 This ergonomic drawing (see Figure 18) shows the space requirements for a full-length mirror for standing or seated users.

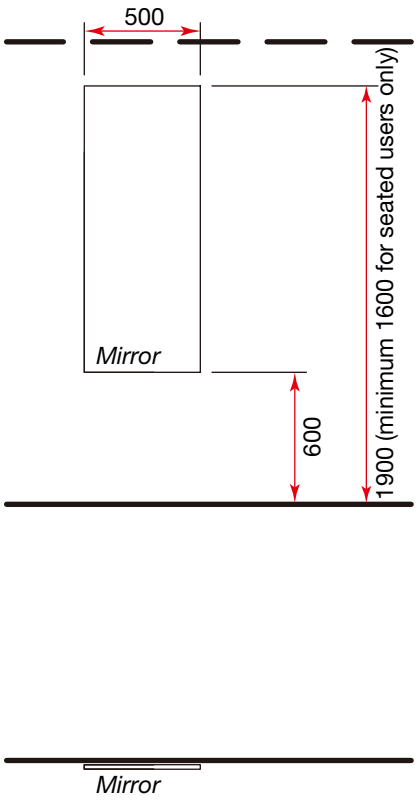


Figure 18 Space requirements for a full-length mirror for standing or seated users

Bathroom: semi-ambulant

Room description and layout

2.62 See Figure 19. The following activities take place in semi-ambulant bathrooms:

- undressing and dressing;
- hanging/holding clothes;
- use of the toilet;
- personal washing;
- use of the bath.

2.63 Semi-ambulant bathrooms should contain a semi-ambulant bath, semi-ambulant toilet and ambulant wash-hand basin.

2.64 Semi-ambulant bathrooms are also suitable for ambulant users.

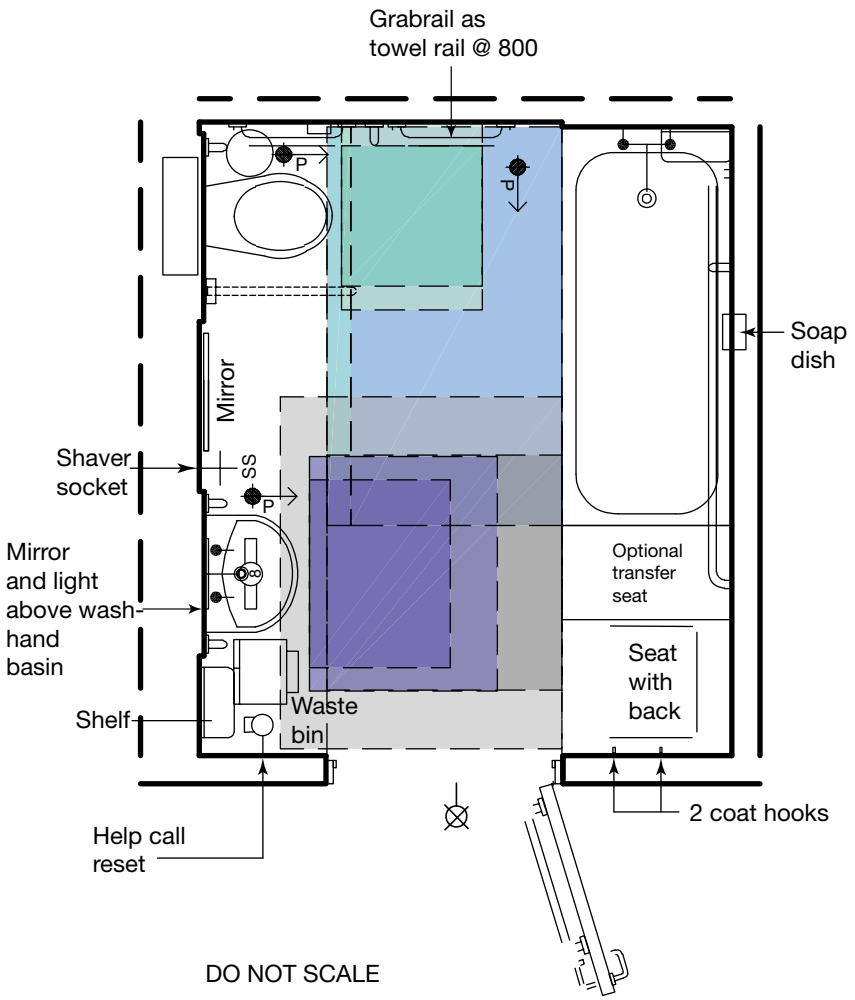


Figure 19 Space requirements for a bathroom: semi-ambulant

Ergonomic drawings

Dressing and undressing: ambulant

2.65 These ergonomic drawings (see Figure 20) show the space requirements for ambulant dressing and undressing.

2.66 An identical space provision is suitable for semi-ambulant users though it should be located adjacent to a seating area.

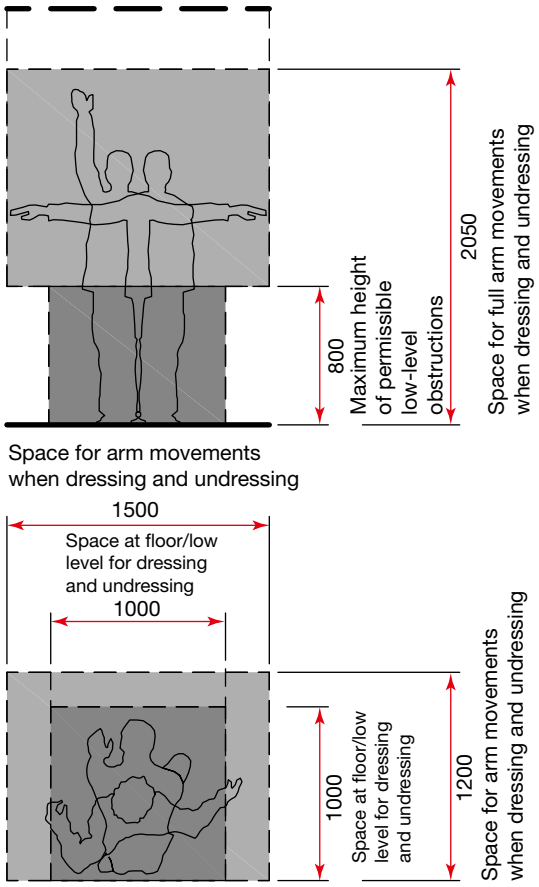


Figure 20 Space requirements for ambulant dressing and undressing

Toilet: semi-ambulant

2.67 This ergonomic drawing (see Figure 21) shows the space requirements for a semi-ambulant toilet.

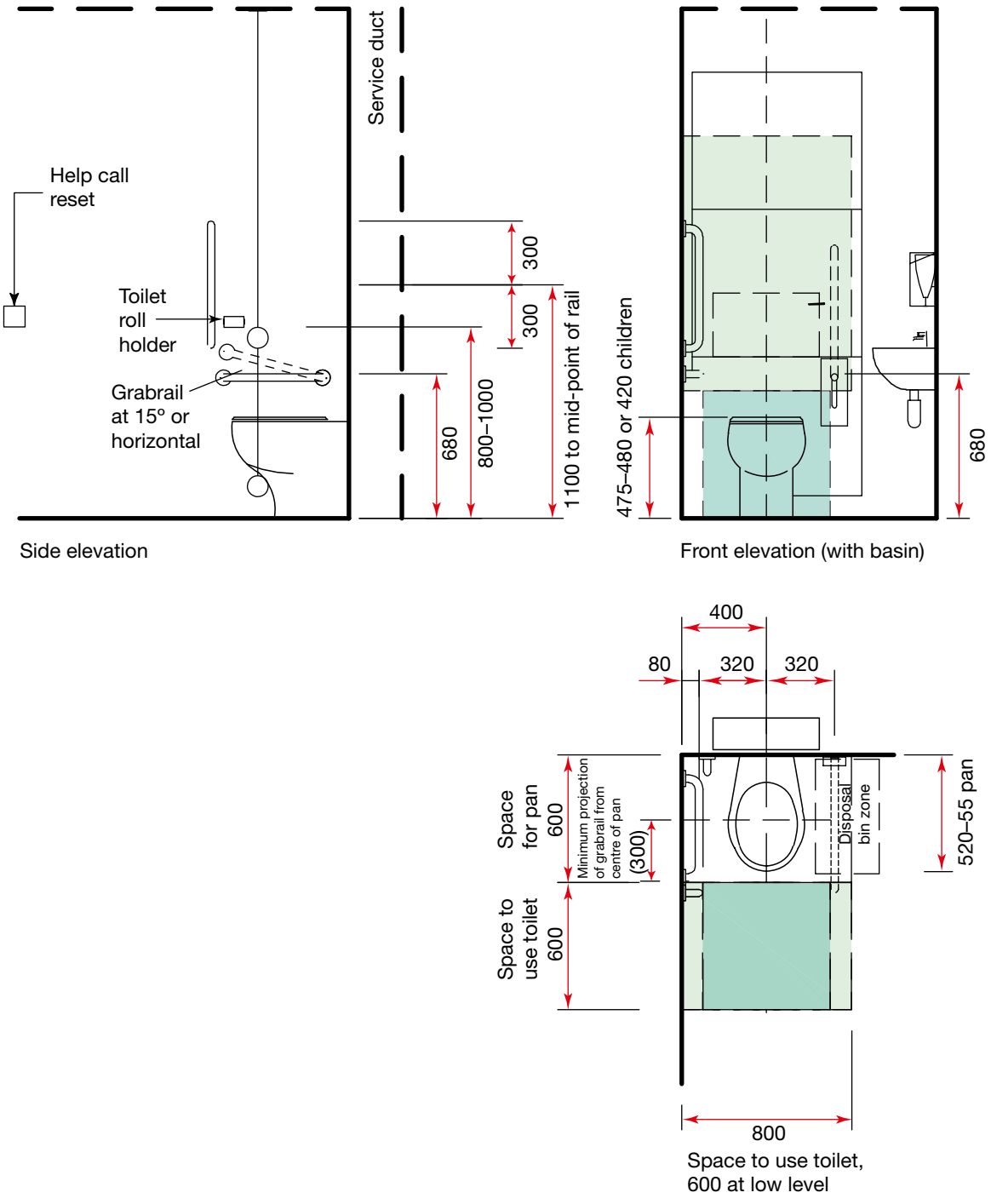


Figure 21 Space requirements for a semi-ambulant toilet

Wash-hand basin: ambulant

2.68 Wash-hand basins may be used for personal washing activities.

2.69 This ergonomic drawing (see Figure 22) shows the space requirements for ambulant/ semi-ambulant use of a 400 mm deep × 500 mm wide wash-hand basin.

2.70 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

2.71 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

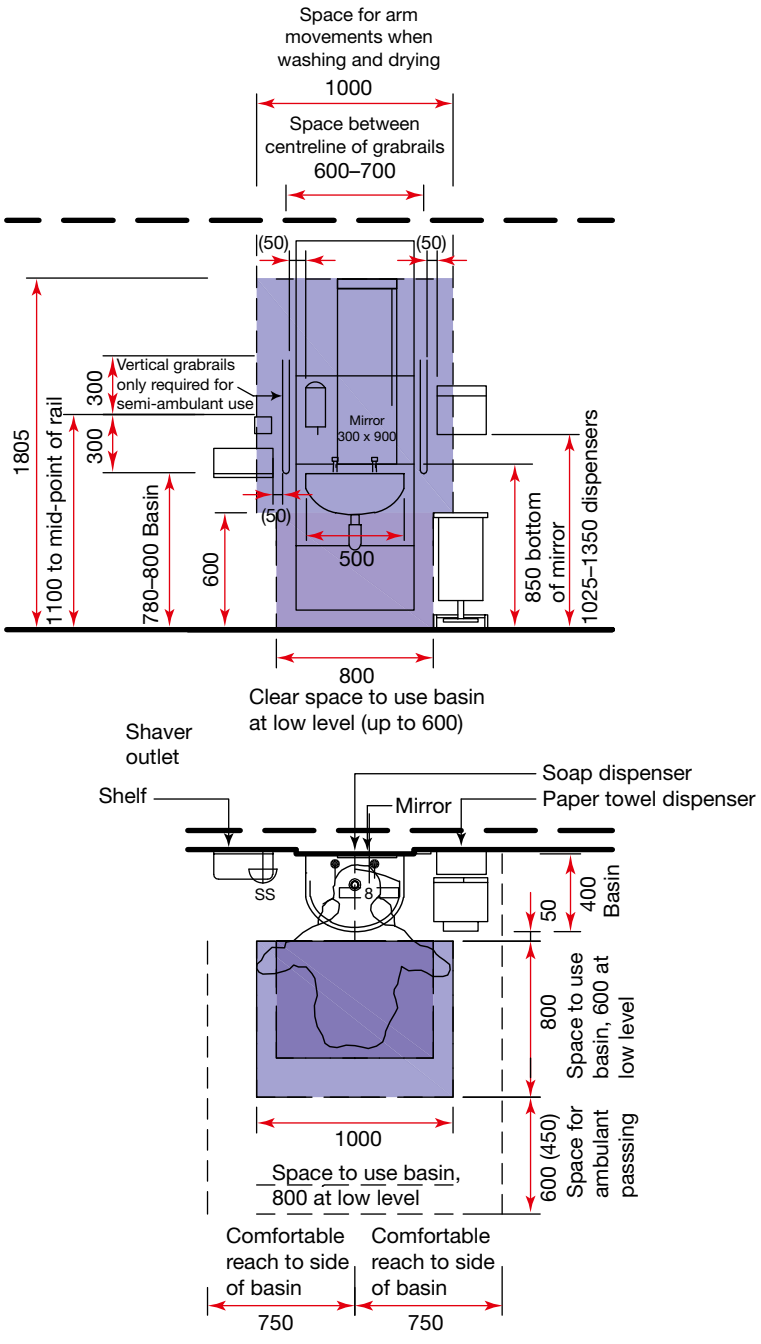


Figure 22 Space requirements for ambulant/semi-ambulant use of a 400 deep x 500 mm wide wash-hand basin

Full-length mirror: standing or seated users

2.72 This ergonomic drawing (see Figure 23) shows the space requirements for a full-length mirror for standing or seated users.

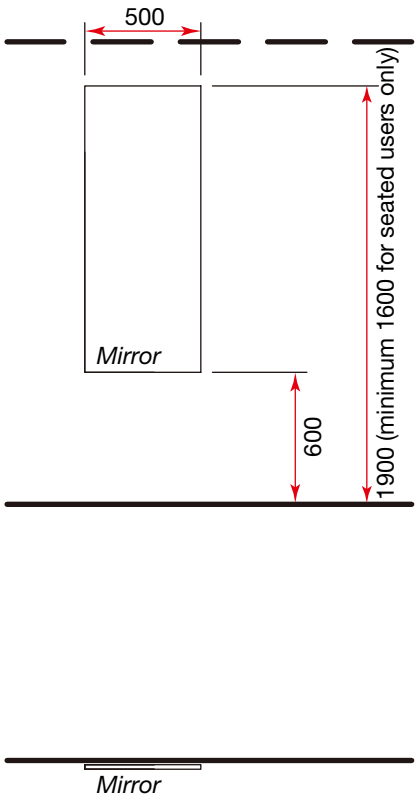


Figure 23 Space requirements for a full-length mirror for standing or seated users

Bath: semi-ambulant

2.73 This ergonomic drawing (see Figure 24) shows the space requirements for a semi-ambulant bath.

2.74 Where a fixed transfer seat is not provided at the foot of the bath, an independent use bath hoist (chair) should be available, of the type that can be securely fixed to the bath rim when required. Manufacturers' advice should be sought regarding space requirements for such bath hoists.

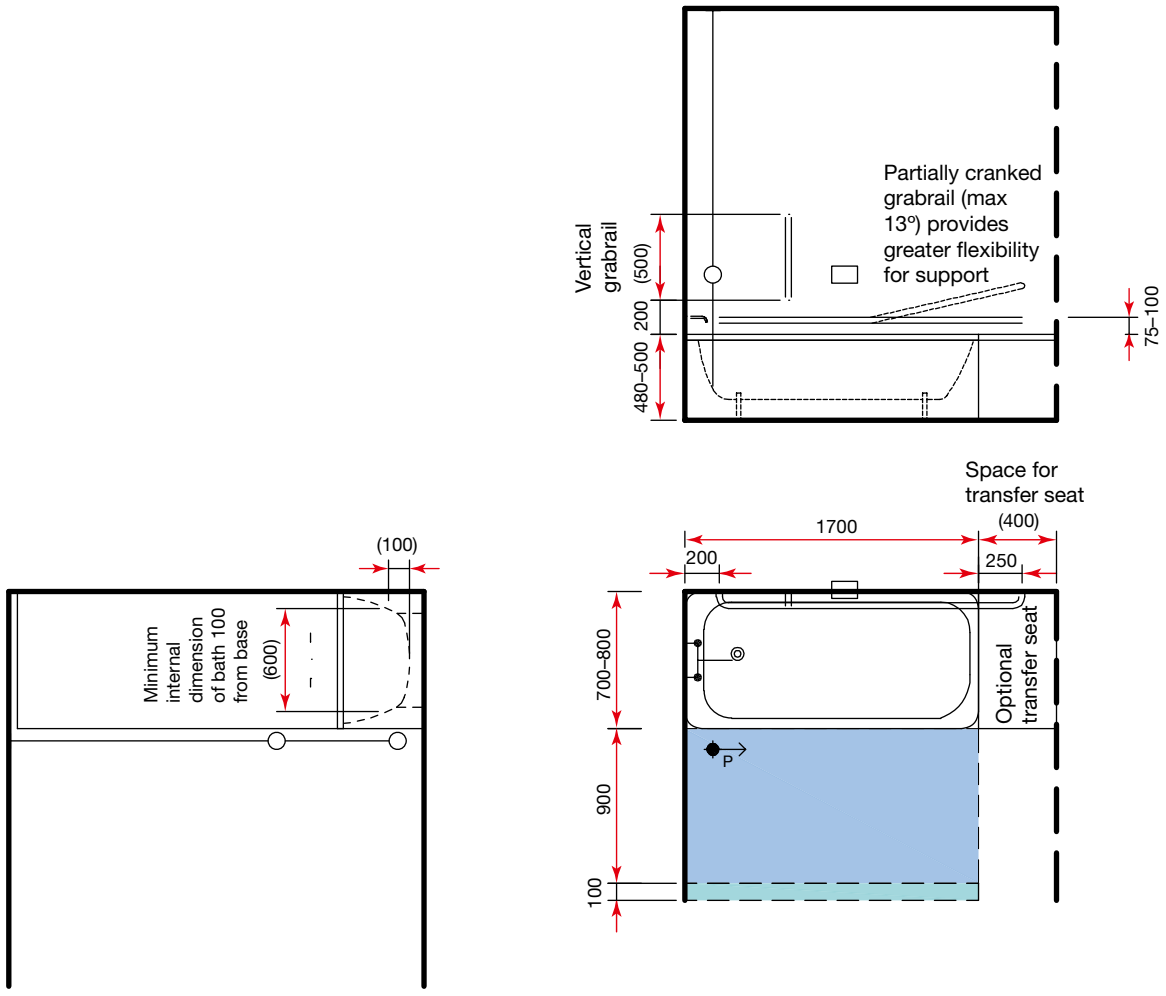


Figure 24 Space requirements for a semi-ambulant bath

3 Changing facilities

Changing area: staff

Room description and layout

3.1 The following activities take place in staff changing areas:

- undressing and dressing;
- changing into clean uniforms, blues or greens (including clean footwear);
- hanging/holding coats and wet clothes;
- storage of clothing and personal belongings;
- storage of clean footwear;
- depositing of dirty uniforms (optional).

3.2 Staff changing areas should include:

- full-length (lockable) lockers for clothing and personal belongings;
- open changing area and/or individual changing rooms;
- changing rails for secure storage of coats and wet clothes;
- storage space for clean footwear (required in theatres etc).

3.3 Separate changing facilities are required for male and female staff.

3.4 Access to the area should be controlled by a keypad lock, close proximity card or similar security system.

3.5 It is assumed that the following facilities will be provided separately but nearby:

- showers;
- wash-hand basins, with soap and paper towel dispensers;
- toilets;
- shaving points (optional);
- power points for hairdryers;
- well-illuminated mirrors with shelves;
- uniform exchange area.

3.6 Consideration should be given to the provision of independent wheelchair showers and WCs in accordance with the requirements of Approved Document M.

3.7 As a minimum, the number of WCs and showers should be provided in accordance with the requirements of the Workplace (Health, Safety & Welfare) Regulations 1992, or current legislation.

3.8 Hand-rinse or personal washing facilities should be provided either within the associated WCs or immediately outside them, accessible from the changing area.

3.9 The room layout provided generally assumes ambulant or semi-ambulant use. Where independent wheelchair access is required, an independent wheelchair changing room(s) should be included and the minimum distance between lockers should be increased to 1500 mm. The area allocation, per locker, should therefore be increased accordingly.

3.10 Locker numbers should be provided on the following basis:

- for a shift system: twice the number of lockers as the maximum number of staff on duty at any one time (to allow for staff changeover), plus an allowance for visiting staff;

- for a non-shift system: the same number of lockers as the maximum number of staff on duty at any one time, plus an allowance for visiting staff.

3.11 The changing area provided should allow at least half the maximum number of staff on duty at any one time to change simultaneously. It is generally assumed that this will be in an open-plan space between lockers. At least one individual changing room should be provided.

3.12 The room layout (see Figure 25) includes 20 lockers and space for six people to change (suitable for a maximum of 10 staff on duty at any one time, including visiting staff).

3.13 The room layout includes the recommended minimum of one semi-ambulant changing room. Consideration should be given to:

- the number of individual changing rooms required. This will depend on local policy;
- the provision of independent wheelchair changing rooms in accordance with the requirements of Approved Document M.

3.14 The actual space requirements for lockers and changing will depend upon the size and quantity of lockers and whether changing space is provided in open-plan space between the lockers or in individual changing rooms. However, as a general guide the following space allocations should be allowed:

a. Where changing space is generally provided in the open space between lockers, 1.1 m² per full-height locker for up to 30 lockers and 0.75 m² per full-height locker for greater than 30 lockers;

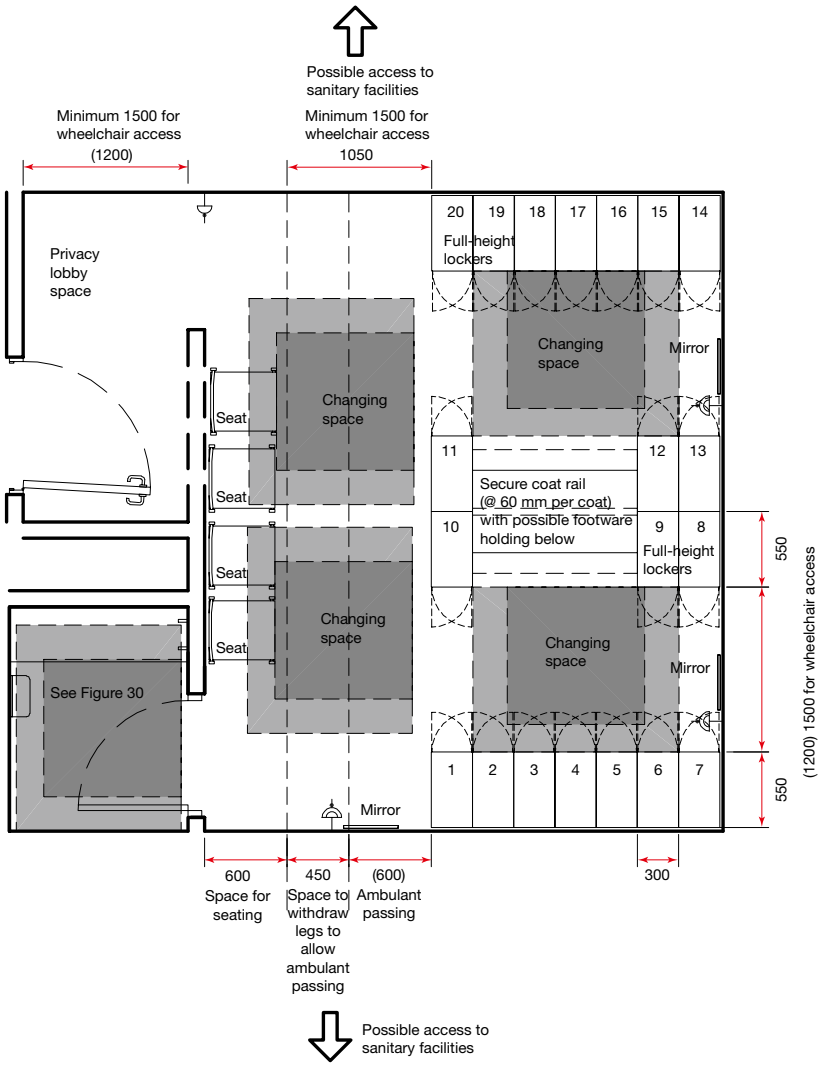


Figure 25 Space requirements for changing area: staff, 20 lockers

b. Where changing space is provided within separate changing cubicles, 0.75 m² per full-height locker for up to 50 lockers.

3.15 For the purposes of creating a briefing schedule, staff changing areas may be sized at 1.4 m² per locker. This allows for full height lockers, communal changing space for approx 25% of the lockers, an allowance for local uniform exchange, one individual semi-ambulant changing room and one ambulant shower room for every 20 lockers. It assumes cube lockers for personal belongings, if provided, are located elsewhere. See the table below.

3.16 The allowance does not include WCs, which need to be calculated separately based on the total number of staff.

3.17 When dividing changing areas into separate male and female allowance each space should be overprovided by, say, 10% to allow for flexibility in the percentage split between male and female users.

3.18 The staff multiplier for uniform exchange assumes that not everybody works full-time. In critical care areas, the multiplier may be as big as 5 but generally:

- 3.5 is considered reasonable for a facility with a shift system;
- 1.2 is considered acceptable for a facility without a shift system.

Table 1 Changing areas: staff

Shift system 40 lockers = 20 staff on duty						
	Staff multiplier for uniform exchange	**Qty**	**Area (m²)**	**Total**		
Changing area: 20 lockers		2	20	40		
Semi-ambulant changing room		2	2	4		
Ambulant shower room		2	2	4		
Uniform exchange lockers	5	100	0.1	10		
				58	**or**	**1.45 sq m per locker**
Shift system 40 lockers = 20 staff on duty						
	Staff multiplier for uniform exchange	**Qty**	**Area (m²)**	**Total**		
Changing area: 20 lockers		2	20	40		
Semi-ambulant changing room		2	2	4		
Ambulant shower room		2	2	4		
Uniform exchange lockers: 70	3.5	70	0.1	7		
				55	**or**	**1.38 sq m per locker**
Non-shift system 40 lockers = 40 staff on duty						
	Staff multiplier for uniform exchange	**Qty**	**Area (m²)**	**Total**		
Changing area: 20 lockers		2	20	40		
Semi-ambulant changing room		2	2	4		
Ambulant shower room		2	2	4		
Uniform exchange lockers: 80	1.2	48	0.1	4.8		
				52.8	**or**	**1.32 sq m per locker**
			AVERAGE			**1.4 sq m per locker**

Ergonomic drawings

Dressing and undressing: ambulant

3.19 These ergonomic drawings (see Figure 26) show the space requirements for ambulant dressing and undressing.

3.20 An identical space provision is suitable for semi-ambulant users though it should be located adjacent to a seating area.

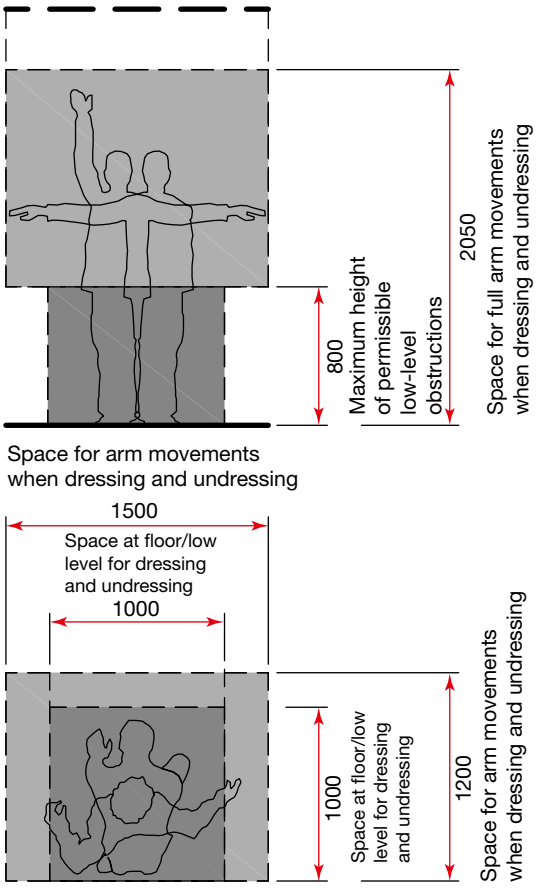


Figure 26 Space requirements for ambulant dressing and undressing

Full-length mirror: standing or seated users

3.21 This ergonomic drawing (see Figure 27) shows the space requirements for a full-length mirror for standing or seated users.

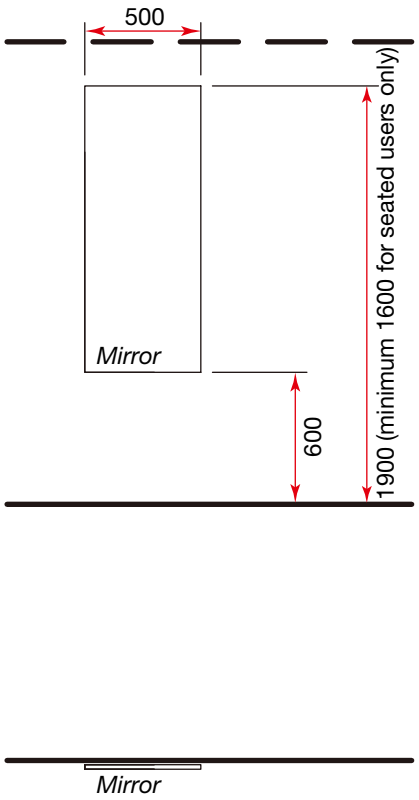


Figure 27 Space requirements for a full-length mirror for standing or seated users

Changing room: independent wheelchair

Room description and layout

3.22 See Figures 28 and 29. The following activities take place in independent wheelchair changing rooms:

- undressing and dressing;
- hanging/holding clothes;
- wheelchair transfer to the bench or tip-up seat.

3.23 Independent wheelchair changing rooms should contain a full-length mirror, a shelf for holding personal belongings, a bench or tip-up seat and two coat hooks for hanging garments.

3.24 Help call should be provided if the room is for staff or patient use.

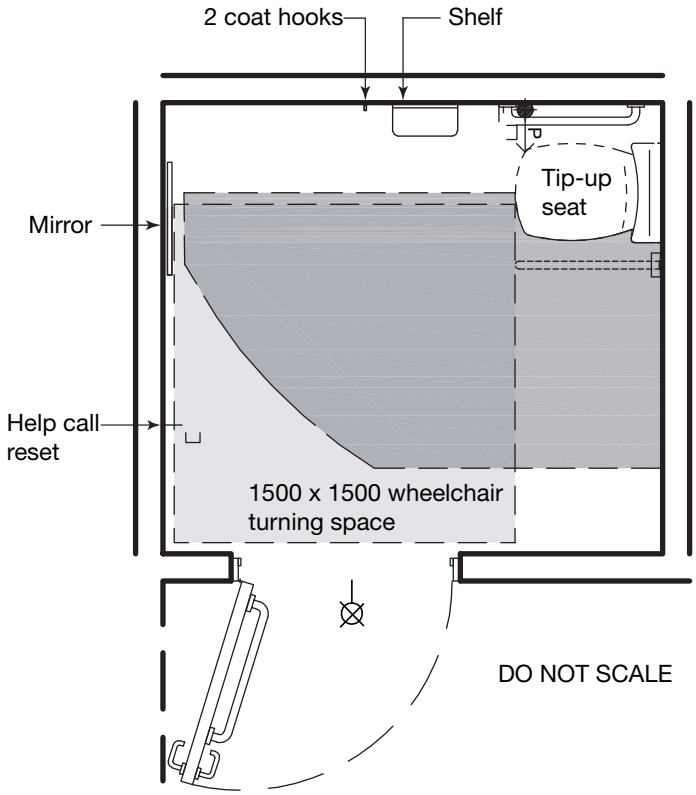


Figure 28 Space requirements for independent wheelchair changing room

Ergonomic drawings

Independent wheelchair changing

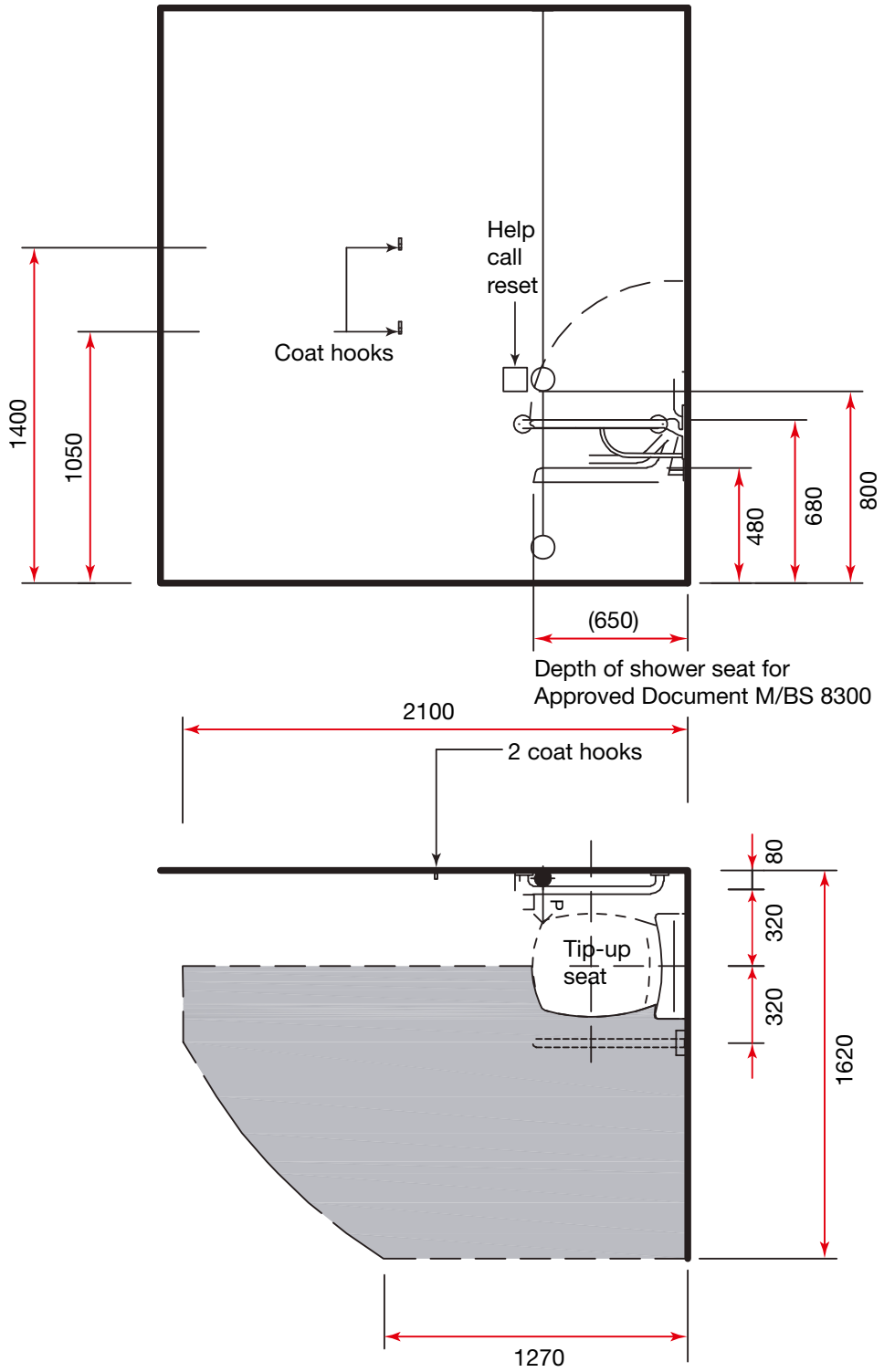


Figure 29 Independent wheelchair changing room

Changing room: semi-ambulant

Room description and layout

3.25 See Figure 30. The following activities take place in semi-ambulant changing rooms:

- undressing and dressing;
- hanging/holding clothes.

3.26 Semi-ambulant changing rooms should contain a full-length mirror, a shelf for holding personal belongings, a bench or tip-up seat and two coat hooks for hanging garments.

3.27 They are also suitable for ambulant use.

3.28 Help call should be provided if the room is for patient use.

3.29 The room should be lockable. Clothes/belongings may either be locked in the room or in a separate locker, or kept with the patient.

3.30 Access arrangements to and from the room and its relationship with changed waiting areas (where provided) should ensure patient privacy and dignity.

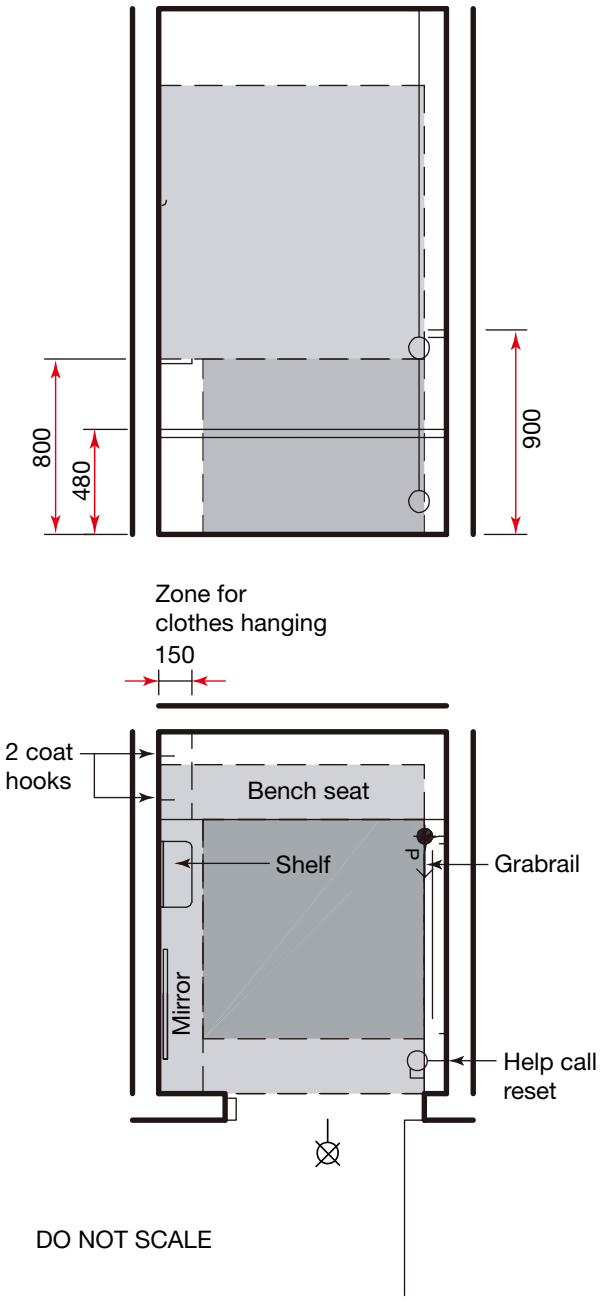


Figure 30 Space requirements for changing room: semi-ambulant

Ergonomic drawings

Dressing and undressing: ambulant

3.31 These ergonomic drawings (see Figure 31) show the space requirements for ambulant dressing and undressing.

3.32 An identical space provision is suitable for semi-ambulant users though it should be located adjacent to a seating area.

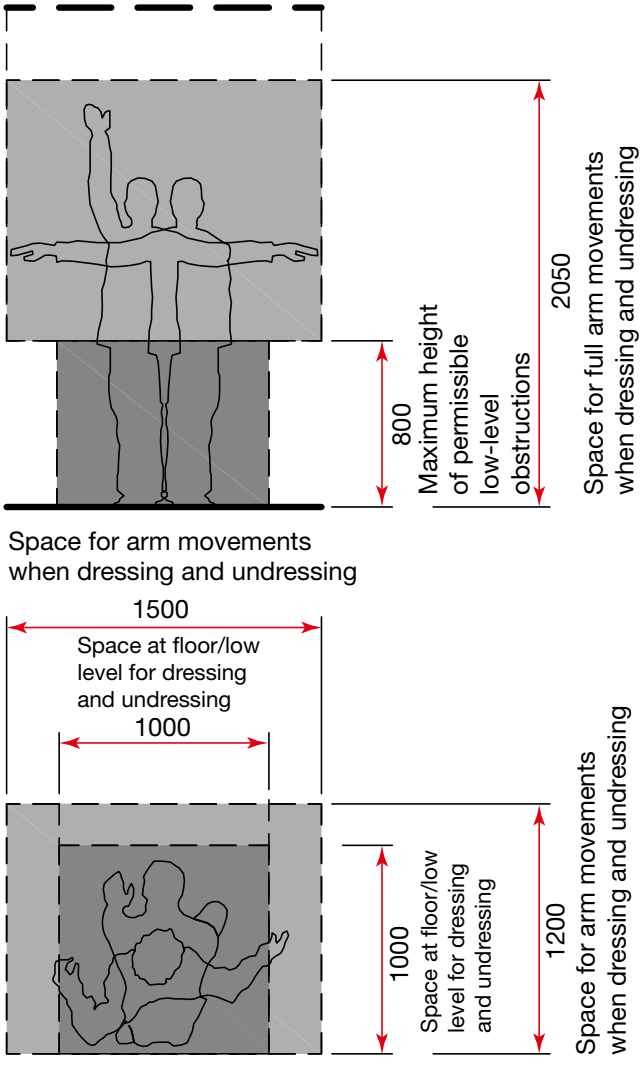


Figure 31 Space requirements for ambulant dressing and undressing

Full-length mirror: standing or seated users

3.33 This ergonomic drawing (see Figure 32) shows the space requirements for a full-length mirror for standing or seated users.

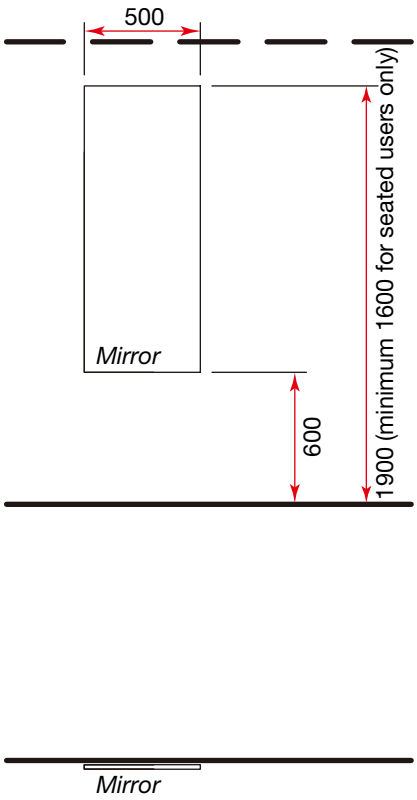


Figure 32 Space requirements for a full-length mirror for standing or seated users

Nappy changing room

Room description and layout

3.34 The following activities take place in nappy changing rooms:

- changing infants' nappies;
- disposal of soiled nappies;
- personal washing.

3.35 Nappy changing rooms are suitable for use by a single ambulant adult with a baby or infant.

3.36 Nappy changing rooms should contain the following:

- changing table;
- shelf, at worktop height, at the end of the table for placing packs of wipes etc (not above the table, as the parent/carer may hit their head when rising);
- seat for a parent/carer;
- wash-hand basin with sensor-operated taps;
- disposal bin for soiled nappies and other clinical waste;
- soap dispenser and paper towel dispenser;
- waste bin for used paper towels.

3.37 Sensor-operated taps are recommended for infection control; users may have heavily soiled hands and, as this is a public space, the room may not be fully cleaned between usages.

3.38 The folding nappy changing table recommended in Approved Document M (paragraph 5.14d) for use in larger semi-ambulant WCs is not recommended in healthcare premises. In healthcare premises, it is recommended that nappy changing facilities should be provided separately from WC provision.

3.39 The room layout provided (see Figure 33) illustrates two options for the changing table within the same overall space: a fold-down table with primary access from the end and a fixed or adjustable-height changing table with access from one end.

3.40 Sound attenuation of doors, ceilings and partitions should be considered to prevent the sound of crying children travelling into adjacent spaces.

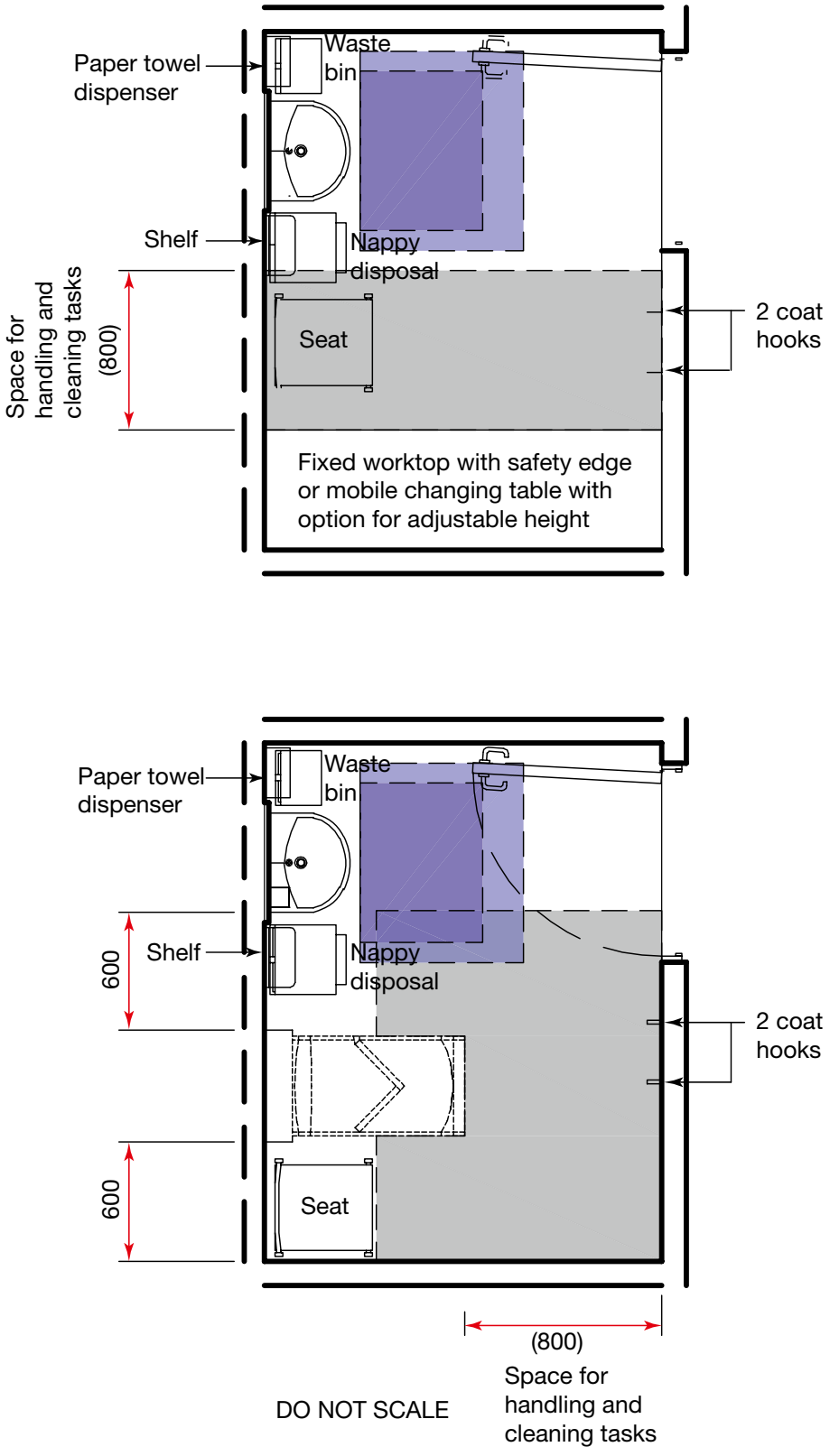


Figure 33 Space requirements for nappy changing room

Ergonomic drawings

Wash-hand basin: ambulant

3.41 Wash-hand basins may be used for personal washing activities.

3.42 This ergonomic drawing (see Figure 34) shows the space requirements for ambulant/ semi-ambulant use of a 400 mm deep × 500 mm wide wash-hand basin.

3.43 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

3.44 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

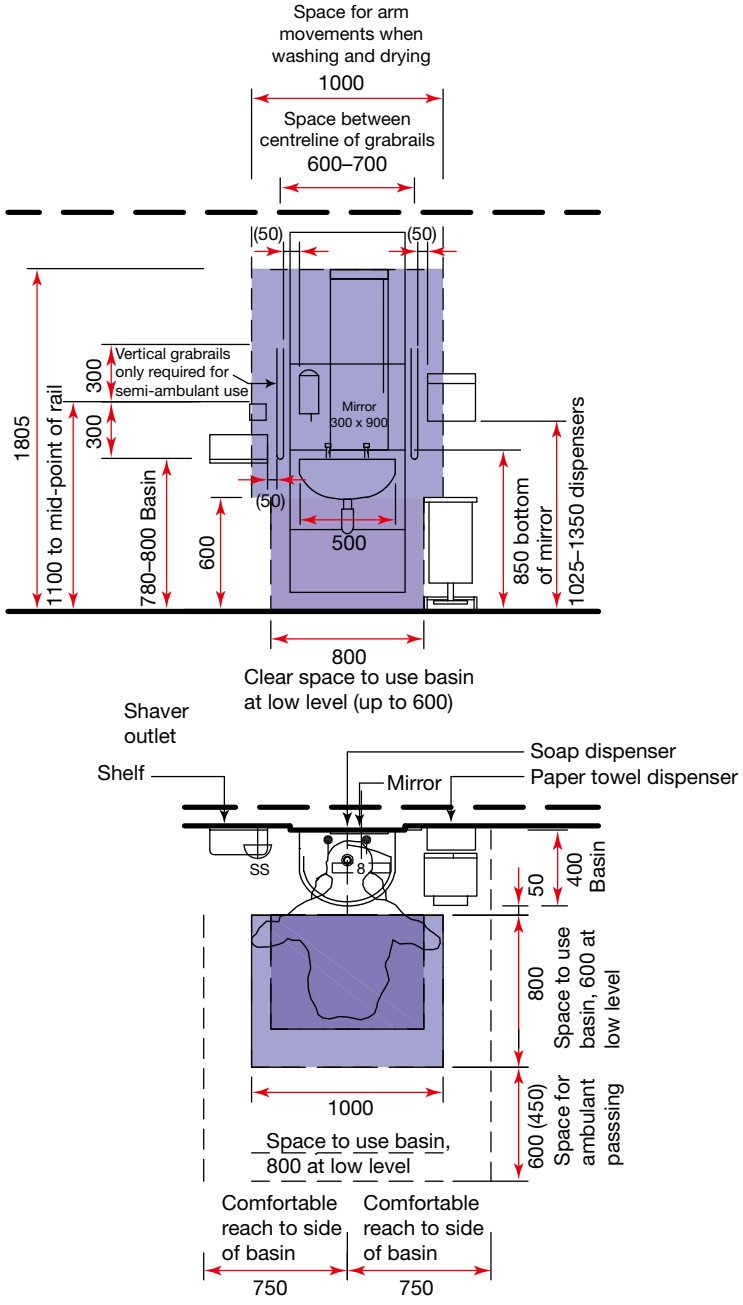


Figure 34 Space requirements for ambulant/semi-ambulant use of a 400 mm deep x 500 mm wide wash-hand basin

Uniform exchange area

Room description and layout

3.45 It is assumed that separate lockers will be provided for uniform exchange (for personalised uniforms only). Non-personalised uniforms may be provided in the changing areas or adjacent lobby.

3.46 The layout provided (see Figure 35) shows 70 lockers, 10 high in each bank, with a built-in dirty uniform collection point.

3.47 The actual number of uniform exchange lockers required will depend upon the number of staff working in any given area. An allowance of 0.1 m² per uniform locker has been allowed.

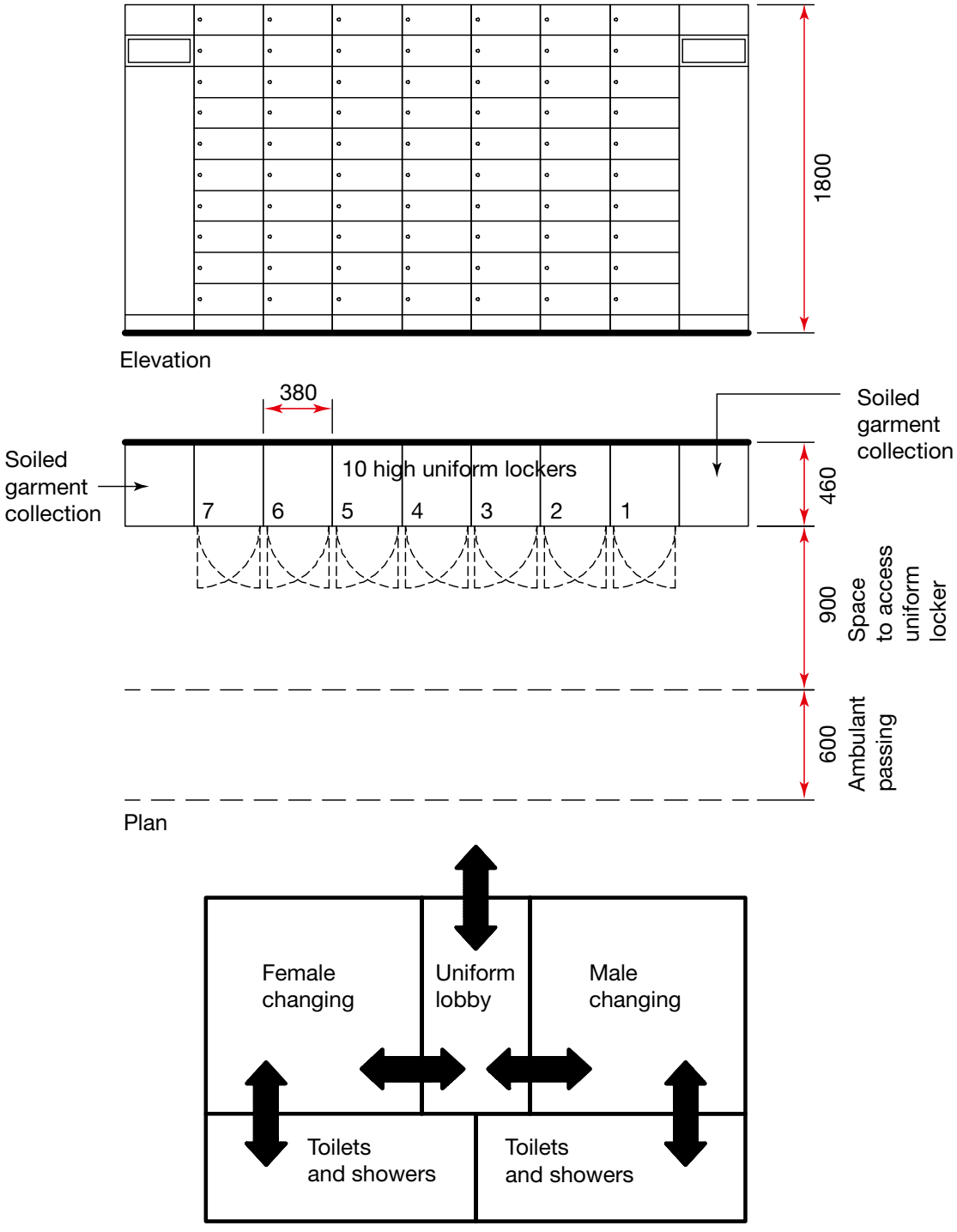


Figure 35 Space requirements for 70 lockers, 10 high in each bank, built-in dirty uniform collection point

4 Shower rooms

Shower room: ambulant

Room description and layout

4.1 See Figure 36. The following activities take place in ambulant shower rooms:

- undressing and dressing;
- hanging/holding clothes;
- showering.

4.2 Ambulant shower rooms (without toilets or tip-up shower seats) are only suitable for fully ambulant staff or visitors.

4.3 The use of shower trays is acceptable in ambulant shower rooms. They should not be used in any patient areas as they present a tripping hazard.

4.4 An inward-opening door may be used without increasing the space requirements within the room.

4.5 The room layout provided shows a small mirror. Alternatively, a full-length mirror may be provided.

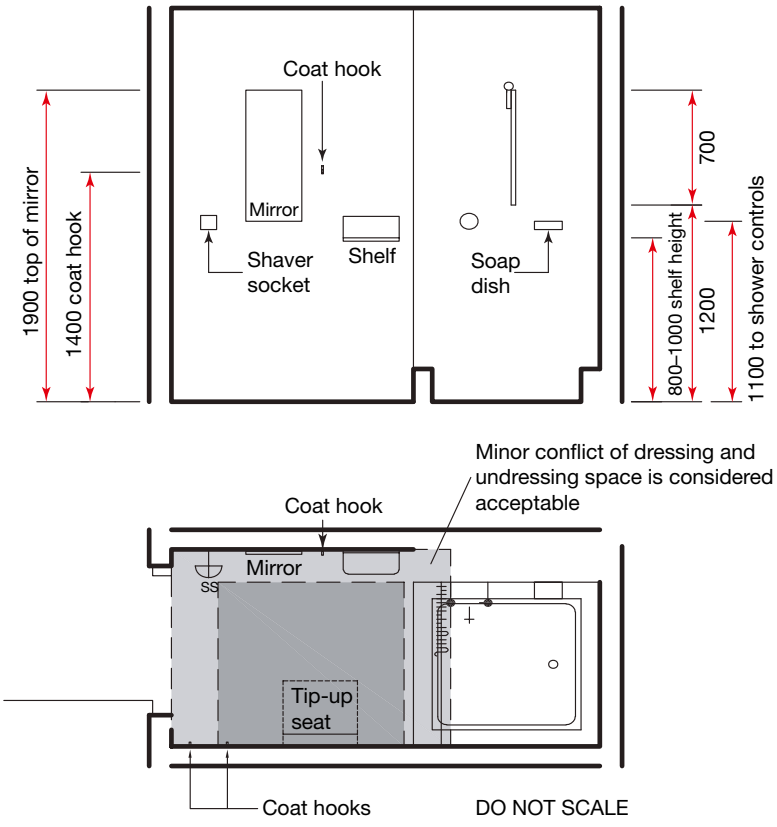


Figure 36 Space requirements for ambulant shower room

Ergonomic drawings

Dressing and undressing: ambulant

4.6 These ergonomic drawings (see Figure 37) show the space requirements for ambulant dressing and undressing.

4.7 An identical space provision is suitable for semi-ambulant users though it should be located adjacent to a seating area.

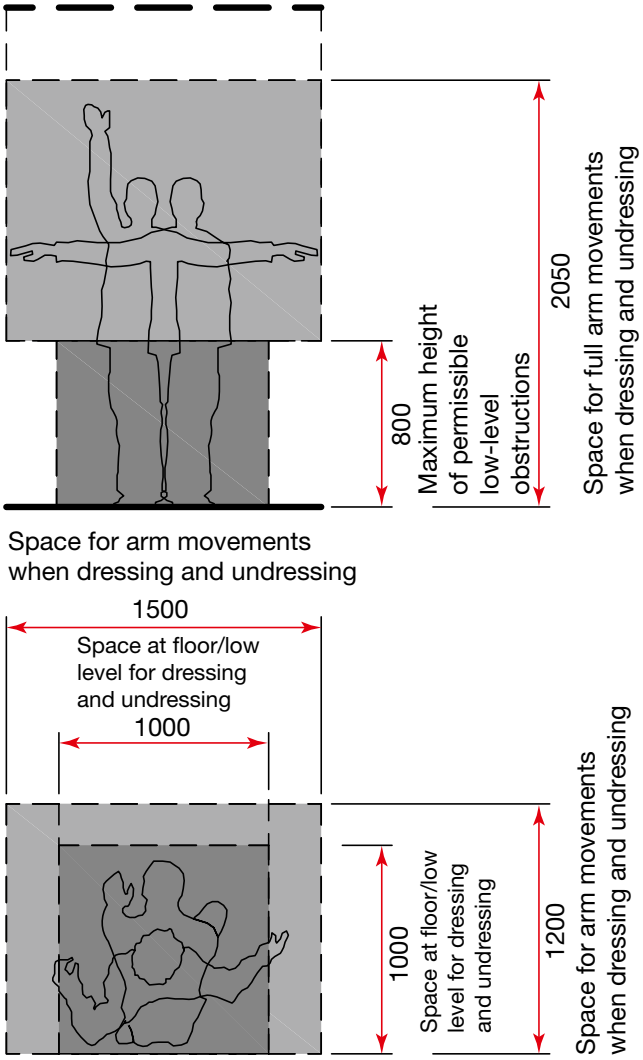


Figure 37 Space requirements for ambulant dressing and undressing

Shower room: assisted

Room description and layout

4.8 The following assisted activities take place in assisted shower rooms:

- undressing and dressing;
- hanging/holding clothes;
- wheelchair, sanitary chair and shower chair access to the toilet, wash-hand basin and shower;
- mobile hoist access to transfer a patient to the toilet or shower seat or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet or shower seat (supervised only);
- use of the toilet;
- personal washing (whilst seated);
- showering (whilst seated).

4.9 An assisted shower room should contain an assisted shower with tip-up shower seat, assisted toilet and wheelchair wash-hand basin.

4.10 The assisted shower should provide staff access from both sides and from the front of the shower and to the shower controls.

4.11 Staff should be able to remain dry whilst assisting in showering.

4.12 Mobile hoist access will be required if a patient collapses on the floor, even if it is not used for transferring patients to the toilet.

4.13 The room layout provided (see Figure 38) includes a fixed tip-up shower seat. A mobile shower chair may be used instead of the tip-up shower seat.

4.14 Assisted wheelchair and hoist transfer to the shower seat is only possible from the right-hand side of the shower (if facing the shower). Consideration should be given to providing both left- and right-hand versions of this layout to allow for all users.

4.15 Where assisted shower rooms are provided en-suite to bedrooms and additional assisted shower rooms or bathrooms are provided nearby, consideration may be given to reducing the clear space in front and to the side of the toilet in accordance with the en-suite shower room layouts.

4.16 To enable this space to be suitable for ambulant and semi-ambulant use as well as assisted use, an adjustable-height wash-hand basin may be provided in place of the wheelchair wash-hand basin.

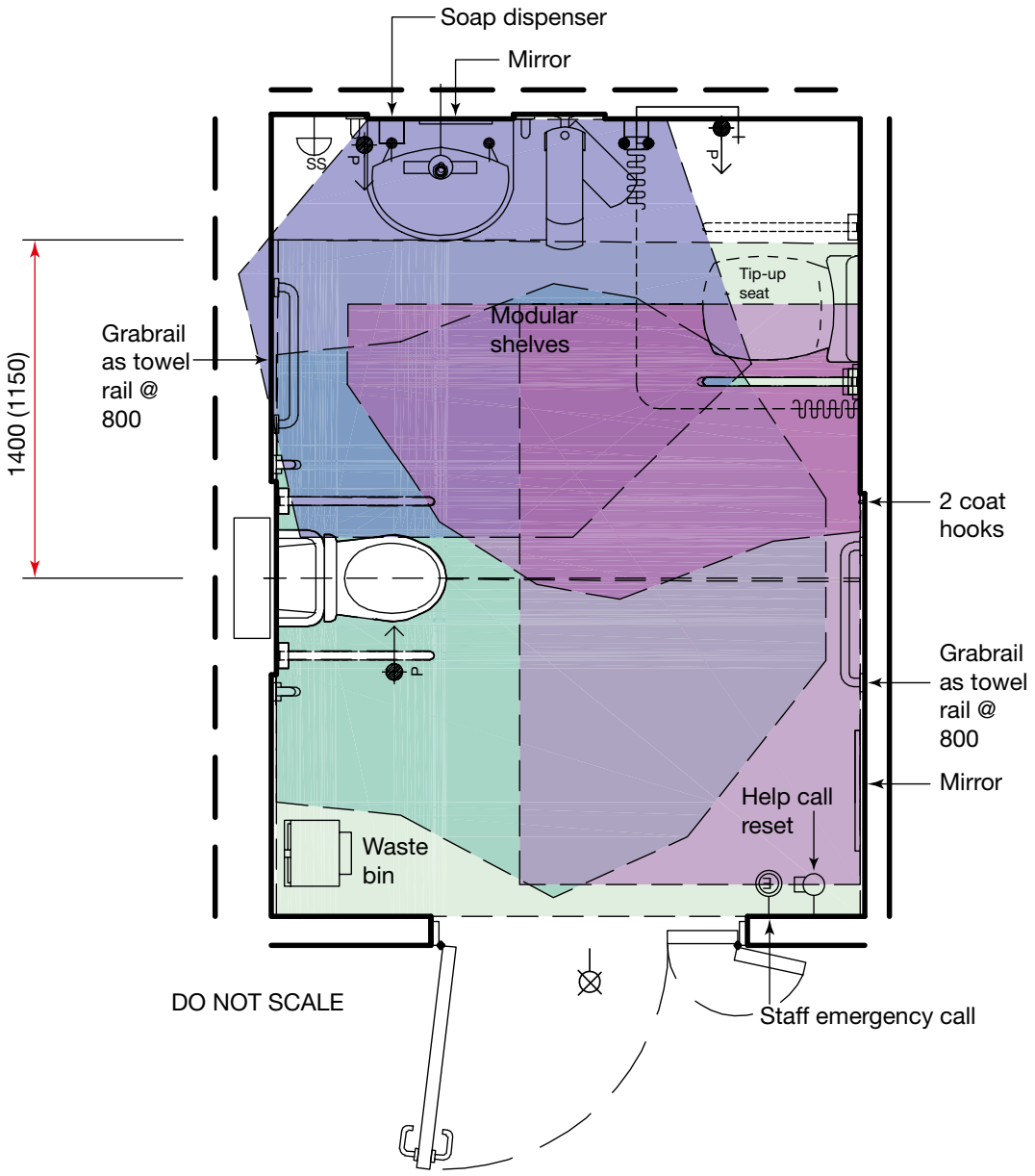


Figure 38 Space requirements for shower room: assisted

Ergonomic drawings

Assisted shower with fixed tip-up shower seat

4.17 This ergonomic drawing (see Figure 39) shows the space requirements for an assisted shower with a fixed tip-up shower seat.

4.18 Fixed-position shower controls should be sited close to the shower curtain and at a height of 900–1000 mm to satisfy both staff and seated users.

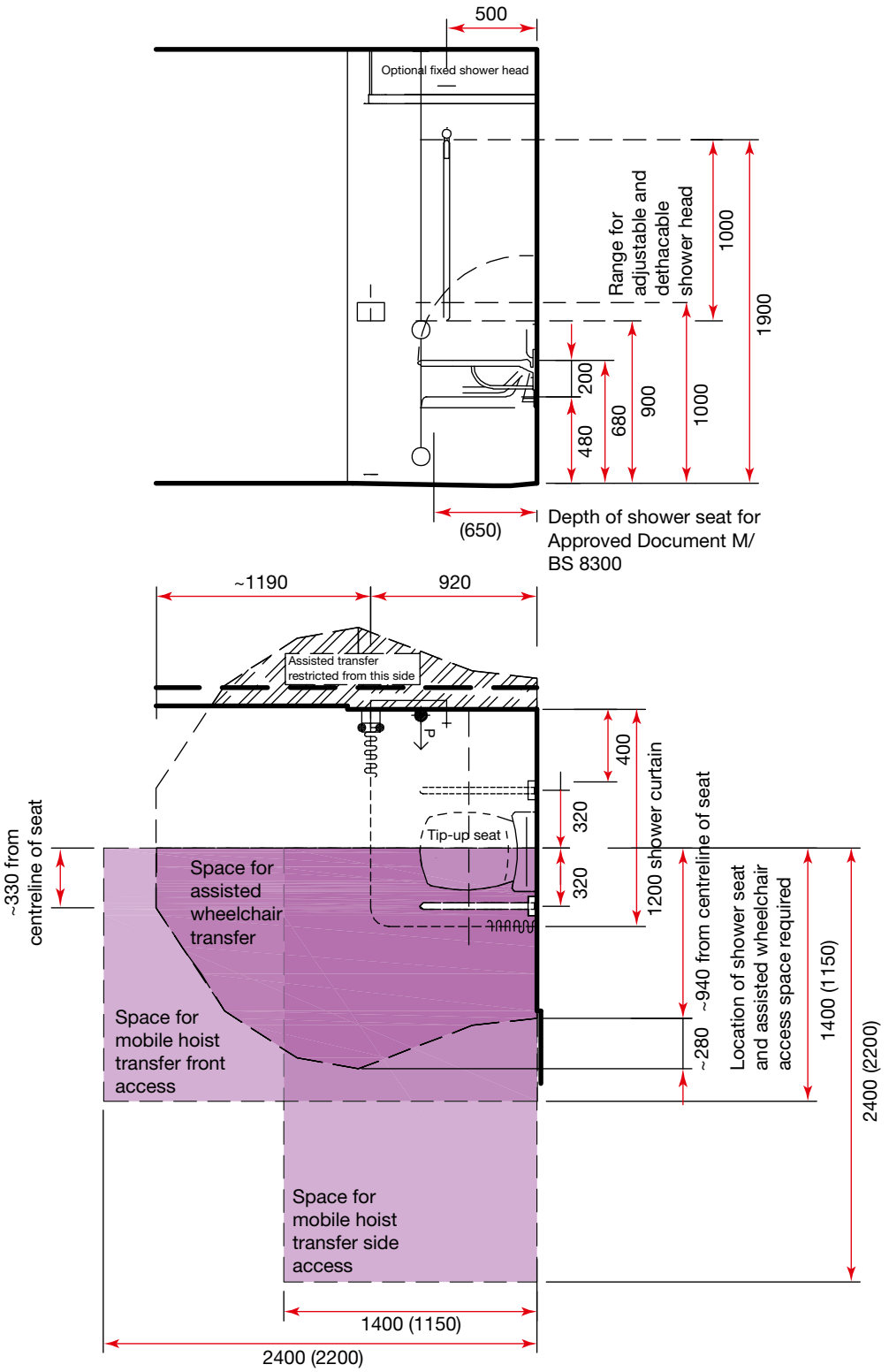


Figure 39 Space requirements for assisted shower with fixed tip-up shower seat

Toilet: assisted

4.19 This ergonomic drawing (see Figure 40) shows the space requirements for an assisted toilet.

4.20 The clear space on either side of the toilet for mobile hoist transfer is greater than that recommended in BS 8300 (Figure 55).

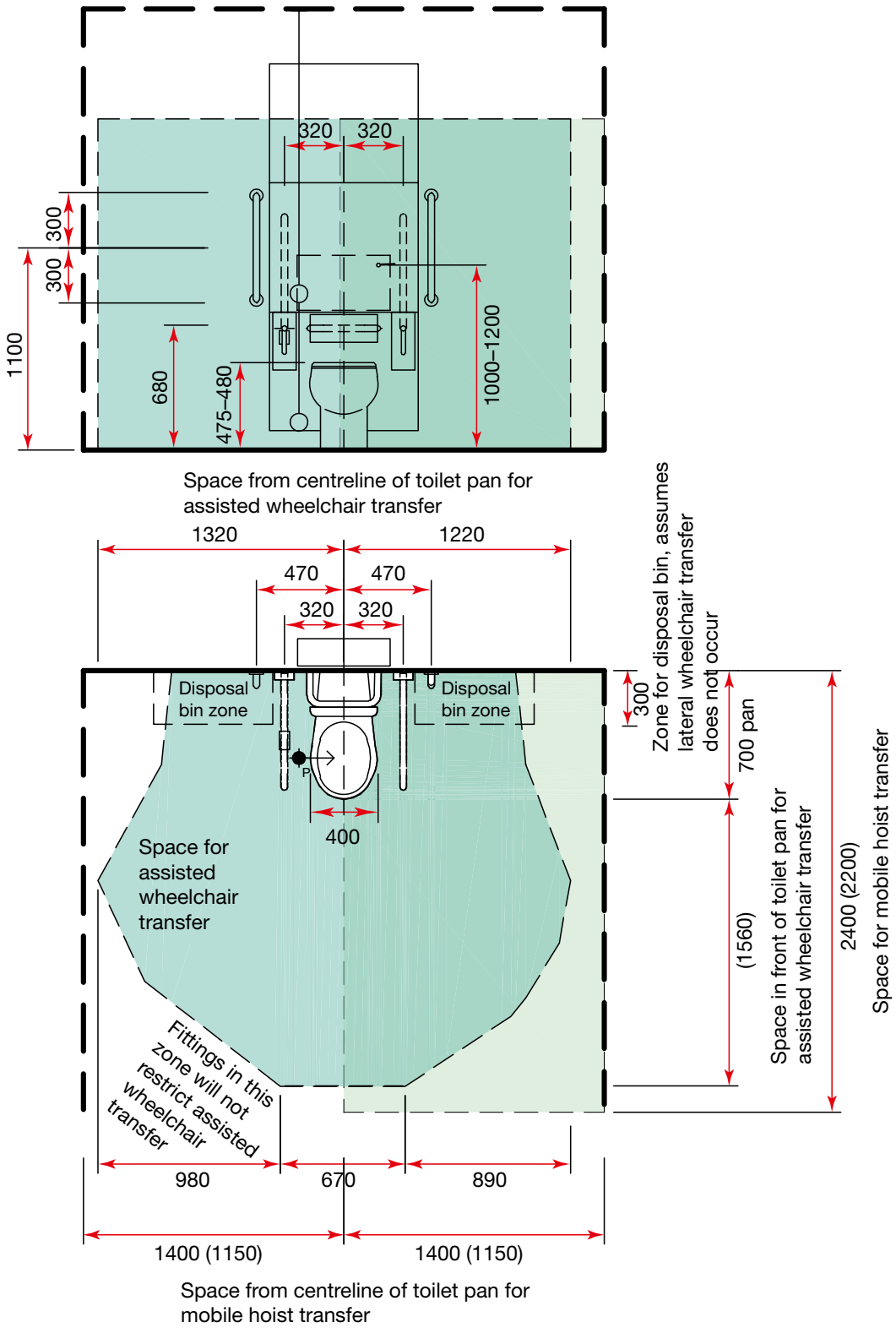


Figure 40 Space requirements for assisted toilet

Wash-hand basin: wheelchair

4.21 Wash-hand basins may be used for personal washing activities.

4.22 This ergonomic drawing (see Figure 41) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

4.23 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

4.24 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

4.25 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

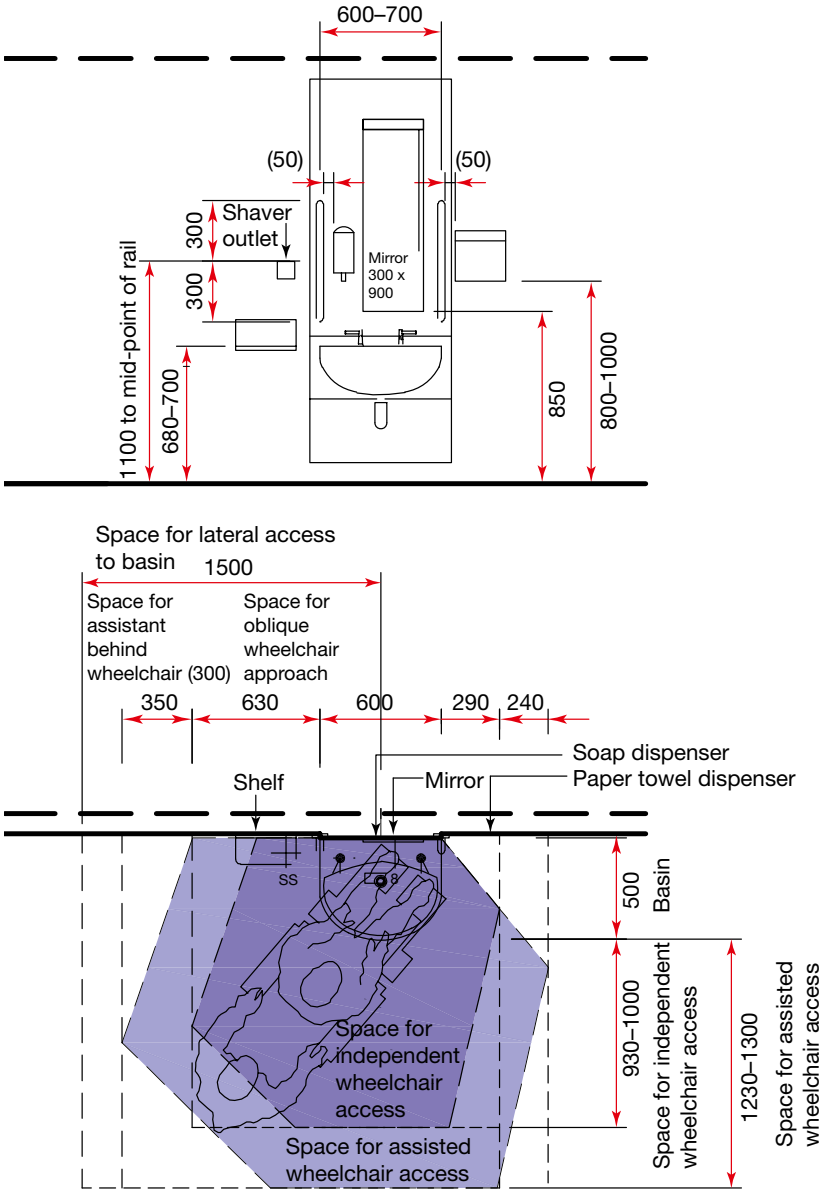


Figure 41 Space requirements for wheelchair accessible wash-hand basin, suitable for seated use

Full-length mirror: standing or seated users

4.26 This ergonomic drawing (see Figure 42) shows the space requirements for a full-length mirror for standing or seated users.

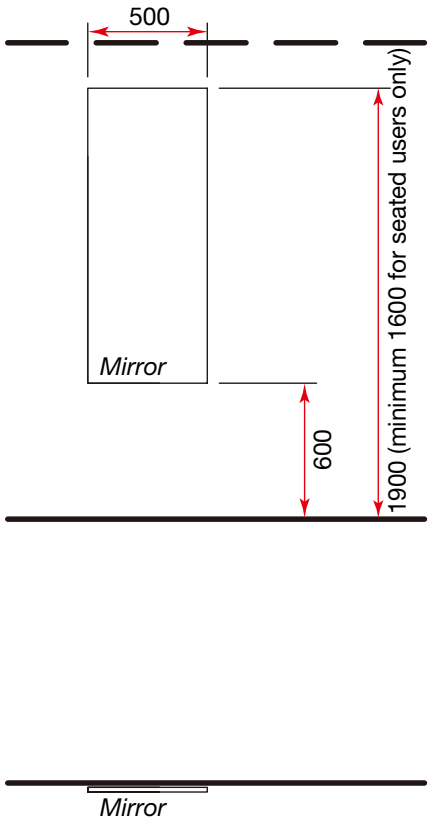


Figure 42 Space requirements for wheelchair accessible wash-hand basin, suitable for seated use

Shower room: en-suite: chamfered

Room description and layout

4.27 The following activities take place in chamfered en-suite shower rooms:

- assisted wheelchair, sanitary chair and shower chair access to the toilet, wash-hand basin and shower;
- mobile hoist access to transfer a patient to the toilet or shower seat or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet or shower seat (supervised only);
- independent transfer from a wheelchair to the toilet or shower seat;
- use of the toilet;
- personal washing;
- showering (whilst seated).

4.28 The room layout provided (see Figures 43 and 44–45) is a variation on the en-suite shower room with a reduction in the shower room area but no saving on overall area when combined with a single-bed room.

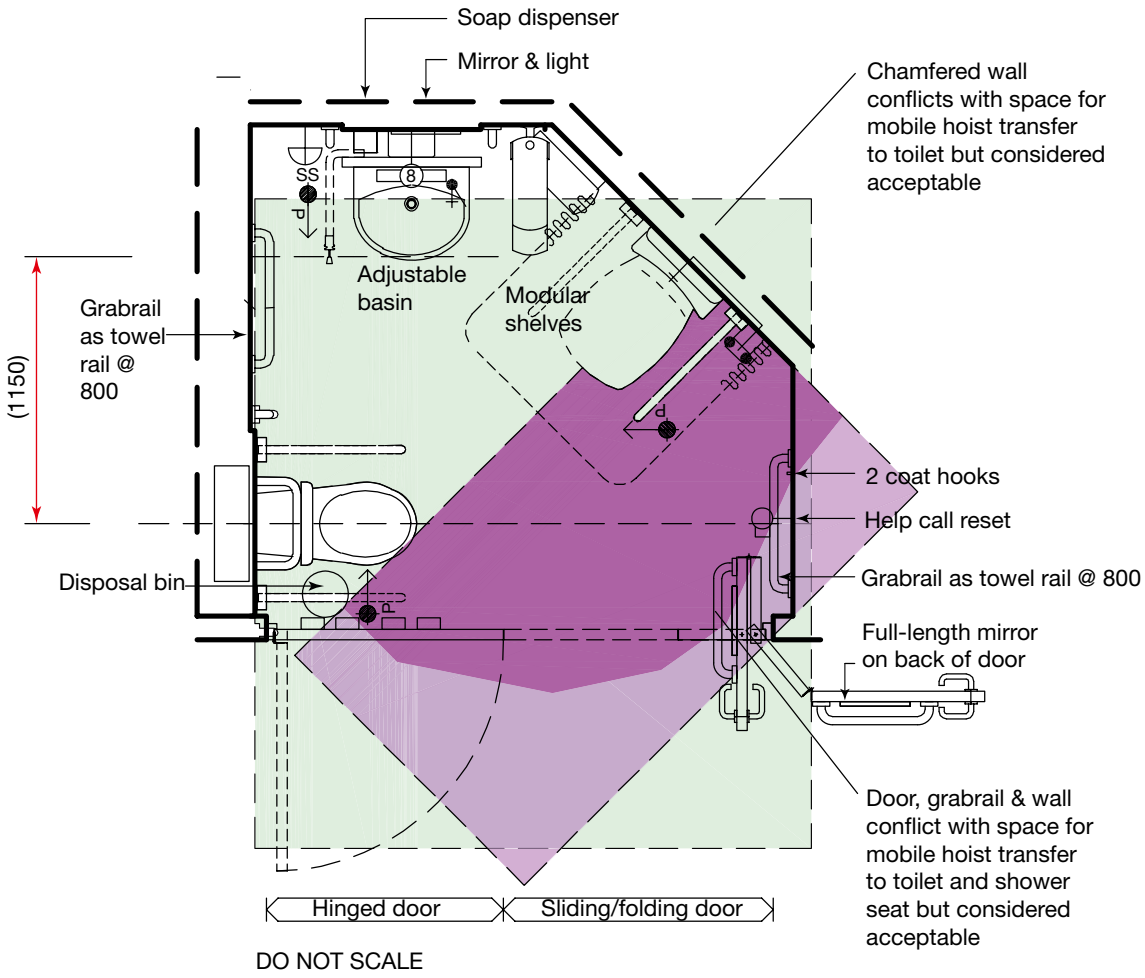


Figure 43 Shower room: en-suite: chamfered: mobile hoist access

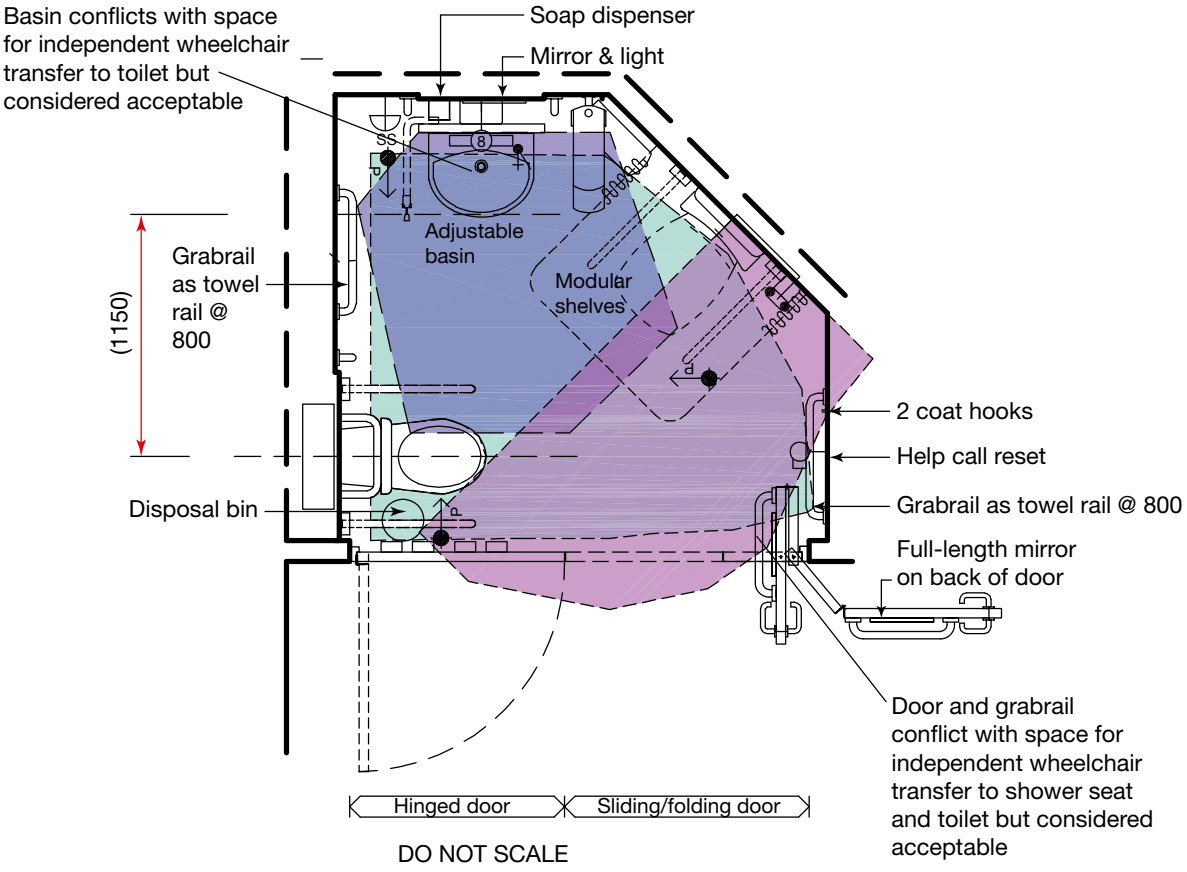


Figure 44 Shower room: en-suite: chamfered: assisted wheelchair access

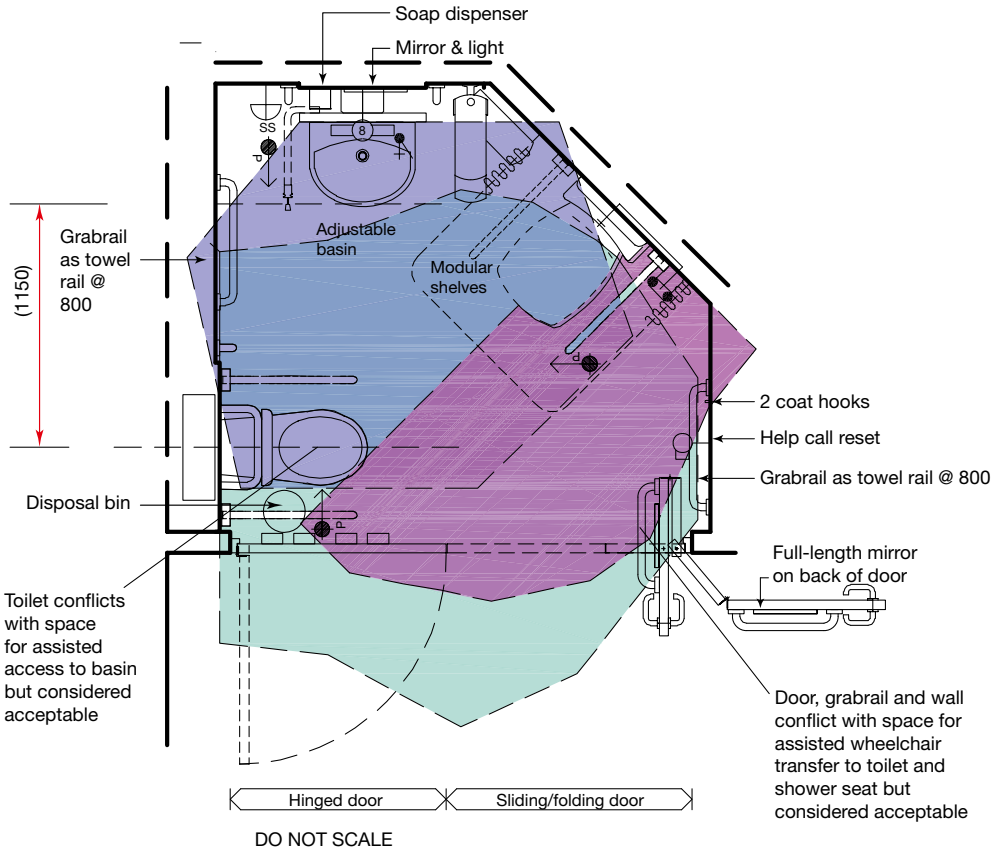


Figure 45 Shower room: en-suite: chamfered: independent wheelchair access

Ergonomic drawings

En-suite toilet

4.29 This ergonomic drawing (see Figure 46) shows the space requirements for an en-suite toilet (as used in the en-suite shower rooms).

4.30 The dispensers mounted on the back of the hinged door should not project more than approximately 50 mm (depending on the door design) to ensure they do not conflict with the use of the hinged grabrail between the door and the toilet pan.

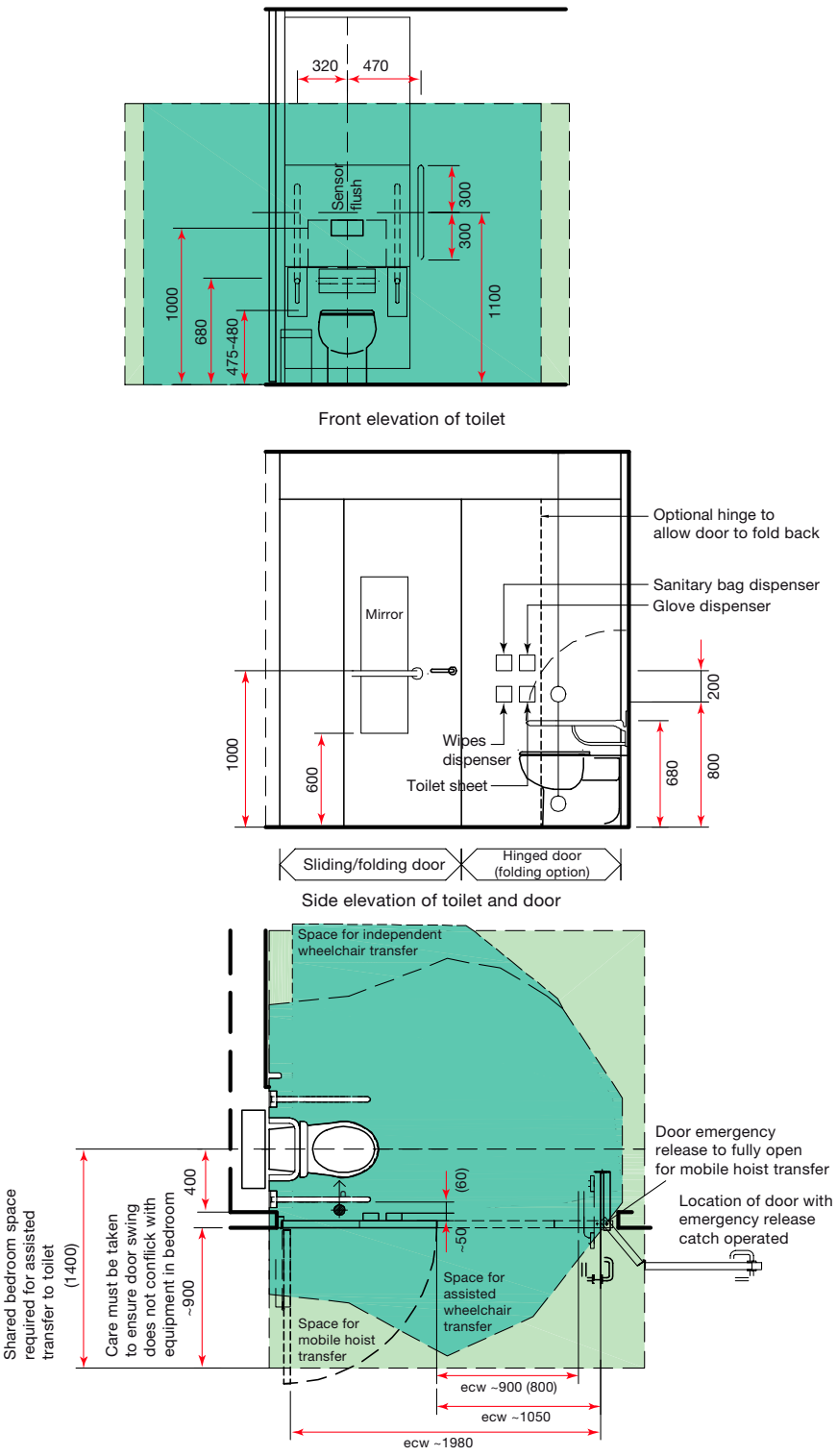


Figure 46 Space requirements for en-suite toilet

Adjustable-height wash-hand basin

4.31 This ergonomic drawing (see Figure 47) shows the space requirements for an adjustable-height wash-hand basin.

4.32 The position of the grabrails and fixtures should not conflict with the height-adjustment mechanism of the basin.

4.33 The general recommended lowest height of a mirror above a basin is 800 mm. However, 900 mm is acceptable where a lower height would conflict with the height-adjustment mechanism.

4.34 Consideration should be given to the choice of height-adjustment mechanism for ease of use; the controls should be accessible without interfering with normal access to the basin.

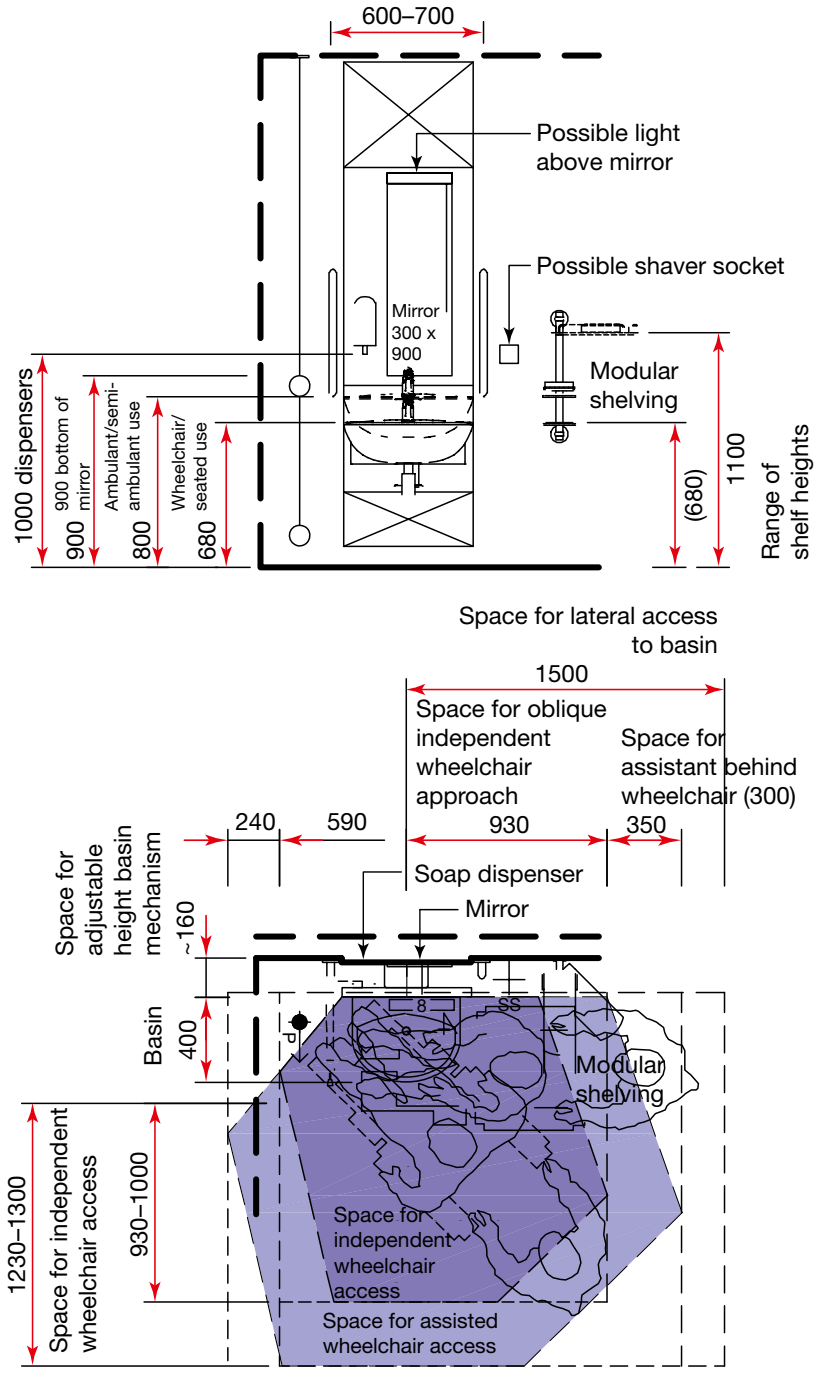


Figure 47 Space requirements for adjustable-height wash-hand basin

Shower for chamfered en-suite shower room

4.35 This ergonomic drawing (see Figure 48) shows the space requirements for the shower for use in the chamfered en-suite shower room.

4.36 Unassisted use of the shower may be limited because of the position of fixed shower controls on the back wall.

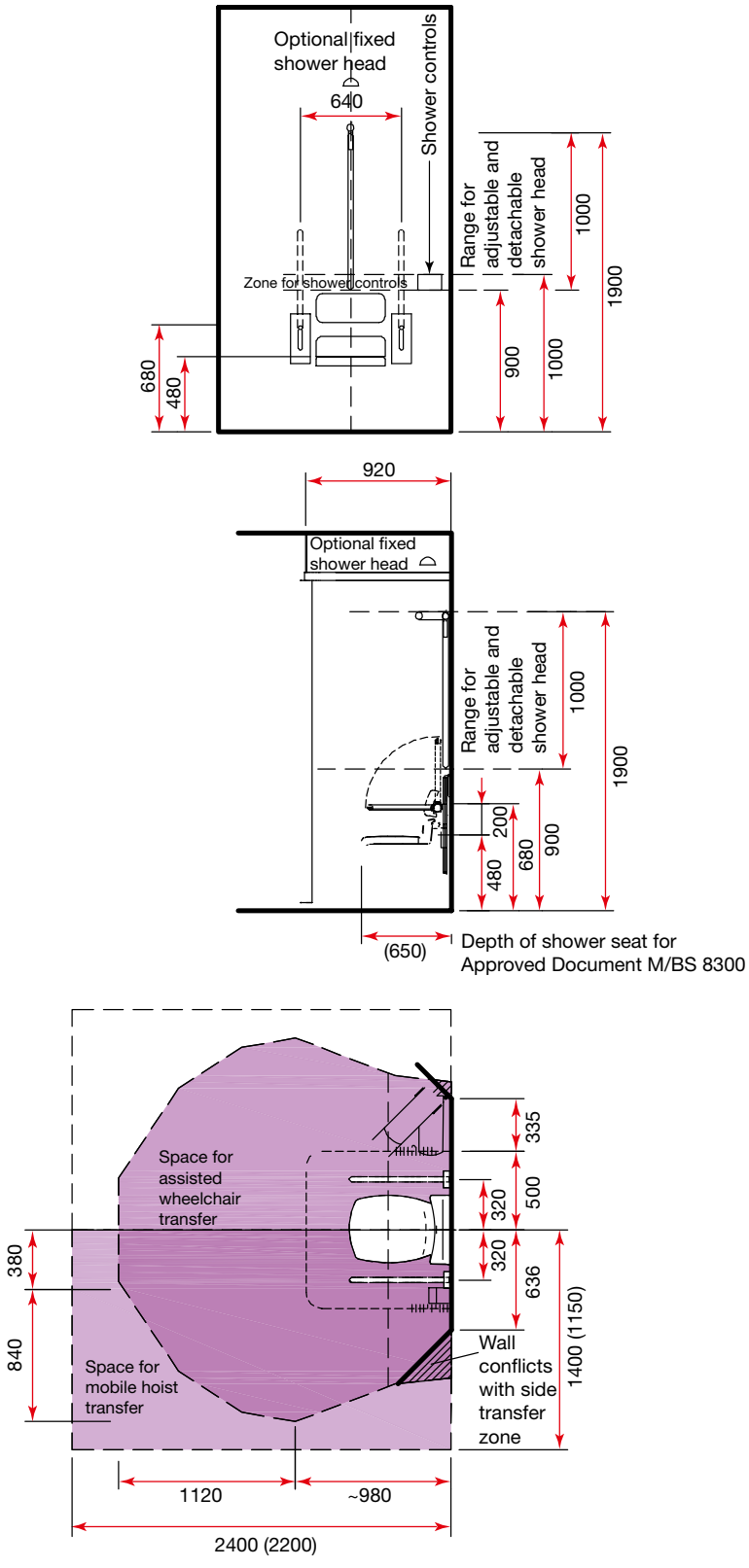


Figure 48 Space requirements for shower for use in chamfered en-suite shower room

Full-length mirror: standing or seated users

4.37 This ergonomic drawing (see Figure 49) shows the space requirements for a full-length mirror for standing or seated users.

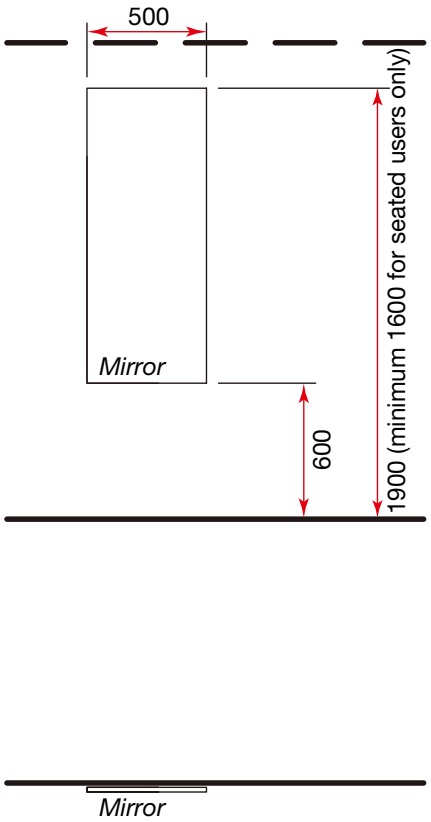


Figure 49 Space requirements for full-length mirror for standing or seated users

Shower room: en-suite

Room description and layout

4.38 The following activities take place in en-suite shower rooms:

- assisted wheelchair, sanitary chair and shower chair access to the toilet, wash-hand basin and shower;
- mobile hoist access to transfer a patient to the toilet or shower seat or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet or shower seat (independent or supervised);
- use of the toilet;
- personal washing;
- showering (whilst seated).

4.39 The room layout provided (see Figure 60) shows a shower room and part of the adjoining single-bed room. The adjoining room is required to provide the necessary space for assistance and to maintain patient privacy.

4.40 The double door to the shower room consists of a sliding/folding door and a hinged door. The sliding/folding door provides staff and unassisted patient access. Both doors need to be fully open for assisted use of the facilities.

4.41 The sliding/folding door is designed to release from the overhead track in order to provide mobile hoist access to the room and transfer to one side of the toilet.

4.42 A roller catch may be provided on the sliding/ folding door rather than the lever handle indicated.

4.43 The hinged door should be able to open unhindered. To maximise the free space in the bedroom, consideration should be given to making this a folding door.

4.44 Assisted wheelchair and hoist transfer to the shower seat is only possible from the right-hand side of the shower (if facing the shower).

4.45 The room layout (see Figure 50) utilises the minimum clear space requirement to the side of the toilet for mobile hoist transfer (that is, 1150 mm from the centreline of the toilet to the nearest obstruction), on the basin side of the toilet only.

4.46 This is less than that generally recommended for right-hand independent wheelchair transfer to the toilet but was considered acceptable in the mock-up trials and complies with Approved Document M.

4.47 The clear space in front of the toilet is less than that generally recommended for mobile hoist transfer but was considered acceptable in the mock-up trials.

4.48 The room layout includes an adjustable tip-up shower seat. This is to allow for both non-assisted and assisted showering. The position of the shower seat should be adjusted between uses as required.

4.49 A depth of approximately 160 mm has been allowed for the height-adjustment mechanism on the basin. Where a greater depth is required, the internal room dimensions may need to increase or the room layout may need to be altered to maintain the required activity space.

4.50 The shower rooms are assumed to be wet rooms. The slope of the floor and location of the floor gully should ensure that water does not escape into the adjoining bedroom.

4.51 Where the en-suite is intended for independent wheelchair use, call reset buttons should be located near to the toilet (on the back of the door).

4.52 The disposal bin, adjacent to the toilet, should be a maximum of 200 mm wide and 480 mm high and capable of being operated with one hand.

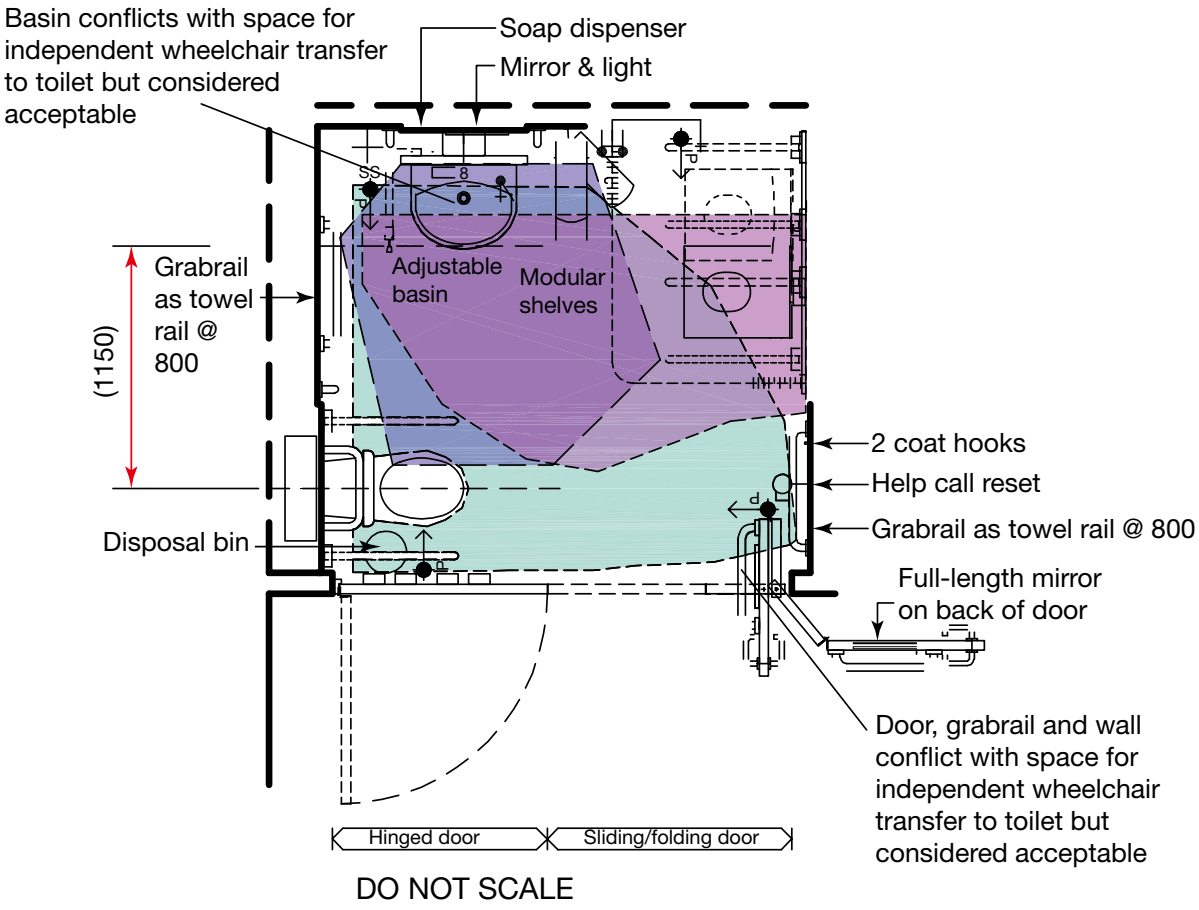


Figure 50 Space requirements for shower room: en-suite

Ergonomic drawings

En-suite toilet

4.53 This ergonomic drawing (see Figure 51) shows the space requirements for an en-suite toilet (as used in the en-suite shower rooms).

4.54 The dispensers mounted on the back of the hinged door should not project more than approximately 50 mm (depending on the door design) to ensure they do not conflict with the use of the hinged grabrail between the door and the toilet pan.

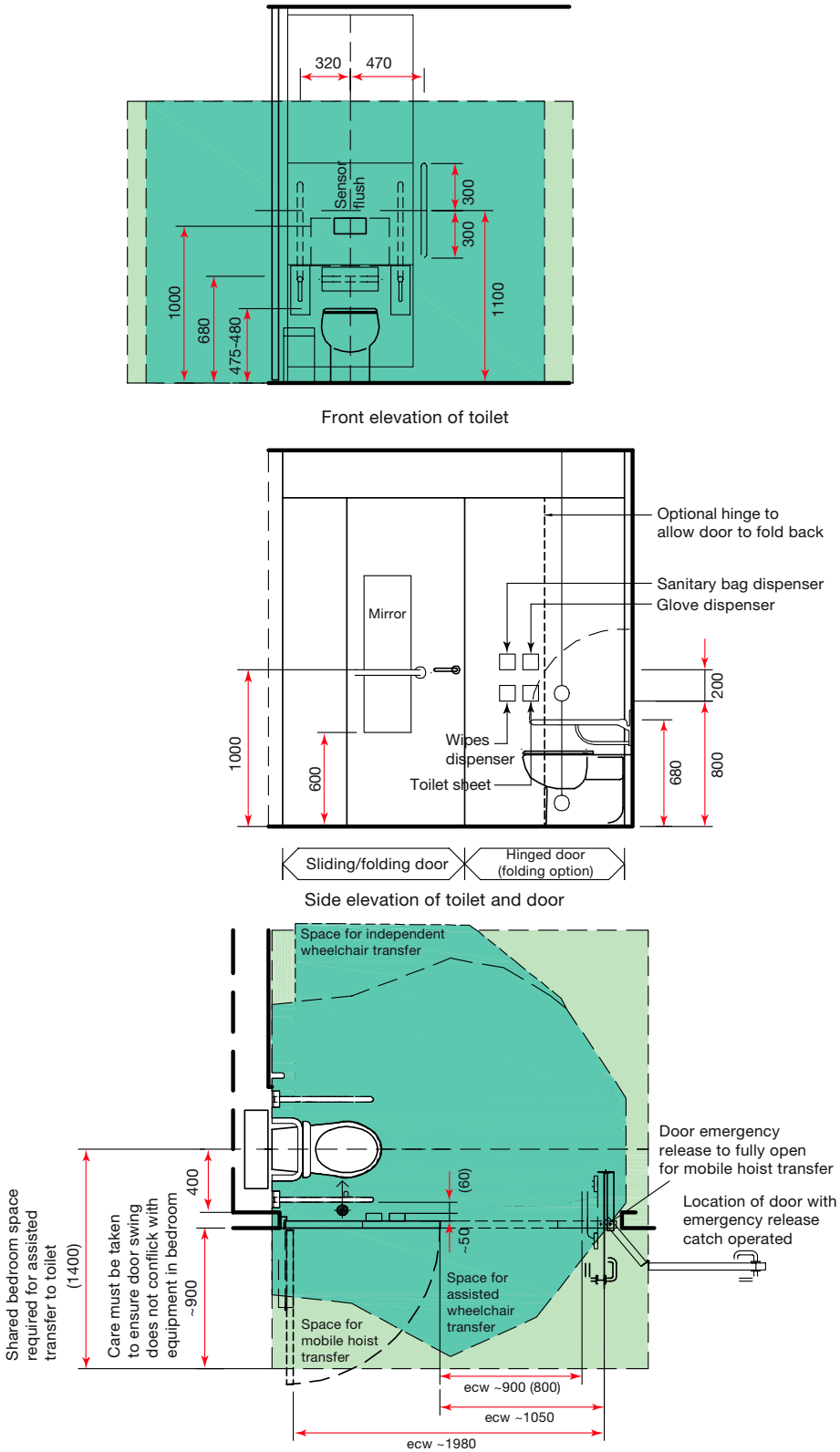


Figure 51 Space requirements for adjustable-height wash-hand basin

Adjustable-height wash-hand basin

4.55 This ergonomic drawing (see Figure 52) shows the space requirements for an adjustable-height wash-hand basin.

4.56 The position of the grabrails and fixtures should not conflict with the height-adjustment mechanism of the basin.

4.57 The general recommended lowest height of a mirror above a basin is 800 mm. However, 900 mm is acceptable where a lower height would conflict with the height-adjustment mechanism.

4.58 Consideration should be given to the choice of height-adjustment mechanism for ease of use; the controls should be accessible without interfering with normal access to the basin.

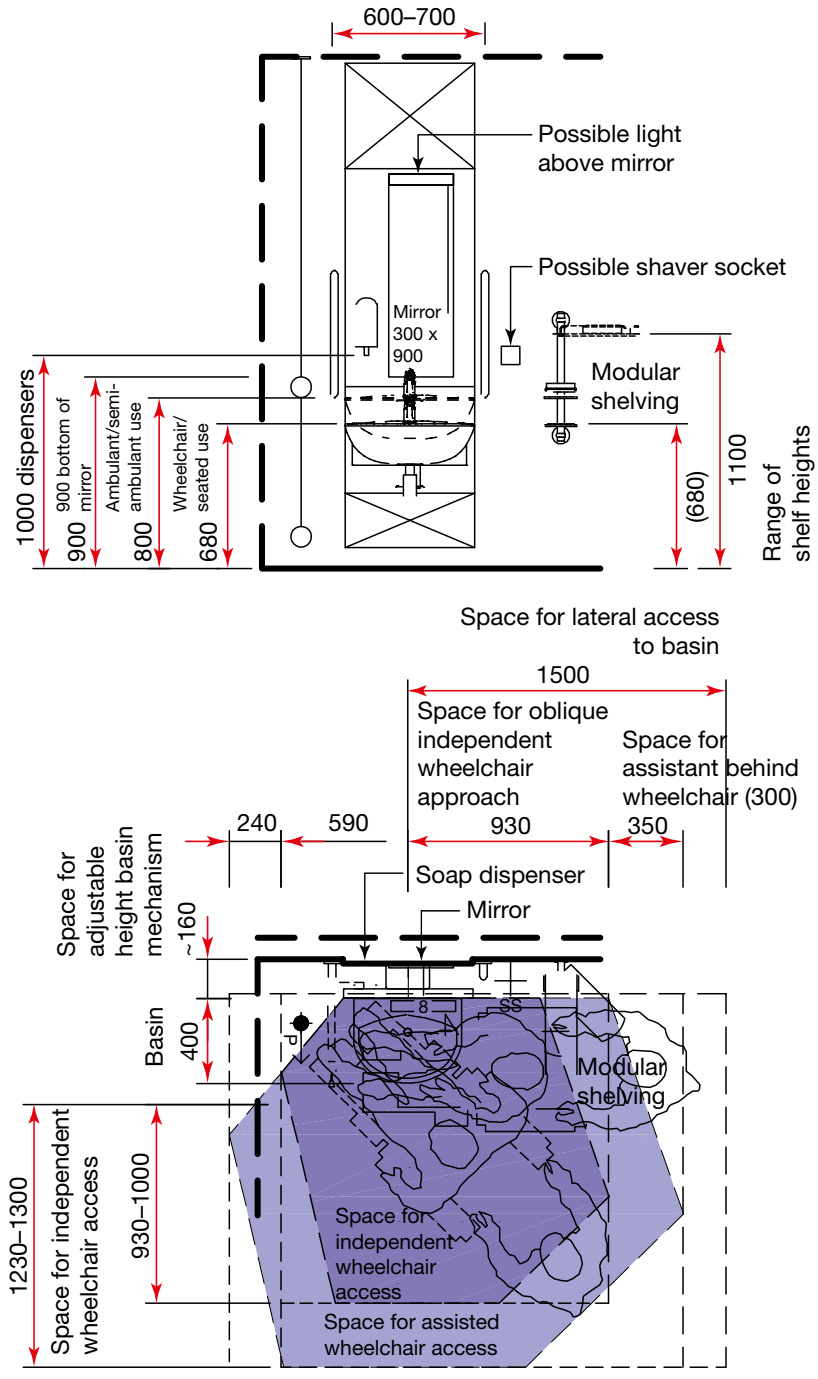


Figure 52 Space requirements for adjustable-height wash-hand basin

Shower with adjustable tip-up shower seat

4.59 This ergonomic drawing (see Figure 53) shows the space requirements for a shower with an adjustable tip-up shower seat.

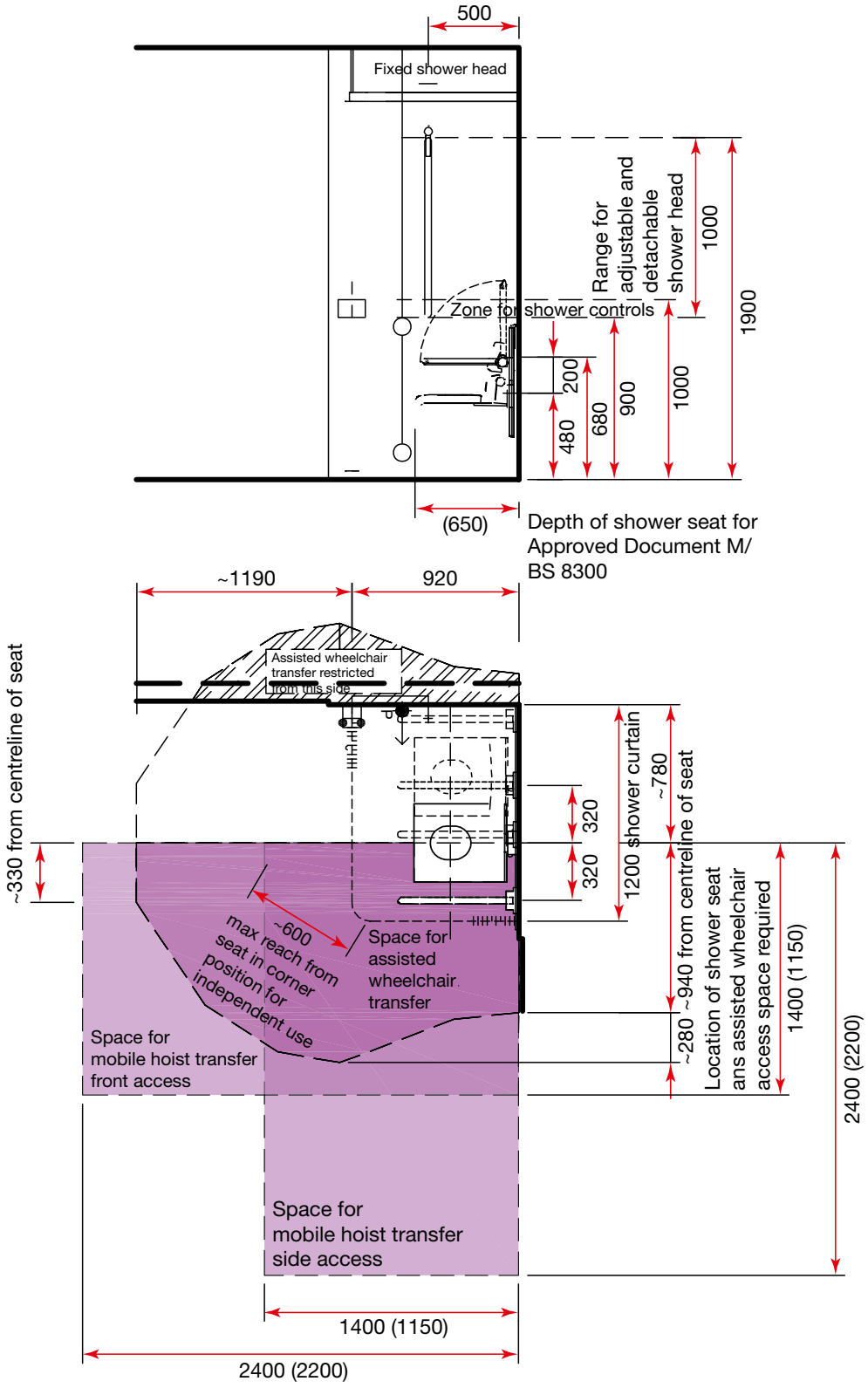


Figure 53 Space requirements for shower with adjustable tip-up shower seat

Full-length mirror: standing or seated users

4.60 This ergonomic drawing (see Figure 54) shows the space requirements for a full-length mirror for standing or seated users.

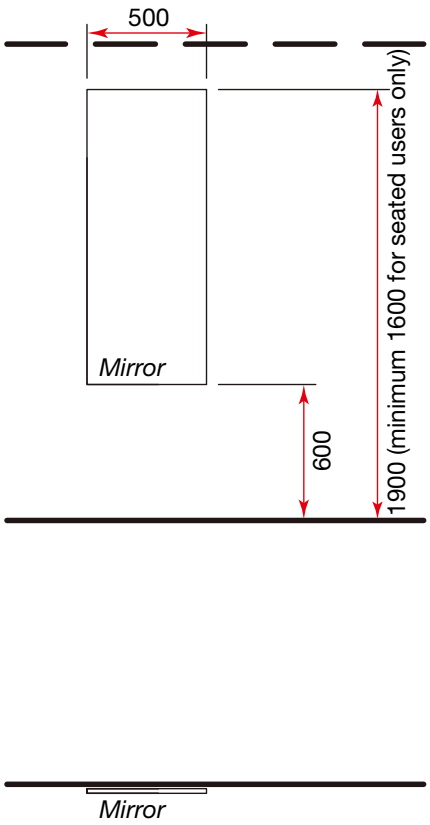


Figure 54 Space requirements for full-length mirror for standing or seated users

Shower room: independent wheelchair

Room description and layout

4.61 The following activities take place in independent shower rooms:

- undressing and dressing;
- hanging/holding clothes;
- wheelchair access to the toilet, hand-rinse basin, wash-hand basin and shower seat;
- independent transfer from a wheelchair to the toilet or shower seat;
- use of the toilet;
- disposal of sanitary towels and wipes;
- emptying of urine bottles and colostomy bags;
- hand-rinsing (whilst in a wheelchair facing the hand-rinse basin or seated on the toilet);
- personal washing (whilst seated);
- showering (whilst seated).

4.62 Independent shower rooms should contain an independent wheelchair toilet with adjacent hand-rinse basin, and separate wheelchair wash-hand basin for personal washing.

4.63 This facility is also suitable for semi-ambulant users with, or without, "hands-off assistance" who may wish to sit down to wash their hands when using the toilet or whilst showering.

4.64 In healthcare premises, for the privacy and dignity of patients, it is generally considered preferable for shower rooms to include a toilet. It may be acceptable to provide an independent wheelchair shower room without toilet facilities in staff-only areas.

4.65 The room layout provided (see Figure 55) allows for right-hand independent wheelchair transfer to the toilet and shower seat. Where more than one independent wheelchair shower room is provided, both left-hand and right-hand transfer options should be available.

4.66 To enable this space to be suitable for all unassisted use, an adjustable-height wash-hand basin may be provided in place of the wheelchair wash-hand basin.

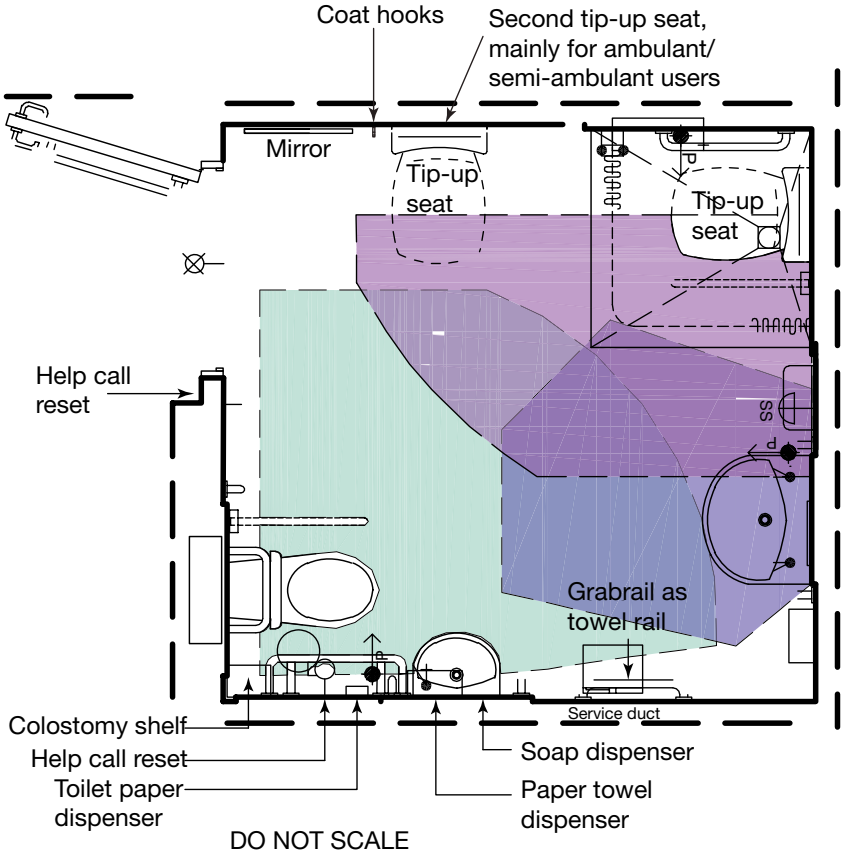


Figure 55 Space requirements for shower room: independent wheelchair

Independent wheelchair shower

4.67 This ergonomic drawing (see Figure 56) shows the space requirements for an independent wheelchair shower.

4.68 BS 8300 recommends a hinged grabrail at right-angles in front of shower seats for independent wheelchair transfer. This grabrail is to help prevent users falling forward. This rail is not considered necessary in healthcare premises. However, a risk assessment is recommended to confirm requirements.

4.69 The shower curtain consists of two parts to assist seated users to close the curtain, that is, to draw one half of the curtain from either side. The locations of the shower curtains and shower controls conflict with the recommendations in Approved Document M and BS 8300, and were informed by ergonomic studies and the mock-up trials for the en-suite shower rooms.

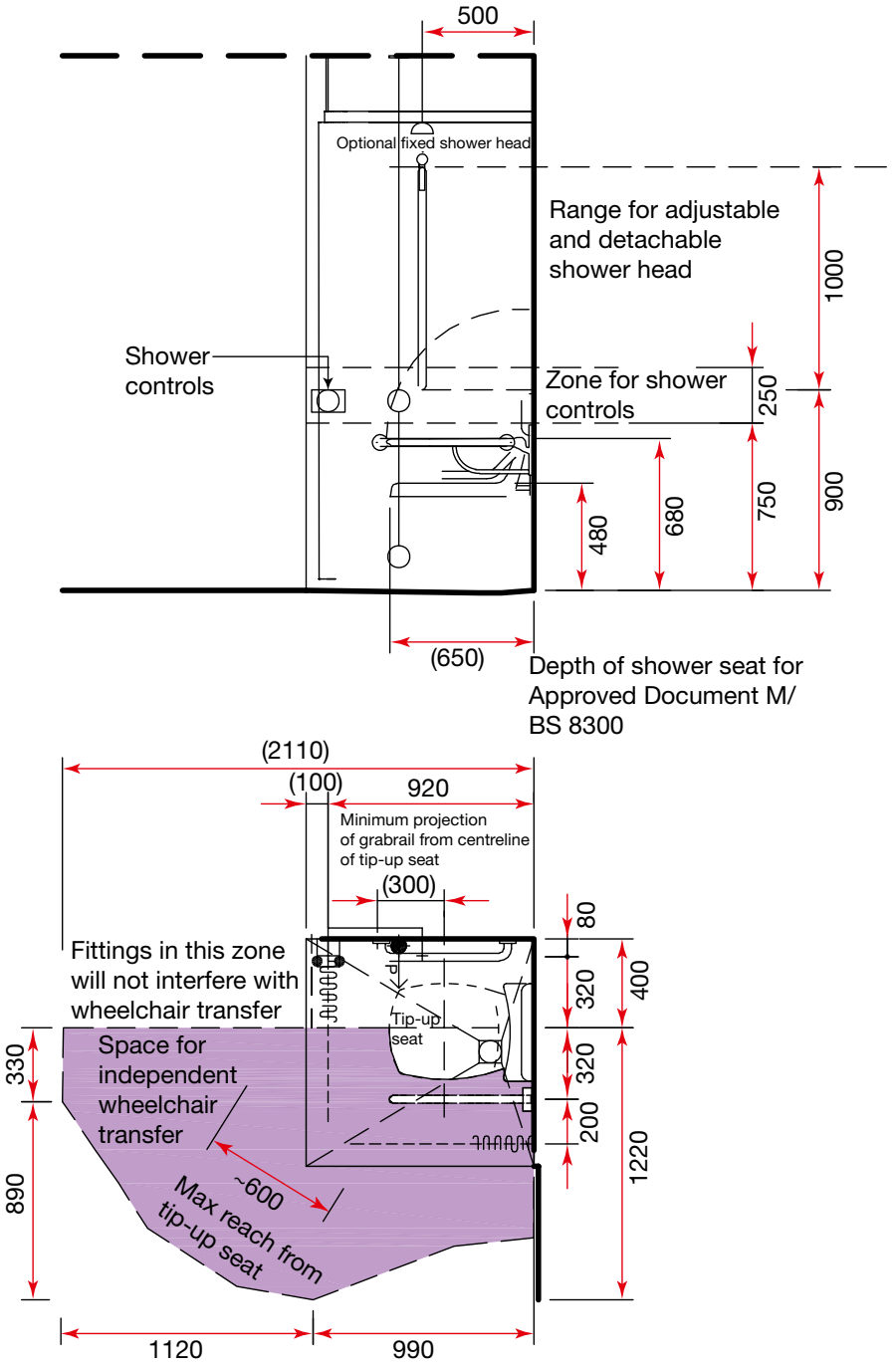


Figure 56 Space requirements for an independent wheelchair shower

Toilet and adjacent hand-rinse basin: independent wheelchair: grabrail options

4.70 These ergonomic drawings (see Figure 57) show the fixing position of grabrails for an independent wheelchair toilet and adjacent hand-rinse basin.

4.71 Grabrails should be provided symmetrically on either side of the toilet at 320 mm from the centreline of the toilet pan. This conflicts with the recommendations in Approved Document M and BS 8300.

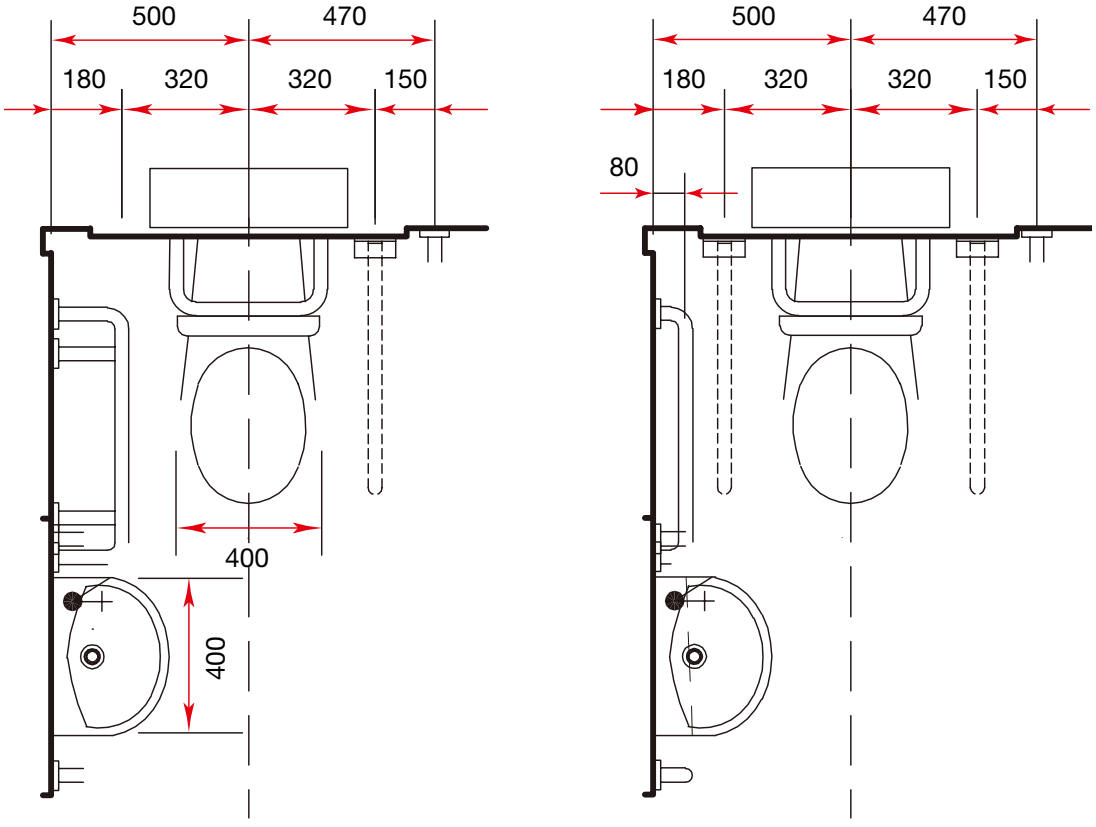
4.72 Approved Document M (paragraph 5.10j) states: "where the horizontal support rail on the wall adjacent to the toilet is set with the minimum spacing from the wall, an additional dropdown rail should be provided on the wall side at a distance of 320 mm from the centreline of the toilet."

Note

Where the maximum spacing defined in Approved Document M, 85 mm, is used, this positions the grabrail approximately 390 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

4.73 BS 8300 (paragraph 12.6.3.5 b) states: "A fixed horizontal rail should be located on the side wall with a 50 mm to 60 mm clearance between the rail and the wall." This places the rail approximately 420 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

4.74 The ergonomic drawings provided illustrate two options for the provision of grabrails. The room layouts on this website are based on option one.



Fixed grabrail between toilet and wall

Alternative fixed and hinged grabrail between toilet and wall

Figure 57 Space requirements showing fixing positions of grabrails for an independent wheelchair toilet and adjacent hand-rinse basin

Toilet and adjacent hand-rinse basin: independent wheelchair

4.75 This ergonomic drawing (see Figure 58) shows the space requirements for an independent wheelchair toilet and adjacent hand-rinse basin.

4.76 The recommended clear space in front and to the open side of the toilet (for independent wheelchair transfer) is greater than the recommendations in Approved Document M and BS 8300.

4.77 Approved Document M and BS 8300 recommend a minimum clear distance of 1000 mm to the open side of the centreline of the toilet for independent wheelchair transfer. Robert Feeney Associates (RFA) research for BS 8300 indicates that this will allow just over 60% of wheelchair users to comfortably transfer onto the toilet. The same research indicates that a clear space of 1400 mm accommodates 90% of wheelchair users and this is, therefore, recommended.

4.78 Approved Document M and BS 8300 recommend a 750 mm long toilet pan for independent wheelchair transfer. However, RFA research indicated that a 700 mm long toilet pan allows independent wheelchair transfer. For maximum space efficiency a 700 mm pan is recommended.

4.79 As a consequence of the reduction in pan length, the hand-rinse basin is located closer to the corner of the room than the position given in Approved Document M and BS 8300, to allow hand-rinsing from a seated position on the toilet.

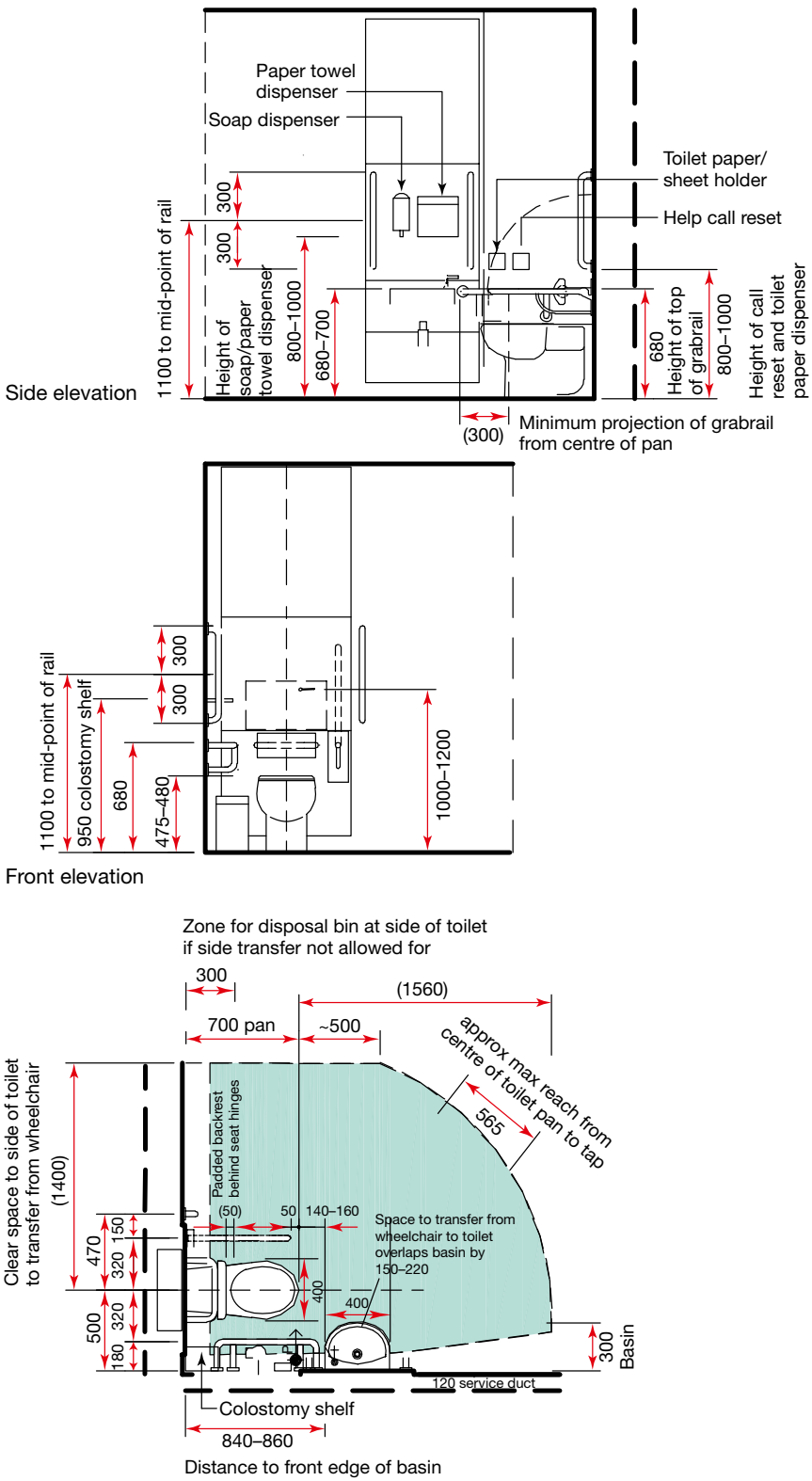


Figure 58 Space requirements for an independent wheelchair toilet and adjacent hand-rinse basin

Wash-hand basin: wheelchair

4.80 Wash-hand basins may be used for personal washing activities.

4.81 This ergonomic drawing (see Figure 59) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

4.82 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

4.83 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

4.84 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

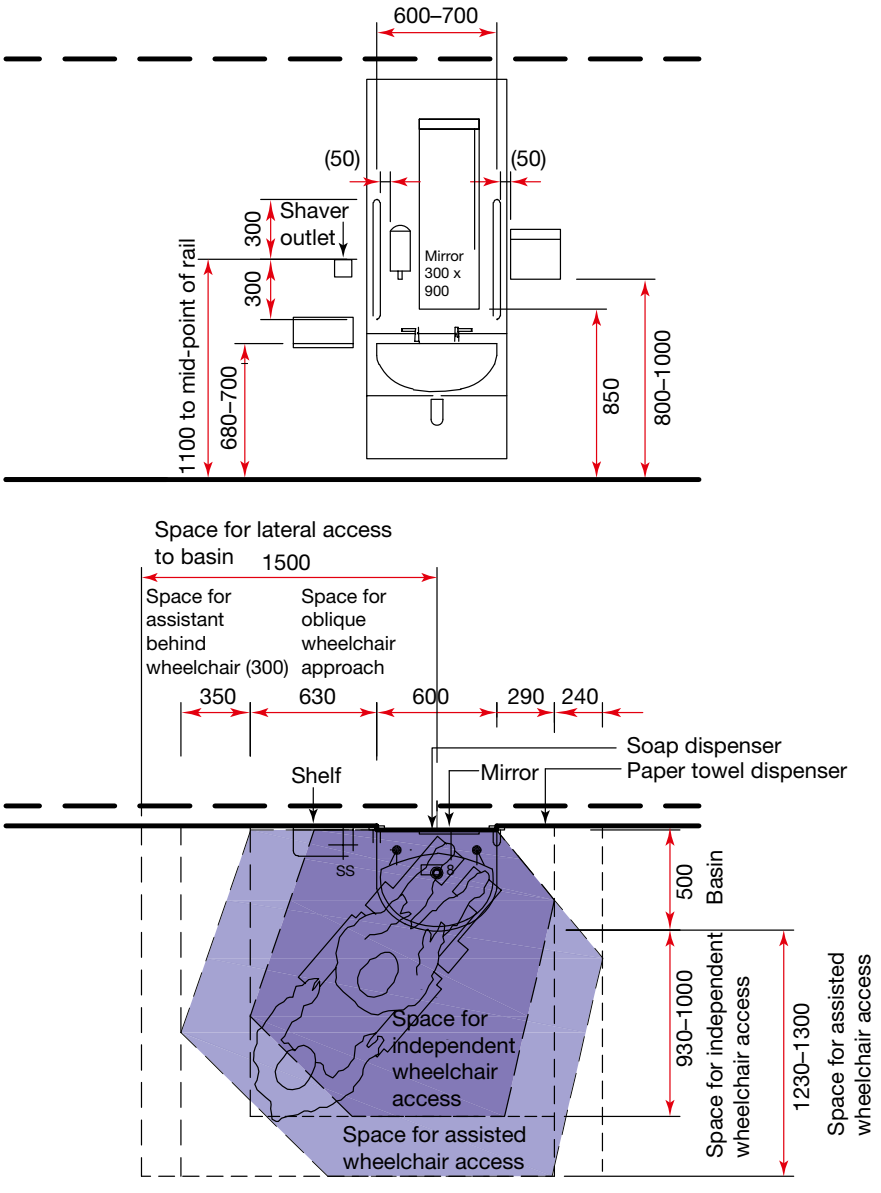


Figure 59 Space requirements for wheelchair accessible wash-hand basin

Full-length mirror: standing or seated users

4.85 This ergonomic drawing (see Figure 60) shows the space requirements for a full-length mirror for standing or seated users.

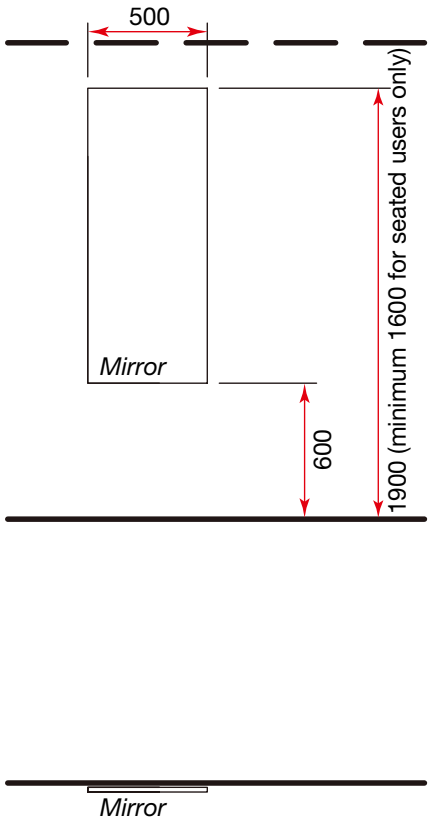


Figure 60 Space requirements for full-length mirror for standing or seated users

Shower room: semi-ambulant: standing use

Room description and layout

4.86 See Figure 61. The following activities take place in semi-ambulant shower rooms:

- undressing and dressing;
- hanging/holding clothes;
- use of the toilet;
- personal washing;
- showering (whilst standing).

4.87 Shower rooms for semi-ambulant use should contain a semi-ambulant toilet, ambulant wash-hand basin and a wet floor shower area (not a shower tray).

4.88 Semi-ambulant shower rooms are also suitable for ambulant users.

4.89 A continuous horizontal grabrail should be provided within the shower area. Users should be able to touch two sides of the shower area/two grabrails, opposite or at right angles, in order to keep their balance.

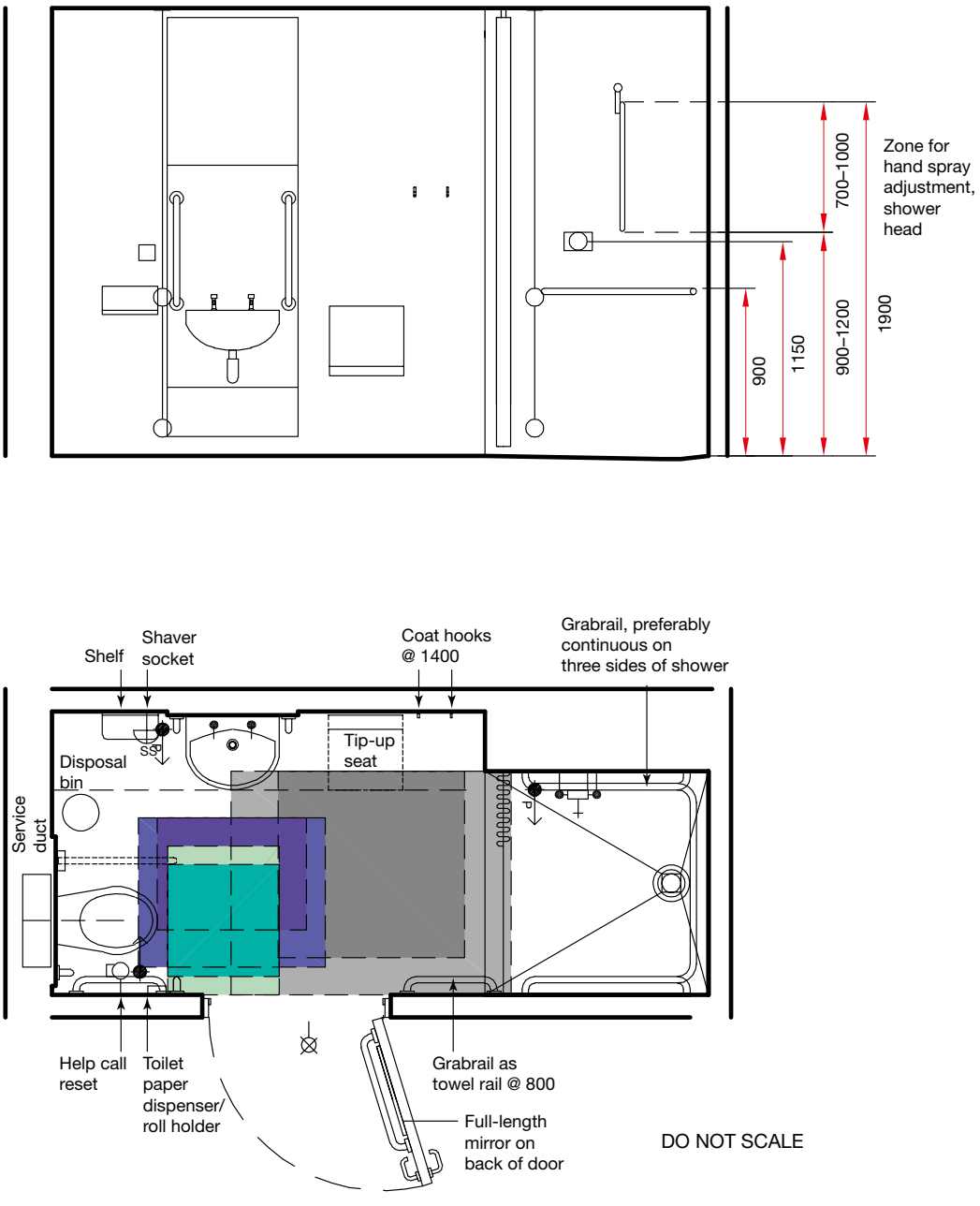


Figure 61 Space requirements for shower room: semi-ambulant: standing use

Ergonomic drawings

Toilet: semi-ambulant

4.90 This ergonomic drawing (see Figure 62) shows the space requirements for a semi-ambulant toilet.

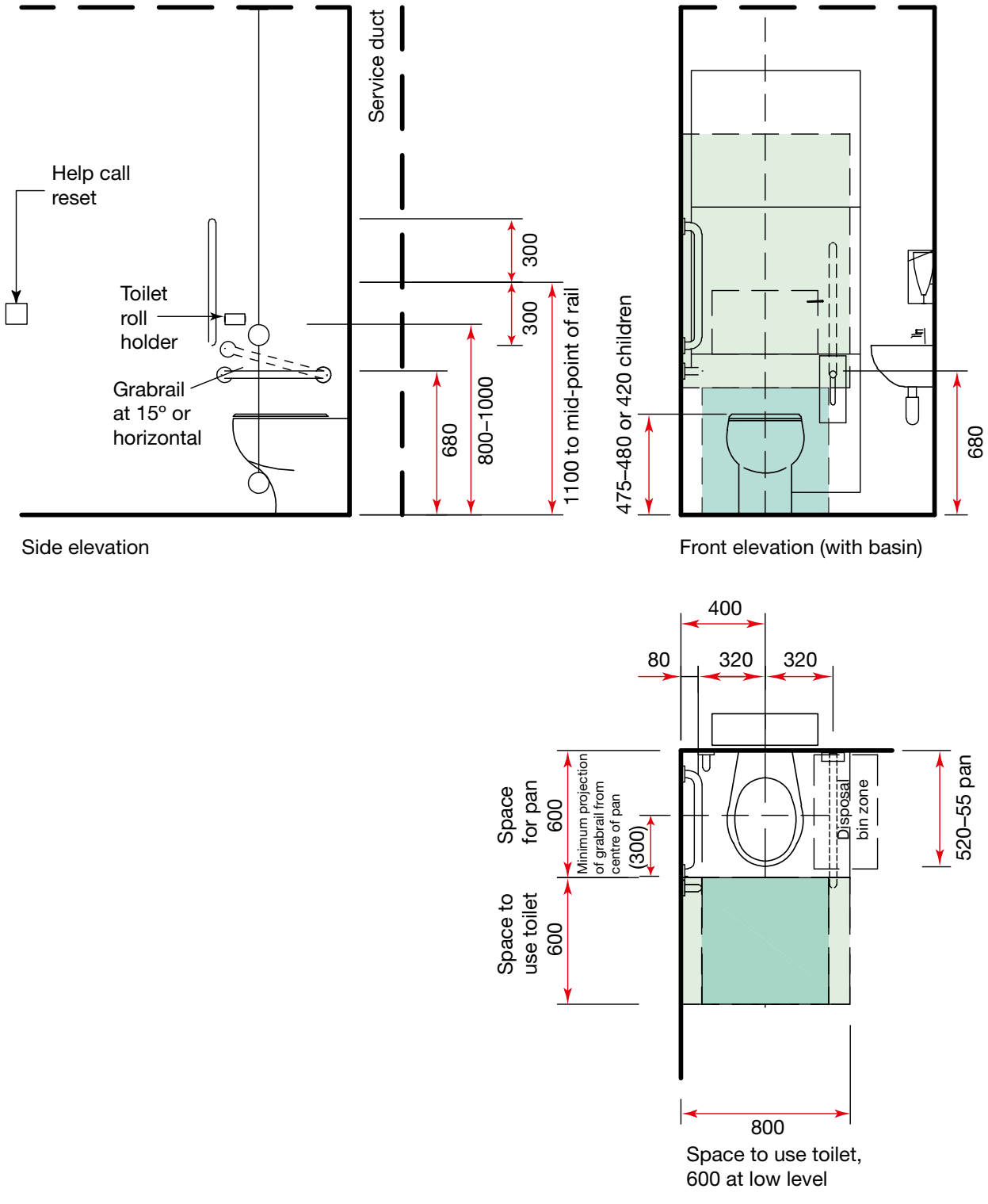


Figure 62 Space requirements for semi-ambulant toilet

Wash-hand basin: ambulant

4.91 Wash-hand basins may be used for personal washing activities.

4.92 This ergonomic drawing (see Figure 63) shows the space requirements for ambulant/ semi-ambulant use of a 400 mm deep × 500 mm wide wash-hand basin.

4.93 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

4.94 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

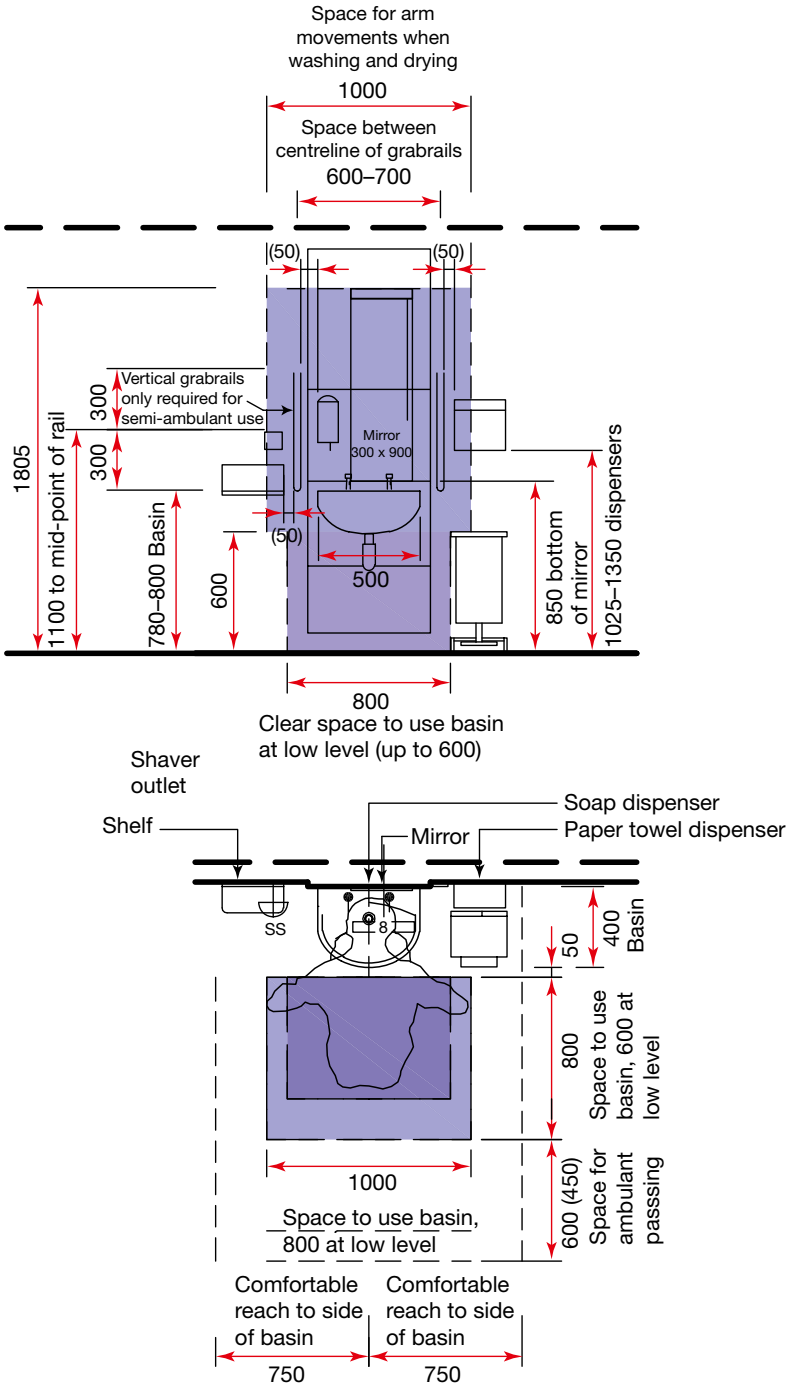


Figure 63 Space requirements for ambulant/semi-ambulant use of a 400 mm deep x 500 mm wide wash-hand basin

Full-length mirror: standing or seated users

4.95 This ergonomic drawing (see Figure 64) shows the space requirements for a full-length mirror for standing or seated users.

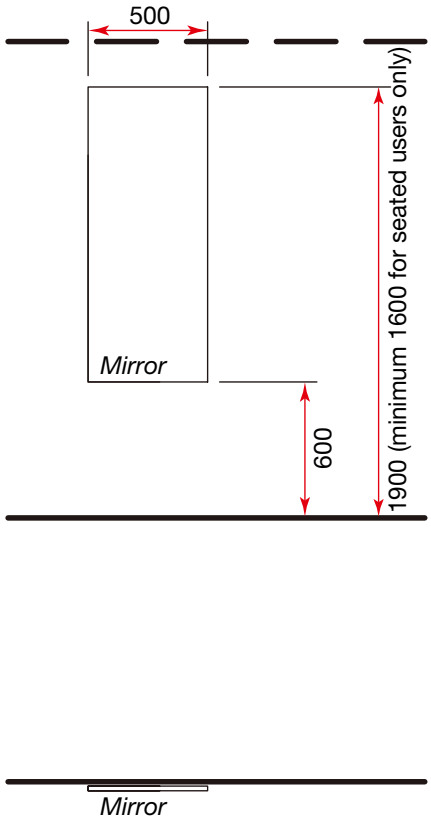


Figure 64 Space requirements for full-length mirror for standing or seated users

Dressing and undressing: ambulant

4.96 These ergonomic drawings (see Figure 65) show the space requirements for ambulant dressing and undressing.

4.97 An identical space provision is suitable for semi-ambulant users though it should be located adjacent to a seating area.

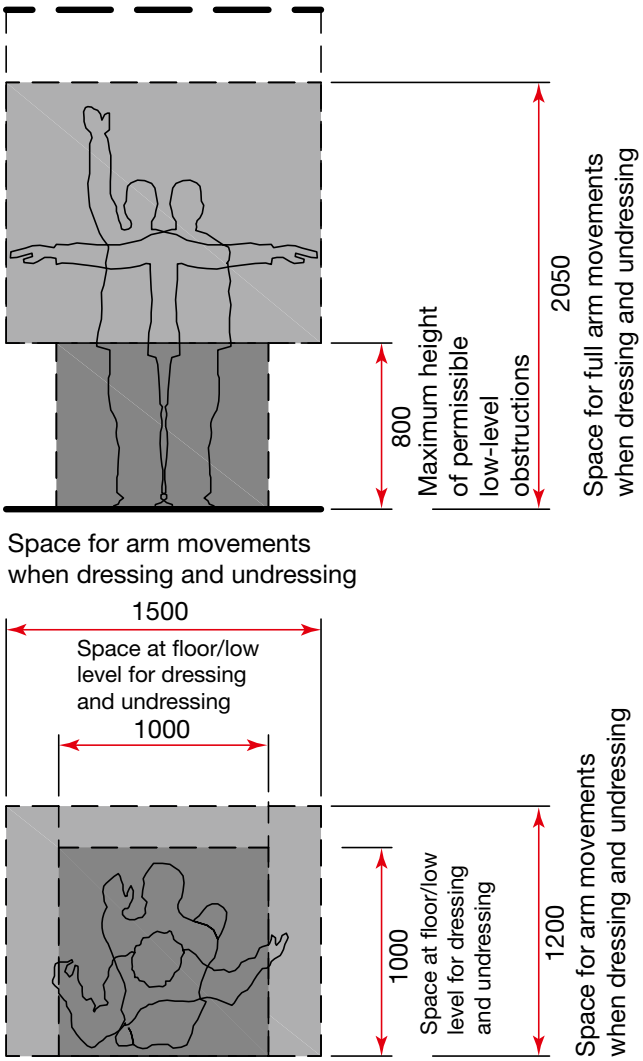


Figure 65 Space requirements for ambulant dressing and undressing

Shower room: trolley access

Room description and layout

4.98 The following assisted activities take place in trolley access shower rooms:

- wheelchair and sanitary chair access to the toilet and wash-hand basin;
- mobile hoist access to transfer a patient to the toilet or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet (supervised only);
- use of the toilet;
- personal washing (whilst the patient is seated);
- shower trolley access to the shower;
- showering (whilst the patient is lying on the shower trolley).

4.99 Trolley access showers are suitable for patients who are reliant on assisted movement. The room layout provided (see Figure 66) utilises the minimum clear space requirement to the side of the toilet for mobile hoist transfer (that is, 1150 mm from the centreline of the toilet to the nearest obstruction), on the basin side of the toilet only.

4.100 It features two toilets: one in the wet area and the other in the dry area. The drainpipe at the foot of the shower trolley should be positioned over the toilet in the wet area to deal with incontinence episodes during showering.

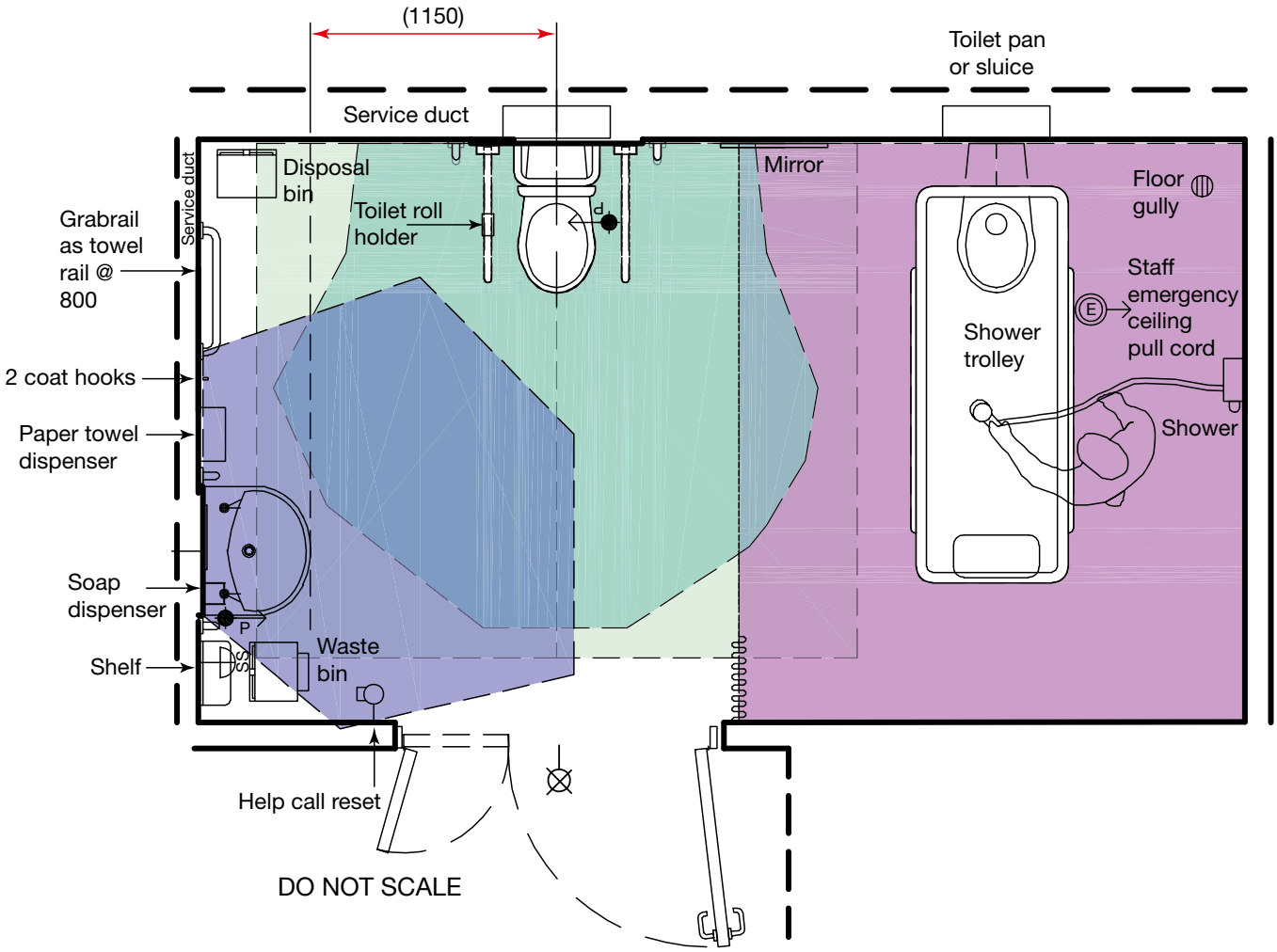


Figure 66 Space requirements for shower room: trolley access minimum space requirement

Ergonomic drawings

Trolley access shower

4.101 This ergonomic drawing (see Figure 67) shows the space requirements for a trolley access shower.

4.102 A minimum of 800 mm clear space at the head of the trolley is required if staff need to stand in this position during showering.

4.103 The shower panel should have a pressure and temperature control thermostatic mixer. The shower hose should be long enough to allow staff to shower the full length of the patient from either side with a trigger handle. This shower fitting is not specifically covered in Health Building Note 00-10 Part C – 'Sanitary assemblies'.

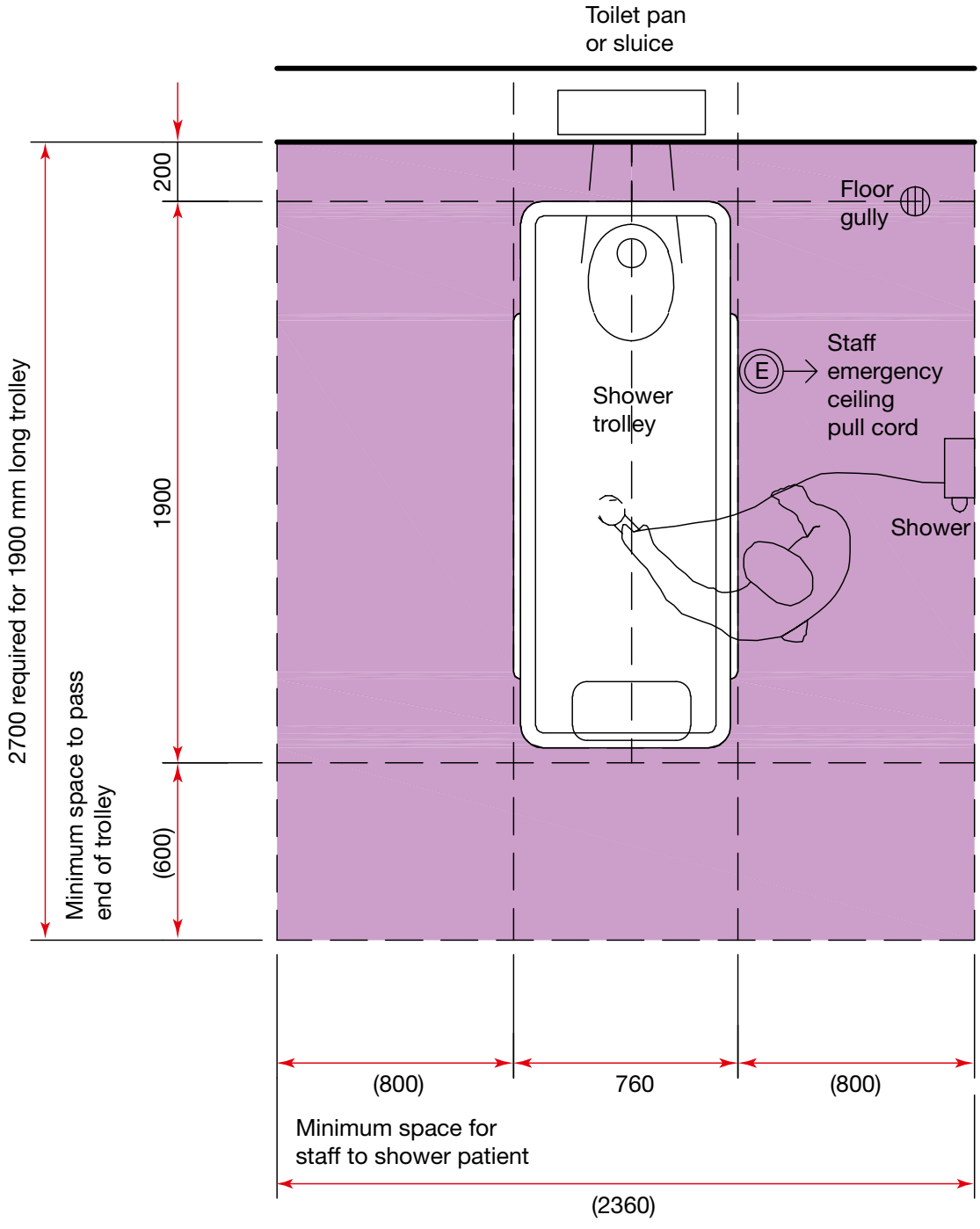


Figure 67 Space requirements for trolley access shower

Toilet: assisted

4.104 This ergonomic drawing (see Figure 68) shows the space requirements for an assisted toilet.

4.105 The clear space on either side of the toilet for mobile hoist transfer is greater than that recommended in BS 8300 (Figure 55).

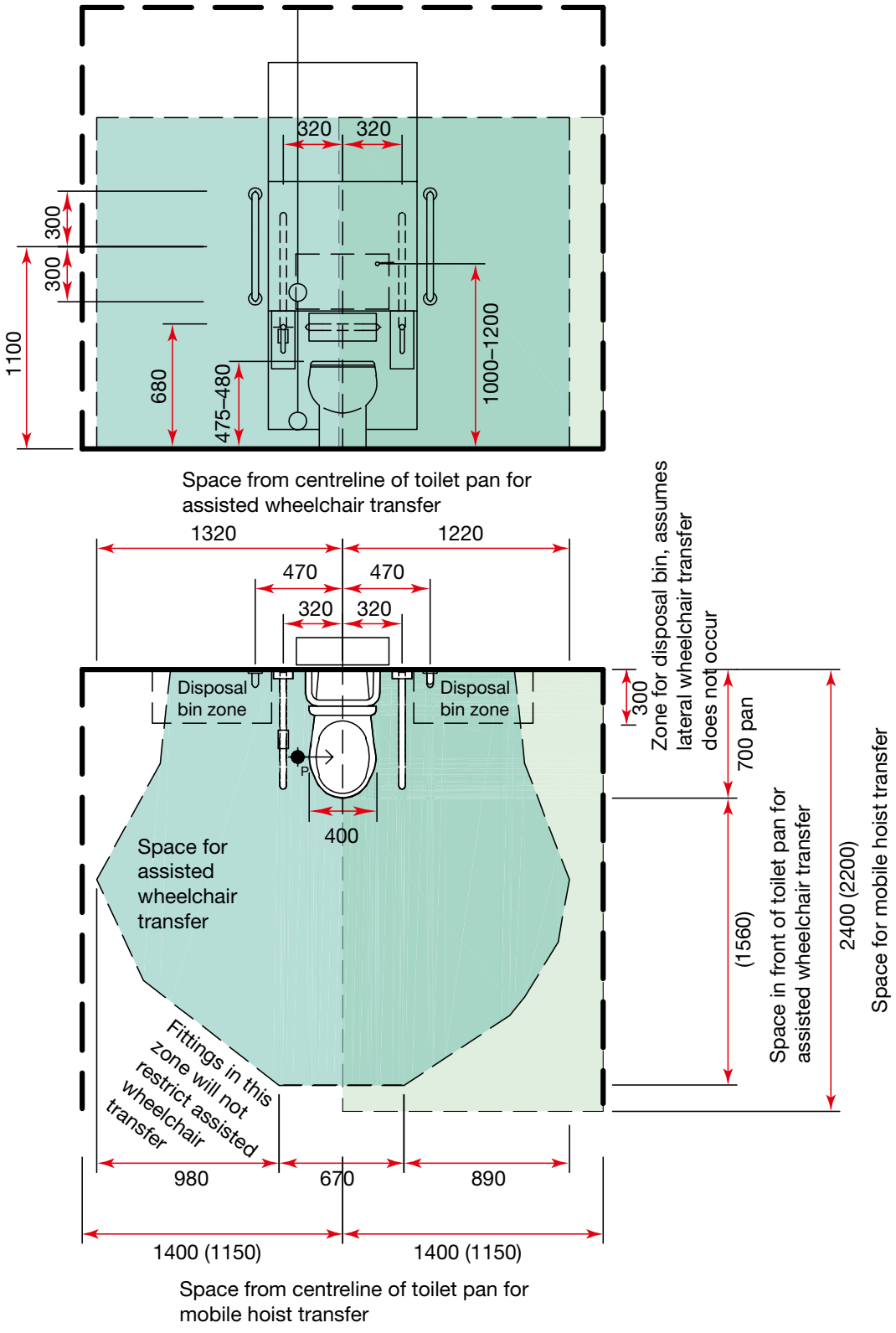


Figure 68 Space requirements for assisted toilet

Wash-hand basin: wheelchair

4.106 Wash-hand basins may be used for personal washing activities.

4.107 This ergonomic drawing (see Figure 69) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

4.108 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

4.109 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

4.110 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

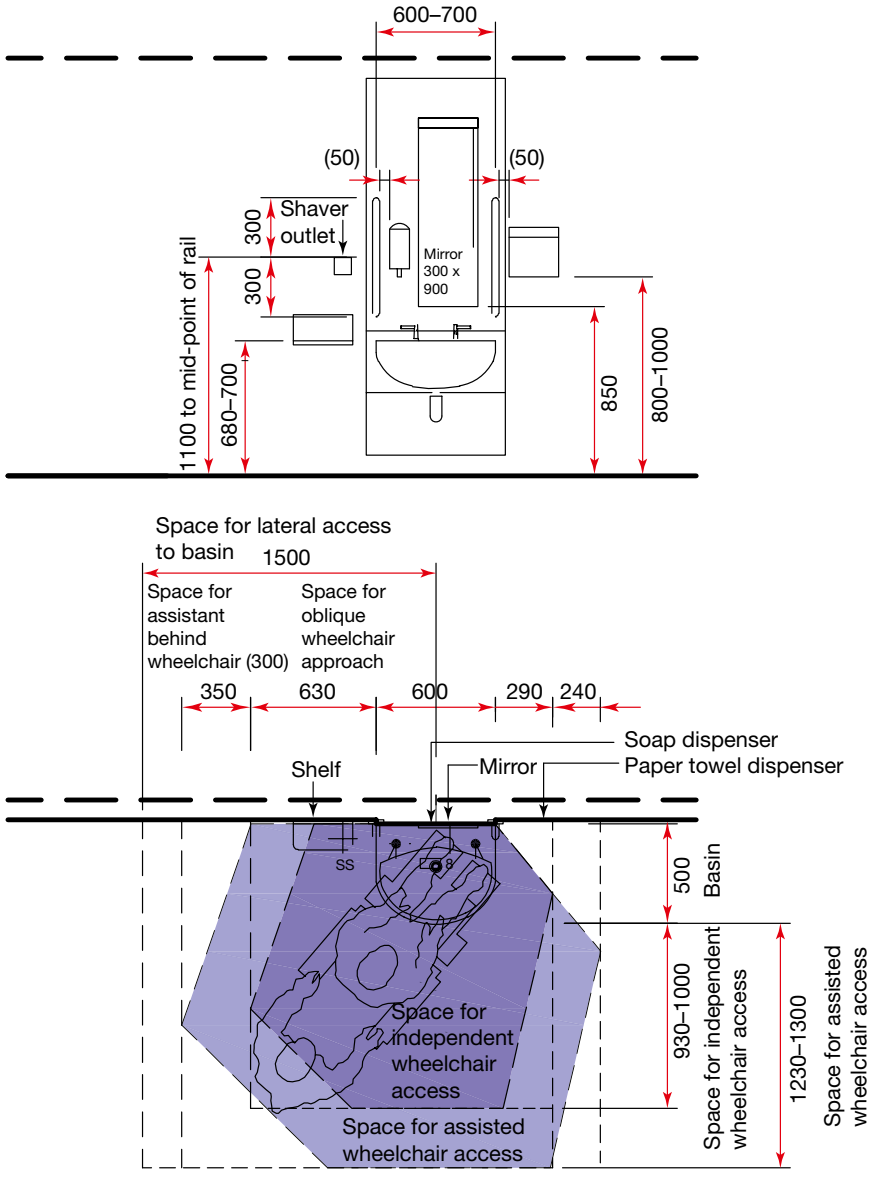


Figure 69 Space requirements for wheelchair accessible wash-hand basin

Full-length mirror: standing or seated users

4.111 This ergonomic drawing (see Figure 70) shows the space requirements for a full-length mirror for standing or seated users.

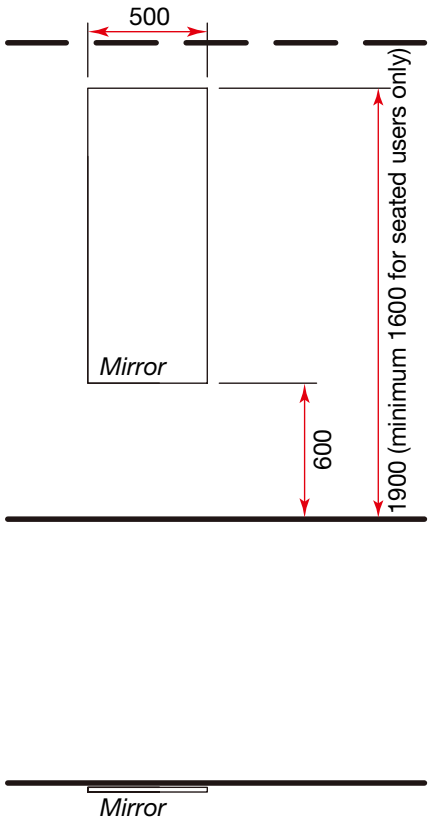


Figure 70 Space requirements for full-length mirror for standing or seated users

Shower room: trolley access: private use

Room description and layout

4.112 The following assisted activities take place in trolley access shower rooms:

- wheelchair and sanitary chair access to the toilet and wash-hand basin;
- mobile hoist access to transfer a patient to the toilet or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet (supervised only);
- use of the toilet;
- personal washing (whilst the patient is seated);
- shower trolley access to the shower;
- showering (whilst the patient is lying on the shower trolley).

4.113 Trolley access showers are suitable for patients who are reliant on assisted movement. The room layout provided (see Figure 71) utilises the minimum clear space requirement to the side of the toilet for mobile hoist transfer (that is, 1150 mm from the centreline of the toilet to the nearest obstruction), on the basin side of the toilet only.

4.114 The drainpipe at the foot of the shower trolley should be positioned over the toilet to deal with incontinence episodes during showering.

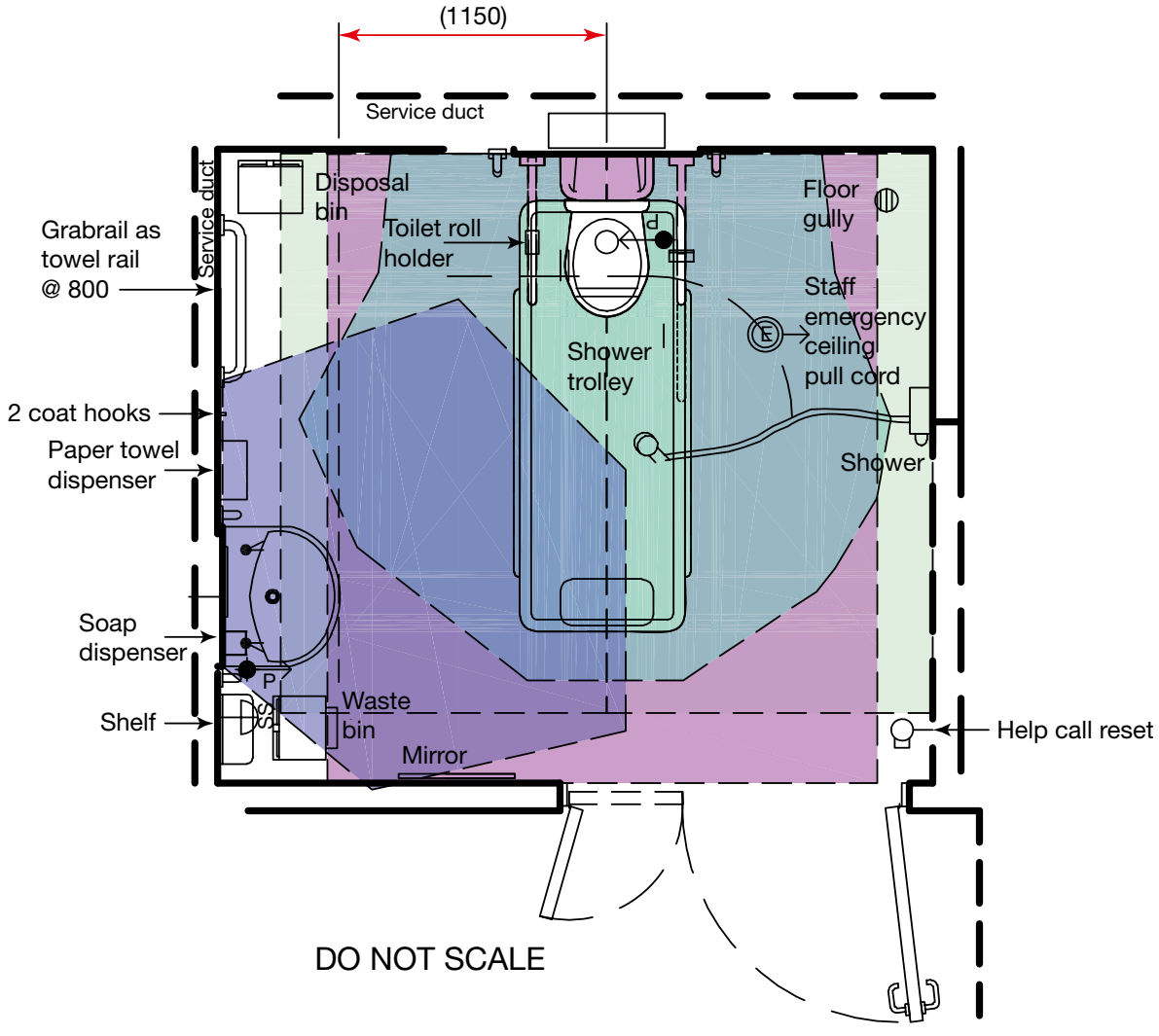


Figure 71 Space requirements for shower room: trolley access: private use, minimum clear space requirement for mobile hoist transfer

Ergonomic drawings

Trolley access shower

4.115 This ergonomic drawing (see Figure 72) shows the space requirements for a trolley access shower.

4.116 A minimum of 800 mm clear space at the head of the trolley is required if staff need to stand in this position during showering.

4.117 The shower panel should have a pressure and temperature control thermostatic mixer. The shower hose should be long enough to allow staff to shower the full length of the patient from either side with a trigger handle. This shower fitting is not specifically covered in Health Building Note 00-10 Part C – 'Sanitary assemblies'.

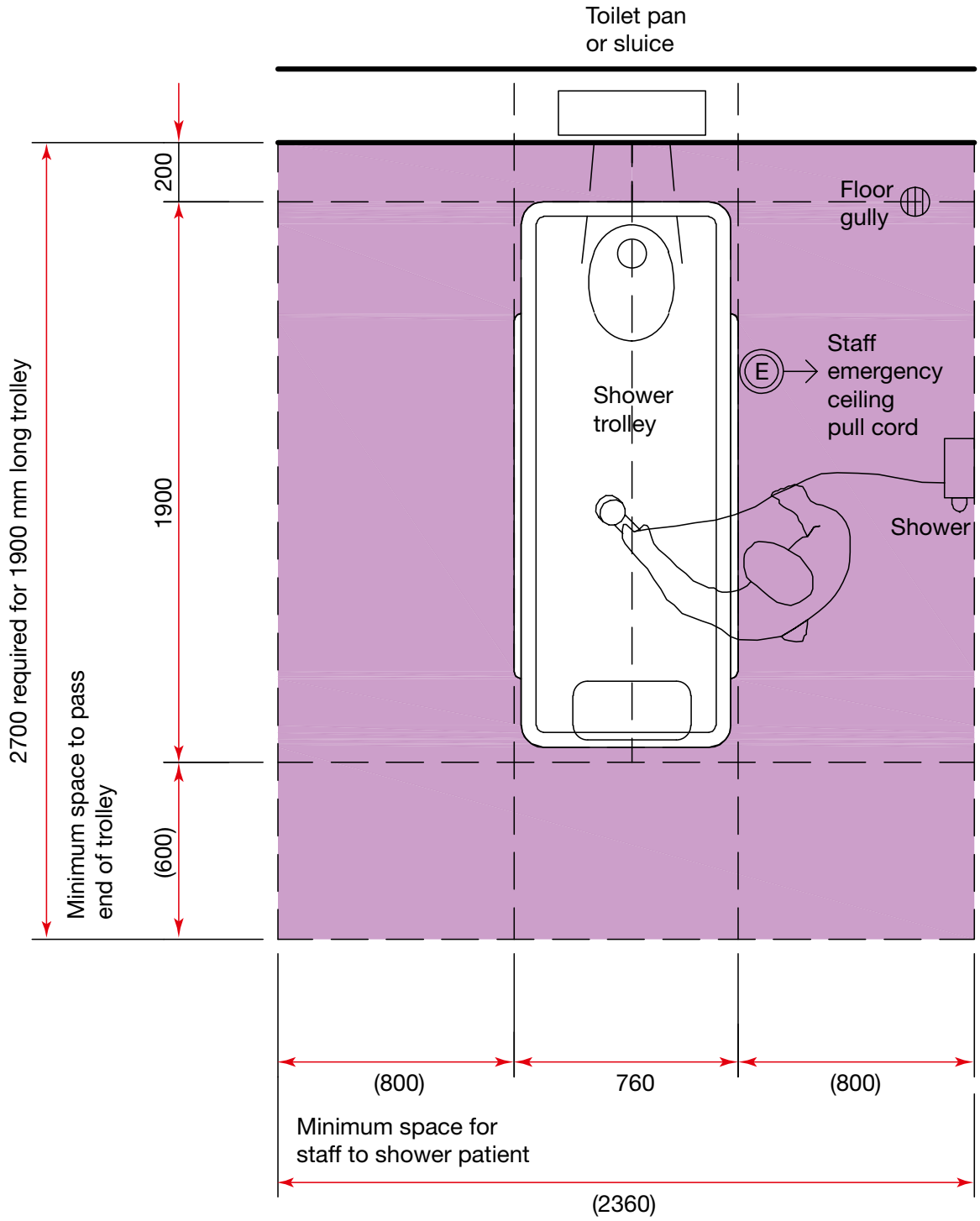


Figure 72 Space requirements for trolley access shower

Toilet: assisted

4.118 This ergonomic drawing (see Figure 73) shows the space requirements for an assisted toilet.

4.119 The clear space on either side of the toilet for mobile hoist transfer is greater than that recommended in BS 8300 (Figure 55).

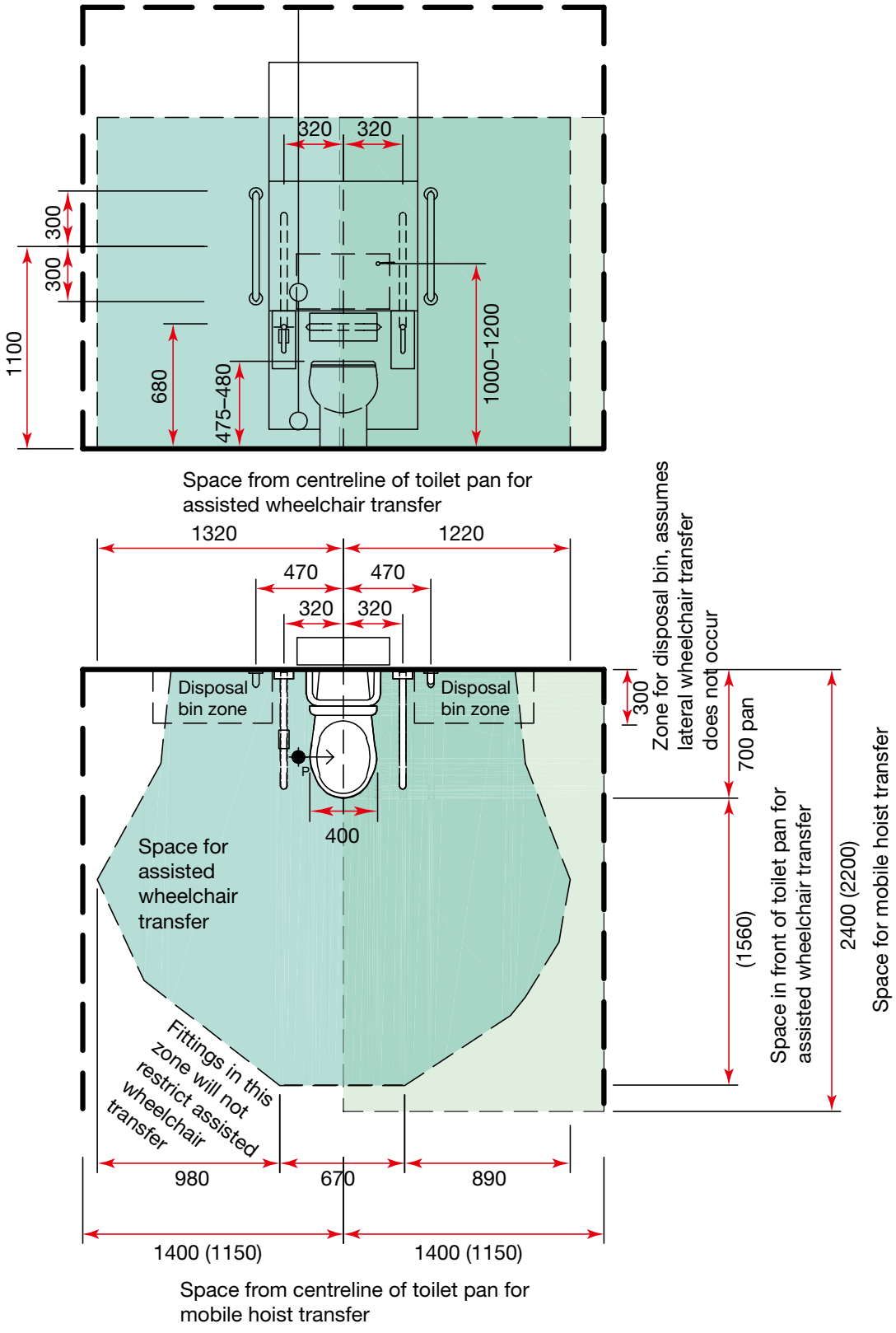


Figure 73 Space requirements for assisted toilet

Wash-hand basin: wheelchair

4.120 Wash-hand basins may be used for personal washing activities.

4.121 This ergonomic drawing (see Figure 74) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

4.122 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

4.123 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

4.124 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

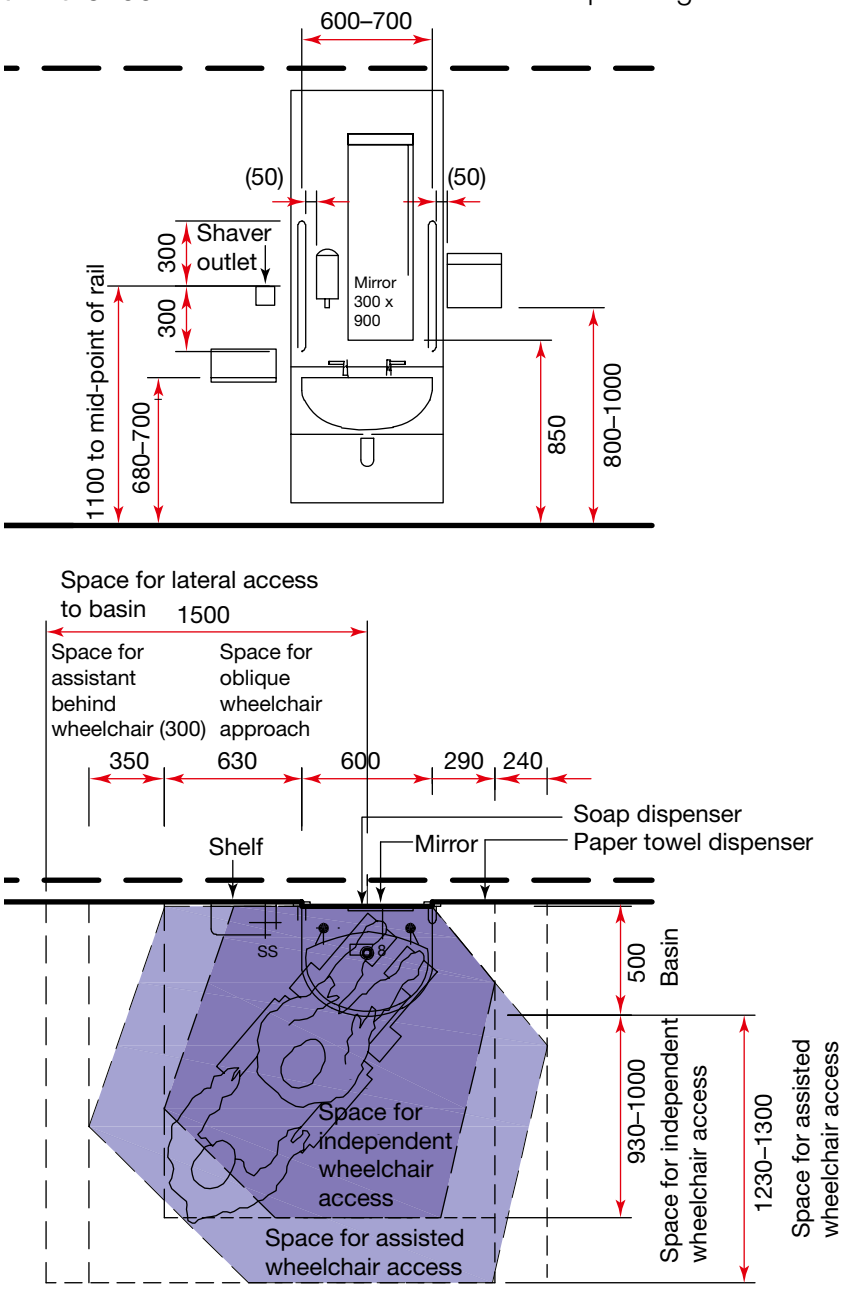


Figure 74 Space requirements for wheelchair accessible wash-hand basin

Full-length mirror: standing or seated users

4.125 This ergonomic drawing (see Figure 75) shows the space requirements for a full-length mirror for standing or seated users.

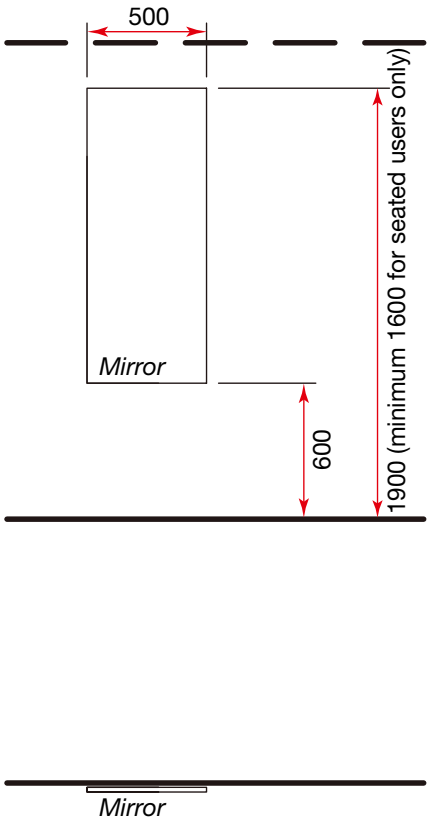


Figure 75 Space requirements for full-length mirror for standing or seated users

5 WCs

WC: ambulant

Room description and layout

5.1 The following activities take place in ambulant WCs:

- use of the toilet:
- disposal of sanitary towels (optional);
- hand-rinsing.

5.2 Ambulant WCs are only suitable for fully ambulant users and should not be used in patient spaces.

5.3 Toilet seats should be provided in ambulant WCs.

5.4 The room layout provided (see Figure 76) includes a 300 mm deep hand-rinse basin. Where a larger hand-rinse basin (up to 350 mm deep) is used, minimum internal room dimensions may need to increase to maintain the required activity space.

5.5 A space allocation for luggage has been included to allow belongings/bags to be comfortably taken into the WC for security.

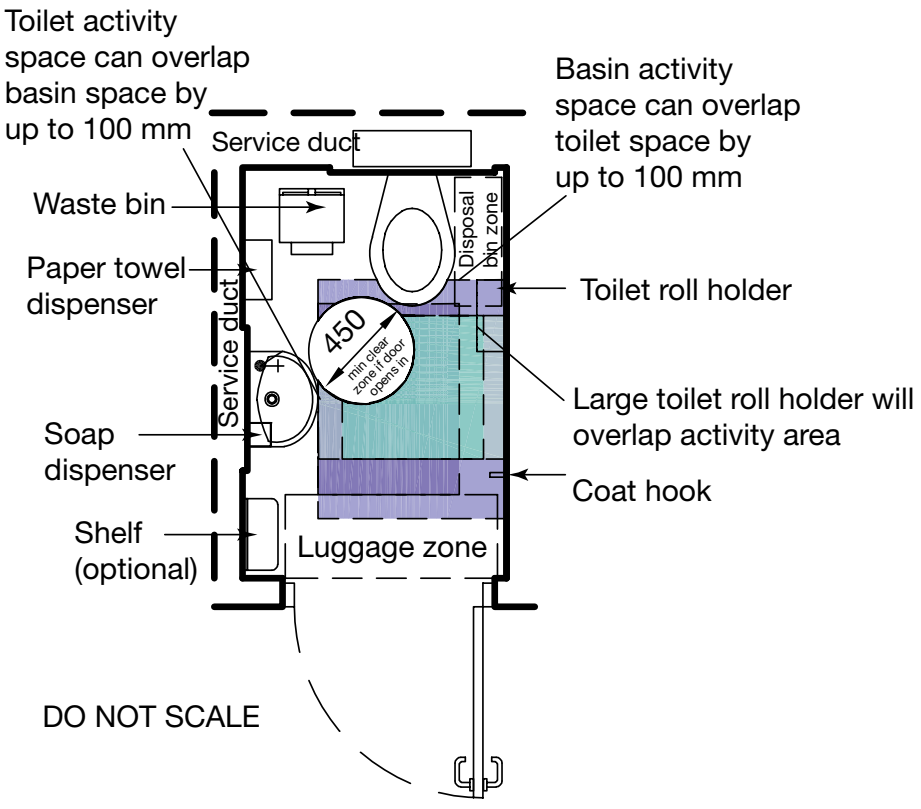


Figure 76 Space requirements for WC: ambulant, 300 mm deep hand-rinse basin

Ergonomic drawings

Toilet: ambulant

5.6 This ergonomic drawing (see Figure 77) shows the space requirements for an ambulant toilet.

5.7 A large toilet roll holder would overlap the activity area.

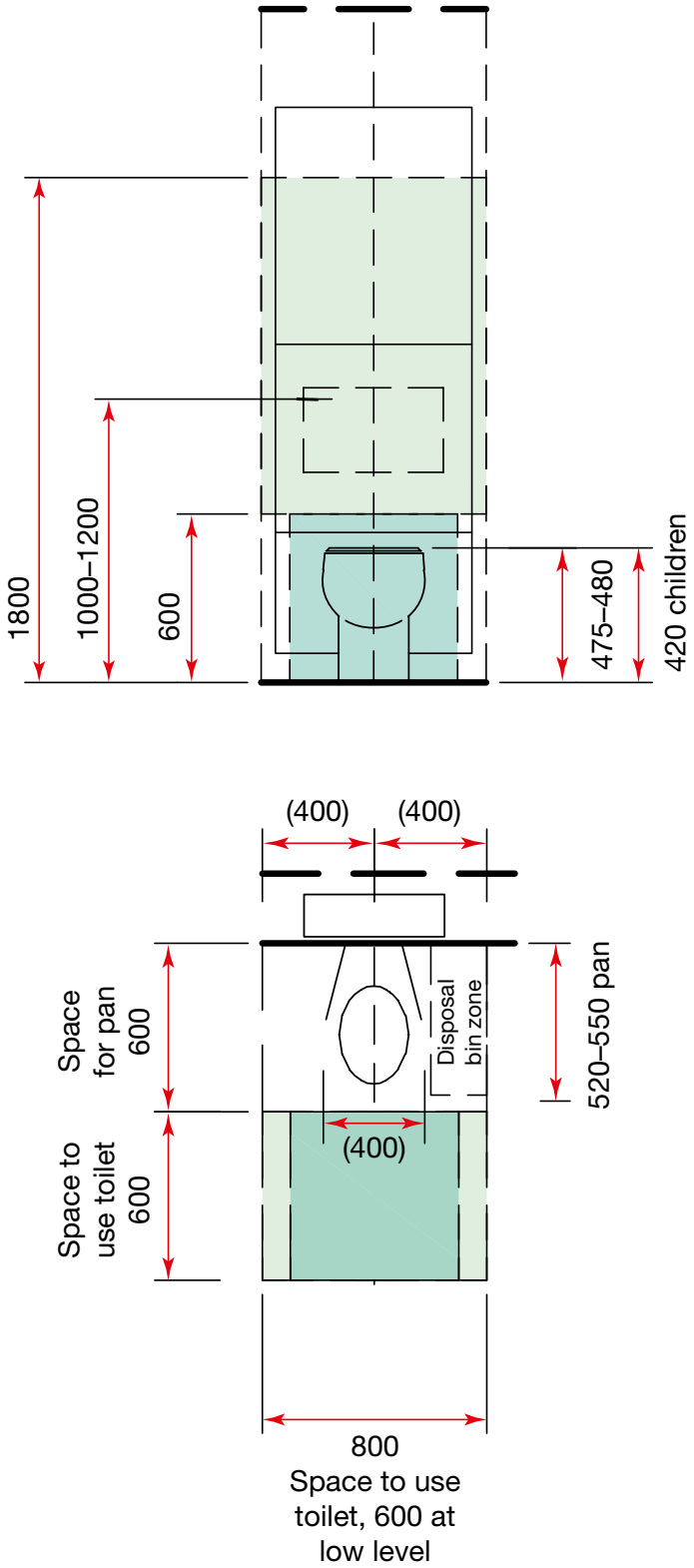


Figure 77 Space requirements for ambulant toilet

Hand-rinse basin: ambulant

5.8 This ergonomic drawing (see Figure 78) shows the space requirements for a 300 mm deep hand-rinse basin. It is suitable for ambulant and semi-ambulant use.

5.9 Hand-rinse basins are generally only suitable for rinsing hands under running water. They should have a single mixer tap.

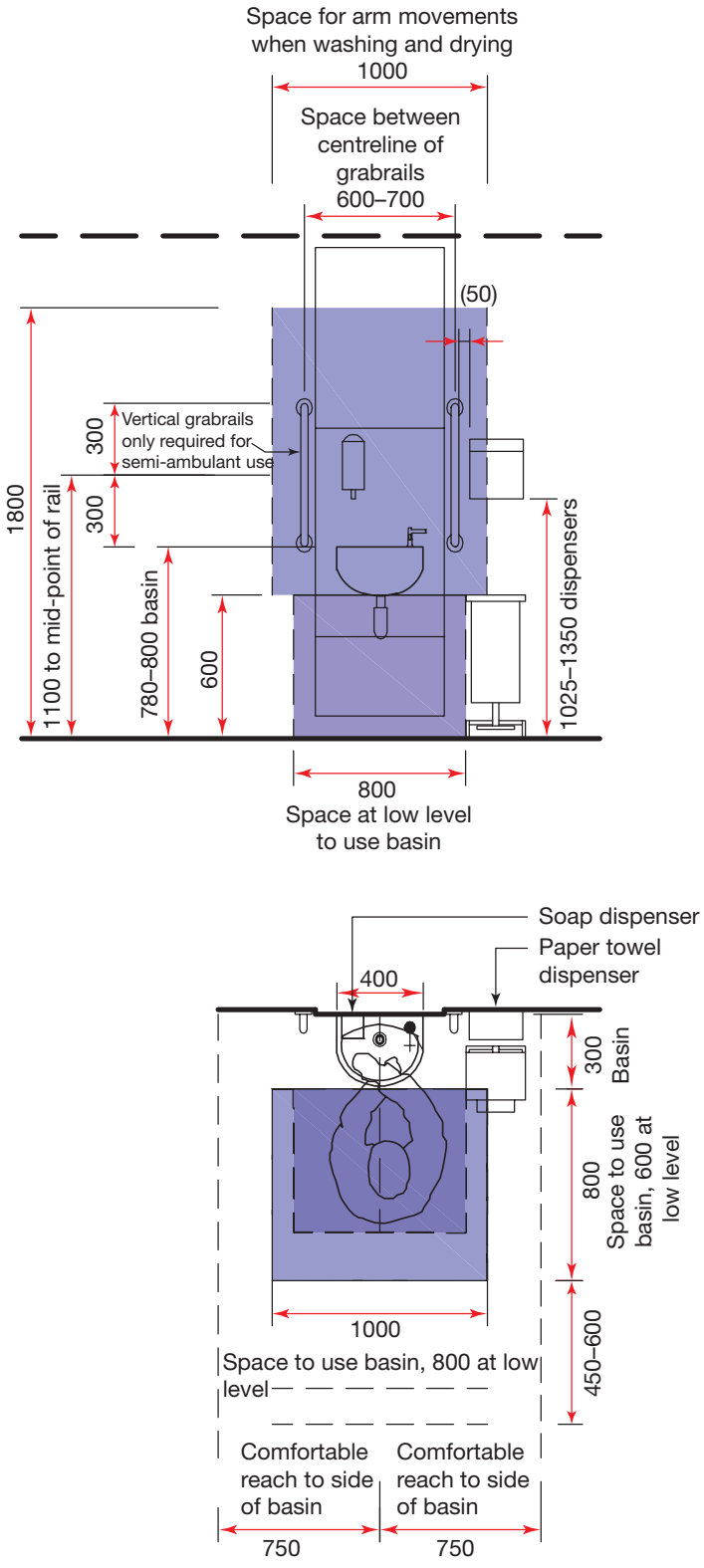


Figure 78 Space requirements for 300 mm deep hand-rinse basin suitable for ambulant and semi-ambulant use

WC: assisted

Room description and layout

5.10 The following assisted activities take place in assisted WCs:

- wheelchair and sanitary chair access to the toilet and wash-hand basin;
- mobile hoist access to transfer a patient to the toilet or to attend to a patient collapsed on the floor;
- patient transfer from a wheelchair to the toilet (supervised only);
- use of the toilet;
- personal washing (whilst the patient is seated).

5.11 Peninsular (also known as island) toilets are required to allow space on either side of the toilet pan for assistance. With the absence of an adjacent wall, this layout may not provide the same feeling of security as a corner toilet layout and is not considered suitable for independent wheelchair users.

5.12 An assisted WC should contain a wheelchair wash-hand basin. A hand-rinse basin, accessible from the toilet, is not acceptable since this would conflict with the space requirements for assistance.

5.13 Assisted WCs should only be used where appropriate assistance is available.

5.14 Mobile hoist access will be required if a patient collapses on the floor even if it is not used for transferring patients to the toilet.

5.15 The room layout provided (see Figure 79) utilises the minimum clear space requirement to the side of the toilet for mobile hoist transfer (that is, 1150 mm from the centreline of the toilet to the nearest obstruction), on the basin side of the toilet only.

5.16 To enable this space to be suitable for ambulant and semi-ambulant use as well as assisted use, an adjustable-height wash-hand basin may be provided in place of the wheelchair wash-hand basin.

5.17 The disposal bin is shown located away from the toilet to maximise the space for transfer and because it is assumed that the assistant will transfer waste to the bin or move the bin closer to the toilet when required.

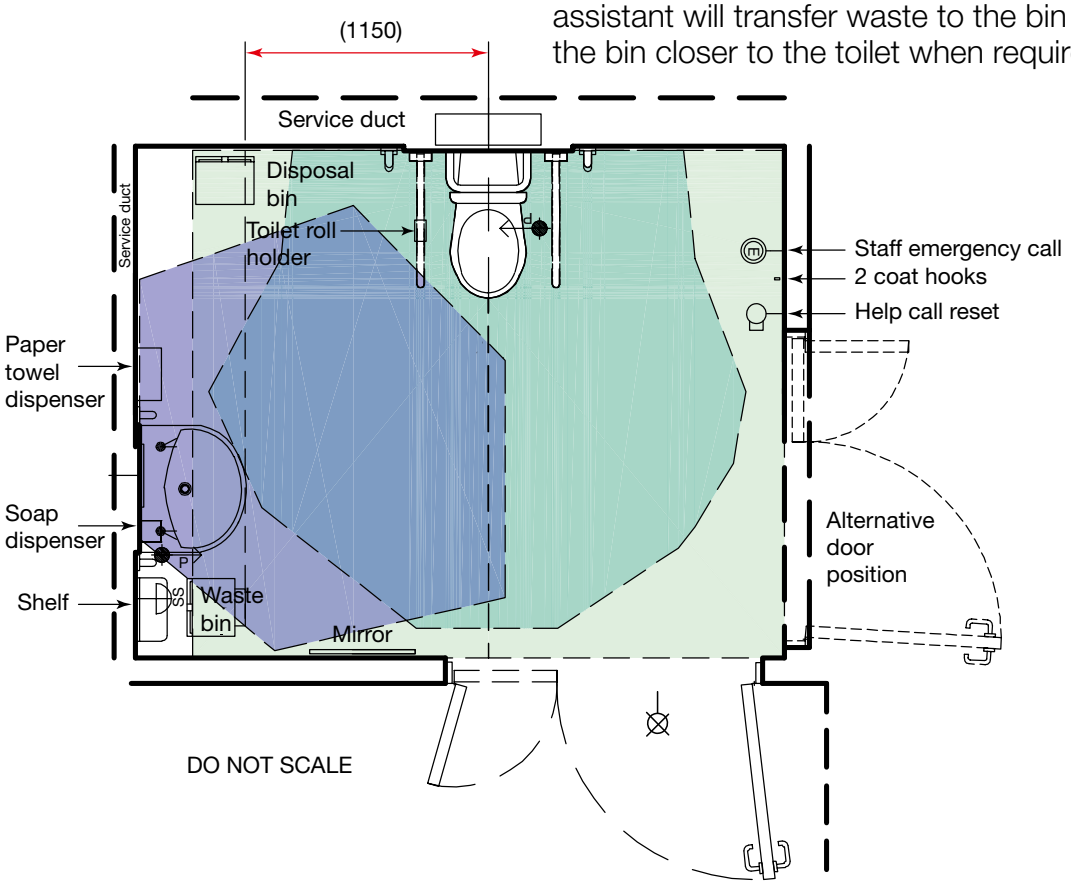


Figure 79 Space requirements for WC: assisted with minimum clear space requirement for mobile hoist transfer

Ergonomic drawings

Toilet: assisted

5.18 This ergonomic drawing (see Figure 80) shows the space requirements for an assisted toilet.

5.19 The clear space on either side of the toilet for mobile hoist transfer is greater than that recommended in BS 8300 (Figure 55).

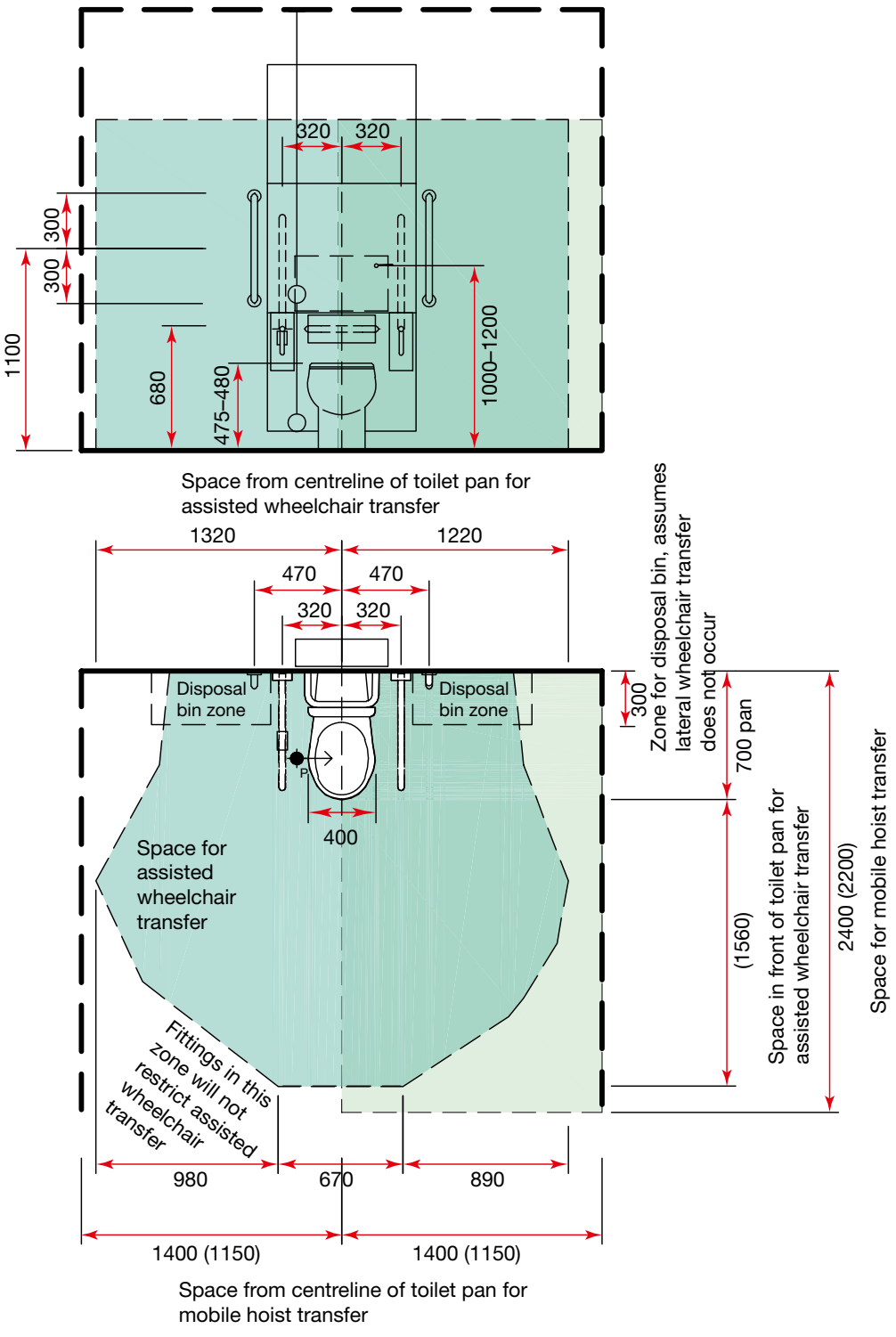


Figure 80 Space requirements for assisted toilet

Wash-hand basin: wheelchair

5.20 Wash-hand basins may be used for personal washing activities.

5.21 This ergonomic drawing (see Figure 81) shows the space requirements for a wheelchair accessible wash-hand basin. It is also suitable for seated use.

5.22 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

5.23 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

5.24 Wheelchair-accessible wash-hand basins should have a size and profile that maximises access and reduces obstructions. They should:

- be as shallow as possible, that is, tapered from the rim to a depth not exceeding 250 mm at the outlet, which in turn should be positioned as near the supporting wall as possible;
- preferably project 500 mm in order to provide adequate leg room underneath the basin.

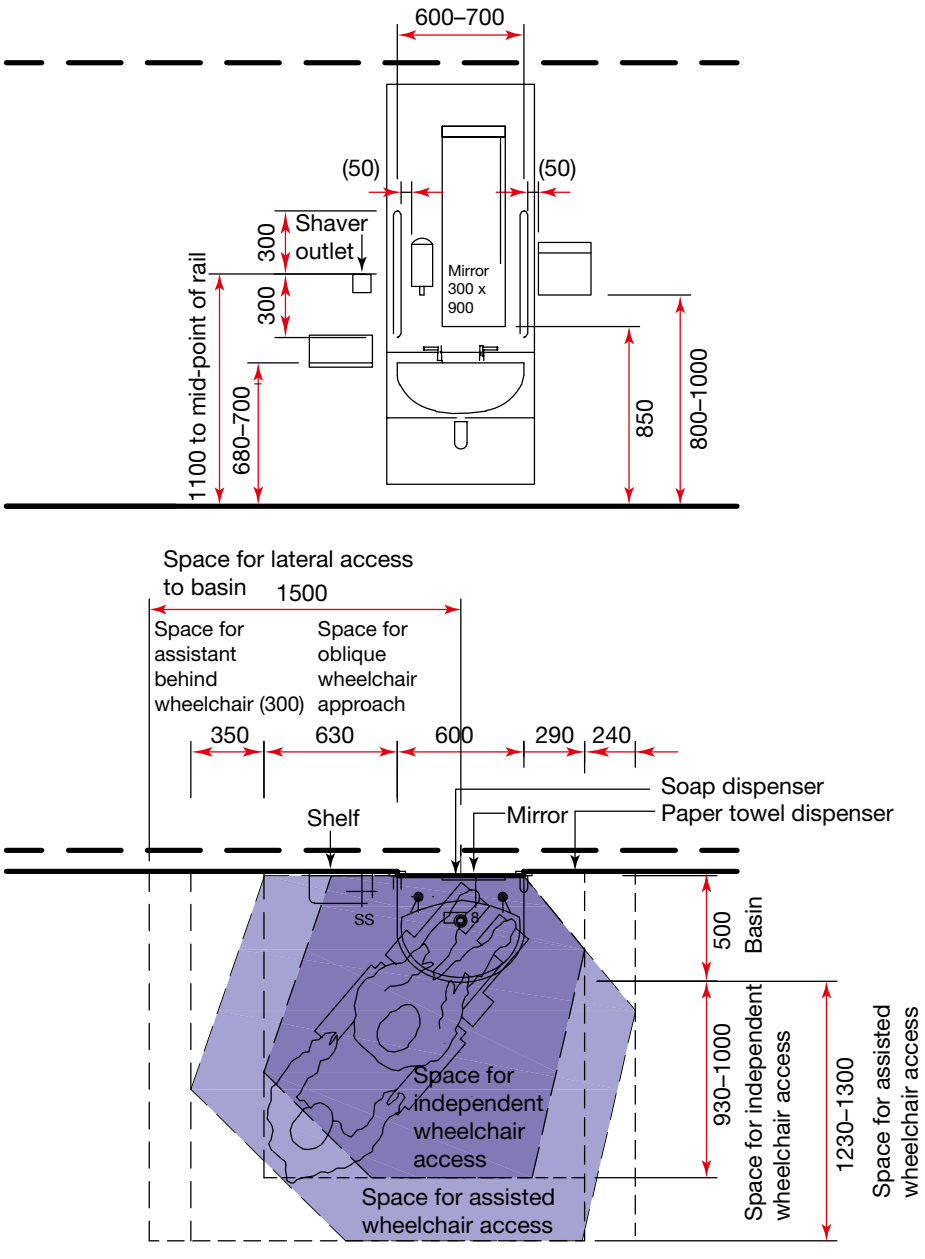


Figure 81 Space requirements for wheelchair accessible wash-hand basin

Full-length mirror: standing or seated users

5.25 This ergonomic drawing (see Figure 82) shows the space requirements for a full-length mirror for standing or seated users.

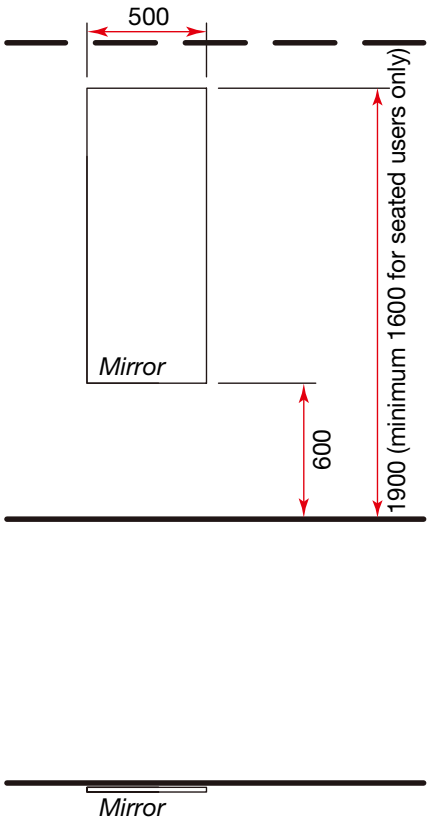


Figure 82 Space requirements for full-length mirror standing or seated users

WC: independent wheelchair/semi-ambulant

Room description and layout

5.26 The following activities take place in independent wheelchair/semi-ambulant WCs:

- wheelchair access to the toilet and hand-rinse basin;
- independent transfer from a wheelchair to the toilet;
- use of the toilet;
- disposal of sanitary towels and wipes;
- emptying of urine bottles/colostomy bags;
- hand-rinsing (whilst in a wheelchair facing the hand-rinse basin or seated on the toilet);
- personal washing (for semi-ambulant users).

5.27 An independent wheelchair/semi-ambulant WC should be provided where it is the only WC within an area. See BS 8300 (paragraph 12.6.1) and Approved Document M (paragraph 5.10e).

5.28 Wheelchair users need to be able to rinse and dry their hands from a seated position on the toilet before transferring back onto their wheelchairs (to avoid the possibility of staining clothes or wheelchairs and to assist with infection control). This is only possible with a corner toilet with an adjacent hand-rinse basin.

5.29 To facilitate good access to the hand-rinse basin from the toilet, the mixer tap should be positioned on the side of the hand-rinse basin nearest to the toilet. Left or right-handed tap hole hand-rinse basins may be required depending on the layout of facilities.

5.30 The flush system should be located on the open (transfer) side of the toilet to ensure it is easily reachable by a wheelchair user facing the toilet.

5.31 The layout (see Figure 83) allows for right-hand independent wheelchair transfer to the toilet.

5.32 It includes a separate ambulant wash-hand basin for semi-ambulant users.

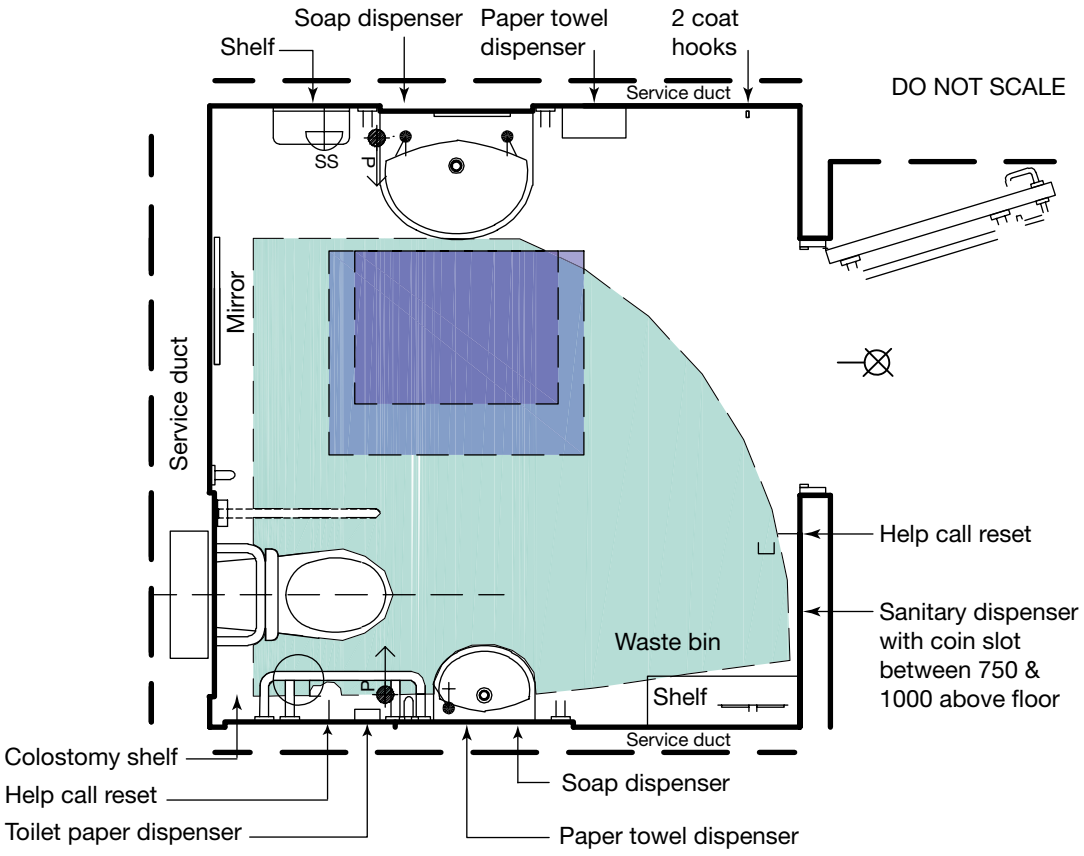


Figure 83 Space requirements for WC: independent wheelchair/semi-ambulant use with right-hand independent wheelchair transfer

Ergonomic drawings

Toilet and adjacent hand-rinse basin: independent wheelchair

5.33 This ergonomic drawing (see Figure 84) shows the space requirements for an independent wheelchair toilet and adjacent hand-rinse basin.

5.34 The recommended clear space in front and to the open side of the toilet (for independent wheelchair transfer) is greater than the recommendations in Approved Document M and BS 8300.

5.35 Approved Document M and BS 8300 recommend a minimum clear distance of 1000 mm to the open side of the centreline of the toilet for independent wheelchair transfer. Robert Feeney Associates (RFA) research for BS 8300 indicates that this will allow just over 60% of wheelchair users to comfortably transfer onto the toilet. The same research indicates that a clear space of 1400 mm accommodates 90% of wheelchair users and this is, therefore, recommended.

5.36 Approved Document M and BS 8300 recommend a 750 mm long toilet pan for independent wheelchair transfer. However, RFA research indicated that a 700 mm long toilet pan allows independent wheelchair transfer. For maximum space efficiency a 700 mm pan is recommended.

5.37 As a consequence of the reduction in pan length, the hand-rinse basin is located closer to the corner of the room than the position given in Approved Document M and BS 8300, to allow hand-rinsing from a seated position on the toilet.

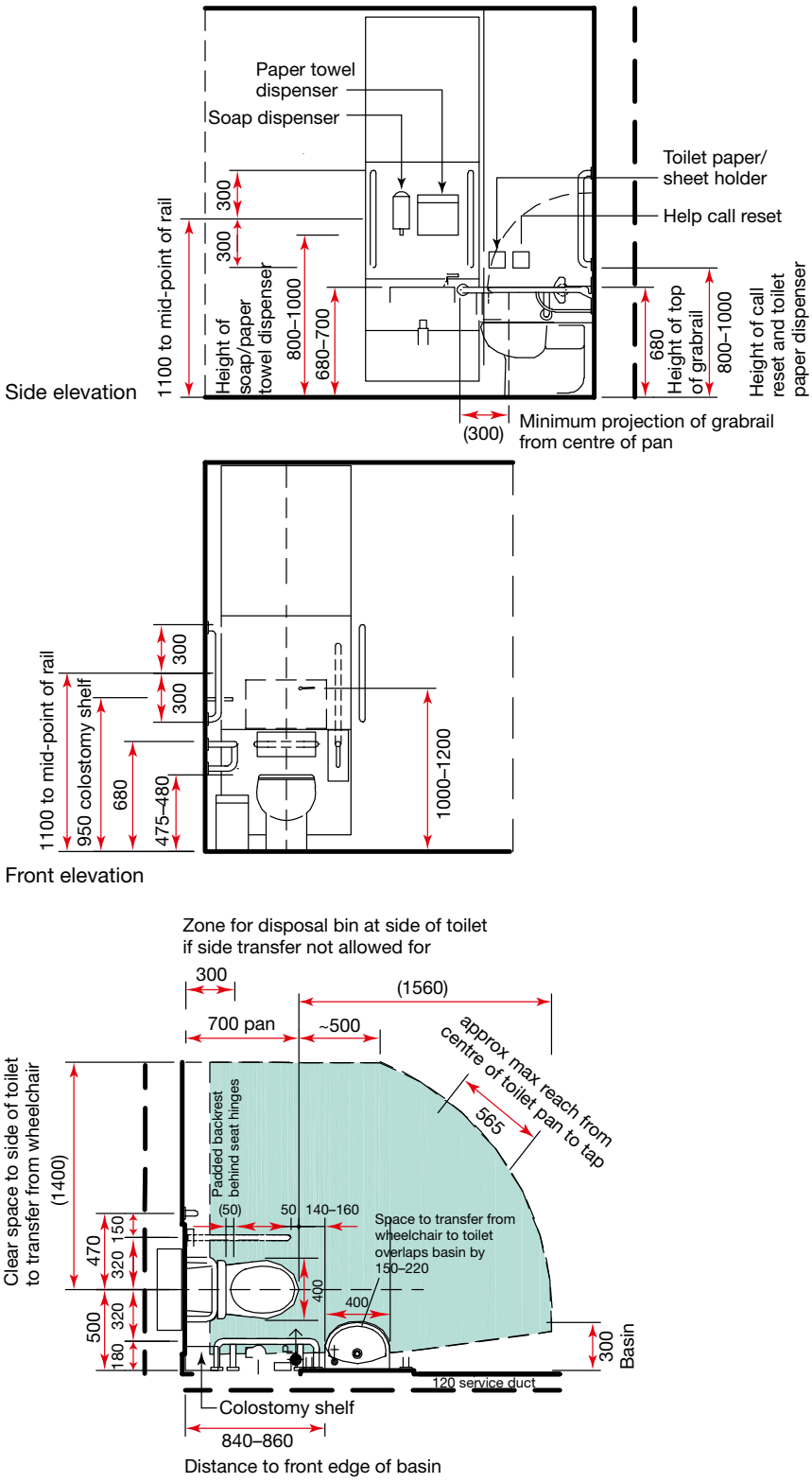


Figure 84 Space requirements for an independent wheelchair toilet and adjacent hand-rinse basin

Toilet and adjacent hand-rinse basin: independent wheelchair: grabrail options

5.38 These ergonomic drawings (see Figure 85) show the fixing position of grabrails for an independent wheelchair toilet and adjacent hand-rinse basin.

5.39 Grabrails should be provided symmetrically on either side of the toilet at 320 mm from the centreline of the toilet pan. This conflicts with the recommendations in Approved Document M and BS 8300.

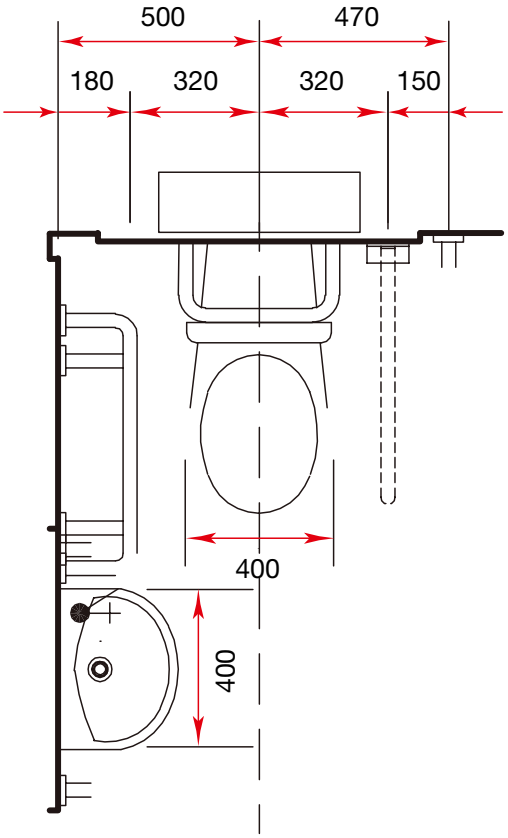
5.40 Approved Document M (paragraph 5.10j) states: "where the horizontal support rail on the wall adjacent to the toilet is set with the minimum spacing from the wall, an additional dropdown rail should be provided on the wall side at a distance of 320 mm from the centreline of the toilet."

Note

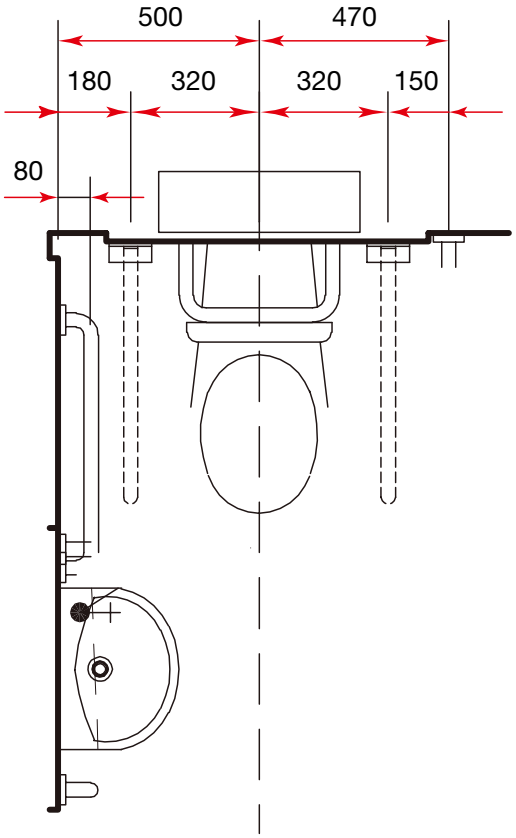
Where the maximum spacing defined in Approved Document M, 85 mm, is used, this positions the grabrail approximately 390 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

5.41 BS 8300 (paragraph 12.6.3.5 b) states: "A fixed horizontal rail should be located on the side wall with a 50 mm to 60 mm clearance between the rail and the wall." This places the rail approximately 420 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

5.42 The ergonomic drawings provided illustrate two options for the provision of grabrails. The room layouts on this website are based on option one.



Fixed grabrail between toilet and wall



Alternative fixed and hinged grabrail between toilet and wall

Figure 85 Space requirements showing fixing position of grabrails for independent wheelchair toilet and adjacent hand-rinse basin

Wash-hand basin: ambulant

5.43 Wash-hand basins may be used for personal washing activities.

5.44 This ergonomic drawing (see Figure 86) shows the space requirements for ambulant/ semi-ambulant use of a 400 mm deep × 500 mm wide wash-hand basin.

5.45 It includes a shaver socket adjacent to the wash-hand basin and a light above the mirror; these are optional. The inclusion of a shaver socket depends on project requirements. The need for a local light depends on the overall lighting scheme within the room.

5.46 The drawing also shows two short lever taps. Alternatively a single mixer tap or sensor-operated taps may be used. See Health Building Note 00-10 Part C – 'Sanitary assemblies' for details.

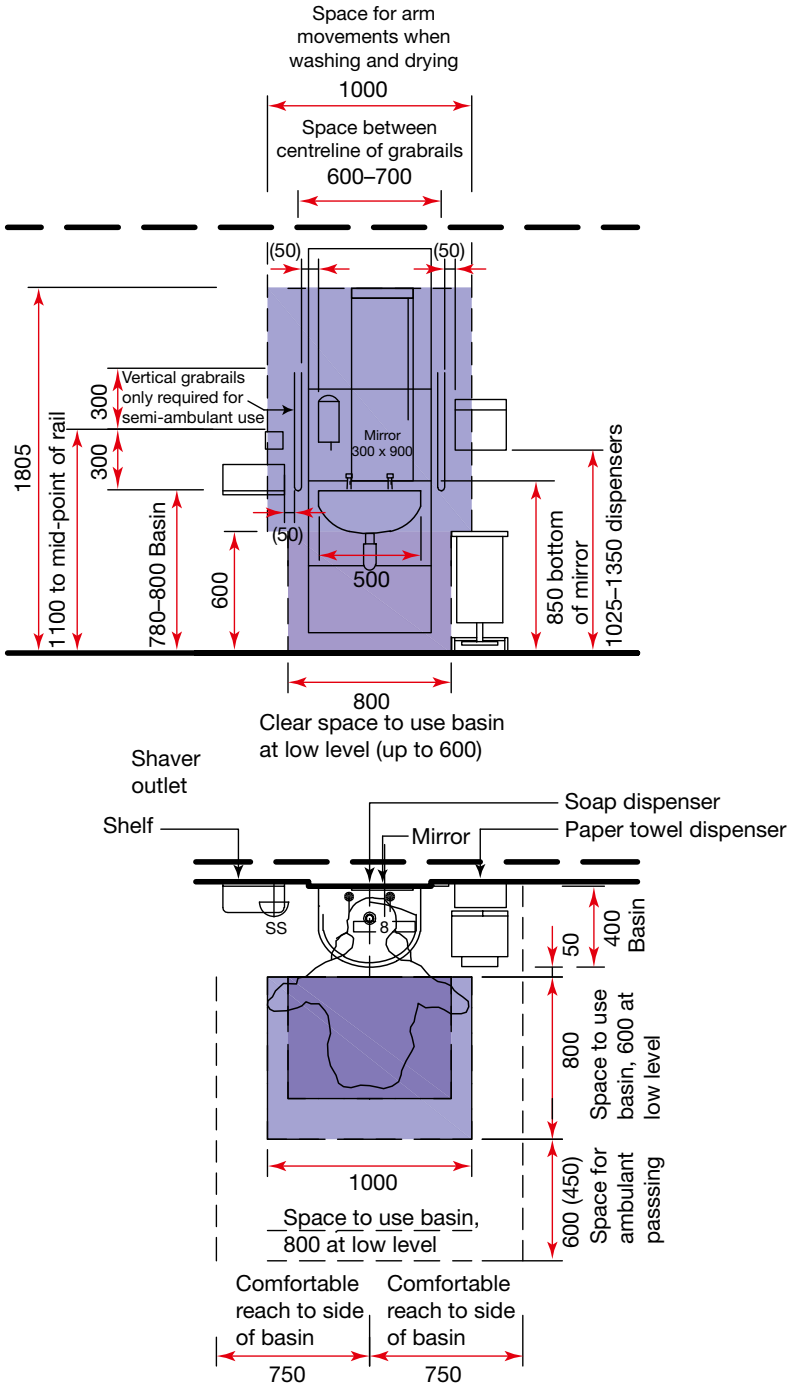


Figure 86 Space requirements for ambulant/semi-ambulant use of 400 mm deep x 500 mm wide wash-hand basin

Full-length mirror: standing or seated users

5.47 This ergonomic drawing (see Figure 87) shows the space requirements for a full-length mirror for standing or seated users.

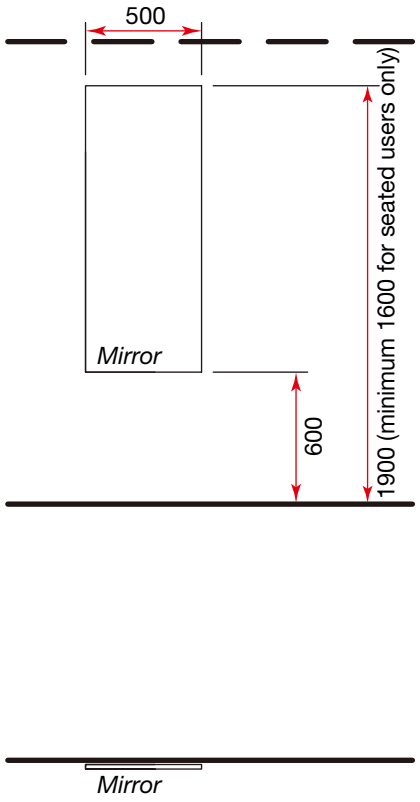


Figure 87 Space requirements for full-length mirror for standing or seated users

WC: Semi-ambulant

Room description and layout

5.48 The following activities take place in a semi-ambulant WC (see Figure 88):

- use of the toilet;
- disposal of sanitary towels (optional);
- hand-rinsing.

5.49 Semi-ambulant WCs are also suitable for fully ambulant users.

5.50 The semi-ambulant WC layout includes a hand-rinse basin.

5.51 A space allocation for luggage has been included to provide room for belongings/ bags to be comfortably taken into the WC for security.

5.52 The minimum clear width is 900 mm. While 1000 mm is preferred for movement with walking aids, 900 mm is considered acceptable since there is additional space above and below the basin for movement.

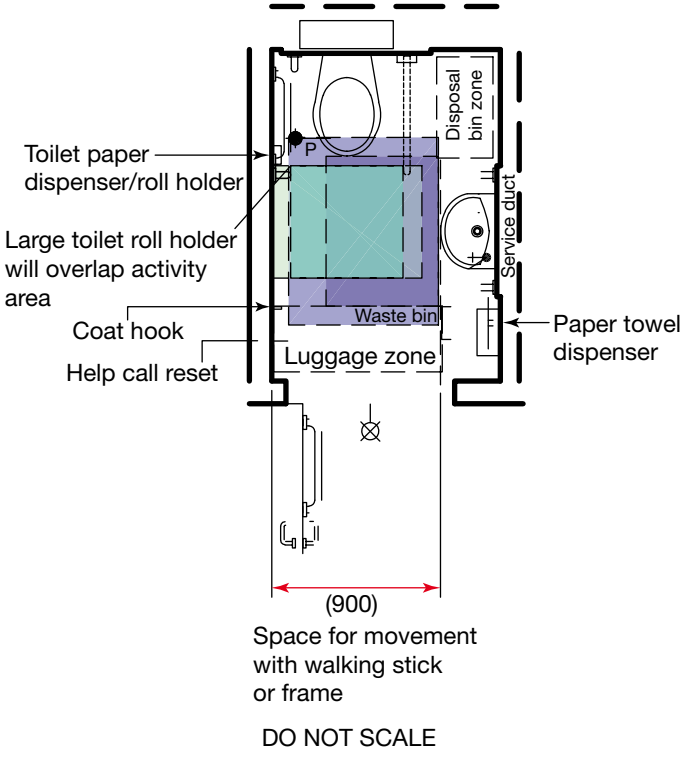


Figure 88 WC: semi-ambulant

Ergonomic drawings

5.53 The ergonomic drawings (see Figure 89) show the space requirements for a semi-ambulant WC and hand-rinse basin.

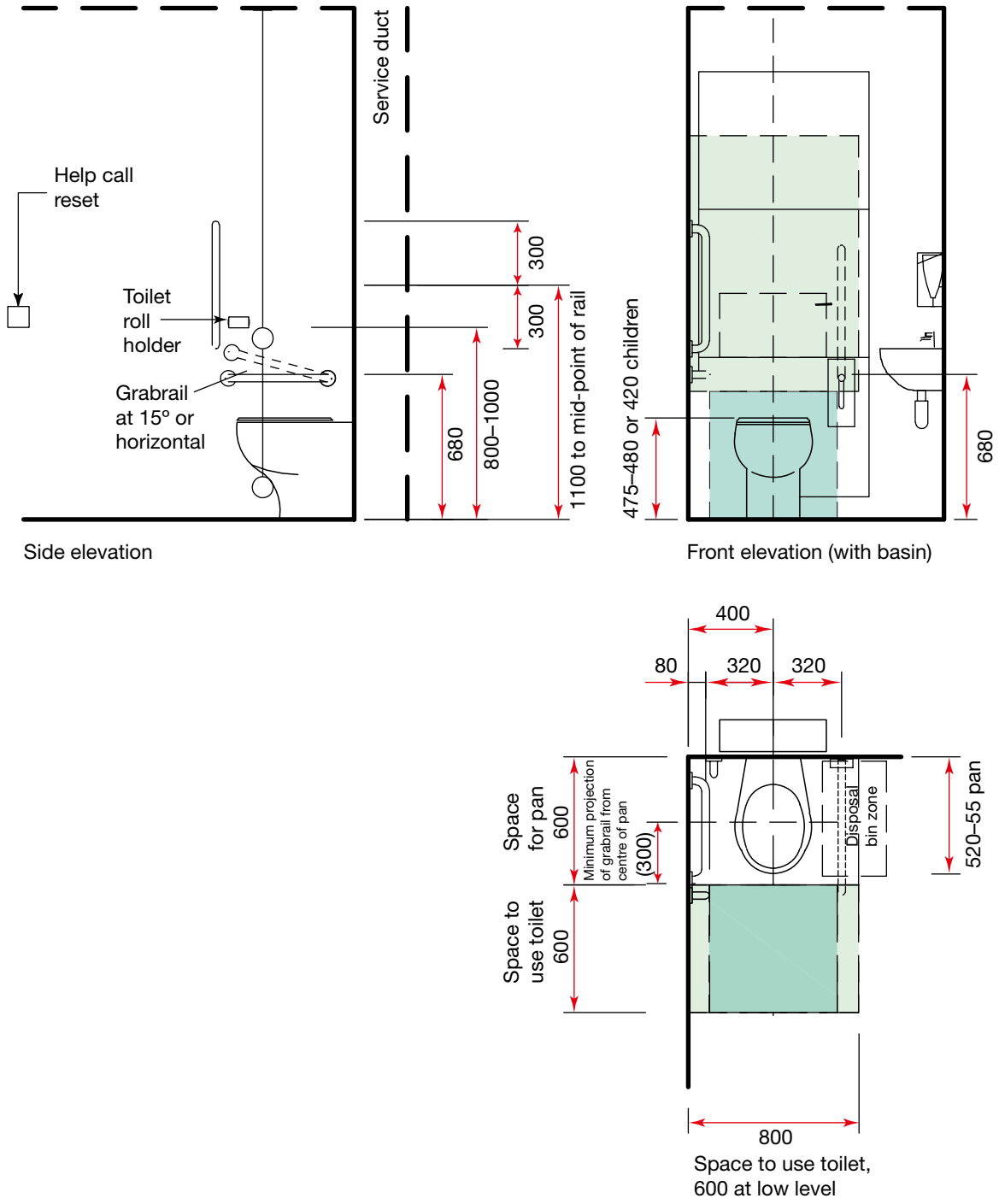


Figure 89 Space requirements for semi-ambulant toilet and adjacent hand-rinse basin

WC: independent wheelchair

Room description and layout

5.54 The following activities take place in independent wheelchair WCs:

- wheelchair access to the toilet and hand-rinse basin;
- independent transfer from a wheelchair to the toilet;
- use of the toilet;
- disposal of sanitary towels and wipes;
- emptying of urine bottles/colostomy bags;
- hand-rinsing (whilst in a wheelchair facing the hand-rinse basin or seated on the toilet).

5.55 Users need to be able to rinse and dry their hands from a seated position on the toilet before transferring back onto their wheelchairs (to avoid the possibility of staining clothes or wheelchairs and to assist with infection control). This is only possible with a corner toilet with an adjacent hand-rinse basin.

5.56 To facilitate good access to the hand-rinse basin from the toilet, the mixer tap should be positioned on the side of the hand-rinse basin nearest to the toilet. Left or right-handed tap hole hand-rinse basins may be required depending on the layout of facilities.

5.57 The flush system should be located on the open (transfer) side of the toilet to ensure it is easily reachable by a wheelchair user facing the toilet.

5.58 Independent wheelchair WCs are also suitable for semi-ambulant users with, or without, “hands-off assistance” who may wish to sit down to wash their hands.

5.59 The room layout provided is larger than the equivalent space in Approved Document M and BS 8300.

5.60 Approved Document M and BS 8300 recommend a minimum room length of 2200 mm for independent wheelchair WCs. Robert Feeney Associates research for BS 8300 indicates that a clear space of 1600 (1560) mm in front of the toilet is required for transfer. This equates to a minimum room length of 2300 (2260) mm (using a 700 mm long toilet pan) and is recommended.

5.61 The room layout (see Figure 90) allows right-hand transfer to the toilet. Where more than one independent wheelchair WC is provided within a facility, left-hand and right-hand options should be available. See Approved Document M, paragraph 5.10d.

5.62 The disposal bin adjacent to the toilet should be a maximum of 200 mm wide and 480 mm high and capable of being operated with one hand.

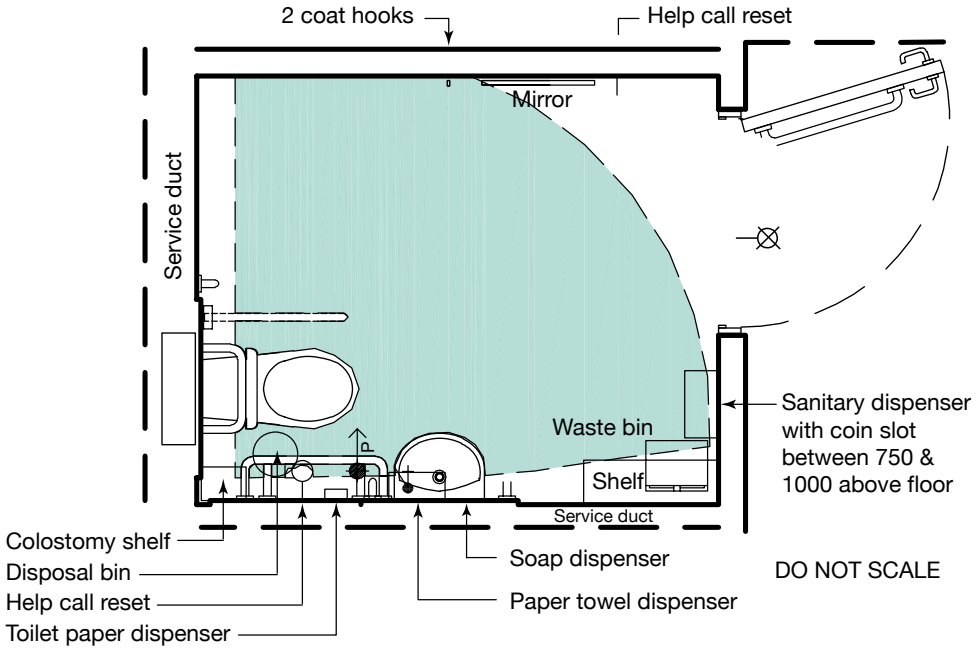


Figure 90 Space requirement for WC: independent wheelchair with right-hand transfer to toilet

Ergonomic drawings

Toilet and adjacent hand-rinse basin: independent wheelchair

5.63 This ergonomic drawing (see Figure 91) shows the space requirements for an independent wheelchair toilet and adjacent hand-rinse basin.

5.64 The recommended clear space in front and to the open side of the toilet (for independent wheelchair transfer) is greater than the recommendations in Approved Document M and BS 8300.

5.65 Approved Document M and BS 8300 recommend a minimum clear distance of 1000 mm to the open side of the centreline of the toilet for independent wheelchair transfer. Robert Feeney Associates (RFA) research for BS 8300 indicates that this will allow just over 60% of wheelchair users to comfortably transfer onto the toilet. The same research indicates that a clear space of 1400 mm accommodates 90% of wheelchair users and this is, therefore, recommended.

5.66 Approved Document M and BS 8300 recommend a 750 mm long toilet pan for independent wheelchair transfer. However, RFA research indicated that a 700 mm long toilet pan allows independent wheelchair transfer. For maximum space efficiency a 700 mm pan is recommended.

5.67 As a consequence of the reduction in pan length, the hand-rinse basin is located closer to the corner of the room than the position given in Approved Document M and BS 8300, to allow hand-rinsing from a seated position on the toilet.

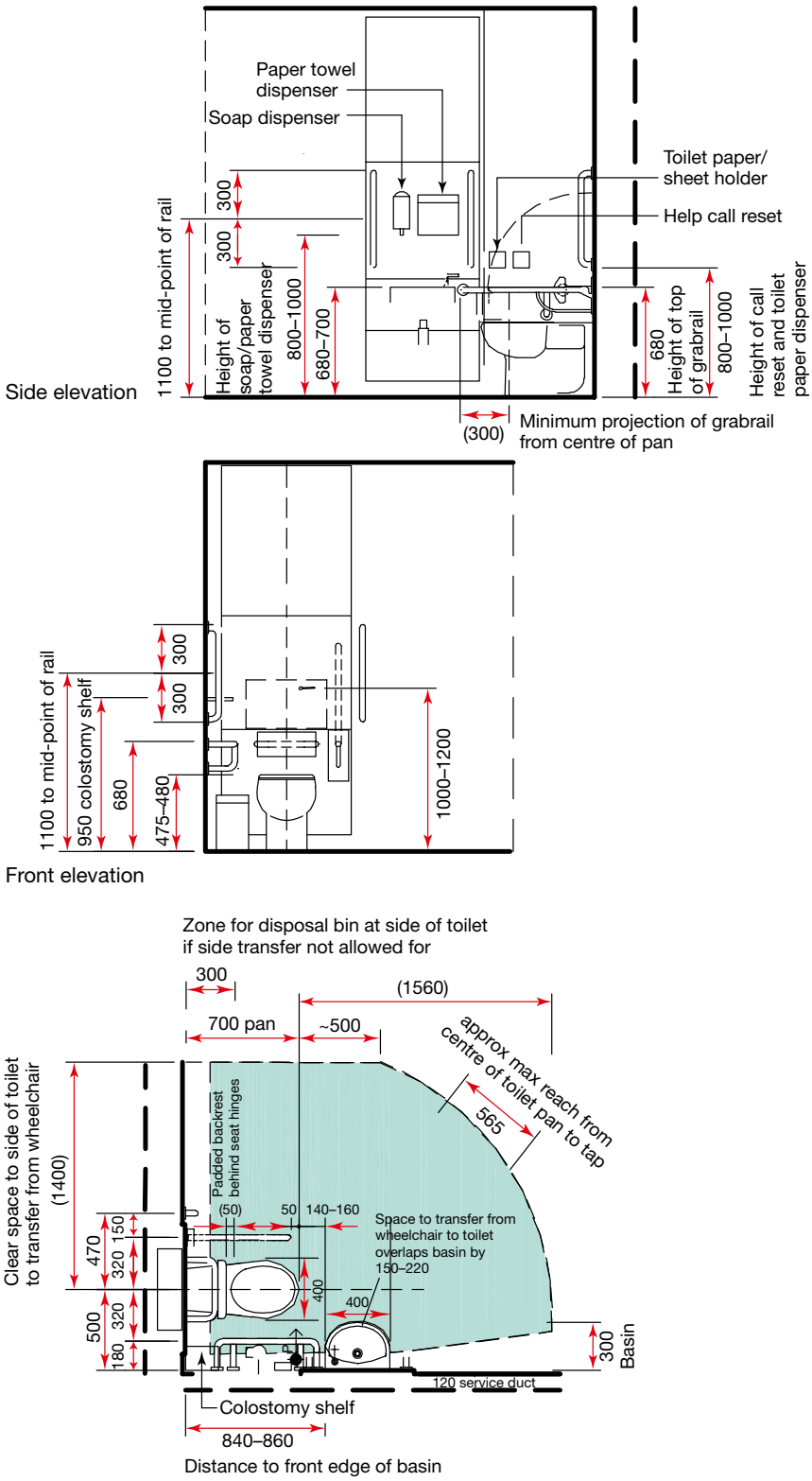


Figure 91 Space requirements for independent wheelchair toilet and adjacent hand-rinse basin

Toilet and adjacent hand-rinse basin: independent wheelchair: grabrail options

5.68 These ergonomic drawings (see Figure 92) show the fixing position of grabrails for an independent wheelchair toilet and adjacent hand-rinse basin.

5.69 Grabrails should be provided symmetrically on either side of the toilet at 320 mm from the centreline of the toilet pan. This conflicts with the recommendations in Approved Document M and BS 8300.

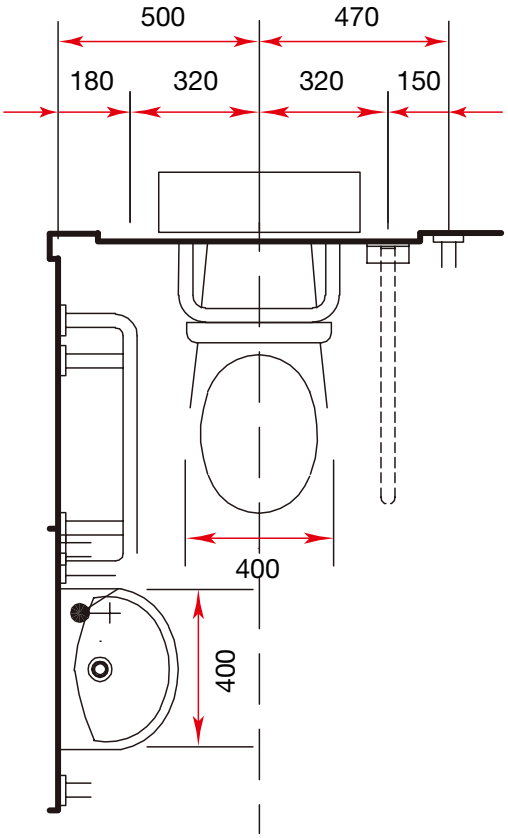
5.70 Approved Document M (paragraph 5.10j) states: "where the horizontal support rail on the wall adjacent to the toilet is set with the minimum spacing from the wall, an additional dropdown rail should be provided on the wall side at a distance of 320 mm from the centreline of the toilet."

Note

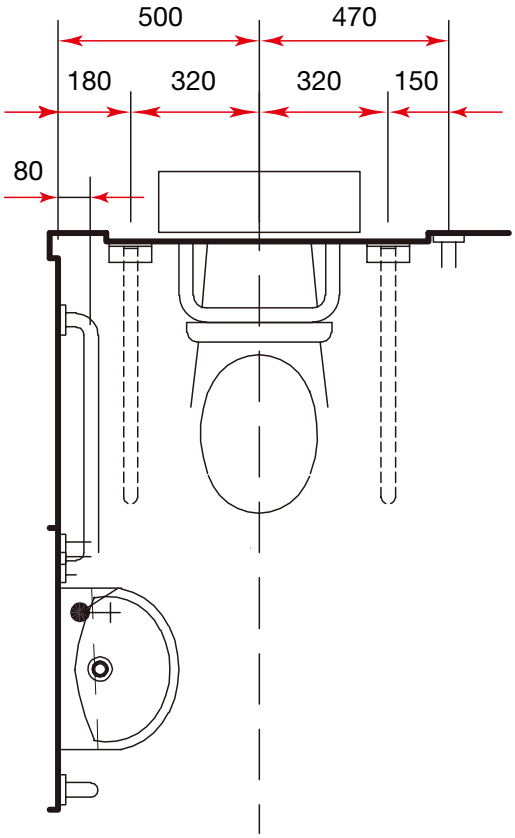
Where the maximum spacing defined in Approved Document M, 85 mm, is used, this positions the grabrail approximately 390 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

5.71 BS 8300 (paragraph 12.6.3.5 b) states: "A fixed horizontal rail should be located on the side wall with a 50 mm to 60 mm clearance between the rail and the wall." This places the rail approximately 420 mm from the centreline of the toilet, which is not symmetrical with the hinged grabrail on the other side.

5.72 The ergonomic drawings provided illustrate two options for the provision of grabrails. The room layouts on this website are based on option one.



Fixed grabrail between toilet and wall



Alternative fixed and hinged grabrail between toilet and wall

Figure 92 Space requirements showing fixing position of grabrails for independent wheelchair toilet and adjacent hand-rinse basin

Full-length mirror: standing or seated users

5.73 This ergonomic drawing (see Figure 93) shows the space requirements for a full-length mirror for standing or seated users.

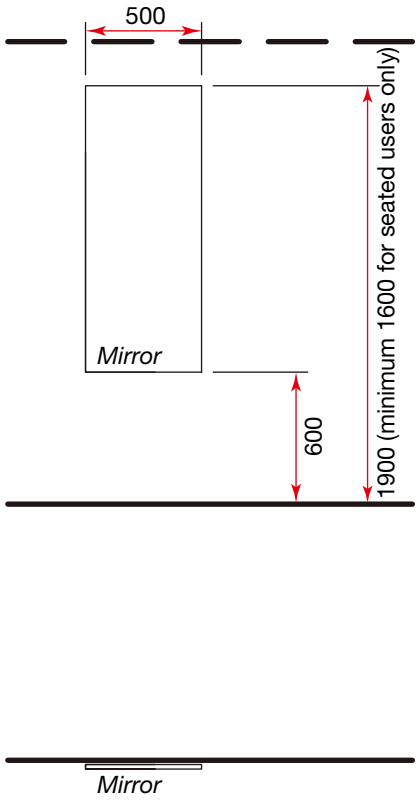


Figure 93 Space requirements for full-length mirror for standing or seated users

WC: 'Changing Places'[1]

Room description and layout

5.74 The following activities take place in a 'Changing Places' toilet:

- wheelchair access to the changing table, toilet and hand-rinse basin;
- transfer from a wheelchair to the toilet or changing table;
- use of the toilet;
- use of a hoist;
- changing older children/adults with continence problems;
- disposal of soiled nappies/continence pads;
- hand rinsing;
- personal washing.

5.75 'Changing Places' toilets provide the right equipment, including a changing bench and hoist, to support disabled people who cannot use standard accessible toilets. The range of people who might use a 'Changing Places' toilet includes:

- people with profound and multiple learning disabilities;
- people with conditions that may affect their movement, including cerebral palsy, multiple sclerosis, motor neurone disease;
- people with head injuries or severe spinal injuries;
- people living with stroke;
- older people who require assistance.

5.76 Where provided, they should be in public areas for ease of access to everyone who needs to use them.

5.77 Comprehensive guidance on the design and equipment which should be provided in these toilets together with advice on health and safety and day-to-day operational management is available in:

- 'Changing Places: the practical guide', published by the Changes Places Consortium and available as a download from http://changing-places.org/; and
- BS 8300:2009, Design of buildings and their approaches to meet the needs of disabled people – Code of practice.

[1] The Changing Places Consortium launched its campaign in 2006 on behalf of people who cannot use standard accessible toilets. To use the toilet in safety and comfort, many people need to be able to access a 'Changing Places' toilet. See http://www.changing-places.org/ for details.

References

Health Building Note 00-10 Part C – 'Sanitary assemblies'.

Changing Places website.

Approved Document M (2010).

BS 8300:2009.

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Scottish Health Technical Memorandum 2010

(Part 1 of 6)

Overview and management responsibilities

Sterilization

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NHSScotland, P&EFEx, June 2001

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1. Sterilization and the role of management

Introduction

"The fundamental cause of this disaster is to be found in human failings ranging from simple carelessness to poor management of men and plant. The Committee heard of no imminent technological advance in the field of production of intravenous fluids which will eliminate the need for skilful men devoted to their work ... Too many people believe that sterilization of fluids is easily achieved with simple plant operated by men of little skill under a minimum of supervision ... Public safety in this, as in many other technological fields, depends ultimately on untiring vigilance ... "

1.1 The quotation above comes from the principal conclusions of the committee chaired by Sir Cecil Clothier and appointed to investigate an incident in which five patients died as a result of a faulty sterilizer. The tragedy led to a thorough overhaul of the methods of managing sterilizers, among which was the revision of Health Technical Memorandum 2010 (then HTM 10), the last edition of which was published in 1980.

1.2 No disaster on a comparable scale has been reported since. Nonetheless, both the law and public opinion are now less forgiving of lapses than they were two decades ago. Tighter statutory control, resulting from new European Union (EU) Directives, will soon extend to almost every aspect of sterilization, and practices which were common a few years ago will no longer be acceptable or even lawful.

1.3 The science and art of sterilization are complex and subtle. The testing, maintenance and reporting procedures described in this SHTM may seem excessive to some, but they are based upon good practice in both the UK and Europe, as formalised in European Standards designed to support the new EU Directives.

The European Union Directives on medical devices

1.4 Until now, statutory controls on the practice of sterilization, other than in the manufacture of medical products, have been few. The major Acts and Regulations which are likely to affect the management of a sterilizer are described in Chapter 3, but specific references to sterilization in the legislation were rare. This has changed as a series of three EU Directives came into effect regulating the safety, quality and effectiveness of medical devices.

1.5 This section summarises basic information about the Directives. Further details are available from the Medical Devices Agency of the Department of Health, England, which has a UK remit.

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Definition of medical device

1.6 The Directives define a medical device as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:

a. diagnosis, prevention, monitoring, treatment or alleviation of disease;

b. diagnosis, monitoring, treatment, alleviation or compensation of an injury or handicap;

c. investigation, replacement or modification of the anatomy or of a physiological process;

d. control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Council Directive 93/42/EEC).

1.7 The Directives apply equally to “accessories”. An accessory is defined as “an article which, whilst not being a device, is intended specifically by its manufacturers to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device”.

The three Directives

1.8 The three EU directives are as follows:

a. the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC) covers all powered implants or partial implants that are left in the human body. (Heart pacemakers are the most common example of powered implants.) The directive was adopted by the EU council on 20 June 1990 and came into effect in the UK on 1 January 1993 as the Active Implantable Devices Regulations 1992 (see paragraph 3.32);

b. the Medical Devices Directive (Council Directive 93/42/EEC) covers most other medical devices ranging from first aid bandages and tongue depressors through to hip prostheses and will therefore have a wide impact on sterilization. The directive was adopted by the EU council on 14 June 1993. It came into effect on 1 January 1995;

c. the In Vitro Diagnostic Medical Devices Regulations 2000 (SI 1315) implements the council directive 98/79/EC and covers any medical device, reagent product, kit, instrument, apparatus or system which is intended to be used in vitro for the examination of substances derived from the human body. Some examples of in-vitro diagnostic devices are blood group reagents, pregnancy test kits, and hepatitis B test kits.

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The regulatory framework

1.9 The Directives set out the essential requirements that devices must not compromise the health or safety of the patient, user or any other person and that any risks associated with the device are compatible with patient health and protection. Any side-effects must be acceptable when weighed against the intended performance.

1.10 Devices meeting these requirements will be entitled to carry the “CE” marking, signifying that the device satisfies the requirements essential for it to be fit for its intended purpose. All devices except custom-made devices and devices intended for clinical trials, (“investigations” in the directive), whether used in public-sector or private-sector hospitals and nursing homes, or sold in retail outlets, will have to carry the “CE” marking.

1.11 Adoption of the Directives has meant that the UK’s voluntary system of manufacturer registration and product approval for controlling certain medical devices used by the NHS has been replaced by a more comprehensive statutory system covering all devices used in the UK. The Medical Devices Agency (MDA) of the Department of Health, is the competent authority to carry out the requirements of the Directives in the UK. The main role of the MDA is to ensure compliance with the UK regulations, evaluate vigilance reports received from manufacturers, and carry out a preclinical assessment of devices intended for clinical investigation. The MDA is also responsible for approving the independent certification organisations (the notified bodies) that will check and prove that defined classes of medical devices meet the essential requirements and thus enable manufacturers to apply the “CE” marking to their products.

1.12 The Medical Devices Directive includes a classification system whereby the level of regulatory control applied to devices is proportional to the degree of risk inherent in the device. The strictest controls will therefore only apply to the limited number of high-risk products.

Impact on sterilization

1.13 Managers who ensure that their machines and procedures comply with the guidance in this SHTM should have no difficulty in complying with the Medical Devices Directive.

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Summary of management responsibilities

1.14 SHTM 2010 will assist managers and other personnel to ensure that sterilizers are operated safely and effectively and in compliance with existing and anticipated legislation and standards. To this end, the major responsibilities of management can be summarised as follows:

a. to ensure that sterilization is carried out in compliance with the law and policy of the Scottish Executive Health Department;

b. to ensure that all personnel connected with sterilization, whether NHS employees or contract personnel, are suitably qualified and trained for their responsibilities;

c. to ensure that purchased sterilizers conform to legal requirements, the minimum specifications set out in British and European standards, and any additional requirements of the Scottish Executive Health Department

d. to ensure that sterilizers are installed correctly and safely with regard to proper functioning, safety of personnel and environmental protection;

e. to ensure that newly installed sterilizers are subject to a documented scheme of validation comprising installation checks and tests, commissioning tests and performance qualification tests before they are put into service;

f. to ensure that sterilizers are subject to a documented scheme of periodic tests at yearly, quarterly, weekly and (in some cases) daily intervals;

g. to ensure that sterilizers are subject to a documented scheme of preventative maintenance;

h. to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice;

i. to ensure that procedures for dealing with malfunctions, accidents and dangerous occurrences are documented and adhered to.

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2. Sterilizers – an overview

Introduction

2.1 This Scottish Health Technical Memorandum groups sterilizers into two broad categories according to their use:

a. **clinical sterilizers** are designed to process medical devices, medicinal products and other goods and materials that are used in the clinical care of patients;

b. **laboratory sterilizers** are designed to process goods and materials and are not directly used in the clinical care of patients.

2.2 Their operation should be kept strictly separate. Loads intended for processing in a clinical sterilizer should not be put into a laboratory sterilizer, and vice-versa.

2.3 Sterilizers can also be classified according to the sterilizing agent (the sterilant) used:

a. high-temperature steam;

b. low-temperature steam and formaldehyde;

c. ethylene oxide.

2.4 High-temperature steam is the sterilant of choice because of its superior performance. Machines using other sterilants should be reserved either for loads which would be damaged by exposure to high-temperature steam (such as certain surgical devices) or for loads that would not be sterilized by exposure to high-temperature steam (such as certain non-aqueous fluids).

2.5 Clinical sterilizers are available employing any one of the four sterilants. The laboratory sterilizers described in this SHTM use only high-temperature steam.

2.6 Guidance on selection and specification, operational management, validation and verification is given in the other parts of this SHTM.

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Clinical sterilizers using high-temperature steam

2.7 These are by far the most common sterilizers used in the NHS, and are manufactured in three basic types according to the nature of load they are designed to process: porous loads, fluids, or unwrapped instruments and utensils. The operating cycles are designed to cope with the differing properties of the various types of load. It is essential that a sterilizer is used only for the type of load for which it is designed.

2.8 High-temperature steam inactivates pathogens by a combination of moisture and heat. The process is well understood and the attainment of sterilization conditions can normally be confirmed by simple physical measurements. (This is not so for sterilizers using chemical sterilants, where microbiological test procedures are necessary.)

2.9 High-temperature steam sterilizers are large machines requiring permanently installed engineering services (including good-quality steam) and purpose-built accommodation. Some smaller models are transportable and generate steam from an internal reservoir.

Porous loads

2.10 Clinical sterilizers using high-temperature steam to process porous loads are commonly known as “porous load sterilizers”. They are intended to deal with porous items such as towels, gowns and dressings; and medical and surgical equipment, instruments and utensils packaged or wrapped in porous materials such as paper or fabrics.

2.11 Sterilization is achieved by direct contact of the load items with good-quality saturated steam at a preferred sterilization temperature of 134°C.

2.12 As porous loads trap both air and moisture, an efficient and reliable air removal system is essential. An air detector is fitted to ensure that the operating cycle does not proceed until sufficient air and other non-condensable gases have been removed from the chamber and load. The correct functioning of the air detector is crucial to the performance of the sterilizer.

Fluids

2.13 Clinical sterilizers using high-temperature steam to process aqueous fluids are commonly known as “fluids sterilizers”. They are used to sterilize fluids in sealed containers (normally bottles) of either glass or plastic. They operated at a preferred sterilization temperature of 121°C.

2.14 Fluids in glass containers can be hazardous. At a temperature of 121°C the pressure inside a one-litre bottle having a normal fill of fluid is approximately 4 bar. If the door were to be opened at this temperature, and the load

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exposed to ambient air, the thermal stresses arising in the glass would be sufficient to crack the bottle and cause an explosion. A temperature of 80°C is regarded as a safe maximum at which the door can be opened (even at this temperature the pressure inside a one-litre bottle is still 1.8 bar). Fluid sterilizers are fitted with a thermal door-lock to ensure that when glass containers are being processed the door cannot be opened until the temperature inside all the containers has fallen below 80°C. Failure to observe this requirement has led to serious accidents resulting from the explosion of glass containers.

2.15 Fluids in plastic containers present less of a hazard. Operating cycles for plastic containers allow the door to be opened when the temperature inside the containers falls below 90°C.

Unwrapped instruments and utensils

2.16 This type of sterilizer is used to process unwrapped surgical components intended for immediate use. Sterilization is achieved by the direct contact of the component with saturated steam at a preferred sterilization temperature of 134°C.

2.17 These sterilizers should not be used to process wrapped instruments and utensils, where the wrapping could inhibit the removal of air and the penetration of steam. Neither should they be used for unwrapped instruments and utensils with narrow lumens, where air removal and steam penetration would similarly be impaired.

2.18 Since the sterilized instruments and utensils are exposed to the air on being removed from the chamber, they are susceptible to immediate recontamination. These sterilizers are therefore suitable for clinical use only within the immediate environment in which the instruments are to be used. Wherever possible, instruments and utensils should be wrapped and processed in a porous load sterilizer.

2.19 Transportable (bench-top) models are electrically heated, requiring only a 13 Amp socket-outlet and no piped services. They are commonly used in theatre suites where there is no central supply service and in primary healthcare units such as general practitioners' and dentists' surgeries.

Clinical sterilizers using hot air

2.20 Clinical sterilizers using hot air as a sterilant are correctly known as "dry-heat sterilizers", and sometimes as "hot-air sterilizers" or "sterilizing ovens". They are intended to process materials such as oils, powders and some ophthalmic instruments, which can withstand high temperatures but are likely to be damaged or not sterilized by contact with steam. They operate at a preferred sterilization temperature of 160°C.

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2.21 They are not suitable for use as drying cabinets (see BS 2648 for specifications for drying cabinets).

2.22 Dry-heat sterilizers are essentially electric ovens and are therefore simpler than the other pressure sterilizers described in this SHTM. A filter and fan are used to maintain the chamber slightly above atmospheric pressure to ensure that the sterility of the product and the integrity of the clean-room environment are not compromised. Although the cycle is under automatic control, the operator is allowed considerable freedom in selecting the required combination of sterilization temperature and time. Recommended combinations are shown in Table 2.1 and advice on their selection is given in Part 4 of this SHTM.

2.23 Dry-heat sterilizers are not efficient. It is difficult to obtain an even temperature distribution within the chamber, air circulation is inhibited when the chamber is full (even with a circulating fan), and heat transfer from the air to the load can be very slow. A complete cycle, including cooling to 80°C, takes approximately eight hours for a full test load as described in Part 3 of this SHTM. If this time is unacceptable, a sterilizer fitted with assisted cooling is recommended, reducing the cycle time for the same load to approximately five hours.

Clinical sterilizers using low-temperature steam and formaldehyde

2.24 Heat-sensitive materials (wrapped or unwrapped) which will withstand saturated steam at temperatures up to 80°C are normally processed in either low-temperature steam disinfectors (“LTS disinfectors”) or low-temperature steam and formaldehyde sterilizers (“LTSF sterilizers”). Sterilizers designed for LTSF will normally incorporate an LTS disinfection cycle.

2.25 Disinfection is achieved by the direct contact of the load with saturated steam at a minimum temperature of 71°C at sub-atmospheric pressure. Sterilization is achieved by contact with both saturated steam and formaldehyde gas. Either process may also be used to decontaminate soiled surgical components before they are washed and reprocessed.

2.26 Formaldehyde is a toxic gas. Part 5 of this SHTM contains safety information.

2.27 Since the sterilization process is ultimately dependent on chemical action, microbiological test methods are required to confirm that sterilization conditions have been attained.

NOTE: Despite their name, LTSF sterilizers are disinfectors.

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Clinical sterilizers using ethylene oxide

2.28 Clinical sterilizers using ethylene oxide gas as a sterilant are commonly known as “ethylene oxide sterilizers” or “EO sterilizers”.

2.29 EO sterilizers are used to process heat-sensitive materials and devices which cannot withstand low-temperature steam. They should not be used to process items which can be sterilized by alternative methods, that is, by high-temperature steam, dry heat or LTSF. They should not be used to re-sterilize items which have been sterilized by irradiation.

2.30 EO sterilizers are used extensively in industrial manufacture of sterile medical devices but are relatively uncommon in hospitals. Two classes of EO sterilizers are suitable for NHS use:

a. small sterilizers, of chamber volumes around 150 litres, where the sterilant is pure EO at sub-atmospheric pressure supplied from a disposable cartridge contained within the chamber;

b. large sterilizers, of chamber volume up to 500 litres, where the sterilant is either pure EO or EO diluted with another gas, supplied from cylinders. EO sterilizers have the potential to cause serious environmental pollution. Sterilizers using chlorofluorocarbon (CFC) gases as diluents should no longer be installed.

2.31 EO is a highly reactive liquid and gas which is toxic, flammable and explosive. The safe operation of EO sterilizers requires careful consideration of all aspects of the installation and operation of equipment.

2.32 The entire EO process is complex and requires specialised facilities for washing, packaging and preconditioning loads before processing and degassing before use. Large sterilizers will also require additional plant to dispose safely of exhaust products.

2.33 The efficacy of the process is affected by the packaging used to wrap goods for sterilization. Since the sterilization process is ultimately dependent upon chemical action, microbiological test methods are required to confirm that sterilization conditions have been attained.

2.34 Managers considering installing EO sterilizers should be aware of the following points:

a. the difficulty in validating and monitoring suitable cleaning processes for loads before they are sterilized;

b. the difficulty in carrying out representative performance qualification tests for the wide variety of loading conditions that may be used;

c. the difficulty in carrying out meaningful bioburden studies on small numbers of widely differing devices to be sterilized;

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d. the problems associated with determining the levels of residual EO and its reaction products when small numbers of widely differing devices are processed.

Laboratory sterilizers/autoclaves

2.35 Laboratory sterilizers, also known as autoclaves, are used for making-safe discard material and processing apparatus and materials to be used within clinical laboratories. They are not intended for the sterilization of medical devices or medicinal products intended for the clinical care of patients.

2.36 Unlike clinical sterilizers, the laboratory sterilizers covered in this SHTM are designed for use only with high-temperature steam. No chemical sterilants are used.

2.37 Certain common laboratory operations may be carried out more economically with specialised machines designed for the purpose, and these are described below.

Operating cycles

2.38 Laboratory sterilizers are often required to process a wide range of materials and objects, and they are equipped with one or more operating cycles each designed for a particular application. Different types of load generally require different operating cycles. Cycles are normally preset, and proceed automatically once selected and started.

2.39 The range of cycles that a sterilizer can provide will depend on details of its construction. For example, the methods used to remove air from the chamber, the means employed to cool and dry the load, and the provision of safety features.

2.40 Laboratory sterilizers may be equipped with one or more of the following operating cycles:

a. make-safe of small plastic discard;
b. make-safe of contained fluid discard;
c. sterilization of culture media;
d. disinfection of fabrics;
e. sterilization of glassware and equipment;
f. free steaming.

2.41 Guidance on the specification of operating cycles is given in Part 2 of this SHTM.

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Culture media preparator

2.42 Many of the problems which relate to sterilizing culture media can be solved by the use of small sterilizers in which the media constituents are placed directly into the chamber, thus avoiding the use of glass containers and their attendant hazards.

2.43 The machine consists of two or three modules incorporated into a system designed to provide controlled preparation, sterilization, cooling and dispensing of culture media with a minimum of attention by the operator. The system may also include a module which automatically stacks the completed culture plates.

2.44 The sterilizer module is essentially a pressure-cooker in which water and dehydrated culture media are mixed, sterilized and then cooled to below 80°C. This type of sterilizer is particularly suitable for manufacturing batches of culture media in volumes between 1 and 20 litres.

Köch steamer

2.45 A Köch steamer is designed to expose a load to steam at near-atmospheric pressure and is commonly used for melting solidified agar. Steamers are not sterilizers and the product cannot be regarded as sterile. No further information specific to Köch steamers is given in this SHTM.

Animal house sterilizer

2.46 The very wide range of materials and implements used in the care of laboratory animals is often catered for by specialised sterilizers with capacities as high as 10 m^3, which run several operating cycles. Examples of loads include bedding for discard, fresh bedding, feed bottles, food and water, cages, and tools and implements for use by personnel in the animal house. In view of the specialised nature of these machines, no further information specific to animal house sterilizers is given in this SHTM. Users are advised to adapt the guidance on laboratory sterilizers to their circumstances in consultation with the authorised person.

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Table 2.1 Sterilization temperature bands

	High-temperature steam				Dry heat			LTS	LTSF	Ethylene oxide
Sterilization temperature (°C)[a]	115	121	126	134	160	170	180	71[b]	71	30-56
Maximum allowable temperature (°C)	118	124	129	137[c]	170	180	190	80	80	[d]
Minimum holding time (min)	30	15	10	3	120	60	30	10	180[e]	[f]

Notes:

a. The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.

b. Disinfection temperature.

c. British Standards permit 138°C.

d. For EO, the maximum allowable temperature will normally be 4°C above the sterilization temperature.

e. For LTSF, the sterilization conditions may specify either a continuous holding time or the number of pulses for formaldehyde required to achieve sterilization.

f. For EO, the “gas exposure time” is determined for each sterilizer by microbiological methods during commissioning but is typically 2-7 hours depending upon sterilization temperature and gas concentration.

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3. Statutory requirements

Introduction

3.1 So far as sterilization is concerned, the chief areas of legislation with which managers should be familiar are health and safety, medicinal products and consumer protection.

Health and safety

3.2 The largest body of law with which managers need to be familiar concerns health and safety, in particular the Health and Safety at Work etc Act 1974 (the HSW Act) and its various regulations.

3.3 The HSW Act and its regulations require employers to assess the risk to their employees. Attention is drawn to the following hazards which are implicit in the practice of sterilization:

a. the hazard of scalding from escaping steam;

b. the high temperatures (up to 200°C) at which sterilizers are operated;

c. the stored energy hazards associated with the operation of pressure vessels contained within all steam and some EO sterilizers;

d. the stored energy hazards associated with the pressurised containers in which EO gas is transported;

e. the explosive hazards associated with the sterilization of fluids in sealed glass bottles;

f. the toxic properties of formaldehyde gas used in low-temperature steam and formaldehyde (LTSF) sterilizers;

g. the toxic and explosive properties of ethylene oxide gas used in ethylene oxide (EO) sterilizers;

h. the infection hazard associated with the microbial pathogens that may be handled by personnel using certain laboratory sterilizers;

i. the hazard of infection to patients and staff by the inadvertent release of an unsterile load due to the failure of a sterilization and quality control process;

j. the hazards associated with the handling of heavy and hot loads while loading and unloading sterilizers.

3.4 The guidance given throughout this SHTM is designed to ensure that these hazards are minimised and that sterilization procedures comply with the relevant legislation and established good practice.

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Health and Safety at Work etc Act 1974

3.5 The HSW Act sets out the basic legal responsibilities of employers and employees with regard to health and safety at work.

Management of Health and Safety at Work Regulations 1999

3.6 The Management of Health and Safety at Work Regulations 1999 (SI 3242) expand upon the principles of the HSW Act.

3.7 The core of the regulations is a requirement of employers to make a systematic assessment of the risks to health and safety of their employees and others, arising from work activities.

Workplace (Health, Safety and Welfare) Regulations 1992

3.8 The Workplace (Health, Safety and Welfare) Regulations 1992 (SI 1992/3004) aim to ensure that workplaces meet the health, safety and welfare needs of each member of the workforce, including people with disabilities.

3.9 Most of the regulations deal with the physical requirements of the workplace. Managers concerned with the operation of sterilizers should pay particular attention to the regulations and maintenance, ventilation, temperature, lighting, cleanliness, room dimensions and space, floors, doors and traffic routes.

Provision and Use of Work Equipment Regulations 1998

3.10 The Provision and Use of Work Equipment Regulations 1998 (PUWER) aim to ensure the provision of safe work equipment and its safe use.

3.11 PUWER 98 replaces the existing Provision and Use of Work Equipment Regulations 1992 and applies to all equipment (including lifting equipment) used at work in the health care sector. PUWER 92's requirements are carried forward in full but there are important new additions, including a requirement to inspect work equipment where significant risk could result from incorrect installation or relocation; deterioration; or as a result of exceptional circumstances; and to record the results those inspections (Regulation 6).

Pressure Systems Safety Regulations 2000

3.12 The regulations on pressure systems apply to all steam sterilizers, to EO sterilizers operating above 0.5 bar, and to the steam and compressed air services. They replace the Pressure Systems and Transportable Gas Containers Regulations 1989, which had earlier replaced the sections of the Factories Act 1961 that were relevant to steam sterilizers. Transportable gas containers were also removed from the scope of the 1989 Regulations and are now covered by the Carriage of Dangerous Goods (Classification,

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Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996. This would apply to cartridges and cylinders used to supply sterilant or purging gas to EO sterilizers.

3.13 The regulations also define the duties of the competent person: a competent individual person (other than an employee) or a competent body of persons corporate or unincorporate.

Control of Substances Hazardous to Health Regulations 1999

3.14 Schedule 1 of the Control of Substances Hazardous to Health (COSHH) Regulations lists ethylene oxide and formaldehyde as two substances hazardous to health which are subject to a maximum exposure limit for inhalation. These limits are reviewed annually and updated by amendments to the regulations. The current limits (1999) are given in Table 3.1. These limits must not be regarded as safe work exposures.

3.15 The Health and Safety Executive (HSE) publishes an annually updated guidance note on current exposure limits, *Occupational exposure limits (EH 40)*.

3.16 Users of laboratory sterilizers should note that a “substance hazardous to health” may include a micro-organism which creates a hazard to the health of any person. Guidance on the precautions to be taken when handling micro-organisms may be found in the Health and Safety Committee (HSC) documents, *Categorisation of pathogens according to hazard and categories of containment*, (second edition 1990) complied by the Advisory Committee on Dangerous Pathogens, and *Safe working and the prevention of infection in clinical laboratories*, compiled by the Health Services Advisory Committee.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995

3.17 Commonly known as RIDDOR, these regulations impose duties on persons responsible for the activities of persons at work, and on self-employed persons, to report accidents resulting in death or major injury arising out of or in connection with work, and to report specified dangerous occurrences. They also require certain particulars of accidents at work to be reported both to the Department of Health and also to the Health and Safety Executive, and require records to be kept.

3.18 Steam and certain EO sterilizers contain pressure vessels as defined under Part 1 of Schedule 1.

3.19 Poisoning by ethylene oxide is a reportable disease listed under Schedule 2.

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Manual Handling Operations Regulations 1992

3.20 The regulations require employers to make an ergonomic assessment of all manual handling operations which involve a risk injury, and to reduce the risk as far as is reasonably practicable. Factors to be assessed include the nature of the task, the load, the working environment and individual capability.

3.21 Managers should assess the risks associated with loading and unloading sterilizers, whether by loading trolleys or by hand. Top-loading sterilizers can be especially hazardous if lifting equipment is not available. The mass of the load is not the only source of risk; the temperature and other factors should be taken into account. Risks associated with maintenance and overhauling should also be assessed. Reference should also be made to the Lifting Operations and Lifting Equipment Regulations 1998 (LOLER).

Personal Protective Equipment at Work Regulations 1992

3.22 Managers should assess whether the risks associated with sterilization require the use of personal protective equipment (PPE). Some examples include heat-resistant gloves for use when hot loads are removed from sterilizers, protective gloves for use when handling discard material in laboratories, eye or face protection when testing sterilizers containing fluids in glass bottles, and foot protection of operators loading and unloading sterilizers.

Medicinal products

Medicines Act 1968

3.23 Where a sterilizer is to be used to sterilize medicinal products, the licensing provisions of the Medicines Act 1968 apply. Further information may be found in, *Guidance to the NHS on the licensing requirements of the Medicines Act 1968*, published by the Medicines Control Agency.

Medicines (Standard Provisions of Licences and Certificates) Amendment (No 3) Regulations 1977

3.24 The Medicines (Standard Provisions of Licences and Certificates) Amendments (No 3) Regulations 1977 introduced a qualified person who, in certain circumstances, has statutory responsibility for quality control in the manufacture of medicinal products (see Chapter 5). This will include decisions on release of a sterilized product.

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Medicines (Standard Provision of Licences and Certificates) Amendment Regulations 1992

3.25 The Medicines (Standard Provisions of Licences and Certificates) Amendment Regulations 1992 (SI 1992/2846) give statutory force to the commission document, *The rules governing medicinal products in the European Community Volume IV: Guide to good manufacturing practice for medicinal products*. All provisions in the guide came into force on or before 1 January 1993. The annex on sterilization contains requirements that are implemented by the guidance in this SHTM.

Consumer protection

3.26 In recent years, new legislation has been introduced affording protection to persons who may be harmed by unsafe goods supplied to them. In certain circumstances this may include products from sterilizers.

Consumer Protection Act 1987

3.27 Part 1 implements EU Council Directive 85/374/EEC (the Product Liability Directive) providing for compensation to be paid to persons injured by a defective product. Under the Act a product is defective "if the safety of the product is not such as persons generally are entitled to expect", taking the circumstances into account. It is likely that civil action for damages could be taken against a hospital for supplying, for example, "sterile" products that were not in fact sterile and caused the infection of a patient.

3.28 Part 2 introduces a "general safety requirement" on the suppliers of "consumer goods" only. It is a criminal offence to supply unsafe consumer goods, whether or not actual harm has been caused. Consumer goods are defined as "any goods which are ordinarily intended for private use or consumption", and are regarded as unsafe when "they are not reasonably safe having regard to all the circumstances". It is not clear whether products from hospital sterilizers are to be regarded as consumer goods. (Controlled drugs and licensed medicinal products are exempt from Part 2 since they are governed by other legislation.)

Electromagnetic Compatibility Regulations 1992

3.29 The Electromagnetic Compatibility Regulations (SI 2372) (the EMC Regulations), impose requirements concerning the electromagnetic compatibility of most types of electrical and electronic apparatus which must be complied with, before such apparatus is to be supplied or taken into service.

3.30 A sterilizer (and any ancillary equipment) is a "relevant apparatus" within the terms of the regulations, and will have to meet standards of emission of an immunity to electromagnetic disturbance. Note that it is an offence not only

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to supply but also to “take into service” a sterilizer that does not conform to the regulations.

3.31 The regulations do not apply to any sterilizer supplied to be taken into service in the EU before 28 October 1992. A sterilizer supplied or taken into service in the UK on or before 31 December 1995 is not required to comply with the regulations provided it complies with the requirements of the Wireless Telegraphy Acts listed in Schedule 1 of the regulations.

NOTE: Detailed guidance on the application of the EMC regulations in healthcare premises may be found in SHTM 2014; *Abatement of electrical interference*.

Active Implantable Medical Devices Regulations 1992

3.32 The Active Implantable Medical Devices Regulations 1992 (SI 3146) set out the essential requirements which active implantable medical devices (such as heart pacemakers) must satisfy before they can be placed on the market or put into service.

3.33 Schedule 2, paragraph 7 requires such devices to be designed, manufactured and packed in a non-reusable packaging according to procedures which are sufficient to ensure that:

a. the device is sterile when placed on the market; and

b. if handled in accordance with conditions as to storage and transport laid down by the manufacturer, the device remains sterile until the packaging is removed and the device is implanted.

3.34 Schedule 2, paragraph 14 sets out requirements for the labelling of sterile packs.

Table 3.1 Maximum exposure limits at atmospheric formaldehyde and ethylene oxide

Gas	Short-term exposure limits		Long-term exposure limits	
	[ppm]	[mg m^{-3}]	[ppm]	[mg m^{-3}]
Formaldehyde	2	2.5	2	2.5
Ethylene oxide	–	–	5	9.2

Notes:

The short-term exposure limit (STEL) is the average exposure over any 15-minute period.

The long-term exposure limit (STEL) is the exposure over any 24-hour period expressed as a single uniform exposure over an 8-hour period.

COSHH does not specify a STEL for EO. In such cases the STEL is deemed to be three times the LTEL in accordance with the recommendations of the Health and Safety Executive.

Source: HSE guidance note EH40 (Feb 1999).

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4. British and European standards

Introduction

4.1 Industry standards for sterilization have developed rapidly since the publication of HTM 10 in 1980. British standards which existed at that time have been thoroughly revised and extended. European standards now cover not only design, construction, performance and safety, but also validation, routine testing and operation.

4.2 British and European standards, supplemented by specific requirements for the NHS, form the basis of the guidance given in the 'Design considerations' part of this SHTM.

4.3 The main standards for sterilizers are BS 3970 for clinical sterilizers and BS 2646 for laboratory sterilizers.

European standards

4.4 European standards on sterilization are generally more extensive than British standards in specifying not only design, construction, performance and safety requirements of sterilizers, but also that persons responsible for sterilization operate a quality system and that part of that system is validation and routine testing of the process.

4.5 While the guidance given here is designed to conform broadly with European standards, SHTM 2010 must not be regarded as a substitute for the standards themselves.

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5. Personnel

Introduction

5.1 This chapter introduces the personnel who may share the responsibility for the safe and efficient operation of sterilizers. It gives guidance on qualifications and training and summarises areas of responsibility.

Training

5.2 It is essential that personnel at all levels have a sound general knowledge of the principles, design and functions of sterilizers. They should be trained on those types and models of sterilizers with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, safety of others and general safety. Training given to individuals should be recorded and reviewed regularly.

5.3 Accredited courses on sterilization, suitable for personnel at all levels, are run by various training providers. Further information is available from the NHS in Scotland Property and Environment Forum Executive and the authorised persons (sterilizers).

5.4 Detailed training on particular models of sterilizer is usually available from the manufacturer, either on-site (such as during validation) or by courses at their premises.

Functional responsibility

5.5 There have been profound changes in the management philosophy of the NHS over recent years, and there is a trend towards deregulation and contracting-out of services. It is not possible to prescribe a management structure for sterilization that is universally applicable given the wide range of circumstances in which a sterilizer may be employed, from a busy sterile services department in a major general hospital to a small rural dental practice.

5.6 The approach chosen for this SHTM is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual's role in connection with sterilization, but are not intended to be prescriptive job titles for terms of employment, indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with sterilization and in some cases the same individual may take on more than one role.

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5.7 In every case, however, it is possible to identify a **user** who is responsible for the day-to-day management of the sterilizer. The philosophy of this SHTM is to invest the user with the responsibility for seeing that the sterilizer is operated safely and efficiently.

5.8 The law requires that a **competent person (pressure vessels)** who is not the **user** is designated to exercise certain responsibilities of inspection for all steam sterilizers and other sterilizers containing pressure vessels.

5.9 For small installations where the user is qualified to perform all required test and maintenance functions, no other personnel may be necessary. This may be satisfactory for small sterilizers run by dentists or general practitioners. However, it is strongly recommended that in all cases the user receive professional advice from an **authorised person (sterilizers)**, and that testing and maintenance be carried out by a suitably qualified **test person (sterilizers)** and a **maintenance person (sterilizers)** with assistance from a **microbiologist (sterilizers)** where microbiological testing is required.

5.10 Where the sterilizer is used to manufacture medicinal products, the functions of the user are exercised by a **production manager** and a **quality controller**.

Key personnel

5.11 For the purposes of SHTM 2010, the following are the key roles in the management of sterilization.

Management

5.12 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the sole operation of its premises.

User

5.13 The user is defined as the person designated by management to be responsible for the sterilizer.

5.14 In a hospital, the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the production manager in charge of the entire manufacturing process.

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5.15 The principal responsibilities of the user are as follows:

a. to certify that the sterilizer is fit for use;

b. to hold all documentation relating to the sterilizer, including the names of other key personnel;

c. to ensure that the sterilizer is subject to periodic testing and maintenance;

d. to appoint operators where required and ensure that they are adequately trained;

e. to maintain production records;

f. to establish procedures for product release (for medical products, in cooperation with the quality controller).

Competent person (pressure vessels)

5.16 The competent person (pressure vessels) is defined as a person or organisation designated by the management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a sterilizer described in the Pressure Systems Safety Regulations 2000. The shorter term “competent person” is used in this SHTM.

5.17 The competent person should not be the user, nor any of the other key personnel associated with the sterilizer in question.

5.18 The HSC Approved Code of Practice, ‘Safety of pressure systems’ requires the competent person to have the necessary expertise, knowledge and experience for the system in question.

5.19 The principal duties of the competent person under the regulations are as follows (they need not all be exercised by the same individual):

a. advising on the scope of the written scheme of examination;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

5.20 Most insurance companies maintain a technical division able to advise on appointing a competent person. The authorised person (sterilizers) will also be able to provide advice.

5.21 Further information about the written scheme of examination will be found in Part 4 of this SHTM.

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Authorised person (sterilizers)

5.22 The authorised person (sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness documentation on validation. The shorter term “authorised person” is used in this SHTM.

5.23 The authorised person should:

a. have a minimum of two years recent experience in the validation of sterilization processes to modern standards;

b. have a degree in a relevant science subject or corporate membership of a relevant professional institution;

c. have completed an accredited course for authorised persons (sterilizers) and successfully passed the examination;

or alternatively, should:

d. have applied for registration as an authorised person (sterilizers) no later than 31 December 1994;

e. have at least ten years experience in the validation of porous load and laboratory sterilization processes;

f. have two years experience in a responsible position;

g. successfully pass an accredited examination for authorised persons (sterilizers) within five years of registration.

5.24 The authorised person is required to liaise closely with other professionals in various disciplines and consequently, the appointment should be made known in writing to all interested parties. He or she should have direct contact with the user and other key personnel.

5.25 The principal responsibilities of the authorised person are as follows:

a. to provide general and impartial advice on all matters concerned with sterilization;

b. to advise on programmes of validation;

c. to audit reports on validation, revalidation and yearly tests prepared by the test person;

d. to advise on programmes of periodic tests and periodic maintenance;

e. to advise on operational procedures for routine production.

5.26 A register of suitably qualified authorised persons is maintained by the Institute of Healthcare Engineering and Estate Management (IHEEM).

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Test person (sterilizers)

5.27 The test person (sterilizers) is defined as a person designated by management to carry out validation and periodic testing of sterilizers. The shorter term “test person” is used in this SHTM.

5.28 The test person should:

a. be qualified to at least HNC in engineering or microbiological sciences;

b. have completed an accredited course for test persons (sterilizers) and successfully passed the examination;

c. have been recently employed in an NHS hospital with responsibility for validation and periodic testing for one or more sterilization processes;

or alternatively:

d. have a certificate demonstrating satisfactory completion of an accredited course (City and Guilds or equivalent) in the validation and periodic testing of at least two sterilization processes;

e. have at least three years experience in the validation and periodic testing of porous load sterilizers and at least one other sterilization process.

5.29 The principal responsibilities of the test person are as follows:

a. to conduct the validation tests specified in Part 3 of this SHTM and to prepare the validation report;

b. to conduct the periodic tests specified in Part 3 and to prepare reports as required by the user;

c. to conduct any additional tests at the request of the user.

Maintenance person (sterilizers)

5.30 The maintenance person (sterilizers) is defined as a person designated by management to carry out maintenance duties on sterilizers. The shorter term “maintenance person” is used in this SHTM.

5.31 The maintenance person should be a fitter or an electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of sterilizer. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others.

5.32 The principal responsibilities of the maintenance person are as follows:

a. to carry out the maintenance tasks outlined in Part 4;

b. to carry out additional maintenance and repair work at the request of the user.

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5.33 A maintenance person who has a minimum of two years experience in the maintenance of sterilizers and who has obtained a recognised qualification in the testing of sterilizers may perform the duties of the test person for the daily, weekly and quarterly tests described in Part 3.

Microbiologist (sterilizers)

5.34 The microbiologist (sterilizers) is defined as a person designated by management to be responsible for advising the user on microbiological aspects of the sterilization of non-medical products. The shorter term “microbiologist” is used in this SHTM.

5.35 The microbiologist should have a relevant degree (for example microbiology or medicine) and will normally be a member of the hospital staff.

5.36 The principal responsibilities of the microbiologist are as follows:

a. to advise the user on the microbiological aspects of sterilization procedures for non-medicinal products;

b. to arrange for the culturing of biological indicators used in microbiological tests (normally low-temperature steam and formaldehyde (LTSF) and ethylene oxide (EO) sterilizers);

c. to audit the documentation from all sterilizers which have been tested by microbiological methods.

Personnel for medicinal products

5.37 Where a sterilizer is to be used in the productron of medicinal products, the provisions of the Medicines Act 1968 apply. The responsibilities that would otherwise be exercised by the user are divided between the production manager and the quality controller. Guidance on the duties of each can be found in the EU commission document, *Guide to good manufacturing practice for medicinal products*.

Production manager

5.38 The production manager is defined as a person designated by management to be responsible for the production of medicinal products.

Quality controller

5.39 The quality controller is defined as a person designated by management to be responsible for quality control and medicinal products with authority to establish, verify and implement all quality control and quality assurance procedures.

5.40 He or she should have the authority, independent of the production manager, to approve materials and products and to reject, as seen fit, raw materials, packaging materials, and intermediate, bulk and finished products

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not complying with the relevant specification or not manufactured in accordance with approved procedures.

5.41 The quality controller should be professionally qualified (for example in pharmacy). Any additional qualifications will depend on the type of licence which is held, for example:

a. where a product licence is held, the quality controller should satisfy the requirements of the qualified person as defined in the Medicines (Standard Provisions of Licences and Certificates) Amendment (No. 3) Regulations 1977. If the quality controller does not meet these requirements, a qualified person should be designated to exercise the functions specified in the regulations;

b. where the manufacturer's licence "specials" is held, as is generally the case in hospitals, the quality controller need not satisfy the requirements of a qualified person.

5.42 Further information about qualified person can be found in MAL 45 Medicines Acts 1968, 1971.

Other personnel

5.43 The following personnel are also mentioned in this SHTM.

5.44 The **laboratory safety officer** is defined as a person designated by management to be responsible for all aspects of laboratory safety including equipment, personnel and training relating to safety issues, and ensuring compliance with safety legislation and guidelines.

5.45 An **operator** is defined as any person with the authority to operate a sterilizer, including the noting of sterilizer instrument readings and simple housekeeping duties.

5.46 The **manufacturer** is defined as a person or organisation responsible for the manufacturer of a sterilizer.

5.47 The **contractor** is defined as a person or organisation designated by management to be responsible for the supply and installation of the sterilizer, and for the conduct of the installation checks and tests. The contractor is commonly the manufacturer of the sterilizer.

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
	Health and Medicines Act	HMSO	1988	
	Registered Establishments (Scotland) Act	HMSO	1998	
	Water (Scotland) Act	HMSO	1980	
SI 3146	Active Implantable Medical Devices Regulations	HMSO	1992	
SI 1995	Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995	HMSO	1995	
SI 2179 & 187	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
SI 2092	Carriage of Dangerous Goods (Classification, Packaging & Labelling) and Use of Transportable Pressure Receptacles Regulations	HMSO	1996	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988	

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Publication ID	Title	Publisher	Date	Notes
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 1315	In Vitro Diagnostic Medical Devices Regulations 2000	HMSO	2000	
SI 3232	Ionising Radiations Regulations 1999	HMSO	1999	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 2051	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulation	HMSO	1992	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
British Standards				
BS 593	**Specification for laboratory thermometers**		1989	
BS 1781	**Specification for linen and linen union textiles**		1981	
BS 2646	**Autoclaves for sterilization in laboratories**	BSI Standards		
	Part 1: Specification for design, construction, safety and performance		1993	
	Part 2: Guide to planning and installation		1990	
	Part 3: Guide to safe use and operation		1993	
	Part 4: Guide to maintenance		1991	
	Part 5: Methods of testing for function and performance		1993	
BS 2648	**Performance requirements for electrically heated laboratory drying ovens (PD2517,6/56)**	BSI Standards	1955	
BS 2775	**Specification for rubber stoppers and tubing for general laboratory use**		1987	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**		1992	
BS 3928	**Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors)**	BSI Standards	1969	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 3970	**Sterilizing and disinfecting equipment for medical products** **Part 1:** Specification for general requirements **Part 2:** Specification for steam sterilizers for aqueous fluids in sealed rigid containers **Part 3:** Specification for steam sterilizers for wrapped goods and porous loads **Part 4:** Specification for transportable steam sterilizers for unwrapped instruments and utensils **Part 5:** Specification for low temperature steam disinfectors **Part 6:** Specification for sterilizers using low temperature steam with formaldehyde	BSI Standards	1990 1991 1990 1990 1993	
BS 4196-0	**Sound power level of noise sources. Guide for the use of basic standards and for the preparation of noise test codes**	BSI Standards	1981	
BS 4275	**Guide to implementing an effective respiratory protective device programme**	BSI Standards	1997	
BS 5164	**Specification for indirect acting electrical indicating and recording instruments and their accessories**		1975	
BS 5295	**Environmental cleanliness in enclosed spaces** **Part 1:** Specification for clean rooms and clean air devices		1989	
BS 5304	**British standard code of practice for safety of machinery**	BSI Standards	1988	
BS 5815	**Sheets, sheeting, pillowslips, towels, napkins and continental quilts secondary covers** **Parts 1:** Specification for sheeting etc **Part 2**: specification for towels etc. **Part 3:** Specification for counterpanes etc.	BSI Standards	1989 1988 1991	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 6000	**Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots**	BSI Standards	1996	
BS 6001	**Sampling procedures for inspection by attributes**	BSI Standards	1991	
BS 6068	**Water quality** **Sect.1.2** Glossary	BSI Standards	1997	
	Sect 6.5 Guidance on sampling of drinking water and water used for food processing		1991	
	Sect. 6.7 Guidance on sampling of water and steam in boiler plants.		1994	
BS 6257	**Specification for paper bags for steam sterilization for medical use**		1989	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**		1984	
BS 7671	**Requirements for electrical installations. IEE wiring regulations**	BSI Standards	1992	16th edition
BS 7720	**Specification for non-biological sterilization indicators equivalent to the Bowie and Dick Test**		1995	
BS EN 134	**Respiratory protective devices. Nomenclature of components. Names of components in three CEN languages and diagrams for respiratory protective equipment**	BSI Standards	1998	
BS EN 285	**Sterilization, steam sterilizers, large sterilizers**	BSI Standards	1997	
BS EN 550	**Sterilization of medical devices. Validation and routine control of sterilization by ethylene oxide**	BSI Standards	1994	
BS EN 552	**Sterilization of medical devices. Validation and routine control of sterilization by irradiation**	BSI Standards	1994	
BS EN 554	**Sterilization of medical devices. Validation and routine control of sterilization by moist heat**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized medical devices to be labelled 'STERILE'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 764	**Pressure equipment. Terminology and symbols: pressure, temperature, volume**	BSI Standards	1995	
BS EN 837-1	**Bourdon tube pressure gauges: dimensions, metrology, requirements and testing**	BSI Standards	1998	
BS EN 866	**Biological systems for testing sterilizers and sterilization processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterilizers **Part 3:** Particular systems for use in moist heat sterilizers	BSI Standards	 1997 1998 1997	
BS EN 867	**Non-biological systems for use in sterilizers** **Part 1:** General requirements **Part 2:** Process indicators **Part 3:** Specification for Class B indicators for use in the Bowie and Dick test	BSI Standards	 1997	
BS EN 868	**Packaging materials and systems for medical devices which are to be sterilized. General requirements**	BSI Standards	1997	
BS EN 980	**Graphical symbols for the use in the labelling of medical devices**	BSI Standards	1997	
BS EN 1174	**Sterilization of medical devices. Estimation of population of micro-organisms on product**	BSI Standards	1996	
BS EN 1422	**Sterilizers for medical purposes – ethylene oxide sterilizers – specification**	BSI Standards	1998	
BS EN 22872	**Complete, filled transport packages. Method for determination of resistance to compression**	BSI Standards	1993	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 25667-1	**Water quality. Guidance on design of sampling programmes**	BSI Standards	1994	
BS EN 25667-2	**Water sampling . Guidance on sampling techniques**	BSI Standards	1993	
BS EN 30993	**Biological evaluation of medical devices**	BSI Standards		
	Part 3: Tests for genotoxicity, carcinotoxicity, and reproductive toxicity		1994	
	Part 4: Selection of tests for interaction with blood		1994	
	Part 5: Tests for cytotoxicity, in vitro methods		1994	
	Part 6: Tests for local effects after implantation		1995	
BS EN ISO 3746	**Acoustics. Determination of sound power levels of noise sources using sound pressure. Survey method using an enveloping measurement surface over a reflecting plane**	BSI Standards	1996	
BS EN 45003	**Calibration and testing laboratory accreditation systems, general requirements for operation and recognition**	BSI Standards	1995	
BS EN 45011	**General requirements for bodies operating product certification systems**	BSI Standards	1998	
BS EN 45012	**General requirements for bodies operating assessment and certification/registration of quality system**	BSI Standards	1998	
BS EN 45014	**General criteria for supplier's declaration of conformity**	BSI Standards	1993	
BS EN 45020	**Standardization and related activities**	BSI Standards	1998	
BS EN 46001	**Specification for the application of EN ISO9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for the application of EN ISO9002 to the manufacture of medical devices**	BSI Standards	1994	

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Publication ID	Title	Publisher	Date	Notes
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	1998 1995	
BS EN 60079-14	**Electrical apparatus for explosive gas atmospheres. Electrical installations in hazardous areas (other than mines)**	BSI Standards	1997	
BS EN 60581-2	**Thermocouples. Manufacturing tolerances**	BSI Standards	1996	
BS EN 60584-1	**Thermocouples reference table**	BSI Standards	1996	
BS EN 60651	**Specification for sound level meters**	BSI Standards	1994	
BS EN 60751	**Industrial platinum resistance thermometer sensors**		1996	
BS EN 60804	**Specification for integrating averaging sound level meters**		1994	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **-1:** General requirements **-2-041:** Particular requirements for autoclaves and sterilizers using steam for the treatment of medical materials and for laboratory processes **-2-042:** Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes **-2-043:** Particular requirements for autoclaves and sterilizers using either hot air or hot inert gas for the treatment of medical materials and for laboratory processes		1993 1997 1997 1998	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing**	BSI Standards	1994	
BS EN ISO 9002	**Quality systems. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	
European Union Directives				
65/65/EEC	Approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.	Official Journal of the European Communities (OJEC), no 22, 9/2/65, p 369		
75/107/EEC	Approximation of the laws of member states relating to bottles used as measuring containers.	Official Journal of the European Communities (OJEC), L42, 15/2/75		
90/385/EEC	Approximation of the laws of the Member States relating to active implantable medical devices.	Official Journal of the European Communities (OJEC), L189 20/7/90, p 17		
91/356/EEC	Laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.	Official Journal of the European Communities (OJEC). L193 17/7/91, p 30		
80/778/EEC	Quality of water intended for human consumption	Official Journal of the European Communities, 1980		
93/42/EEC	Medical Devices Directive	Official Journal of the European Communities (OJEC), L169 12/7/93, p 1		
98/79/EC	In Vitro Diagnostic Medical Devices Directive	Official Journal of the European Communities, (OJEC), L331 7/12/98		
Scottish Health Technical Guidance				
SHTM 2007	Electrical services supply and distribution	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2014	Abatement of electrical interference	P&EFEx	2001	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems	P&EFEx	2001	CD-ROM
SHTM 2023	Access and accommodation for engineering services	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilizers	P&EFEx	2001	CD-ROM
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHTM 2045	Acoustics	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	HMSO	1994	
SHPN 15	Accommodation for pathology services	HMSO	1994	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	EEF	1999	CD-ROM
SHTN 4	General Purposes Estates and Facilities Model Safety Permit-to-Work system	EEF	1998	CD-ROM
SHGN	'Safe' hot water and surface temperatures	EEF	1999	CD-ROM
	NHS in Scotland – PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
UK Health Technical Guidance				
HBN 29	Accommodation for pharmaceutical services	HMSO	1988	
HTM 67	Building components: laboratory fitting out system	HMSO	1993	
CONCODE	Contracts and commissions for the NHS estate – contract procedures	HMSO	1994	
MES	Model Engineering Specifications	NHS Estates	1997	As required
MES C14	Sterilizers	NHS Estates	1993	
HBN 13	Supplement 1 – Ethylene oxide sterilization section	HMSO	1994	
MES C02	Thermal insulation	NHS Estates	1993	
Health and Safety Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
HN(76)126	Hospital design note 4 (noise control): amendments to appendices II, IV and VII	DHSS	1976	
STB3A/85/12	Performance and safety specification for media sterilizers. Media devices directorate	DHSS	1985	
	Emmerson, A. M. *Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Committee to the Department of Health Medical Devices Directorate.* Medical devices directorate	Department of Health	1993	
	Biological tests for graded milk. Memo 139/Foods.	Ministry of Health	1937	

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Publication ID	Title	Publisher	Date	Notes
	Scottish Infection Manual Guidance on the core standards for the control of infection in hospitals, healthcare premises and at the community interface	The Scottish Office	1998	
	Programmable electronic systems in safety related applications: General technical guidelines	HSE	1987	
	Programmable electronic systems in safety related applications: an introductory guide	HSE	1987	
L 5	General COSHH ACOP (Control of substances hazardous to health) Carcinogens ACOP (Control of carcinogenic substances) and Biological agents ACOP (Control of biological agents) Control of Substances Hazardous to Health Regulations1999 Approved Code of Practice	HSE	1999	
L 22	Safe use of work equipment: Approved code of practice and guidance	HSE	1998	
L 23	Manual handling operations: guidance on regulations	HSE	1998	
L 24	Workplace health, safety and welfare: Approved code of practice and guidance	HSE	1992	
L25	Personal protective equipment at work at work: guidance on regulations		1992	
L113	Safe use of lifting equipment: Approved code of practice and guidance	HSE	1998	
L122	Safety of pressure systems: Pressure Systems Safety Regulations 2000. Approved Code of Practice	HSE Books	2000	
PM73	Safety at Autoclaves	HSE Books	1998	
	Precautions for work with human and animal. Transmissible Spongiform Encaphalopathies	HSE (ACDP)		
	Categorisation of pathogens according to hazard and categories of containment	HSE (ACDP)	1995	4th Edition
	Safe working and the prevention of infection in clinical laboratories	HSC (HSAC)		
HS(R)23	A guide to the 'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995	HSE	1995	

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Publication ID	Title	Publisher	Date	Notes
Miscellaneous References				
GGMP Volume IV	Guide to good manufacturing practice for medicinal products – The rules governing medicinal products in the European Community			
	Atomic absorption spectrophotometry 1979 version	HMSO	1979	(out of print)
	Cadmium in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Colour and turbidity of waters 1981	HMSO	1981	(out of print)
	Determination of anions and cations, transition metals, and other complex ions and organic acids and bases in water by chromatography 1990	HMSO	1990	
	Lead in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Lead and cadmium in fresh waters by atomic absorption spectrophotometry (second edition) a general introduction to electrothermal atomization atomic absorption spctrophotometry 1986	HMSO	1986	(out of print)
	Measurements of electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters.	HMSO		(out of print)
	Mercury in waters, effluents, soils and sediments etc, additional methods	HMSO	1985	(out of print)
	Phosphorus and silicon in waters, effluents and sludges 1992	HMSO	1993	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
LG 2	Lighting guide: hospitals and healthcare buildings	Chartered Institution of Building Services Engineers	1989	
	Sterilization and disinfection of heat-liable equipment	Central Sterilizing Club	1986	

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Scottish Health Technical Memorandum 2010

(Part 2 of 6)

Design considerations

Sterilization

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NHSScotland, P&EFEx, June 2001

Preface

SHTM 2010 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the following types of sterilizer in use in the National Health Service:

a. clinical sterilizers:
   (i) high-temperature steam sterilizers used for processing porous loads (including instruments and utensils wrapped in porous materials);
   (ii) high-temperature steam sterilizers used for processing aqueous fluids in sealed containers;
   (iii) high-temperature steam sterilizers used for processing unwrapped solid instruments and utensils;
   (iv) dry-heat sterilizers (hot-air sterilizers);
   (v) low-temperature steam (LTS) disinfectors and low-temperature steam and formaldehyde (LTSF) sterilizers;

> **NOTE:** Despite their name LTSF sterilizers are disinfectors.

   (vi) ethylene oxide (EO) sterilizers;
b. laboratory sterilizers:
   (i) high-temperature steam sterilizers used with one or more specialised operating cycles;
   (ii) culture media preparators.

No guidance is given on sterilization by irradiation, hydrogen peroxide, gas plasma or filtration. Users who wish to employ these processes bear the responsibility of ensuring that the validation procedures comply with the principles outlined in Part 3 of this SHTM, 'Validation and Verification', and that the intended operating procedures will ensure an efficacious process for the different types of load.

This SHTM is intended primarily as a guide for technical personnel, whether specialists in sterilizers and sterilization procedures or those responsible for maintenance and testing. It is also intended for those responsible for the day-to-day running of sterilizers, and will also be of interest to supplies officers, architects, estates managers and others in both the public and private sectors.

Detailed information on the planning and design of a sterile services department, including the level of provision of sterilizers, is given in Scottish Hospital Planning Note 13, *Sterile services department*. Guidance for

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laboratory installations can be found in Scottish Hospital Planning Note 15, *Accommodation for pathology services*.

Although this edition of SHTM 2010 reflects established sterilizer technology, it is recognised that considerable scope exists for the utilisation of emerging technology in the management of sterilizers. This will be kept under review with the aim of introducing recommendations for such technology at the earliest opportunity so that the procedures essential for the efficient, safe and effective operation of sterilizers can be optimised.

The sterilizers described in this SHTM may not be suitable, without modification, for safely processing articles infected either with Hazard Group 4 pathogens or with agents, such as those associated with transmissible spongiform encephalopathies, which are unusually resistant to sterilization. Design considerations for sterilizers intended to process articles infected with such organisms are discussed in Chapter 14.

NOTE: Information about Hazard Groups may be found in the HSC document, *Categorisation of pathogens according to hazard and categories of containment* (4th edition 1995) compiled by the Advisory Committee on Dangerous Pathogens.

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1. General

Introduction

1.1 This Part of SHTM 2010 covers the specification, purchase and installation of the various types of sterilizer used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in sterilization has long been inconsistent and occasionally ambiguous. This SHTM introduces a set of terms consistent with European Standards (see paragraph 1.14) which, it is hoped, will in time be adopted by sterilization workers in the NHS. The Glossary contains definitions referred to in this Part.

1.3 The References contains full references for all the documents referred to in this Part and for selected documents of which the reader should be aware.

Legal frameworks for sterilization

1.4 There are now two legal frameworks applying to products from sterilizers. The long-standing legislation on medicinal products has now been joined by EU Directives on medical devices.

1.5 Purchasers must be clear as to whether the load items they intend to process in a sterilizer are classified as medicinal products or medical devices. While the practical requirements have much in common, their implementation is very different.

1.6 For the guidance given in this SHTM, the various types of sterilizer are presumed to be used primarily as follows:

a. for **medicinal products**: fluid sterilizers, dry-heat sterilizers;

b. for **medical devices**: porous load sterilizers, sterilizers for unwrapped instruments and utensils, dry-heat sterilizers, low-temperature steam (LTS) disinfectors, low-temperature steam and formaldehyde (LTSF) sterilizers, ethylene oxide (EO) sterilizers.

1.7 Where a sterilizer is purchased with the intention of processing both medicinal products and medical devices, purchasers should ensure that the requirements for both types of load are met.

Medicinal products

1.8 The manufacture and supply of medicinal products are controlled by a large body of legislation stemming from the EU Directives on medicinal products and enacted by the UK Medicines Acts and numerous Regulations. Further

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details can be found in Part 1 of this SHTM, 'Overview and management responsibilities'.

1.9 The requirements for the manufacture of medicinal products are set out in the *Guide to good manufacturing practice for medicinal products* published in Volume IV of *The rules governing medicinal products in the European Community* (see References). This document is referred to as the 'GGMP' in this SHTM.

1.10 The GGMP contains an Annex on the *Manufacture of sterile medicinal products* which has considerable implications for the design of sterilizers and the premises in which they are used. Where purchasers are considering installing a sterilizer for the processing of medicinal products, the GGMP should be consulted at an early stage. Attention is drawn to these requirements in the relevant chapters of this SHTM.

1.11 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA).

Medical devices

1.12 Part 1 of this SHTM discusses the three EU Directives on the manufacture and supply of medical devices, active implantable medical devices and in-vitro diagnostic medical devices, which are being implemented by UK Regulations in stages from 1993 onwards. While the full implications of the legislation for the NHS are not yet clear, it is likely that all or most products for clinical use that are not classified as medicinal products will be classified as medical devices. Whether such medical devices will be subject to the Regulations is a complex issue turning on the relationship between the producer and the user of the devices and is beyond the scope of this SHTM.

1.13 One of the essential requirements of the directives is that "devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method". There is no equivalent of the GGMP for medical devices. Instead, the European Committee for Standardisation (Comité Européen de Normalisation, CEN) has prepared a number of draft European Standards on the manufacture of medical devices. These are known as "mandated" standards. Compliance with a mandated standard is considered to be a legal presumption of compliance with the essential requirements of the Directive it supports. Official notification of mandated European Standards supporting EU Directives is published in the Official Journal of the European Communities and in the London, Edinburgh and Belfast Gazettes.

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1.14 Although compliance with a mandated standard is not the only way of complying with the directives, it is the simplest. Purchasers intending to process sterile medical devices in compliance with the directives should therefore ensure that their processes conform with one of the mandated standards. The following British Standards on the validation and control of sterilization processes have been mandated and are discussed in Part 3, 'Validation and verification', and Part 4, 'Operational management', of this SHTM:

a. BS EN 556 covering the requirements for a device to be labelled "STERILE";

b. BS EN 554 covering sterilization by "moist heat" (that is, steam);

c. BS EN 550 covering sterilization by ethylene oxide.

1.15 These standards are themselves supported by the following standards for the specification of sterilizers which are discussed in this Part of this SHTM:

a. BS EN 285 covering "large" porous load sterilizers;

b. BS EN 1422 covering EO sterilizers.

1.16 While the guidance given here is designed to be broadly consistent with the standards, SHTM 2010 should not be regarded as a substitute for the standards themselves when ascertaining compliance with EU Directives and the UK Regulations that implement them.

1.17 Guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency (MDA).

Personnel

1.18 The following personnel are referred to in this Part of SHTM 2010. Further information, including qualifications and areas of responsibility, can be found in Part 1.

1.19 **Management** is defined as the owner, occupier, employer, general manager, chief executive or other person of similar authority who is ultimately accountable for the sole operation of the premises.

1.20 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small, autonomous installations the user may take on this function.

1.21 The **User** is defined as the person designated by management to be responsible for the management of the sterilizer.

1.22 In a hospital the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be

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a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the production manager (see paragraph 1.30) in charge of the entire manufacturing process.

1.23 The **Competent Person (Pressure Vessels)** is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a sterilizer described in the Pressure Systems Safety Regulations 2000. The shorter term “competent person” is used in this SHTM.

1.24 The **Authorised Person (Sterilizers)** is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness documentation on validation. The shorter term “authorised person” is used in this SHTM.

1.25 A list of suitably qualified authorised persons is maintained by the Institute of Healthcare Engineering and Estate Management (see Appendix 1).

1.26 The **Test Person (Sterilizers)** is defined as a person designated by management to carry out validation and periodic testing of sterilizers. The shorter term “test person” is used in this SHTM.

1.27 The **Maintenance Person (Sterilizers)** is defined as a person designated by management to carry out maintenance duties on sterilizers. The shorter term “maintenance person” is used in this SHTM.

1.28 The **Microbiologist (Sterilizers)** is defined as a person designated by management to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. The shorter term “microbiologist” is used in this SHTM.

1.29 The **Production Manager** is defined as a person designated by management to be responsible for the production of medicinal products.

1.30 The **Quality Controller** is defined as a person designated by management to be responsible for quality control of medicinal products with authority to establish, verify and implement all quality control and quality assurance procedures.

1.31 The **Laboratory Safety Officer** is defined as a person designated by management to be responsible for all aspects of laboratory safety including equipment, personnel and training relating to safety issues, and ensuring compliance with safety legislation and guidelines.

1.32 An **Operator** is defined as any person with the authority to operate a sterilizer, including the noting of sterilizer instrument readings and simple housekeeping duties.

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1.33 The **Manufacturer** is defined as a person or organisation responsible for the manufacture of a sterilizer.

1.34 The **Contractor** is defined as a person or organisation designated by Management to be responsible for the supply and installation of the sterilizer, and for the conduct of the installation checks and tests. The contractor is commonly the manufacturer of the sterilizer.

1.35 The **Purchaser** is defined as the person or organisation who orders the sterilizer and is responsible for paying for it.

Safety

1.36 Extensive guidance on the safe operation of the various types of sterilizer is given in Part 4 of this SHTM. Guidance on safe practices in the testing of sterilizers is given in Part 3.

1.37 LTSF sterilizers and EO sterilizers both use toxic gases in the sterilization process. Occupational exposure to formaldehyde and EO is controlled by the Control of Substances Hazardous to Health Regulations 1999. Maximum exposure limits are set out in the annual Guidance Note EH40, *Occupational exposure limits*, published by the Health and Safety Executive. The limits shown in Table 1 (are as at 2001). These limits are statutory maxima but should not be regarded as representing a safe working exposure; employers have a legal obligation to ensure that the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

1.38 The COSHH Regulations 1999 also introduce new controls on biological agents which are of relevance to purchasers of laboratory sterilizers.

Table 1: Maximum exposure limits for atmospheric formaldehyde and ethylene oxide

	Short-term maximum exposure limit		Long-term maximum exposure limit	
Gas	[ppm]	[mg m^{-3}]	[ppm]	[mg m^{-3}]
Formaldehyde	2	2.5	2	2.5
Ethylene oxide	_	_	5	9.2

Note:

The short-term maximum exposure limit (STMEL) is the average exposure over any 15 min period.

The long-term maximum exposure limit (LTMEL) is the exposure over any 24 h period expressed as a single uniform exposure over an 8 h period.

COSHH does not specify a STMEL for EO. In the above table the STMEL is deemed to be three times the LTMEL in accordance with the recommendations of the Health and Safety Executive.

Source: COSHH Regulations 1999, HSE Guidance Note EH40 (2001).

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2. Procurement of a sterilizer – an overview

Introduction

2.1 This chapter gives a short overview of the process of purchasing a sterilizer. It refers to more detailed information in subsequent chapters, including information specific to each type of sterilizer given in Chapters 8 to 14.

Purchasing a sterilizer

2.2 The purchase of a sterilizer can be broken down into the following sequence of steps.

What type of load needs to be processed?

2.3 Knowing the load is the first step in making the correct decision about which sterilizer to purchase. Different loads require different processes. Some loads are degraded by prolonged exposure to heat, others cannot withstand moisture or chemical sterilants, while others, owing to their materials or construction, cannot reliably be sterilized by conventional techniques.

What type of sterilizer is required?

2.4 In this SHTM sterilizers are classified as either clinical or laboratory sterilizers. Clinical sterilizers can use one of four different sterilizing agents ("sterilants"): high-temperature steam, hot air (dry heat), low-temperature steam and formaldehyde (LTSF) or ethylene oxide (EO). High-temperature steam sterilizers are specialised for processing porous loads, fluids or unwrapped instruments and utensils. They are also used in laboratory applications. Guidance on the selection of a sterilizer is given in Chapter 3.

What models are available?

2.5 Once the type of sterilizer has been settled, brochures and data sheets should be obtained from a number of manufacturers. The internal market in the European Union, supported by European Standards on sterilization, has considerably widened the choice open to purchasers. Guidance on what information to look for is given in Chapter 4.

Where will the sterilizer be sited?

2.6 Decide on the location of the sterilizer. Some sterilizers will require considerable building work. Guidance on siting is given in Chapter 5.

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What services are available?

2.7 A sterilizer will require one or more of the following services: steam, electricity, water, compressed air, drainage, ventilation and sterilant gas supply. The manufacturers' data will show which services are required for each model. Determine which of these are available at the proposed site and the capacities of each service. It may be necessary to plan for a new service which would add greatly to the cost of the installation. Further information about services may be found in Chapter 6. Steam supply is crucial and is discussed in detail in Chapter 7.

How big and how many?

2.8 Establish the likely weekly workload that the sterilizer will have to process. Calculate the size and number of sterilizers required to process the workload. A judgement has to be made on the trade-off between size and number. Guidance on how to do this is given in Chapter 3.

What other equipment will be needed?

2.9 A sterilizer installation may require auxiliary equipment such as steam generators, air compressors, preconditioning facilities, degassing facilities and gas disposal plants. If required, these are discussed in Chapters 8 to 14.

What specification?

2.10 Most sterilizers will be constructed to either a European Standard or a British Standard. In some cases additional specifications will be required and these are detailed in Chapters 8 to 14. Advice on preparing a detailed specification for the sterilizer is given in Chapter 4.

What sort of contract?

2.11 Once the specification has been completed, a contract should be drawn up for the supply and installation of the sterilizer. Guidance on suitable forms of contract is given in Chapter 4.

Which manufacturer?

3.12 Invite a number of manufacturers to tender for the supply of the sterilizer. Guidance on tendering is given in Chapter 4.

What happens after delivery?

2.13 Chapter 4 contains advice on the documentation that the manufacturer should include with the sterilizer. After delivery the sterilizer is subject to a programme of validation. This is discussed in detail in Part 3 of this SHTM.

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3. Choice of sterilizer

Introduction

3.1 This chapter contains information relevant to the choice of a new sterilizer. It discusses the types of sterilizer and the loads for which they are suitable, and gives guidance on selecting the size and number of sterilizers required for a given application.

Types of sterilizer

3.2 This SHTM groups sterilizers into two broad categories according to the use to which they are put:

a. **clinical sterilizers** are designed to process medical devices or medicinal products;

b. **laboratory sterilizers** are designed to process laboratory goods and materials that are neither medical devices nor medicinal products and are not intended for use in the clinical care of patients.

3.3 The operation of sterilizers in the two categories should be kept strictly separate. Loads intended for processing in a clinical sterilizer should not be put into a laboratory sterilizer and vice versa.

Sterilants

3.4 Sterilizers can also be classified according to the agent (the sterilant) used to effect sterilization. The following sterilants are in common use in the NHS:

a. high-temperature steam;

b. dry heat (hot air);

c. low-temperature steam and formaldehyde (LTSF);

d. ethylene oxide (EO).

3.5 Because of its superior sterilizing qualities, high-temperature steam is the sterilant of choice. Machines using other sterilants should be reserved either for loads which would be damaged by exposure to high-temperature steam (such as certain surgical devices) or for loads that would not be sterilized by exposure to high-temperature steam (such as non-aqueous fluids).

3.6 Low-temperature steam used without formaldehyde is not considered to be a sterilant but is commonly used for disinfection.

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3.7 Clinical sterilizers may employ any one of the four sterilants. The laboratory sterilizers described in this SHTM use only high-temperature steam.

3.8 High-temperature steam sterilizers are by far the most common sterilizers used in the NHS, and are manufactured in three basic types according to the nature of load they are designed to process: porous loads, fluids, or unwrapped instruments and utensils. The operating cycles are designed to cope with the differing properties of the various types of load, and it is essential that a sterilizer is used only for the type of load for which it is designed.

3.9 High-temperature steam inactivates pathogens by a combination of moisture and heat; water molecules combine with proteins and genetic material, which are then susceptible to thermal disruption. The process is well understood and the attainment of sterilization conditions can normally be confirmed by simple physical measurements. (This is not so for sterilizers using gaseous sterilants, where microbiological test procedures are necessary.)

3.10 Many high-temperature steam sterilizers are large machines requiring permanently installed engineering services (including good-quality steam) and purpose-built accommodation. Smaller models are transportable and generate steam from an internal water reservoir.

Choice of sterilizer

3.11 The choice of sterilizer will be governed by the nature of the loads required to be sterilized. Table 2 summarizes the type of load that can and cannot be processed in each type of machine. More detailed guidance on appropriate processes for different load items can be found in *Sterilization, disinfection and cleaning of medical equipment: Part 1: Principles*, published by the Medical Devices Agency, *Sterilization and disinfection of heat-labile equipment* published by the Central Sterilising Club, and in Part 4 of this SHTM.

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Table 2: Suitable and unsuitable loads for different types of sterilizer

Type of sterilizer	Suitable loads	Unsuitable loads
Porous load (high-temperature steam)	Porous items; items with narrow lumens that may trap air and inhibit the penetration of steam. *Examples*: any item with porous wrapping, dressings, clothing, towels	Items which would be damaged by exposure to steam at 121 - 137°C
Fluid (high-temperature steam)	Aqueous fluids in sealed glass or plastic containers. *Examples*: intravenous fluids	Non-aqueous fluids
Unwrapped instruments and utensils (high-temperature steam)	Solid metal items. *Examples*: surgical or dental instruments, bowls	Items with narrow lumens that may trap air and inhibit the penetration of steam. *Examples*: ENT suction tubes, laparoscopic instruments, orthopaedic reamers
Dry heat	Items which would not be sterilized by high-temperature steam, or would be damaged by doing so. *Examples*: solids, powders, non-aqueous fluids, ointments, ophthalmic instruments, items in closed containers	Aqueous fluids and items which would be damaged by prolonged exposure to dry heat at 160-200°C. *Examples*: fibre optics, rubber, plastics
Low-temperature steam and formaldehyde (LTSF)	Wrapped or unwrapped items which would be damaged or not sterilized by high-temperature steam or dry heat. *Examples*: certain items containing plastic components, electromedical equipment	Items which would be damaged by exposure to steam or formaldehyde gas at 71-80°C; sealed, oily or greasy items; items contaminated with body fluids
Ethylene oxide (EO)	Wrapped or unwrapped items which would not be sterilized by steam or dry heat or would be damaged by doing so. *Examples*: heat-labile plastic items, heart valves, electromedical equipment	Items which can be sterilized by other means; soiled items; items previously sterilized by irradiation. *Examples*: ventilatory and respiratory equipment
Laboratory (high-temperature steam)	Laboratory materials and equipment. *Examples*: infected materials to be made safe, culture media, glassware and other equipment	Medical devices, medicinal products and other items to be used in the clinical care of patients

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3.12 Purchasers should be aware that items suitable for a particular type of sterilizer may still require different operating cycles, which need to be specified before purchase. For example, a porous-load sterilizer is required for wrapped instruments and microbiological filters. However, a cycle suitable for instruments may be harmful to the filters unless the rate of change of pressure is reduced to prevent rupture of the membrane. Similarly, a container with a small orifice will also require a porous-load sterilizer but the duration of each air removal pulse will need to be extended to allow for pressure equilibration; otherwise the air will remain in the container and sterilization will not be achieved. Guidance on the modification of operating cycles to suit particular loads (process development) is given in Part 4 of this SHTM.

3.13 More information about the different types of sterilizer is given in Chapters 8 to 14.

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Table 3: Suggested information to be obtained from manufacturers before inviting tenders

Information required	Objective
The **standards** (BS or EN) to which the sterilizer is designed and constructed and a statement of compliance	To confirm that the sterilizer meets recognised specifications for design, construction, performance and safety
Installation data, including the overall dimensions and mass of the sterilizer; the number of supports and the maximum floor loading at each support; the clearance required for access and the masses of the principal heavy components	To enable the user to establish whether the proposed location is suitable for the sterilizer and the extent of any building work required (see Chapter 5)
The volume of the **usable chamber space** expressed both in litres and an integral number of sterilization modules, and its principal dimensions in metres	To enable the user to determine the capacity of the sterilizer and hence the number of sterilizers required to process the workload
Specifications for each of the **engineering services** required by the sterilizer	To enable the user to establish that the demands of the sterilrzer are within the capacity of the services in the proposed location (see Chapters 6 and 7)
A description of the **operating cycles** offered with the sterilizer, including numerical and graphical representations of typical values of cycle variables throughout each cycle and the extent to which pre-set variables may be adjusted	To enable the user to confirm that the cycles are appropriate for the anticipated loads
For each operating cycle and sterilization temperature the cycle time and corresponding **performance class** for the relevant full load tests specified in Part 3 of this SHTM	To enable the user to determine the capacity of the sterilizer and hence the number of sterilizers required to process the workload
The mean and peak **sound power levels** generated by the sterilizer, expressed as an A-weighted sound power level measured as described in Appendix D of BS 3970: Part 1 or in Part 5 of this SHTM, 'Good practice guide'	To enable the contractor to confirm that the sound pressure level after installation, as measured by the method given in Part 3 of this SHTM, will not exceed that specified for the location (see Chapter 5)
The **fatigue life** of the pressure vessel	To enable the user to estimate the working life of the sterilizer (see Chapter 4)
The type of **doors** and information on the necessary space required for the movement of the doors (see Chapter 4)	To enable the user to make the necessary provisions in the design of the loading area (see Chapter 5)

3.14 Advice on individual cases should be sought from the authorised person before any decision is made. Where an LTSF or EO sterilizer is being considered the microbiologist should also be consulted.

3.15 Once the type of sterilizer has been decided, preliminary enquires should be made with a number of manufacturers to obtain specifications and price lists. Table 3 indicates some of the information that will be useful for planning purposes and which should be obtained at this stage.

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Sterilization conditions

3.16 For the purposes of this SHTM the following definitions have been adopted.

3.17 The **cycle variables** are the physical properties, such as time, temperature, pressure, humidity and sterilant gas concentration, that influence the efficacy of the sterilization process.

3.18 Most operating cycles have a stage in which the load is exposed to the sterilization (or disinfection) conditions for a specified length of time. This period is known as the **holding time**.

3.19 The **sterilization conditions** are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

3.20 The holding time is preceded by a period in which the sterilization conditions are present in the chamber but not yet present throughout the load. This is known as the **equilibration time**.

3.21 Together, the equilibration time and the holding time constitute the **plateau period**. While the plateau period can always be determined from the recorded chamber temperature, the equilibration and holding times cannot be distinguished unless the temperature in the part of the load that is slowest to reach the sterilization temperature is also being recorded or measured.

3.22 Certain LTSF sterilizers may achieve sterilization by exposing the load to a series of pulses of formaldehyde rather than a single holding time.

3.23 For EO sterilizers the plateau period is equivalent to the **gas exposure time**. The holding time cannot be determined by thermometry and is therefore of no practical interest.

3.24 For steam and dry heat sterilizers, the sterilization conditions are specified by a **sterilization temperature band**, defined by a minimum acceptable temperature, known as the **sterilization temperature**, and a maximum allowable temperature. The higher the sterilization temperature, the shorter the holding time and the more rapidly the cycle is completed. A sterilization temperature band can also be quoted for LTSF and EO sterilizers, but since these processes depend primarily upon chemical action such a band is not a complete specification of the sterilization conditions. Bands for the different types of sterilizer are listed in Table 4.

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Table 4: Sterilization temperature bands

	High-temperature steam				Dry heat			LTS	LTSF	EO
Sterilization temperature (°C)[a]	115	121	126	134	160	170	180	71[b]	71	30-56
Maximum allowable temperature (°C)	118	124	129	137[c]	170	180	190	80	80	[d]
Minimum holding time (min)	30	15	10	3	120	60	30	10	180[e]	[f]

Note:

a. The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.

b. Disinfection temperature.

c. British Standards permit 138°C.

d. For EO, the maximum allowable temperature will normally be 4°C above the sterilization temperature.

e. For LTSF, the sterilization conditions may specify either a continuous holding time or the number of pulses for formaldehyde required to achieve sterilization.

f. For EO, the "gas exposure time" is determined for each sterilizer by microbiological methods during commissioning but is typically 2-7 hours depending upon sterilization temperature and gas concentration.

Sizes and numbers

3.25 It is difficult to give precise information on the sizes and number of sterilizers required for particular installations since in practice there are significant variations in patterns of use. The following guidance is applicable to all types of sterilizer. More detailed advice and examples of how to calculate sizes and numbers of sterilizers in a Sterile Services Department (SSD) is given in Scottish Hospital Planning Note 13 for porous loads, and in Supplement 1 to Scottish Hospital Planning Note 13 for EO sterilizers.

3.26 The number of sterilizers required will depend on two critical properties of the machine: the cycle time (denoted by a performance class) and the chamber size (denoted by the volume of the usable chamber space).

Cycle time and performance class

3.27 The time required to complete an operating cycle depends both on the design of the sterilizer (especially the methods used to remove air from the chamber and to heat and cool the load) and on the type and size of load to be processed. An operating cycle is assigned a performance class which is related to the time required to process a standard full load, as specified in the tests described in Part 3 of this SHTM. A Class 1 cycle will be complete in less than 10 min, while a Class 20 cycle will take over 13 hr. The relation between cycle time and performance class is given in Table 5. If the cycle time is to be extended to dry difficult loads, this should be allowed for when calculating the number of sterilizers required.

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Table 5: Performance classes for sterilizers

Class	Full load cycle time [mins]	Class	Full load cycle time [mins]	Class	Full load cycle time [mins]	Class	Full load cycle time [mins]
1	0 – 10	6	61 – 90	11	241 – 300	16	541 – 600
2	11 – 15	7	91 – 120	12	301 – 360	17	601 – 660
3	16 – 30	8	121 – 150	13	361 – 420	18	661 – 720
4	31 – 45	9	151 – 180	14	421 – 480	19	721 – 780
5	46 – 60	10	181 – 240	15	481 – 540	20	over 780

3.28 Loading conditions that present a greater challenge to the cycle than the full loads specified in Part 3 of this SHTM will require further investigation and performance qualification to establish a cycle time. The authorised person will advise on this.

Chamber size

3.29 The size of a sterilizer is denoted by the volume of the usable chamber space, commonly expressed in litres. The usable chamber space is the space inside the chamber which is not restricted by chamber furniture and which is available to accept the load. It should be distinguished from the total chamber volume, which is equal to the volume of water required to fill the chamber and is therefore larger than the usable chamber space.

3.30 With the gradual introduction of European Standards on sterilization, the size of larger sterilizers will be denoted by an integer number of sterilization “modules” which can be accommodated within the usable chamber space. One module is a rectangular box measuring 300 x 300 x 600 mm, of volume 54 litres. In the European Standards a “large” sterilizer can accommodate one or more modules; a “small” sterilizer has a capacity of less than one module. Table 6 lists the recommended sizes for different types of sterilizer.

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Table 6: Recommended sizes for different types of sterilizer

	Usable chamber space [modules][a]						
Type	<1	1	2	4	6	9	12
Porous load	-	-	X[b]	-	X	X	X
Fluid	-	-	X	X	X	X	X
Unwrapped instrument	X	X[b]	X[b]	-	-	-	-
LTSF	-	-	-	-	X	X	-
Dry heat	-	-	-	X	-	-	-
EO	-	X	X	-	-	-	-
Laboratory	X	-	-	-	X	X	-

a. A module is a rectangular box measuring 300 x 300 x 600 mm, of volume 54 litres (see paragraph 3.30).

b. May be used in a surgical facility where supply from an SSD is impractible or not cost effective.

3.31 In the case of sterilizers for unwrapped instruments and utensils and laboratory sterilizers, small transportable units of capacity less than one module are available and may be the most economical solution where workloads are light.

Sizing calculation

3.32 Once the cycle time is known, the size and number of sterilizers to be purchased can be calculated. Size and number are complementary: in principle, the same workload can be processed by a single large sterilizer or a number of smaller sterilizers.

3.33 The first step in making this decision is to establish the workload which the sterilizer is intended to process, expressed in modules per week. (For some types of sterilizer it may be more appropriate to express the workload in other units; for example trays or discard boxes per week.) This is not simply the bulk volume of goods to be processed, but the volume they will occupy inside the sterilizer allowing for spacing within the chamber. Spacing is particularly important for sterilizers using mixtures of steam and air and for dry-heat sterilizers. An item which cannot be fitted into a single module should be allowed two or more modules as appropriate.

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3.34 Once the workload is established, the capacity for a sterilizer of given size can be calculated from

$$\text{capacity} = 60\ \frac{Vf_V\ x\ Tf_T}{t_C}\ \text{modules/week}$$

where

V = the volume of the usable chamber space (modules);

f_v = the loading factor, the average fraction of the usable chamber space occupied by a load (typically 0.5 for an SSD);

T = the "open hours", the number of hours each week for which the sterilizer unit will be operational;

f_T = the utilisation factor, the fraction of the open hours for which the sterilizer is available to process loads. This should allow for loading and unloading, periodic testing and maintenance, and warm-up cycles. It should be chosen so that a sterilizer may be withdrawn from service for planned maintenance and periodic testing without jeopardising production. For an SSD the utilisation factor is typically 0.55;

t_c = the cycle time for the selected operating cycle (minutes).

3.35 The minimum number of sterilizers required to process the workload can then be calculated from

$$\text{Number of sterilizers required x}\ \frac{workload}{capacity}$$

3.36 Purchasers should make the above calculation for a number of different sizes of sterilizer to establish the combinations of size and number that will satisfy the workload requirement.

3.37 In practice, the number of sterilizers of the same type in a single installation will be usually at least two and rarely more than four.

3.38 Where more than one sterilizer of the same type is installed, they should be of the same size and from the same manufacturer. This will allow common loading systems to be used.

3.39 If further sterilizers are likely to be purchased in the future, then consideration should be given to the extra space required both in the plantroom and in the loading area.

3.40 Special considerations for laboratory sterilizers are discussed in Chapter 14.

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4. Specification and contract

Introduction

4.1 This chapter discusses general specifications for sterilizers and the steps to be taken in inviting tenders and issuing a contract. The validation procedure, which begins on installation of the sterilizer, is discussed in detail in Part 3 of this SHTM.

Preparing a specification

4.2 Purchasers are strongly recommended to seek assistance from the authorised person when preparing a specification for a sterilizer.

4.3 To keep abreast of changing requirements, purchasers should ensure that they consult the latest editions of any standards and other specification documents, including any amendments issued after publication. The authorised person will advise on this.

4.4 Most sterilizers are constructed either to a European Standard (EN) or a British Standard (BS). A summary of the current relevant standards is given in Table 7. As many British Standards will be replaced by European Standards in due course, purchasers should specify a European Standard where one exists. The relevant standards are discussed in the ‘Standard specifications’ section of each chapter.

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Table 7: British and European Standards on sterilizers

Topic	British Standard
Clinical sterilizers	
Porous load	BS 3970: Parts 1& 3, BS EN 285
Fluid	BS 3970: Parts 1 & 2
Unwrapped instruments	BS 3970: Parts 1 & 4
Dry heat	-
LTS	BS 3970: Parts 1 & 5
LTSF	BS 3970: Parts 1, 5 & 6
EO	BS EN 1422
Laboratory sterilizers	BS 2646 Parts 1-5
Electrical safety	BS EN 61010: Part 1
Steam	BS EN 61010: Part 2-041
Dry heat	BS EN 61010: Part 2-043
LTSF and EO	BS EN 61010: Part 2-042

Full references for these standards are given in the Reference section

4.5 In some cases the standard specifications may not be adequate for sterilizers to be used in the public service. In these cases, additional specifications are listed below for general design considerations (see paragraphs 4.9 onwards) and, if appropriate, in an 'Additional specifications' section of each chapter.

4.6 Purchasers are strongly advised to use the NHS Model Engineering Specification C14, *Sterilizers* and the *C14 User Guide*, both published by NHS Estates, when ordering sterilizers. C14 is an exhaustive, detailed statement of specifications, conforming both with current standards and with the recommendations of this SHTM. There should be no need for any further documentation, alterations or additions to be included in the tender documents.

4.7 Details of the proposed location for the sterilizer should be stated clearly in the specification.

4.8 Except when the manufacturer is responsible for the installation of the machine, the type and standard of packing for delivery of the sterilizer should be specified. Where site conditions are likely to be poor and damage could occur, a substantial dustproof transit case may be necessary.

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General design considerations

4.9 The following design considerations are applicable to all or most types of sterilizer, but are not necessarily required by the current standards. Where applicable they should be included in the specification for any sterilizer to be operated in the NHS.

4.10 All sterilizers and associated equipment are classed as “work equipment” and should comply with the Provision and Use of Work Equipment Regulations 1998 (PUWER 98), (see Part 1 of this SHTM). Purchasers are reminded that under the Regulations it is the responsibility of the employer, not the manufacturer, to provide a sterilizer that is “suitable for the purpose for which it is used or provided”.

4.11 All sterilizers made or sold in the UK from 1 January 1996 should conform to the emission and immunity requirements of the Electromagnetic Compatibility Regulations 1992. This may be achieved by compliance with BS EN 50081 (emission) and BS EN 50082 (immunity). The manufacturer should be informed of any local sources of electromagnetic disturbance which may affect the operation of the sterilizer (see Chapter 5).

4.12 For maintenance purposes, side, back and top panels for free-standing sterilizers should be easily removable and replaceable.

4.13 Special foundations are not normally required. The weight of the sterilizer, which can be as much as 2.5 tonnes when fully loaded, should be borne by at least four pads, each measuring at least 150 x 150 mm. Floor mountings should be designed to minimise vibration.

Safety features

4.14 Safety features should be designed in accordance with the British Standard code of practice for safety of machinery, PD 5304: 2000, and the British Standard for the safety of electrical equipment, BS EN 61010.

4.15 The design of the control system should ensure that the door cannot be opened except by a key code or tool until the cycle is either complete or returned to a safe condition and a fault is indicated.

4.16 The sterilizer should conform to the requirements listed under *Safeguards* and *Interlocking* in HSE Guidance Note PM73, *Safety at autoclaves*.

4.17 The manufacturer should provide a list of all safety devices together with their settings and methods of adjustment.

4.18 All safety devices should be designed to fail in a manner which does not cause a safety hazard to personnel.

4.19 A safety hazard should not be caused by an error in the control or indication system.

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Instrumentation

4.20 Whilst it is preferable that the recording system is wholly independent of control and indication, a system which combines both control and instrumentation may be used, providing that any fault which could cause a failure to attain specified parameters within all parts of the load is either indicated or recorded. If this requirement cannot be met, an independent recording system should be provided. (See also paragraph 4.30.)

4.21 Where an instrument has a facility for adjusting one or more preset variables (such as a thermostat) the adjustment should be by means of a key, code or tool not available to the operator.

4.22 Where more than one instrument is fitted in the same area, every effort should be made to obtain a uniform appearance. As an alternative to discrete instruments, any or all of the required displays may be provided by a single display unit.

4.23 Where a fault is indicated in the form of an error message shown on a visual display unit, it should be clearly distinguishable from normal messages, for example, by use of a different colour or larger size of text. The indication should remain displayed until acknowledged by the operator.

4.24 The sterilizer contractor should be required to carry out adjustments to the instruments on site so that the accuracies specified at the sterilization temperature can be met with the plant running and under the conditions normally prevailing on site.

4.25 An indicator should show which stage of the operating cycle is in progress and indicate “cycle complete” at the end of the cycle.

4.26 A five-digit counter should be provided to indicate the cumulative total of cycles started. The counter should be tamper-evident or sealed.

4.27 Provision should be made for the attachment of the test instruments required for the tests specified in Part 3 of this SHTM.

a. For temperature testing, a connection should be provided to permit the entry of sensors into the chamber, as described in BS EN 285. A suitable gland for attachment to the connection is illustrated in Part 3 of this SHTM.

b. For pressure or humidity testing, test tees and valve cocks with sealing plugs should be fitted to permit connection of test instruments for the verification and calibration of all pressure and humidity instruments permanently fitted to the sterilizer. The connection should be as described in BS EN 285.

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Programmable electronic systems

4.28 Modern sterilizers frequently use programmable electronic systems (PES) for control and data recording. Where such systems are used, they should be designed in accordance with the principles set out in the two parts of the HSE document, *Programmable electronic systems in safety related applications*.

4.29 Where a PES is used for control or monitoring of the process, the values of cycle variables critical to process performance and determined during validation should be documented in the validation report regardless of whether or not they are held in the PES memory. The version number of the software should be available for display when required.

4.30 Combined control and instrumentation systems that are wholly operated by means of PESs should incorporate at least two timing systems, independent of each other, such that the timer used to control the holding time is verified by the other timer.

Overpressure protection

4.31 Overpressure safety valves should be fitted to protect components that may be damaged by inadvertent high pressures. These include the chamber, jacket, pressurised door-sealing system, heat exchanger system and ballast air system. The discharge from safety valves should be terminated in a safe position (see paragraph 7.15).

4.32 The steam pipework should include a pressure-reducing system with a separator on the high-pressure side. The system should be fitted with a strainer and trap to prevent condensate accumulating in the system.

Access to chamber drain

4.33 For steam sterilizers, the chamber drain should be positioned so that any debris caught on the strainer can be seen and removed by the operator without the need to dismantle any part of the sterilizer.

Doors

4.34 A single door is preferred. Sterilizers with a door at each end (“double-ended” sterilizers) create problems of maintenance and ventilation and should only be considered where alternatives have been discounted.

4.35 Power-operated doors are desirable on sterilizers of 300-litre capacity and over. The following designs are available:

a. sliding doors (vertical or horizontal);

b. side-hinged doors;

c. bell-shaped sterilizer, where the chamber is raised vertically from a fixed bedplate.

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4.36 The choice of design for any particular installation will depend on the workload, space restrictions, price and ease of maintenance. With side-hinged doors there is a risk of the operator touching the hot inside face as the door is opened. If hinged doors are required, the specification should state whether they are to be hinged on the left-hand or right-hand side of the opening. Bell-shaped sterilizers require special guards to ensure the safety of the operator when the chamber is being lowered.

4.37 It should be possible to clean the contact surfaces of the door seal without removing parts of the sterilizer.

Materials of construction

4.38 Table 8 summarises the materials to be used for clinical sterilizers and for laboratory sterilizers.

Table 8: Recommended materials of construction

	Clinical sterilizers	Laboratory sterilizers
Pressure vessel and steam generator	Group A	Group A, B or C
Pipework for circulating media coming into contact with load	Group E	Group G
Pipework for circulating media **not** coming into contact with load	Group J or K	Group H, J or K

Groups are defined in Annex 1 of BS EN 285.

4.39 The fatigue life of sterilizer vessels (see paragraph 4.40) constructed from dissimilar materials welded together can be considerably reduced by unpredictable high stresses caused by differential expansion and weld inconsistencies. For this reason the use of carbon-steel jackets or stiffeners should be avoided on stainless-steel chamber shells.

Fatigue life of pressure vessel

4.40 The fatigue life of a sterilizer vessel will depend on the level of alternating stresses caused by the following:

a. changes of pressure within the chamber;

b. differential temperature changes within the chamber and jacket (if fitted);

c. differential expansion;

d. stresses “locked” within the pressure-retaining parts of the vessel.

4.41 Vessels should be designed to withstand $25{,}000/t_C$ operating cycles, where t_C is the minimum cycle time (in hours) corresponding to the performance class quoted by the manufacturer.

4.42 The manufacturer should determine the fatigue life by the method given in Part 5 of this SHTM (reprinted from BS 3970: Part 1).

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Integral air compressors

4.43 European and British Standards permit the use of built-in air compressors for sterilizers but do not give specifications, current experience indicates, however, that certain small compressors of the type fitted to domestic refrigerators are not suitable for use in sterilizers. Unless they are meticulously maintained, a small air leak can cause them to run continuously, causing rapid carbonisation of the oil and consequent failure of the sterilizer pneumatic system.

Integral steam generators

4.44 Where an integral steam generator is fitted to the sterilizer, it should be equipped with blow-down facilities to enable sludge to be expelled from the boiler.

Loading systems

4.45 Sterilizer loading systems should be designed with regard to the Manual Handling Operations Regulations 1992 and the Lifting Operation and Lifting Equipment Regulations 1998 (LOLER).

Invitation to tender

4.46 Once detailed specifications have been drawn up, manufacturers should be invited to tender for the supply and, if required, the installation of the sterilizer.

4.47 When inviting tenders, purchasers should follow the principles described in Scottish Capital Investment Manual and PROCODE.

4.48 The purchaser should specify that the sterilizer manufacturer operates a quality system in accordance with the principles described in BS 5750 and the EN 9000 series. If the manufacturer has both designed and manufactured the sterilizer, the quality system should conform with EN 9001. If the sterilizer has been manufactured to a design supplied by a third party, the manufacturer's quality system should conform to EN 9002. In either case the manufacturer should ensure that each supplier of accessories, fittings and other materials also operates an appropriate quality system.

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4.49 Prospective contractors should be given the following information:

a. that each sterilizer will be subject to a validation process as described in Part 3 of this SHTM;

b. unless otherwise specified, that the installation checks and tests specified in the validation process must be satisfactorily completed before the sterilizer can be accepted;

c. whether the installation checks and tests are to be witnessed by the purchaser's representative (normally the test person);

d. the date by which all services will be available;

e. the date by which the validation process is expected to be completed.

4.50 In assessing tenders, purchasers should not automatically opt for the lowest quoted price. An unusually low tender should not be chosen without further investigation into the financial circumstances of the prospective contractor.

Contract

4.51 For procurement of sterilizers Conditions of Contract as advised by PROCODE may be used. Modifications to suit local purchasing policy may be required.

4.52 Consideration may also be given to the use of alternative forms of contract, for example MF/1 (available from the Institution of Electrical Engineers, the Institution of Mechanical Engineers or the Association of Consulting Engineers) or the Joint Contracts Tribunal (JCT) suite of documents (available from RIBA Publications). Addresses are given in Appendix 1.

4.53 Purchasers using other forms of contract are strongly advised to seek legal advice, from the Central Legal Office (CLO) especially where a contract proposed by the prospective contractor is being considered.

4.54 Other contracts, notably for the authorised person, the test person, the maintenance person, the competent person and the microbiologist, may need to be considered at this time (see Part 1 of this SHTM). In awarding these contracts, purchasers should ensure that there is no conflict of interest that would compromise the validation process set out in Part 3 of this SHTM.

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Delivery

4.55 On or before delivery of the sterilizer, the manufacturer should provide the purchaser with the information specified in Appendix 2.

4.56 Sterilizers for a particular scheme should not be ordered and stored on site for long periods prior to installation and validation. Disregard of this recommendation could result in the installation of a technically obsolescent sterilizer. Where a long delay is unavoidable, conditions for storage should be agreed with the manufacturer.

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5. Siting

Introduction

5.1 This chapter sets out some of the considerations to be taken into account when siting a sterilizer. A thorough discussion of the planning requirements for a sterile services department (SSD) is given in HBN 13. Additional guidance on the siting of ethylene oxide (EO) sterilizers may be found in Chapter 13 and in Scottish Hospital Planning Note 13, Supplement 1; *Ethylene oxide sterilization section*. Guidance on the siting of laboratory sterilizers is given in Chapter 14 and in BS 2646: Part 2. Guidance on accommodation for ethylene oxide gas cylinders, manifolds and canisters is given in Part 5 of this SHTM.

5.2 The room in which a sterilizer is installed should meet the requirements of the Workplace (Health, Safety and Welfare) Regulations 1992, which have far-reaching implications for the design of sterilizer accommodation.

5.3 Fire safety precautions should comply with the NHS in Scotland Firecode series published by the NHS in Scotland Property and Environment Forum Executive.

5.4 Where possible, sterilizers should be transported as a whole and not partially stripped.

Accommodation

5.5 Except where sterilizers are free-standing (paragraph 5.14) or transportable (paragraph 5.17), a sterilizer installation will normally be separated into two areas: a plantroom containing the sterilizer itself, services and ancillary equipment; and an adjacent loading area from which the sterilizer is loaded and unloaded. The areas are divided by a partition wall into which the front panel and door of the sterilizer are set.

5.6 The wall aperture should meet the tolerances quoted in BS EN 285. The contractor should be required to provide the trim to the wall or provide the panelling. Fascia panels should be adequately supported and insulated to minimise vibration and heat transmission from the plantroom to the loading area. Foamed plastic materials which are either combustible or subject to degradation at the operating temperatures should not be used, nor should asbestos products. Suitable specifications for such insulation may be found in NHS Model Engineering Specifications C02, *Thermal insulation*.

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5.7 Maintenance staff should be able to enter the plantroom without passing through the loading area. Direct access between the plantroom and loading area should be provided for use during testing. Operators will normally require access to the loading area only.

5.8 If a sterilizer with a door at each end is installed (a “double-ended” sterilizer), arrangements for maintenance should be from the “dirty” end. Except where the product would be jeopardised or a microbiological hazard created, maintenance access from the “clean” end should also be provided.

Plantroom

5.9 Wherever practicable the sterilizer should be located on the ground floor and the plantroom should have an outside wall. This arrangement will facilitate easy access for engineering staff and for plant replacement. It will also simplify safety requirements for ventilation and drainage, particularly for low-temperature steam and formaldehyde (LTSF), EO and laboratory sterilizers.

5.10 The plantroom floor should be non-slip and waterproofed to avoid damage to rooms and equipment which may be below the sterilizers. To facilitate cleaning, the floor should fall naturally to a drain.

5.11 Adequate clearance around the machines is essential for access and maintenance. The minimum clearance should be 1.0 m around all parts to which access for routine maintenance is necessary. The minimum ceiling height is 2.7 m above floor level. Spacing should be such that it is possible to replace any sterilizer without disturbing others in the same installation. Particular care should be taken to ensure that sufficient clearance is allowed for large items, such as vacuum pumps, to be withdrawn from the sterilizer frames.

5.12 Extra space should be allowed for installation and maintenance of free-standing equipment such as steam generators, air compressors and water conservation systems. Possible future expansion should be considered. For EO sterilizers, a separate but adjacent manifold room will be required for gas cylinders (see paragraph 6.74).

Loading area

5.13 Where carriage or trolley loading is used, the minimum clearance for access to the sterilizer should be 3.0 m or twice the length of the carriage loading system, whichever is the greater. Careful attention should be paid to height adjustment, so that all sterilizers in a group can be served wherever possible by a common loading system.

Free-standing sterilizers

5.14 Certain permanently installed sterilizers, such as smaller laboratory machines, may be “free standing”, that is, installed in a room with no separation into plantroom and loading area. Such installations may present problems of safety and access, and are not recommended where a more

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conventional arrangement is possible. Where a free standing installation is unavoidable, the authorised person should be consulted at an early stage to ensure that adequate safety precautions are taken.

5.15 A free-standing sterilizer may not meet the environmental quality control standards required for the manufacture of medicinal products or medical devices (see Chapter 1). Advice may be obtained from the authorised person.

Transportable sterilizers

5.16 Benches on which transportable sterilizers are placed should comply with HTM 67, *Laboratory fitting-out system*.

5.17 The sterilizer should be placed within 2 m of a switched 13 A socket outlet. Extension flexes should not be used.

5.18 The pressure relief valve should be able to discharge freely and safely. Equipment which could be damaged by steam or moisture should not be placed near the sterilizer.

5.19 It has been known for the door of a transportable sterilizer to be blown off with considerable force; the sterilizer should therefore be sited so that a safety hazard is not created in the event of an accident. Sterilizers in dental practices should preferably be sited in a different room to that used for operating. If this is impossible, the sterilizer door should face in such a direction that there is no hazard to patients or staff.

5.20 Users should be aware of the heat and water vapour that may be emitted in normal operation by even a small sterilizer and make appropriate provision for ventilation (see Chapter 6). The authorised person will advise on suitable arrangements.

Noise and vibration

5.21 Sound pressure levels sensed in a room are a function of the sound power generated by the sterilizer and the acoustic design of the room in which the sterilizer is installed.

5.22 European and British Standards do not specify permitted sound power levels. The sterilizer manufacturer should state at the time of tendering the A-weighted sound power level determined in accordance with the method detailed in Part 5 of this SHTM. Purchasers should be aware that the uncertainty inherent in this method can amount to a standard deviation of 5 dB for sources containing discrete tones and 4 dB for wide-band noise sources. These uncertainties should be taken into account in the acoustic design of the room in which the sterilizer is installed. The design should ensure that sound pressure levels stated in the sound pressure test described in Part 3 are not exceeded.

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5.23 The sound pressure levels specified in Part 3 are for an area or space where the sterilizer is operating under normal working conditions. The levels include noise from all sources including the sterilizer.

5.24 The room in which the sterilizer is to be installed should be located and designed so that the noise transmitted from the room does not increase the sound pressure levels in adjacent rooms in excess of the levels specified in SHTM 2045; *Acoustics*. Account should be taken of all transmission paths, including open windows and building structures. A fascia panel should not be used to separate a noise-sensitive area from the operating parts of the sterilizer without additional insulation (this may double as thermal insulation – see paragraph 5.6).

5.25 If the sterilizer is in or adjacent to a main building or a noise-sensitive area, open louvres in internal doors and partitions should be avoided; doors should be solid, self-closing and a good fit in their frames, preferably with compressed rubber seals. If this affects natural ventilation, mechanical ventilation may be required (see Chapter 6). The need for such a solution can usually be avoided in the planning stage.

5.26 Vibration transmitted to the building structure is generally produced by pumps, motors and on/off valves connected to the services. If vibration is likely to be a problem the following measures are recommended:

a. transmission of vibration through service connections can be avoided by the use of flexible connections;

b. pumps and motors associated with sterilizers should be resiliently mounted, whether or not they are integral with the sterilizer;

c. the forcing frequency of the vibration generator should be taken into account when designing vibration isolators.

Lighting

5.27 Fluorescent lighting should be used. The stroboscopic effect of the lighting should be minimised in the plantroom by the use of two tube fittings suitably adapted for this purpose or by the use of two phases for the lighting circuits. The fittings should be sited longitudinally between the sterilizers. Further guidance on lighting may be found in *Lighting guide: hospitals and health care premises*, published by the Chartered Institution of Building Services Engineers (CIBSE).

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Electromagnetic compatibility

5.28 Although a new sterilizer will be designed to comply with the Electromagnetic Compatibility Regulations 1992, purchasers should establish whether existing equipment on the premises is likely to give rise to electromagnetic disturbance at the intended location of the sterilizer. If so, the sterilizer manufacturer should be informed at an early stage. Further guidance may be found in SHTM 2014; *Abatement of electrical interference*.

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6. Engineering services

Introduction

6.1 A sterilizer installation will require one or more external services including steam, electricity, water, compressed air, drainage, ventilation and ethylene oxide gas. The manufacturer should make clear at an early stage which services will be needed and the detailed requirements for each, as outlined in Table 9. Steam supply is the most critical of the services and is considered in detail in Chapter 7.

6.2 If the services are to be installed by a contractor other than the contractor installing the sterilizer, care must be taken to ensure that the size and location of terminations are agreed before the contracts are placed.

6.3 All services should be terminated within the plantroom by appropriate valves and isolators within 2.0 m of the sterilizer.

6.4 Care should be taken to ensure that pipework and cables used to connect the sterilizer to the service terminations are of adequate size to meet the demands of the sterilizer. Inadequate services may cause malfunctioning. Pipework and cables should be installed close to a wall and not over the top of a sterilizer.

Electricity

6.5 The electrical power requirements will depend on a number of factors, such as the type of sterilizer and the method used to generate steam. (Local or integral electrical steam generators will result in a high electrical load.) Some sterilizers will require a three-phase supply. The manufacturer should provide details of the type of supply (AC or DC), number of phases, frequency, and voltages with tolerances and loading.

6.6 Each sterilizer should be connected via an isolator. The type of isolator will depend on the nature of the supply:

a. isolators for transportable sterilizers with a maximum current demand of 13 A may be of the simple plug and socket-outlet type, with the plug correctly fused and the socket outlet switched;

b. where a three-phase-and-neutral supply is necessary, or where a maximum single-phase current demand is more than 13 A, the sterilizer should be wired directly to the isolator. The switch should isolate all poles simultaneously and each pole should be fused separately. The cable from isolator to sterilizer should be fixed and protected from the effects of heat, water and steam.

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Table 9: Information on services to be obtained from the sterilizer manufacturer

Steam	a. the maximum flow and usage rate; b. the acceptable range of steam supply pressures; c. where steam is generated within the sterilizer, the maximum hardness value, the range of pH and the conductivity of the boiler feed water.
Electricity	a. type of supply, e.g. AC or DC; b. number of phases (normally one or three) and whether neutral is required for a 3-phase supply; c. supply voltage and frequency including acceptable minimum and maximum values; d. maximum continuous power in kW or kVA.
Water	a. the minimum and maximum supply pressure; b. the flow at minimum pressure; c. the volume used per cycle; d. the maximum temperature of the water; e. the maximum permissible chlorine and chloride content.
Compressed air	a. the minimum and maximum supply pressure; b. the flow at minimum pressure; c. the volume of air used for each cycle.
Sterilant gas	For EO sterilizers, details of the type of sterilant supply required and the quantity required for a single cycle.
Drainage	a. the maximum flow of effluent (water and condensed steam) to the hospital drain; b. the maximum temperature of the effluent on leaving the sterilizer; c. the sources of effluent contributing to the total outflow.
Ventilation	The following quantities should be given as peak values during the cycle and as average values over a complete cycle: a. the heat (in watts) transmitted to the environment when the sterilizer is operated in a nominal ambient temperature of 23 ± 2°C in still air with the doors closed; b. for a recessed sterilizer, the heat (in watts) transmitted to the loading area when the sterilizer is operated in a nominal ambient temperature of 23 ± 2°C in still air with the doors closed.

6.7 Within the loading area an additional switch should be provided so that the operator can electrically isolate the sterilizer or group of sterilizers in the event of an emergency. The switch should be placed between the normal operating position and the exit door.

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6.8 Sterilizers used to process heat-sensitive loads should be connected to the essential supplies circuit, if available, to avoid heat damage in the event of a power failure. Guidance on the supply of electricity in the event of a failure of the normal supply is given in SHTM 2011; *Emergency Electrical Services.*

6.9 All electrical installations should conform to the IEE Regulations contained in BS 7671. Further guidance is given in SHTM 2007; *Electrical services: supply and distribution* and SHTM 2020; *Electrical safety code for low voltage systems* (Escode - LV).

Water

6.10 A water supply of potable quality may be needed for equipment such as condensers, heat exchangers and water-sealed vacuum pumps (feed-water for steam generation is discussed in Chapter 7). Details of the water-quality requirements, the maximum pressure, minimum pressure and maximum flow rate should be obtained from the sterilizer manufacturer.

6.11 To prevent possible contamination of the water main, the supply should be connected to the sterilizer via a backflow protection device, such as a break tank.

6.12 The temperature of water used for sterilizers with vacuum systems should not normally exceed 15°C. Higher water temperatures will reduce the efficiency of vacuum pumps and compromise the specified vacuum levels.

6.13 Performance will also deteriorate if the water is very hard or contains large quantities of solids in suspension. The hardness of the water should be in the range 0.7-2.0 mmol litre^{-1}. Hardness values outside these limits may cause scaling and corrosion problems. This can be overcome by the installation of simple water-treatment plant at the sterilizer site.

6.14 Water economy devices, which sense the temperature of cooling water and adjust the flow rate accordingly, should be fitted to reduce water consumption.

6.15 Chlorine and chlorides may cause corrosion of stainless steel in the presence of heat. Advice on maximum permissible levels should be obtained from the sterilizer manufacturer.

6.16 A copious supply of piped water is required for emergency use in any area where a spillage of liquid EO may occur. The supply should be capable of delivering at least 18 litre min^{-1} at a minimum pressure of 1.5 bar.

6.17 Further guidance on water supply is given in SHTM 2027; *Hot and cold water supply, storage and mains services*.

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Compressed air

6.18 A compressed-air supply may be required for the operation of controls and also for pressure ballasting in certain fluid and laboratory sterilizers. Where the sterilizer does not contain an integral air compressor (see paragraph 4.43), the air may be supplied from a mains supply or from a local compressor.

6.19 If pressure ballasting is required, additional reservoir capacity or compressors will be needed. The system should be capable of delivering at least 12 m^3h^{-1} at 8 bar.

Mains supply

6.20 If air is supplied by pipeline from a central air-compressor system, a pressure gauge, of the Bourdon type complying with BS EN 837, should be fitted inside the plantroom and terminated with an isolation valve.

6.21 A reducing valve or other automatic device should be fitted to reduce the pressure of the air delivered to the sterilizer to not more than the maximum working pressure of the sterilizer. A pressure relief valve will normally be required.

Local compressors

6.22 Where it is not practicable to obtain compressed air from a mains supply, a dedicated compressed-air facility should be installed to supply the sterilizers and other equipment. At least two compressors should be provided, with autochange between the two. The system should be sized to meet all the compressed air requirements of the unit and give priority to the sterilizers.

6.23 The compressors are likely to be too noisy to be installed in the sterilizer plantroom, and it is better to place them in a dedicated location away from any noise-sensitive areas.

6.24 Components which require servicing or maintenance, such as dryers and filters, should be installed in locations where they can be readily serviced or exchanged.

Air quality

6.25 Quality of air is critical and certain types of sterilizer will incorporate the appropriate filters. If the purchaser is to be responsible for supplying filtered air, note the following points:

a. air for controls should be free of liquid water, filtered to 25 µm (5 µm for precision controls) and lubricated with micro-fog oil particles of 2 µm or less;

b. air that could come into direct contact with the load, such as air for pressure ballasting or door seals, should be filtered to remove contaminating oil-mist and micro-organisms. It should have not more

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than 0.5 mg of oil per cubic metre of free air (measured at 1013 mbar and 20°C; see IS0 554), be filtered to an efficiency of at least 95% when tested in accordance with BS 3928 and be free of bacteria.

Drainage

6.26 Condensate from the jacket, heat exchangers and steam traps is suitable for recovery and should be returned to the steam generating plant where there are means for recovery.

6.27 All other effluent from a sterilizer is potentially contaminated and should be disposed of to the main drain. Effluent may originate from one or more of the following sources:

a. air, condensate and steam from the chamber drain, which may contain chemicals and micro-organisms, especially those from a make-safe process;

b. discharge from a water-sealed vacuum pump, ejector or chamber vent, which may also contain micro-organisms;

c. water from a chamber cooling system;

d. water introduced to cool and dilute the discharge from the chamber.

6.28 Drainage requirements for different types of sterilizer are summarised in Table 10 and discussed below.

Non-hazardous effluents

6.29 Effluent from steam-only sterilizers should pass via an air break into a tun-dish or tank before being discharged to the drain. The air break should be preserved at all times so that the sterilizer and its associated piping cannot be contaminated by reverse flow from the drainage system. This can be achieved by ensuring that under all working conditions the discharge rate from the tun-dish is such that the maximum flow rate of effluent from the sterilizer will not cause the water level in the tun-dish to rise to the level of the outlet from the sterilizer. For clinical sterilizers the above equipment is normally provided by the manufacturer and contained within the sterilizer itself, but for certain laboratory sterilizers it is the responsibility of the purchaser to install it in the plantroom.

6.30 The drain system from the plantroom should be trapped and designed to pass the flow rate of water, air and condensed steam specified by the manufacturer, with account taken of peak demands during the operating cycle.

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Table 10: Discharge and ventilation requirements for different types of sterilizer

Type of sterilizer	Effluent discharge	Ventilation
LTSF sterilizers	Trapped and vented, sealed to main drain. No open gulleys	General room ventilation ten changes/hour, non-recirculating. Discharge to stack LEV on sterilizer door, Discharge to stack
EO sterilizers	Small - no drainage required Large - Trapped and vented, sealed to main drain. No open gulleys Very large sterilizers may require fan-assisted venting of drain	General room ventilation ten changes/hour, non-recirculating. Discharge to stack Small - chamber exhaust to stack LEV on sterilizer door, aeration facility door and manifold room. Discharge to stack
Laboratory sterilizers	Trapped and vented, sealed to main drain. No open gulleys	General room ventilation, non-recirculating. Filtered discharge for Category 3 and 4 laboratories
Other sterilizers	Direct to main drain	General room ventilation. No special requirements

6.31 Means should be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical equipment.

6.32 The discharge temperature from a steam sterilizer is unlikely to exceed 80°C, but in the event of failure of the diluting and cooling system it might reach 100°C. The materials used for the construction of the drainage system should be chosen to withstand this temperature. Attention is drawn to the legal requirement (Public Health (Scotland) Act 1897 as amended) that the maximum temperature of any liquid to be emptied into the public sewer or communicating drain is 43°C. This may be interpreted as relating to the main building connection to the sewer and not to the internal building drain.

6.33 Where a tank supplies water to a water-sealed vacuum pump or a water pump used for an ejector vacuum system, the overflow discharge from the tank should also include an air break.

Hazardous effluents

6.34 A sealed and vented drain is required for LTSF sterilizers, large EO sterilizers (supplied from cylinders), EO gas disposal units and laboratory sterilizers used to make-safe discard material. Small EO sterilizers (supplied from cartridges) discharge gas only (see paragraph 6.62).

6.35 Chamber drains and vents should have a sealed independent discharge which should be vented and trapped before it is connected to the drainage system. Open tun-dishes should not be used. The vent should be not less than 30 mm in diameter and terminated above roof level, clear of ventilation

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air inlets or windows. Steam should not issue from the vent. A “Hazardous Discharge” warning notice should be fitted next to it. A similar arrangement should be provided for any safety valves.

6.36 EO is considerably denser than air. For sterilizers with chamber volumes greater than 300 litres there is a risk that the amount of gas discharged into the drainage system could result in pockets of explosive mixtures of EO and air accumulating at the bottom of the vent stack. Although there is no known case of such an explosion in the UK, consideration should be given to installing a fan-driven gas-capture system to draw gas from above the liquid effluent before the liquid is discharged to the main drain. The gas should either be disposed of chemically (see Chapter 13) or discharged at a high level. The vent should meet the requirements of the local exhaust ventilation system (see paragraph 6.61).

6.37 In certain circumstances, such as special research activities involving high concentrations or volumes of pathogens in Hazard Group 3, additional safeguards may be required for laboratory sterilizers. The advice of HSE should be sought in such cases.

6.38 Where a laboratory sterilizer is to be used to make-safe material contaminated with Hazard Group 4 pathogens, further containment, filtration or heat treatment will be necessary. Again, advice should be sought from HSE.

Ventilation

6.39 Ventilation of the area near the sterilizers is needed to remove both excessive heat and odours, and also sterilant gases such as formaldehyde and EO.

6.40 General room ventilation will be sufficient for most sterilizers, but chamber exhaust ventilation will be required for certain small EO sterilizers and local exhaust ventilation will be required to remove local concentrations of EO or formaldehyde. The requirements are summarized in Table 10 and discussed below.

6.41 Electrical systems used in ventilation systems should take account of the explosion risk associated with ethylene oxide and comply with the requirements of BS EN 61010: Part 2-042.

6.42 All ventilation systems should meet the ventilation requirements of the Workplace (Health, Safety and Welfare) Regulations 1992.

6.43 Further guidance on ventilation systems may be found in SHTM 2025; *Ventilation in healthcare premises*.

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General room ventilation

6.44 The air change rate should be related to the heat and vapour emission from the sterilizer and associated equipment and pipework so that working conditions remain acceptable and control equipment is not adversely affected. The ambient temperature in the plantroom with all plant running normally should not be allowed to exceed 35°C at any time.

6.45 Current experience indicates that a 400-litre high-temperature steam sterilizer with door closed will release by radiation and convection approximately 1.0 kW into the loading area and 4.0 kW into the plantroom. Sliding-door machines installed behind a fascia panel with a separate door will release almost all the heat into the plantroom. With the door open, additional heat into the loading area might typically be 3.5 kW for a side-hinged door and 3.0 kW for a sliding door. More specific figures should be obtained from the manufacturer of the sterilizer (see Table 9).

6.46 In designing a ventilation system, account should also be taken of the heat emitted from the sterilized load after it has been removed from the chamber.

6.47 Ventilation air to the plantroom may be taken in either at low level from the loading area or from an independent source and should be discharged to the outside.

6.48 Where the plantroom does not have an outside wall, heat emissions will need to be absorbed by a recirculating cooling unit with remote fan-cooled condensers. The rating of the units should have sufficient reserve capacity to reduce the temperature to 30°C in order to provide a safe and acceptable working environment for staff during maintenance of the plant. Additional plant space is required for the installation of the cooling units.

Room ventilation for LTSF and EO sterilizers

6.49 For LTSF, EO and laboratory sterilizers, the loading area should be maintained at a lower pressure than the main corridor and at a higher pressure than the plantroom. The discharge to the outside should not be sited where the extracted air will be drawn into the building via windows or ventilation inlets.

6.50 Areas containing LTSF or EO sterilizers and aerators should have a dedicated, non-recirculating room-ventilation system which ensures that air movement is from the operator towards the sterilizer both during normal operation and also when local exhaust ventilation (see paragraph 6.54) is operative. During normal operation, exposure to formaldehyde and EO should not be allowed to exceed the exposure limits given in Table 1.

6.51 Room ventilation for LTSF and EO sterilizers should be designed to permit the extraction of the maximum possible leakage of gas within a reasonable time. This requires at least ten air changes an hour. For example, Figure 1 shows the relationship between the volume of a room and the number of air

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changes required to reduce the concentration of EO to 5 ppm when a standard 134 g cartridge is discharged into the room.

6.52 Sensing devices and interfaces should be provided to ensure that if the room ventilation fails to maintain a rate of flow sufficient to ensure ten air changes an hour:

a. a visual and audible alarm is given;

b. where the operating cycle has progressed beyond the point where sterilant has been admitted into the chamber, it is not possible to open the door at the end of the cycle until the room ventilation is restored to normal operation;

c. it is not possible to start a new cycle until the room ventilation is restored to normal operation.

Requirement 6.52(b) may be waived if the load can be transferred from the sterilizer to an aeration facility without gas escaping into the atmosphere. This would normally require a local exhaust ventilation system with a common extractor hood covering both the door of the sterilizer and the door of the aeration facility. If such a system is installed, it should be validated to demonstrate that the specified rates of flow (see paragraph 6.54) can be achieved when the room ventilation is not operating.

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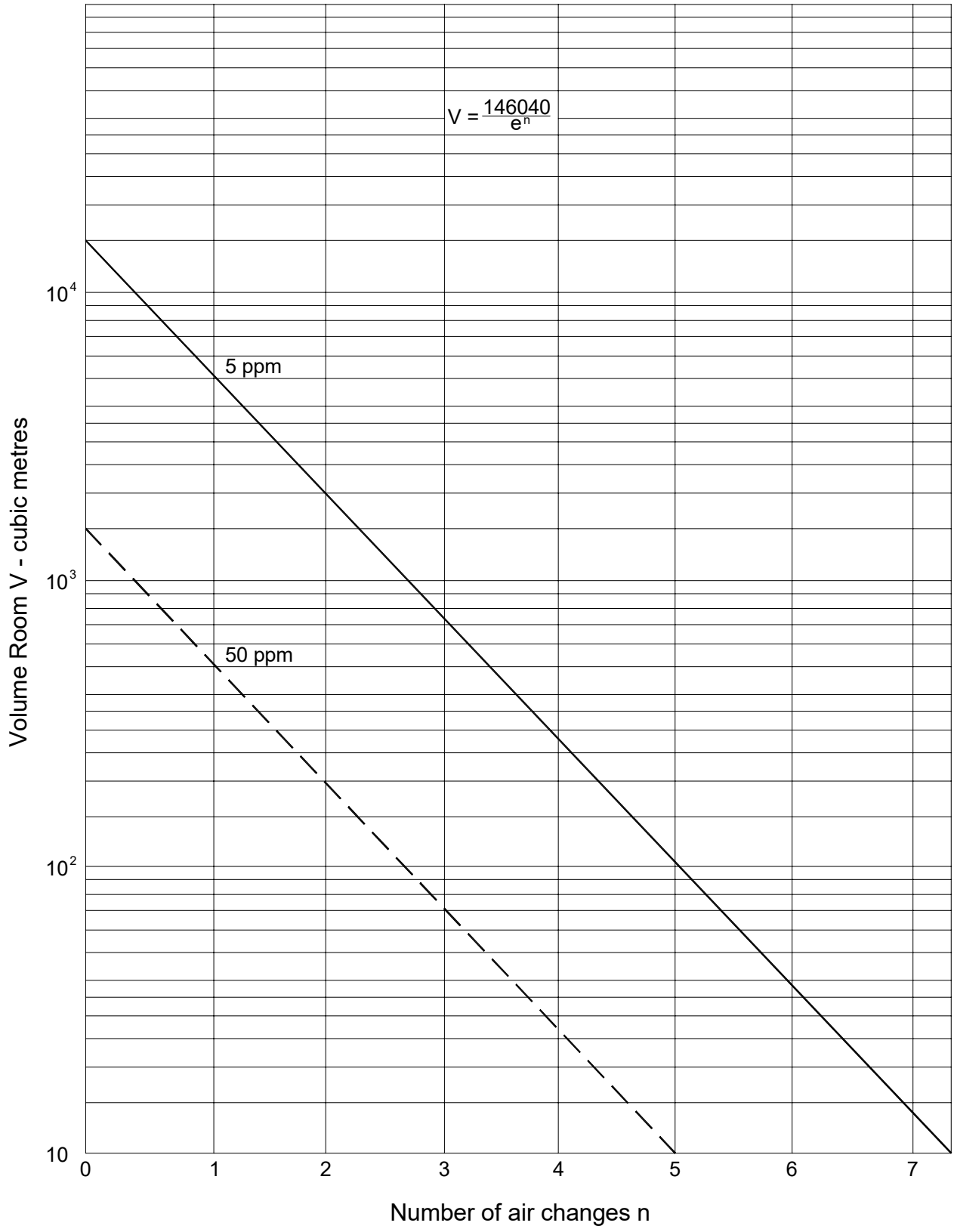
Figure 1: Air changes required to reduce the concentration of ethylene oxide to 50 ppm and 5 ppm following the sudden release of 134g of the gas into the workroom



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Local exhaust ventilation

6.54 In addition to the room ventilation, LTSF sterilizers, EO sterilizers and EO aerating equipment should be fitted with an independent local exhaust ventilation (LEV) system having a minimum flow of 0.3 m^3s^{-1} at each extractor hood. The system should have hoods near any place where formaldehyde or EO could be released into the atmosphere; for example, around the doors of sterilizers and aeration cabinets and in the manifold room where cylinders are connected to the EO supply manifold (see paragraph 6.74).

6.55 When activated, the LEV should operate for a preset period of up to 30 min.

6.56 Sensing devices and interfaces should be provided to ensure that the LEV is activated on the following occasions:

a. when the door is ready to be released at the end of an operating cycle;
b. when sterilant cylinders are being changed;
c. on a pressurization failure of inflatable or pressure-activated door seals;
d. whenever the atmospheric concentration of sterilant gas exceeds a preset safe level not greater than the short-term maximum exposure limit given in Table 1.

6.57 Controls should be provided both within and outside the loading area to activate the LEV manually.

6.58 Sensing devices and interfaces should be provided to ensure that if the LEV, when activated, fails to attain or maintain a flow of at least 0.3 m^3s^{-1} :

a. an audible and visual alarm is given;
b. it is not possible to open the door at the end of the cycle until the LEV is restored to normal operation;
c. it is not possible to start a new cycle until the LEV is restored to normal operation.

6.59 Make-up air provision, preferably by indirect means, will be required.

6.60 Ducts designed to carry formaldehyde or EO gas should be maintained under negative pressure, for example by locating the extractor fan at the discharge end.

6.61 The discharge should be above roof level and away from windows, doors and air intakes. This may be the same vent used to discharge gas from the chamber. A “Hazardous Discharge” notice should be fitted next to the outlet. For EO sterilizers supplied from cylinders, the discharge stack should be fitted with a flame arrestor.

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Chamber exhaust ventilation

6.62 Small EO sterilizers (supplied from cartridges) and EO aerators will require a chamber exhaust ventilation (CEV) independent of the room and LEV systems.

6.63 The CEV for a sterilizer should extract gas from the sterilizer chamber during the gas removal stage and throughout any aeration stage.

6.64 The CEV for an aerator should operate whenever an aeration cycle is in operation. If an aeration room is used, the temperature and ventilation should be controlled within adjustable ranges from ambient temperature to 55°C and nominally zero to ten air changes an hour.

6.65 Interfaces should be provided so that in the event of a failure of the CEV:

a. an audible and visual alarm is given;

b. where the operating cycle has progressed beyond the point where EO has been admitted to the chamber, it is not possible to open the door at the end of the cycle until the CEV is restored to normal operation;

c. it is not possible to start a new cycle until the CEV is restored to normal operation.

6.66 The discharge should be above roof level and away from windows, doors, and air intakes. This may be the same vent used for the LEV. A “Hazardous Discharge” notice should be fitted next to the outlet.

6.67 The CEV alarm circuit should be independent of the mains electricity supply. It is recommended that the CEV system itself be connected to the essential supplies circuit in the event of a mains power failure.

Ethylene oxide gas

6.68 Ethylene oxide gas may be supplied either from disposable cartridges (pure EO) or from cylinders (pure EO or EO mixed with diluent gases). Both the containers and the delivery system are subject to the Pressure Systems Safety Regulations 2000.

Supply from cartridges

6.69 The number of cartridges kept within the plantroom should be limited to those actually in use and those required for immediate stand-by. Cartridges should be stored as described in Part 5 of this SHTM. Cartridges for immediate use may be held in the loading area.

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Supply from cylinders

6.70 All pipework intended to carry EO should be in stainless steel. Flexible hoses should be of stainless steel, preferably lined with PTFE or nitrile rubber.

6.71 Cylinders should be stored as described in Part 5 of this SHTM.

6.72 Where EO is stored at a temperature below its normal boiling point (10.7°C) it is essential to exclude air by pressurising the cylinder with nitrogen or other diluent gas. Even when nominally empty of liquid EO, cylinders should be maintained at a minimum pressure of 2 bar. Nitrogen used for pressurising will stay in the gaseous state and will not mix with the liquid EO.

6.73 Fittings to the cylinder, such as valves and pressure gauges, should be protected against mechanical damage. Cylinders should be secured to prevent them falling over or colliding during storage and transport.

6.74 Cylinders should be connected to the sterilizer supply line in a dedicated manifold room separate from the plantroom. The room should not have direct access from the loading area. The manifold room should meet the requirements of SHTM 2022. Local exhaust ventilation should be installed as described in paragraph 6.54.

6.75 A duty and a reserve cylinder should each be connected to a common gas manifold via a manual stop valve, at least one automatic stop valve, and a vent with a stop valve (for use during cylinder change and inert gas purging). These are in addition to the valve on the cylinder itself. The system should be designed and constructed to allow only one cylinder at a time to supply gas to the sterilizer. An indicator should show which cylinder is being used.

6.76 Each cylinder should be located on weighing scales with sufficient tare capacity for the largest cylinder expected to be used. The scales should be accurate enough to determine the mass of gas admitted to an accuracy of ± 1% of the mass of gas required to fill the empty chamber to the preset operating pressure. Recording scales are preferable, since the data obtained may be used in the routine monitoring of the operating cycle.

6.77 An automatic change-over facility is recommended so that the reserve cylinder can be brought on-line without interruption of the supply. An electrical signal from the weighing scales may be used to determine when the duty cylinder is nearly empty and to initiate the change-over automatically.

6.78 The temperature of the cylinders should not be allowed to exceed the maximum stated by the supplier, and in any case not more than 45°C. The temperature of the manifold and supply line should be kept above 11°C to prevent EO condensing inside the pipework.

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6.79 The number of cylinders kept within the manifold room should be limited to those actually in use and those required for immediate stand-by.

6.80 Cylinders of an inert gas such as nitrogen should be available for purging the pipework before maintenance and testing.

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7. Steam supply

Introduction

7.1 A continuous supply of saturated steam is required for steam sterilization, low-temperature steam and formaldehyde (LTSF) sterilization and for humidification in certain ethylene oxide (EO) sterilizers and EO preconditioning units.

7.2 The critical variables are the dryness of the steam (expressed as a dryness value) and the level of non-condensable gases (expressed as a fraction by volume). Before a newly installed or replaced sterilizer is handed over to the user, the steam supply should be examined and tested by the methods described in Part 3 of this SHTM to ensure that it is satisfactory.

7.3 Users should note that where the steam is supplied from the mains, quality can vary greatly during the course of a working day. In many hospitals, steam demand is greatest early in the morning when sterile service departments (SSDs), kitchens and laundries may start work at the same time. Care should be taken to sample the steam at times throughout a typical working day to gauge the likely range of steam quality.

7.4 Where a sterilizer is to be used in the aseptic production of medicinal products, the steam should also be free of pyrogens. Details on the supply of apyrogenic steam can be found in SHTM 2031; *Clean steam for sterilization.*

7.5 BS EN 554 and BS EN 285 provide guidance on the chemical quality of steam and quality of environment in contact with a medical device. Further guidance on steam quality can be found in SHTM 2031; *Clean steam for Sterilization*.

Engineering considerations

7.6 Except where the steam is generated within the chamber (such as in transportable sterilizers), steam is generally obtained from the hospital mains and the delivery of high-quality steam depends on careful engineering.

7.7 Occasionally, suitable steam may be available from the high-pressure hot-water systems used in some hospitals. Steam from this source is not recommended for porous-load sterilizers since the steam is generally too wet for reliable sterilization, even with a recommended minimum return temperature of 150°C.

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Capacity

7.8 The steam service should be designed to meet the maximum steam demand of the sterilizer for short periods, while keeping the fall in pressure before the final pressure-reducing system to not more than 10%. Experience shows that a single porous-load sterilizer of up to 600 litres requires a boiler of at least 50 kW and storage to meet a peak demand of 125 kW for 15 min. The effect on the steam supply of the demands of other sterilizers and equipment should be carefully considered.

Pipework

7.9 Except for vertical rises between floors, steam pipework should be designed so that any condensate flows by gravity in the same direction as the steam. This general principle applies equally to steam mains, branch connections and pipework on the sterilizer itself. Air vents and steam traps should be fitted at each vertical rise. Care should be taken to trap, drain and return any condensate which may be collected in pockets in the pipework. Dead-legs should be avoided.

7.10 The accumulation of condensate in the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the manifold and the sterilizer chamber. This can be achieved by the correct declination of each portion of pipework and by adequate trapping throughout the steam distribution system.

7.11 Figure 2 shows a suggested layout for the steam service in the plantroom. The supply main should terminate in an adequately vented and trapped manifold, not less than 150 mm nominal bore, running the entire length of the room (this provides for future expansion). A vent, with a cooling pot, should be installed on the manifold upstream of the supply pipes to individual sterilizers. A pressure gauge should be fitted to the manifold.

7.12 Where the supply pressure at the inlet to the sterilizer would exceed the maximum value specified by the manufacturer, a pressure-reducing system and separator should be fitted to the supply pipe at least 3 m from the sterilizer. Heat loss from the section between the pressure-reducing system and the sterilizer will help prevent superheating (paragraph 7.24).

7.13 If the sterilizer manufacturer has not already fitted them, an appropriate and correctly installed separator and steam trap should be fitted upstream of the sterilizer reducing valve.

7.14 Three suitable test connections should be provided on the supply pipe to each sterilizer to permit the attachment of a needle valve, a pitot tube and a temperature sensor as shown in Figure 2. (Details of the use of these items can be found in Part 3 of this SHTM.)

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7.15 Careful attention should be paid to the location of all pressure relief valves to ensure that the sterilizer is properly protected. Relief valves and their discharge pipes should be large enough to prevent the pressure in the supply pipe rising to more than 10% above the design pressure for the sterilizer. The discharge pipe should terminate outside the building in a safe, visible position not affected by frost. Any rising discharge pipe should be fitted with a drain at the lowest point to prevent the accumulation of condensate. A tell-tale pipe of narrow bore should be connected to the drain point and terminate inside the plantroom.

Materials

7.16 Steel and copper piping have traditionally been used for steam supply, but these materials will not be acceptable if compliance with the EU Directives on medical devices is required. Suggested minimum standards for steam purity are given in BS EN 285 (analytical methods for testing for these impurities, including tests for pyrogens, is included in SHTM 2031), but these are unlikely to be achieved with plant currently installed in the UK. Moreover, steam of such purity would be severely corrosive to the steel and copper piping in the majority of sterilizers in use in the NHS.

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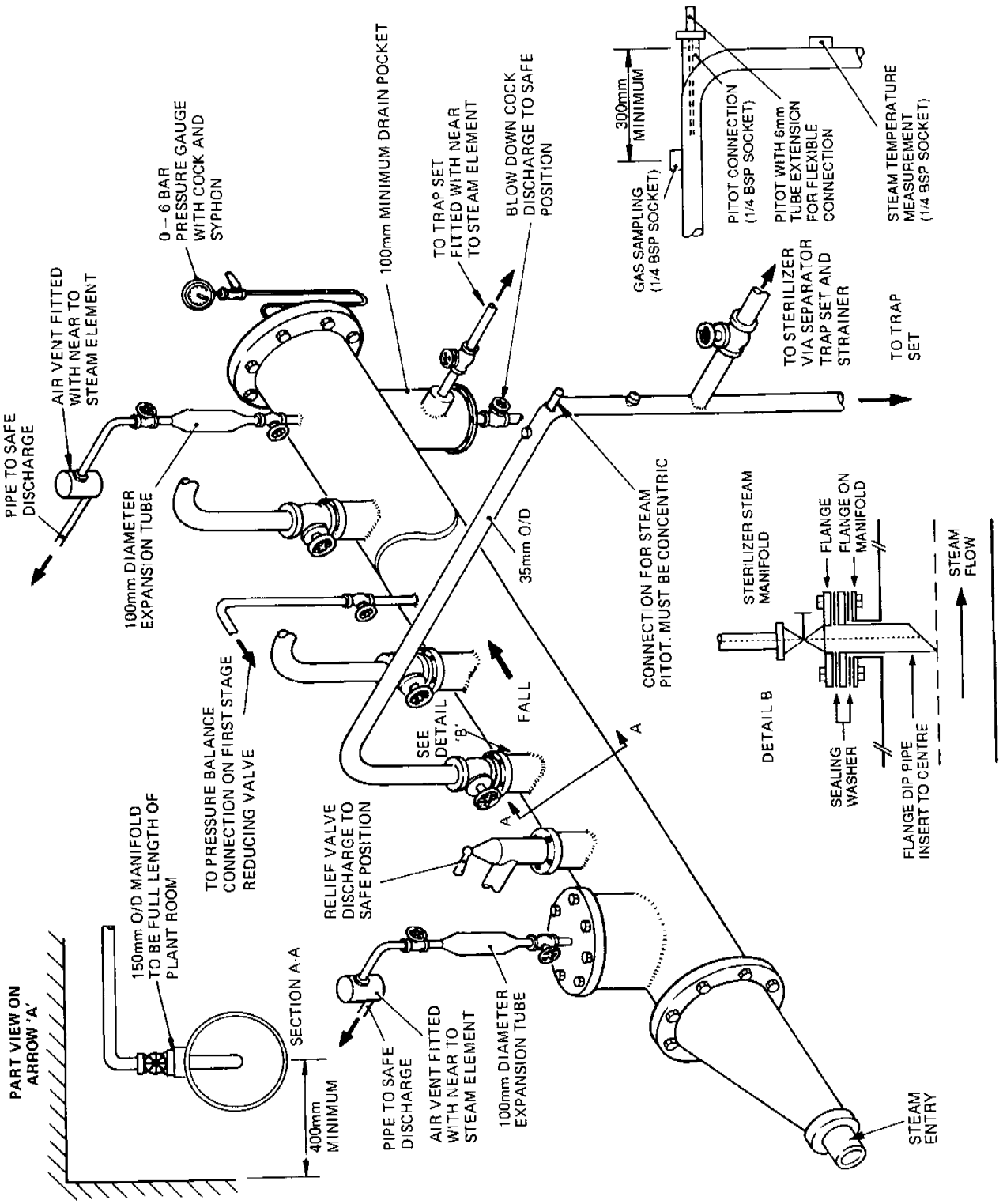
Figure 2: Layout of steam service in the plantroom



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7.17 To meet the suggested purity standard for clinical sterilizers it will be necessary for parts in contact with steam entering the chamber to be constructed from low-carbon or stabilised stainless steel. However, in designing a steam service purchasers should bear in mind that the steam service (and indeed the sterilizer itself) may need to be upgraded within the life of the sterilizer and that compliance for steam purity may be achieved at that stage. Until the detailed implications of the Directives are known, it is recommended that steel and copper piping continue to be used, but that space be reserved in the plantroom for a mains steam conditioning unit. A space approximately 1.5 m square by 2.0 m high will accommodate a unit capable of supplying two 600 litre porous-load sterilizers.

Dryness

7.18 The dryness of the steam is of vital importance to the performance of any steam sterilizer. Excess moisture may cause damp loads in porous materials and uneven temperature distributions in non-porous loads, particularly those containing a large number of small items such as ampoules. When steam is required to be in direct contact with the surface to be sterilized, such as in porous-load sterilizers, sterilising conditions may not be attained if the moisture contained in the steam supply is insufficient to prevent the steam from becoming superheated when expanding into the chamber.

7.19 Steam dryness is traditionally characterised by a “dryness fraction”, but this is not appropriate for sterilizers because the method of measurement is difficult and requires a constant flow of steam. The low-volume sampling technique described in the steam dryness test (Part 3 of this SHTM) cannot be regarded as measuring a true dryness fraction because the sample is taken from the centre of the steam supply pipe and condensate flowing along the pipe wall is not collected. Consequently the term “dryness value” is used, where 1.0 represents dry, saturated steam. This method is used to determine whether performance problems could occur during testing and routine production. It is suitable for sterilizer installations because control valves and pipe services fitted to the sterilizer considerably reduce the amount of condensate entering the sterilizer chamber such that the sample has a similar amount of free condensate to the steam in the chamber.

7.20 European Standards require that sterilizers be designed to operate with steam having a dryness value of not less than 0.9 when measured in accordance with the steam dryness test described in Part 3 of this SHTM. For metal loads, the dryness value should not be less than 0.95. In practice, problems are unlikely to occur if the dryness value lies between 0.9 and 1.0, if it is reasonably constant and if the pressure reduction through the final pressure-reducing system is of the order two to one.

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7.21 Although experience has shown that acceptable conditions are sometimes achieved when optimum conditions do not prevail, significant deviations are likely to cause the following problems:

a. wet loads, resulting from too low a dryness value;

b. superheating, resulting from either too high a dryness value before the pressure-reducing system, or excessive pressure reduction through the valve (superheating may be severe if both conditions are present simultaneously);

c. difficulties with operation of the pressure-reducing system, resulting from a low pressure-reduction ratio, water hammer, water logging, dirt and other carry-over.

Excessive moisture

7.22 Excessive moisture, where droplets of water are present at the same temperature as that of the steam, will cause wet loads in porous-load sterilizers, low-temperature steam (LTS) disinfectors and LTSF sterilizers. It will reduce formaldehyde concentration in LTSF sterilizers and impair the efficacy of the process. Humidification may be impaired in EO sterilizers. Some causes of wet loads are as follows:

a. steam pipes or manifolds may be incorrectly sloped and drained;

b. the sterilizer may be supplied from an inadequately drained and vented “dead-leg” rather than a live steam main;

c. the pipework between the boiler and the sterilizer may be insufficiently insulated, causing excessive condensation of the supply steam.

7.23 If wet steam continues to be a problem, “priming” may be occurring in the boiler, causing water droplets to be delivered in the steam. Modern compact and high rated boilers and steam generators are particularly sensitive to the quality of feed-water treatment and are much more likely to prime than boilers of traditional design. Priming or foaming (which results in carry-over of the boiler water) may be caused by any of the following:

a. incorrect feed-water treatment;

b. boiler water level being set too high;

c. forcing a boiler which needs internal cleaning;

d. violent boiling under fluctuating load conditions;

e. a high level (typically 2000 ppm) of total dissolved solids.

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Superheating

7.24 Superheated steam is an unsuitable medium for moist heat sterilization and can cause failure to sterilise, scorching of textiles and paper and rapid deterioration of rubber. Superheat conditions within the load and chamber may result from adiabatic expansion, exothermic reaction or both.

7.25 European Standards require that the superheat in free steam at atmospheric pressure should not exceed 25°C when measured by the superheat test described in Part 3 of this SHTM.

7.26 Superheating caused by **adiabatic expansion** is usually the result of an excessive reduction in pressure through a throttling device, such as a pressure-reducing system or a partially closed main steam valve. It is unlikely to be of significance in the circumstances normally encountered in hospital steam distribution systems, but superheating may arise if the main steam supply is dry, or the pressure is unusually high before the throttling device. This superheat can sometimes be avoided by the measures described in paragraph 7.12, which will reduce the dryness value of the steam at the inlet to the sterilizer pressure-reducing system. The reduced pressure ratio will minimise the effect of the expansion through it.

7.27 Superheating arising from **exothermic reaction** may occur during sterilization as a result of rehydration of exceptionally dry hygroscopic material. Methods of avoiding this are described in Part 4 of this SHTM.

Non-condensable gases

7.28 Non-condensable gases (NCGs) are defined as gases which cannot be liquefied by compression under the range of conditions of temperature and pressure used during the sterilization process. Low levels of NCGs contained in steam supplied to sterilizers can markedly affect the performance of the sterilizer and the efficacy of the process, cause chamber overheat and lead to inconsistencies in the performance of air detectors and failure of the Bowie-Dick test (see Part 3). The major NCGs are air and carbon dioxide.

7.29 British and European Standards require that sterilizers be designed to operate with steam having a fraction of NCGs not exceeding 3.5% by volume when measured by the method described in the non-condensable gas test (see Part 3).

7.30 The main source of NCGs in the steam supply is the boiler feed-water and the level will be greatly influenced by the water treatment employed. In some cases a study by a water treatment specialist will be necessary. The study should cover analysis of the water, venting and the blow-down regime required in order to ensure protection of the boiler against corrosion whilst minimising the entrainment of NCGs in the steam supply.

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7.31 If anti-foaming agents and oxygen-scavenging agents (such as sodium sulphite) are used it is essential to ensure that the dosages are accurate.

7.32 Water-softening treatment is required to prevent the formation of scale. Except in hard water areas, a simple base-exchange system may be adequate in which bicarbonate ions are effectively converted into sludge-forming carbonates. This releases carbon dioxide into the water. A properly managed blow-down regime is essential to remove the accumulated sludge.

7.33 The most effective way of driving off dissolved air, carbon dioxide and other NCGs is by degassing the boiler feed-water before use by heating in a vented tank (a hot well). This will also break down bicarbonate ions, driving off further carbon dioxide. For the degassing to be effective, it is important that the temperature of the feed-water does not fall below 80°C at any time. The following measures should be adopted:

a. pipework returning condensate to the hot well should be well lagged to keep the condensate hot;

b. the amount of cold make-up water in the hot well should at no time exceed 15% (the rest being returned condensate) since new water will both lower the temperature and introduce further NCGs;

c. the water in the well should be kept well mixed; this may be achieved by locating the feed-water inlet on the opposite side of the tank from the outlet, and by arranging for the feed-water to be “sparged” from the inlet through a number of small openings.

7.34 In very hard water areas the level of NCGs may still be high despite these measures, and dealkalisation treatment of the feed-water may then be necessary. In such cases the maintenance of high temperatures in the hot well is even more critical. Treatment with filming amines should be avoided since this method requires careful control and monitoring.

7.35 Users should note that, even with a well-designed system, the level of NCGs can be affected by competing demands on the steam service. For example, where a central steam boiler supplies both a sterilizer unit and a laundry through the same distribution system, the level of NCGs in the steam at the sterilizer may rise when the laundry demand is high. This is the result of an influx of cold make-up water into the hot well. Paradoxically, in some installations the NCG level may also rise when steam demand is low. In this case NCGs which would normally be removed by the laundry are being carried through to the sterilizer.

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7.36 Some other causes of the presence of NCGs in the steam are as follows:

a. the boiler may be priming (paragraph 7.23);

b. air may be being drawn into the system either through the boiler feed-pump glands or through a leak in the steam pipework between the boiler and the sterilizer;

c. steam pipework may be inadequately vented;

d. where NCGs are found in the sterilizer chamber during a production cycle:

   (i) there may be an air leak into the chamber;

   (ii) packaging materials, for example certain boxes, inks, adhesives, labels or trays, may be liberating gases. See Part 4 for guidance on packaging materials.

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8. Porous-load sterilizers

Introduction

8.1 This chapter discusses specifications for clinical sterilizers designed to process porous items such as towels, gowns and dressings; and medical and surgical equipment, instruments and utensils that are packaged or wrapped in porous materials such as paper or fabrics. Clinical sterilizers using high-temperature steam to process porous loads are commonly known as “porous-load sterilizers”.

8.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the Standards discussed in Chapter 1.

8.3 Sterilization is achieved by direct contact of the load items with good-quality saturated steam at a preferred sterilization temperature of 134°C (see Table 4).

8.4 Porous-load sterilizers are distinguished from other high-temperature steam sterilizers by the following features:

a. as porous loads trap both air and moisture, the sterilizer has a vacuum system to ensure that sufficient air is removed from the chamber and load before steam is admitted to the chamber. It also ensures that the pressure during the drying stage is sufficiently reduced so that the load is sensibly dry on completion of the cycle;

b. an air detector is fitted to the chamber to ensure that the plateau period cannot start until sufficient air has been removed from the chamber and load (see paragraph 8.7);

c. a heated jacket is generally used to prevent condensate from forming on the chamber walls and to assist drying of the load.

Standard specifications

8.5 Porous-load sterilizers should conform to the specifications in BS EN 285 and the safety specifications in BS EN 61010: Part 2-041.

Additional specifications

8.6 The following specifications are additional to those in BS EN 285 and permitted as options.

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Air detector

8.7 BS EN 285 requires means to be provided to ensure that the requirement for steam penetration throughout the chamber and load is achieved for each cycle. The most reliable way to do this is to specify an air detector to ensure that the plateau period cannot commence if sufficient air and other non-condensable gases have not been removed from the chamber. The correct functioning of the air detector is crucial to the performance of the sterilizer.

8.8 Although an air detector is not required by BS EN 285, there is no other proven means of assuring that air is not present during production cycles. (The quantity of air sufficient to cause a failure of a sterilization cycle is small and for this reason the comparison of pressure and temperature within the chamber is by itself an unacceptable alternative.) An air detector is the most cost-effective way of ensuring that the sterilization conditions established during validation continue to apply.

8.9 If an air detector is not fitted, microbiological testing as described in BS EN 285 will be required, along with more frequent periodic testing and more demanding performance qualification. This option is expensive.

Port for air-flow metering device

8.10 A quarter-inch BSP port should be fitted on the side of the sterilizer, preferably towards the lower front, for the attachment of an air-flow metering device used for testing air-detector performance and chamber integrity (see Part 3).

Absolute pressure indicator

8.11 For leak-testing purposes an absolute pressure indicator (0 to 160 mbar) should be fitted, conforming to clause 6.2.2.2 of BS EN 285.

Bowie-Dick test cycle

8.12 Sterilizers for use in the NHS should be provided with a Bowie-Dick test cycle.

Extended drying

8.13 An additional cycle with extended drying time should be provided to process loads which are difficult to dry.

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9. Fluid sterilizers

Introduction

9.1 This chapter discusses specifications for clinical sterilizers designed to sterilise aqueous fluids in sealed containers (normally bottles) of either glass or plastic. Such sterilizers are commonly known as “fluid sterilizers”.

9.2 The guidance given here assumes that the sterilizer is to be used to process medicinal products in compliance with the GGMP and EU Directives discussed in Chapter 1.

9.3 Sterilization is achieved by direct contact of the load items with a heating medium, normally good-quality saturated steam, and then by heat transfer through the container to increase and maintain the product at a preferred sterilization temperature of 121°C (see Table 4).

9.4 Fluid sterilizers are distinguished from other high-temperature steam sterilizers by the following features:

a. a thermal door lock is fitted to ensure that when glass containers are being processed the door cannot be opened until the temperature inside all the containers has fallen below 80°C: this prevents the containers fracturing due to thermal stress;

b. operating cycles for plastic containers allow the door to be opened when the temperature inside the containers has fallen below 90°C: this prevents “blooming” of the containers;

c. cooling is usually by means of a water spray. The water may be either derived from steam condensate collected in the chamber or sterile water fed in from outside;

d. during all or parts of the cycle air may be introduced into the chamber to prevent large pressure differences arising between the inside and outside of containers; this is known as “pressure ballasting” (see paragraph 9.8).

Standard specifications

9.5 Fluid sterilizers intended for the sterilization of fluids in sealed rigid containers (glass bottles) should conform to the specifications in BS 3970: Parts 1 and 2 and the safety specifications in BS EN 61010: Part 2-041. See paragraph 9.8 for additional specifications for flexible (plastic) containers.

9.6 A European Standard for fluid sterilizers is being planned.

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Additional specifications

9.7 The following specifications are in addition to those in BS 3970: Parts 1 and 2.

Cycle for plastic containers

9.8 Where the sterilizer is to be used to process plastic containers, a modified operating cycle may need to be specified. This is similar to the standard glass cycle but with the following modifications:

a. pressure ballasting should be used to prevent pressure differences arising between the inside and the outside of containers sufficient to burst or distort them;

b. the design pressure for the sterilizer chamber should be at least 10% higher than the allowable pressure; the operating pressure will typically be 3.3 bar gauge for a sterilization temperature of 121°C;

c. the thermal door lock (9.4a) should be set so that the door cannot be opened until the temperature of the fluid in all the containers has fallen below 90°C.

9.9 If loads consisting solely of plastic containers are to be processed infrequently, then it may be better to specify a single cycle suitable for both glass and plastics (rarely used cycles may not be reliable). In that case the thermal door lock should be set so that the door cannot be opened until the temperature of the fluid in all the containers has fallen below 80°C.

Heat exchanger

9.10 The design of the coolant system should be such that, whenever a single fault occurs in the coolant system, the quality of all water in contact with the load complies with the requirements of the full-load test described in Part 3 of this SHTM. One example is a system whereby during any part of each operating cycle the primary coolant pressure is known to be less than the pressure external to each load container.

9.11 Connections for a pressure test gauge should be provided so that measurements can be made of:

a. the pressure in the primary circuit;

b. the differential pressure between the primary and secondary circuits.

Monitoring and control by F_0

9.12 F_0 is a measure of the “lethality” delivered to a load throughout an operating cycle, including the heating and cooling stages. It is expressed as a time in minutes equivalent to a continuous period at 121°C. Guidance on the use of F_0 is given in Part 4 of this SHTM and an extensive discussion of the theory and applications of F_0 can be found in Part 5.

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9.13 F_0 may be used instead of the standard time - temperature relationships given in Table 4 to determine whether sterilization conditions have been achieved. When F_0 measured inside the load attains a certain value (normally 8 min or more) the load may be deemed to be sterile. It is particularly useful for heat-sensitive loads that can withstand the heat received during the prescribed holding time, but not the additional heat received during the heating and cooling stages, or for loads which would not survive a second operating cycle.

9.14 F_0 may be used either to monitor or to control an operating cycle:

a. where monitoring is required, a recorder displays the accumulated F_0 throughout the operating cycle. This facility may be useful in borderline cases where the batch process record falls just outside the permitted tolerances established during performance qualification. Quality control procedures may then permit heat-sensitive products which would not survive resterilization to be released provided that the required F_0 has been attained;

b. where control is required, the holding time continues until the required F_0 is attained.

9.15 Sterilizers monitored by F_0 should be equipped with a load temperature probe to be inserted into the container of the load known to receive the lowest F_0 The probe should be connected to a recorder displaying accumulated F_0 throughout the cycle.

9.16 Sterilizers controlled by F_0 should have at least two load-temperature probes to be inserted into two containers of the load known to receive the lowest F_0. The probe showing the lowest accumulated F_0 at any instant should be used to control the cycle.

9.17 The recorder should display accumulated F_0 computed from the following equation:

$$F_O = \Delta t \sum_i log^{-1}\left[\frac{T_i - 121}{10}\right]$$

where:

Δt = sampling interval;

T_i = temperature of sample *i*.

9.18 The sampling interval, Δt, should be not greater than two seconds.

9.19 The precision and accuracy of the measuring and computing equipment should be such that the performance requirements given in BS 3970: Part 2 can be met.

9.20 If an F_0 system is to be specified, then the responsibility is on the user to determine the nature of the bioburden in the load and also to determine that

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the proposed cycle will ensure that the probability of survival of micro-organisms on any given load item does not exceed 10^{-6}. Guidance on how to do this is given in Part 4 of this SHTM.

9.21 Whenever F_0 is used either to control the operating cycle or to influence product release, it should be part of a complete quality assurance system and the validation and routine control subject to independent assessment by the licensing authority.

9.22 The GGMP (see paragraph 1.9) requires validation and control of equipment and processes. Any computer software used to determine the F_0 delivered to the product should also be validated and any modifications controlled.

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10. Sterilizers for unwrapped instruments and utensils

Introduction

10.1 This chapter discusses specifications for clinical sterilizers designed to process unwrapped solid instruments and utensils intended for immediate use.

10.2 The guidance given here assumes that the sterilizer is to be used to process medical devices. However, these sterilizers do not meet the essential requirements of the EU Directives discussed in Chapter 1, which do not permit the supply of unpackaged sterile medical devices.

10.3 Sterilization is achieved by direct contact of the load items with good-quality saturated steam at a preferred sterilization temperature of 134°C (see Table 4).

10.4 Sterilizers for unwrapped instruments and utensils are distinguished from other high-temperature steam sterilizers by the following features:

a. air is removed from the sterilizer by passive displacement, either downward or upward depending whether the steam is supplied externally or generated internally. These sterilizers should therefore not be used to process either wrapped instruments and utensils or unwrapped instruments and utensils with narrow lumens which could inhibit the removal of air and the penetration of steam. Such items should be processed in a porous-load sterilizer (see Chapter 8);

b. except where vacuum is used to dry the load (normally in larger, fixed sterilizers), the load is partially dried by natural evaporation after it has been removed from the chamber;

c. since the sterilized items are exposed to the air on being removed from the chamber, they are susceptible to rapid recontamination. These sterilizers are therefore suitable for clinical use only within the immediate environment in which the load items are to be used.

10.5 Where practicable, instruments and utensils should be wrapped and processed in a porous-load sterilizer.

10.6 Sterilizers for unwrapped instruments and utensils may either be transportable or fixed.

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Transportable sterilizers

10.7 The majority of sterilizers are transportable (bench-top) models which are electrically heated, requiring only a 13 A socket outlet and no piped services. They are commonly used in theatre suites where there is no SSD service and in primary health care units, such as GP and dental practices.

10.8 Steam is generated within the sterilizer chamber and a supply of distilled, deionised or reverse-osmosis water is required. Tap water should not be used as it may cause scaling and chlorine dissolved in the water may corrode the chamber.

10.9 Certain machines, known as “flash” sterilizers, operate at 150°C with a holding time of a few seconds. Although they are intended for rapid sterilization of unwrapped instruments and utensils, the time saved in sterilization is lost in waiting for the load to cool. They do not conform to BS 3970 (see paragraph 10.11) and their use is not recommended.

Fixed sterilizers

10.10 Fixed sterilizers are generally discouraged, but may be installed in an operating theatre to replace existing fixed sterilizers where supply from a porous-load sterilizer is impracticable.

Standard specifications

10.11 Transportable sterilizers for unwrapped instruments and utensils should conform with the specifications in BS 3970: Parts 1 and 4 and the safety specifications in BS EN 61010: Part 2-041. A European Standard on “small” sterilizers (less than one module) is under development and will eventually supersede the relevant clauses of BS 3970.

10.12 Fixed sterilizers should meet the performance requirements of BS 3970: Parts 1 and 4.

Additional specifications

10.13 The following specifications are permitted as options to those in BS 3970: Parts 1 and 4.

Operating cycle

10.14 A transportable sterilizer should have a single operating cycle. Option A of BS 3970: Part 4 (134-138°C) is recommended for NHS use. Some sterilizers may be equipped to provide other optional operating cycles, specified by the purchaser, but the selection of the cycle should be by means of a key, code or tool not available to the operator.

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Temperature recorder

10.15 A temperature recorder is optional in BS 3970: Part 4 but is recommended where documented evidence of correct functioning is required.

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11. Dry-heat sterilizers

Introduction

11.1 This chapter discusses specifications for clinical sterilizers designed to sterilise load items by exposure to hot, dry air. Such sterilizers are correctly known as “dry-heat sterilizers” and sometimes as “hot-air sterilizers” or “sterilising ovens”. They are intended to process materials such as oils, powders and some ophthalmic instruments, which can withstand high temperatures but are likely to be damaged or not sterilized by contact with steam.

11.2 The guidance given here assumes that the sterilizer is to be used to process either medicinal products or medical devices in compliance with the EU Directives discussed in Chapter 1.

11.3 Sterilization is achieved by direct contact of the load items with hot, dry air at a preferred sterilization temperature of 160°C (see Table 4).

11.4 Purchasers should be aware that, owing to the low thermal conductivity of air, it is difficult to obtain an even temperature distribution within the chamber and heat transfer from the air to the load can be very slow. A complete cycle, including assisted cooling to 80°C, takes approximately five hours for a full test load as described in Part 3 of this SHTM.

11.5 Dry-heat sterilizers are not suitable for use as drying cabinets (see BS 2648 for specifications for drying cabinets).

Standard specifications

11.6 The only British Standard covering dry-heat sterilizers was BS 3421: 1961, which has long been inadequate and is now withdrawn. There are no immediate plans for future British or European Standards covering dry-heat sterilizers. In the absence of a current standard, dry-heat sterilizers should conform to Model Engineering Specification C14 published by NHS Estates and to the safety specifications in BS EN 61010: Part 2-043.

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Additional specifications

11.7 The GGMP requires dry-heat sterilizers to have the following characteristics:

a. air should be circulated within the chamber to promote a uniform temperature distribution;

b. positive pressure should be maintained inside the chamber to prevent the entry of non-sterile air;

c. any air admitted to the chamber should be passed through a bacteria-retentive filter.

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12. Low-temperature steam disinfectors and low-temperature steam and formaldehyde sterilizers

Introduction

12.1 This chapter discusses specifications for clinical disinfectors and sterilizers designed to process heat-sensitive items (wrapped or unwrapped) which will withstand saturated steam at temperatures up to 80°C.

12.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1. Low-temperature steam and formaldehyde (LTSF) is not listed in the GGMP as a suitable method for sterilization of medicinal products.

12.3 Disinfection is achieved by the direct contact of the load items with good-quality saturated steam at a disinfection temperature of 71°C at sub-atmospheric pressure ("LTS disinfectors"). Sterilization is achieved by contact with both saturated steam and formaldehyde gas ("LTSF sterilizers"). Sterilizers designed for LTSF will normally incorporate an LTS disinfection cycle.

NOTE: Despite their name, LTSF sterilizers are disinfectors.

12.4 Formaldehyde is a toxic gas. Exposure to formaldehyde is controlled by the COSHH Regulations 1999 and subject to the maximum exposure limits detailed in Table 1. Operational safety information is given in Part 4 of this SHTM.

12.5 LTS disinfectors and LTSF sterilizers operate for the whole of the cycle with the chamber pressure below atmospheric pressure. An air leak rate which is too small to affect the efficacy of a porous-load process may in the case of LTS and LTSF cause an unacceptable volume of air to enter the chamber. Air detectors currently available cannot reliably detect at negative pressures, so as an alternative manufacturers now include a vacuum leak monitor, set to fail the cycle at a leak rate not exceeding 5.2 mbar min^{-1} (see the vacuum leak monitor test in Part 3 of this SHTM). A vacuum leak monitor is less effective than an air detector.

12.6 Since the sterilization process is ultimately dependent on chemical action, microbiological test methods are required to confirm that sterilization conditions have been attained (see Part 3).

12.7 LTSF sterilizers require special precautions for ventilation and drainage (see Chapter 6).

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Standard specifications

12.8 LTS disinfectors (or LTSF sterilizers with an LTS cycle) should conform to the specifications in BS 3970: Parts 1 and 5. LTSF sterilizers should conform to the specifications in BS 3970: Parts 1, 5 and 6 and the safety specifications in BS EN 61010: Part 2-042.

12.9 No European Standards are currently planned for LTS disinfectors or LTSF sterilizers.

Additional specifications

12.10 The following specifications for LTSF sterilizers are in addition to those given in BS 3970: Parts 1 and 6.

Room ventilation

12.11 The sterilizer manufacturer should supply the appropriate interfaces to enable the sterilizer to function with the room ventilation system as described in Chapter 6.

Local exhaust ventilation

12.12 LTSF sterilizers should be connected to a local exhaust ventilation system (LEV) to ensure that the emission of formaldehyde gas into the atmosphere does not present a safety hazard. The sterilizer manufacturer should supply the appropriate hoods and interfaces to enable the sterilizer to function with the LEV system as described in Chapter 6.

Formalin supply

12.13 The formalin reservoir within LTSF sterilizers should be installed in a sealed, recessed enclosure protected from mechanical damage. The means of attachment of the reservoir should minimise the possibility of spillage. The top of the reservoir should be no more than 1.5 m above floor level.

12.14 An indicator, visible from the front of the sterilizer, should show:

a. how much formalin has been used in the current cycle;

b. how much formalin remains in the reservoir.

Degassing facilities

12.15 A space or room should be allocated for the aeration and storage of processed loads. Load items do not normally absorb formaldehyde and providing the gas removal is satisfactory, the load may be placed in the downstream part of the ventilation flow in a designated area of the finished goods store.

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Gas monitoring system

12.16 Gas detectors should be placed wherever there is a risk of people being exposed to formaldehyde. Such places would normally include both the loading area and plantroom. The detectors should be placed close to the normal working positions of personnel. The monitoring system should be set to sound a visual and audible alarm when the atmospheric concentration of formaldehyde exceeds a preset level no greater than the short-term maximum exposure limit specified in Table 1.

12.17 Interfaces with the ventilation systems will also be required as discussed in Chapter 6.

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13. Ethylene oxide sterilizers

Introduction

13.1 This chapter discusses specifications for clinical sterilizers designed to sterilise load items by exposure to ethylene oxide gas. Such sterilizers are commonly known as “ethylene oxide sterilizers” or “EO sterilizers”.

13.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1.

13.3 EO is a highly reactive liquid and gas which is toxic, flammable and explosive. Exposure to EO is controlled by the COSHH Regulations 1999 (see Chapter 1). The safe operation of EO sterilizers requires careful consideration of all aspects of the installation and operation of equipment. Operational safety information is given in Part 4 of this SHTM.

13.4 EO sterilizers should be installed in dedicated areas which are not used for any other working purposes.

13.5 An EO sterilization process may include preconditioning and degassing procedures requiring additional equipment. Further information about preconditioning is given in paragraph 13.21 and about degassing in paragraph 13.35.

13.6 EO sterilizers have the potential to cause serious environmental pollution. Large sterilizers will require additional plant to dispose safely of exhaust products and this will add considerably to the cost. Such plant is described in paragraph 13.39. Precautions in ventilation and drainage systems are outlined in Chapter 6.

13.7 Since the sterilization process is ultimately dependent upon chemical action, microbiological test methods are required to confirm that sterilization conditions have been attained. These are described in Part 3 of this SHTM.

13.8 Purchasers of an EO sterilizer should be aware of the following points:

a. the difficulty in validating and monitoring suitable cleaning processes for loads before they are sterilized (see Part 4);

b. the difficulty in carrying out representative performance qualification tests for the wide variety of loading conditions that may be used (see Part 3);

c. the difficulty in carrying out meaningful bioburden studies on small numbers of widely differing devices to be sterilized (see Part 4);

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d. the problems associated with determining the levels of residual EO and its reaction products when small numbers of widely differing devices are processed (see Part 3);

e. the need for specialist technical resources dedicated to the operation and maintenance of the equipment (see Part 4).

13.9 EO installations can be expensive both to buy and to run. As there are few items which need to be sterilized by EO, their provision cannot normally be justified by individual hospitals. Where there is a clear need for EO sterilization, the service should be run by a well-supported specialist unit where microbiological testing, environmental controls, degassing procedures and evaluation of residual EO in the sterilized product can be assured.

Types of sterilizer

13.10 Two types of EO sterilizer are suitable for NHS use.

Low-pressure sterilizers

13.11 These are small sterilizers, of chamber volumes around 150 litres, where the sterilant is pure EO at sub-atmospheric pressure. The gas is supplied from a single-use, disposable cartridge contained within the chamber. The cartridge limits the amount of EO in use at any one time and reduces the toxic and explosive hazards. The chamber is designed to contain the effects of an explosion of the contents of a single cartridge.

13.12 Low-pressure sterilizers are relatively cheap to install and to run, requiring no piped EO service and no gas disposal plant. The low pressure in the chamber allows pressure-sensitive equipment to be processed safely.

High-pressure sterilizers

13.13 These are large sterilizers, of chamber volume up to 500 litres, where the sterilant is EO diluted with another gas, supplied from cylinders.

13.14 The mixtures are chosen to expose the load to an EO concentration of around 500-1000 mg litre^{-1} while keeping the potential hazards to a minimum. Two gas systems are in common use:

a. EO with chlorofluorocarbons (CFCs) at pressures up to 2 bar: CFCs have traditionally been used as a diluent gas but are no longer acceptable for environmental reasons;

b. EO with carbon dioxide at pressures up to 6 bar.

13.15 Because of their larger size, high-pressure sterilizers require gas disposal plant to remove EO from the chamber exhaust (see paragraph 13.39).

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Standard specifications

13.16 EO sterilizers should conform to the specifications in BS EN 1422 and the safety specifications in BS EN 61010: Part 2-042. Two types of sterilizer are specified:

a. **type A** sterilizers have operating cycles programmable by the user and may have very large chamber volumes; they are intended primarily for use in industry;

b. **type B** sterilizers have one or more preset operating cycles; the chamber volume is no greater than 1000 litres.

13.17 EO sterilizers for use in the NHS should conform to Type B. They may be either low-pressure or high-pressure systems (see paragraph 13.10).

Additional specifications

13.18 The following specifications for EO sterilizers are in addition to those given in BS EN 1422.

Room ventilation

13.19 The sterilizer manufacturer should supply the appropriate interfaces to enable the sterilizer to function with the room ventilation system as described in Chapter 6.

Local exhaust ventilation

13.20 EO sterilizers should be connected to a local exhaust ventilation system (LEV) to ensure that the emission of EO gas into the atmosphere does not present a safety hazard. The sterilizer manufacturer should supply the appropriate hoods and interfaces to enable the sterilizer to function with the LEV system as described in Chapter 6.

Preconditioning facilities

13.21 For successful sterilization the load should be at a predetermined temperature and humidity before the start of the operating cycle. This may be achieved by exposing the load to the required conditions in an environmentally controlled room or chamber. This preconditioning procedure is considered an integral part of the sterilization process. See Part 4 for more information about routine preconditioning.

13.22 Preconditioning requires either a chamber (designed to accommodate one sterilizer load) or a room (two or more loads).

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13.23 Humidification should be by direct injection of low-pressure steam and should be controlled by direct measurement of relative humidity (RH) within the chamber or room. Humidifiers which operate by dispersion of water into an aerosol (such as spinning-disk humidifiers or nebulizers) are potent sources of microbial contamination and should not be used.

13.24 Provision should be made for continuous monitoring and recording of temperature and RH at locations determined as being representative of the conditions prevailing throughout the chamber or room.

13.25 The temperature and RH at which the chamber or room is controlled should be compatible with the conditions prevailing during the sterilizer operating cycle. They should be selected so that the temperature and RH of the load going into the sterilizer are neither so low that problems of long heat-up and condensation occur, nor so high that temperature control of the cycle is compromised. The uniformity of conditions should be established during validation.

Preconditioning chamber

13.26 All internal surfaces should be smooth, impermeable, durable and easily cleanable. Wherever possible internal corners should be rounded with a minimum radius of 25 mm.

13.27 Chambers constructed of metal should be of stainless steel, mild steel clad with stainless steel or nickel, or anodised aluminium. Alternatively, metal surfaces may be treated to inhibit corrosion.

13.28 The chamber should have assisted air circulation designed to provide effective airflow around all load items (whether partly or fully loaded) and to maintain uniform temperature and humidity throughout the chamber. Air entering the chamber should be filtered.

13.29 Door interlocks should be provided so that after the door has been closed it cannot be opened until the preset preconditioning time has elapsed.

Preconditioning room

13.30 The room should be segregated from assembly and packaging areas but located close to the sterilizer loading area to permit rapid transfer of the load.

13.31 Consideration should be given to cleanliness and ease of cleaning, especially in the design and location of equipment. The room should have a standard of finish similar to that of environmentally controlled areas. All internal surfaces should be smooth and free from cracks. Surface finishes should be impermeable, durable and easily cleanable. Ledges should be kept to a minimum. Wherever possible, internal corners should be rounded with a minimum radius of 25 mm. Any services required for cleaning should be provided within the room.

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13.32 Corrosion of metal components may be a problem in the high-humidity conditions prevailing in the room. Uncoated metal surfaces should be either stainless steel or anodised aluminium.

13.33 The room should have assisted air circulation designed to provide effective airflow around all load items (whether the room is partly or fully loaded) and to maintain uniform temperature and humidity throughout the room. Air recirculation should incorporate a filtration system.

13.34 The door should be fitted with an audible and visual alarm set to operate if the door is left open for more than the time for which the conditions in the room can be maintained. This time should be established during validation (see Part 3 of this SHTM).

Degassing facilities

13.35 Most, if not all, materials subject to EO sterilization retain varying amounts of EO gas. The residual EO in medical devices must be reduced to a safe level, both for personnel handling the product and for the patient. The general term for this procedure is aeration. Aeration within the operating cycle is known as flushing. Aeration following the operating cycle is known as degassing.

13.36 Other compounds may also be present as reaction products of EO, for example ethylene chlorhydrin, and the concentration of these will also need to be reduced. Reference in this SHTM to reduction of EO concentration should be read as applying equally to any other toxic reaction products which may be present.

13.37 Reduction of residual EO occurs naturally as gas diffuses from the product into the surrounding air. Under normal ambient conditions this process may be very slow and significant amounts of EO may be released into the environment. For these reasons degassing by storage under ambient conditions is not recommended. Mechanical degassing should be used.

13.38 A degassing facility may be either a purpose-made aeration cabinet or a room. Some sterilizers incorporate an additional flushing stage as part of the operating cycle and this may be sufficient. Within the NHS the volume of product and the number of cycles a week will be small; for most installations a separate aeration cabinet is not normally necessary.

Disposal of EO

13.39 When an EO sterilizer is purchased consideration must be given to the method to be used to dispose of gases exhausted from the chamber. For a low-pressure sterilizer, chamber exhaust ventilation as described in Chapter 6 is adequate. For high-pressure sterilizers, however, the quantity of EO is likely to be too high to be disposed of safely without further processing.

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13.40 Five basic methods are available: water scrubbing, incineration, catalytic oxidation, reclamation and EO absorption and modification. Of these, catalytic oxidation is recommended for use in the NHS.

13.41 Catalytic oxidation oxidizes EO to carbon dioxide and water by heating the exhaust gases in the presence of a catalyst at a temperature of approximately 300°C. Maximum efficiency is in excess of 99%.

13.42 Inlet gas streams must be diluted to contain less than 1% EO to prevent significant heating of the catalyst bed. High EO concentrations may cause a runaway reaction and under these conditions, in addition to the fire and explosion hazard, any CFCs present in the gas may be degraded to give toxic products such as phosgene.

13.43 The purchase and running costs are moderate to high. Little routine maintenance is required other than periodic replacement of the catalyst bed.

13.44 Small units suitable for installation with small EO sterilizers are commercially available and present few installation problems.

Gas monitoring system

13.45 Gas detectors should be placed wherever there is a risk of people being exposed to EO. Such places would normally include the loading area, plantroom, manifold room and degassing room. The detectors should be placed close to the normal working positions of personnel. The monitoring system should be set to sound a visual and audible alarm when the atmospheric concentration of EO exceeds a preset level no greater than the short-term maximum exposure limit specified in Table 1.

13.46 Interfaces with the ventilation systems will also be required as discussed in Chapter 6.

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14. Laboratory sterilizers

Introduction

14.1 This chapter discusses specifications for sterilizers ("laboratory sterilizers") used for the processing of materials and equipment to be used in clinical laboratories.

14.2 These sterilizers are not intended for the processing of medical devices or medicinal products. There is therefore no need for them to comply with the EU Directives discussed in Chapter 1.

14.3 Guidance on validation and periodic testing of laboratory sterilizers is given in Part 3 of this SHTM. Guidance on operation is given in Part 4.

Provision of laboratory sterilizers

14.4 The HSE Advisory Committee on Dangerous Pathogens recommends that laboratory sterilizers capable of making safe infected material be provided as shown in Table 11.

Table 11: Provision of laboratory sterilizers

Containment level	Provision
1	No sterilizers are required
2	A sterilizer with a make-safe cycle must be readily accessible, normally in the same building as the laboratory
3	A sterilizer with a make-safe cycle should be preferably situated within the laboratory, but one must be readily accessible in the laboratory suite
4	A double-ended sterilizer with interlocking doors with entry in the laboratory and exit in a clean area must be provided

Source: *Categorisation of pathogens according to hazard and categories of containment* (4th edition), HSE 1995.

14.5 General information on the requirements for the four containment categories can be found in the HSE document *Categorisation of pathogens according to hazard and categories of containment*, published by HMSO. Purchasers should note that the containment requirements have been given statutory force by the Control of Substances Hazardous to Health Regulations 1999.

14.6 Sufficient sterilizers should be installed to ensure that contaminated material can continue to be made safe if any sterilizer is removed from service. A cycle for the make-safe of small plastic discard (see paragraph 14.38) and a cycle for the make-safe of contained fluid discard (see paragraph 14.42) should be available at all times. The need for other cycles to be duplicated

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will depend on the nature and volume of the work being done in the laboratory.

14.7 Where possible, at least one sterilizer should be designated solely for the processing of discard material.

14.8 Laboratory sterilizers intended to process discard material should be sited as close as possible to the area in which the discard is produced, to avoid contaminated material being transported through rooms where it would not normally be stored or handled. Laboratory sterilizers intended to process culture media should be directly accessible from the media preparation area.

14.9 The preferred type of sterilizer is a front-loading unit, recessed into a panel separating the loading area from the plantroom, as described in Chapter 5. Such sterilizers are available with a wide range of chamber sizes and operating cycles.

14.10 Sterilizers with a door at each end are essential for Containment Level 4 laboratories, though they present special problems of installation and access for maintenance.

14.11 Free-standing machines, with chambers up to 500 litres, are also available. They are either top-loading or front-loading. For top-loading sterilizers, where there may be difficulties in load handling and lifting and a hazard from hot surfaces, the practical limit is 250 litres. Multiple free-standing sterilizers are not normally cost-effective when used in centralised sterilising facilities.

14.12 Transportable sterilizers, which generate steam from an internal reservoir, may be appropriate for small laboratories.

Design considerations

14.13 A laboratory sterilizer may provide one or more operating cycles, each designed for processing a particular type of load. The number and nature of the operating cycles which can be supported by any particular machine will depend on details of its design and construction. It will depend in particular on the methods used to remove air from the chamber and load, the methods used for cooling and drying the load and the provision of thermal door locks. Purchasers should carefully consider which operating cycles they are likely to need in the future, so that the manufacturer can install the necessary hardware. Otherwise it may not be possible to add a new operating cycle to a sterilizer without expensive modification. It is not merely a matter of “reprogramming.”

14.14 The following three considerations are crucial. The cycles themselves are described in paragraphs 14.36-14.55.

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Air removal

14.15 Laboratory sterilizers commonly employ one of two principles for removing air from the chamber, each of which can be implemented in several ways:

a. **passive:** steam comes in at the top of the chamber and air is forced out at the bottom (downward displacement). This is the simpler (and cheaper) method, but only suitable for loads such as sealed bottles which do not impede the removal of air from the chamber. (In certain machines, notably transportables, passive air removal may be by upward displacement.)

b. **active:** the chamber is subjected to successive pressure changes to draw air from the chamber. This is required for loads such as fabrics, glassware and other equipment where trapped air cannot reliably be removed by passive methods. The more difficult air is to remove, the more pressure pulses will be required. Active air removal is always faster than passive methods.

Cooling and drying

14.16 Where necessary, one of four cooling methods may be used:

a. **natural:** the load is allowed to cool naturally in the chamber until it reaches a safe temperature. This is the cheapest option and acceptable if lengthy cycle times are tolerable and the load is not likely to be damaged by remaining hot for long periods;

b. **dry assisted:** either cold water is circulated through the jacket or through cooling coils, or air is circulated through the chamber (with or without pressure pulsing) to accelerate the cooling process. This is faster than natural cooling;

c. **wet assisted:** the load is sprayed or deluged with coolant water. This is faster than dry assisted cooling, therefore the method of choice for products which cannot withstand long periods at high temperature, but is only acceptable for loads such as sealed bottles where the coolant cannot come into contact with the contents. It is not suitable for loads contained in discard boxes;

d. **vacuum:** the chamber is evacuated to permit the remaining heat in the load to evaporate moisture, simultaneously cooling and drying the load. This is suitable for loads which trap moisture (in general these are the same as the loads which trap air).

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Thermal door locks

14.17 Laboratory sterilizers constructed to BS 2646 will have one or two door locks designed to prevent the door from being opened until the load cools to a preset temperature:

a. all sterilizers will have an interlock that prevents the door from being opened until the temperature of any fluid in the chamber and load (including condensate) has fallen below the boiling point of water at local atmospheric pressure (100°C at sea level);

b. sterilizers designed to process discard and fluid loads (cycles for make-safe of discard in large containers, sterilization of culture media, and free steaming) will have an additional interlock (a “thermal door lock”) to ensure that the door cannot be opened until the temperature of fluid in sealed containers has fallen below 80°C (see paragraph 14.26 for additional specifications). Note that this requirement will considerably lengthen the cycle time.

Standard specifications

14.18 Specification of laboratory sterilizers is covered by the various parts of BS 2646, *Autoclaves for sterilization in laboratories*, which has been radically revised in recent years:

Part 1: 1993 - Specification for design, construction and performance;

Part 2: 1990 - Guide to planning and installation;

Part 3: 1993 - Guide to safe use and operation;

Part 4: 1991 - Guide to maintenance;

Part 5: 1993 - Methods of test for function and performance.

14.19 While BS 2646 is a sound basic specification for laboratory sterilizers, the UK Health Departments recommend additional specifications which are detailed in paragraphs 14.23-14.34.

14.20 Laboratory sterilizers constructed in accordance with BS 2646 will not be suitable for processing material infected with Hazard Group 4 pathogens unless provision is made to contain and sterilise all chamber effluents before disposal. Such a sterilizer should not be operated without a full fault-and-effect analysis to ensure that the containment remains secure if a failure occurs. The advice of the Public Health Laboratory Service or the NHS in Scotland Management Executive should be sought before specifying a sterilizer for a Containment Level 4 laboratory.

14.21 BS 2646 does not cover culture media preparators. A UK Health Departments specification for these is discussed in paragraph 14.56.

14.22 A European Standard on laboratory sterilizers is in preparation but is unlikely to be published in the near future.

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Additional specifications

14.23 The following specifications are additional to those required by BS 2646: Part 1. Purchasers should ensure that they are agreed with the manufacturer before any contract is made.

Instruments and controls

14.24 BS 2646: Part 1: 1993 requires only that sterilizers be fitted with a chamber temperature indicator and a chamber pressure indicator. Laboratory sterilizers for use in the NHS must have a temperature recorder and a pressure recorder, complying with the requirements of BS 3970: Part 1.

14.25 A cycle counter complying with BS 3970: Part 1 will also be required.

Thermal door-lock override

14.26 Where the sterilizer is provided with a thermal door lock designed to prevent the door being opened until the temperature of fluids in sealed containers has fallen to 80°C (14.17b), a means should be provided to override the lock during the cooling stage of the operating cycle. The override is intended for use by trained persons who wish to gain access at temperatures above 80°C to loads which will not present an explosive hazard.

14.27 The override should meet the following specifications:

a. the override switch is accessible only by means of a key, code or tool unique to the sterilizer;

b. it operates only during the cooling stage of the cycle and causes the cooling stage to terminate;

c. there is a visual indication that the override has been operated;

d. the switch resets automatically when released;

e. at the end of the cycle the door cannot be opened except by means of a key, code or tool.

14.28 Where the sterilizer is intended to be used exclusively for the make-safe of discard in small containers, compliance with paragraphs 14.27d and 14.27e may be waived with the agreement of the laboratory safety officer. In this case, the switch should reset automatically whenever a different operating cycle is selected or whenever the power supply is interrupted.

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Load-temperature probe

14.29 Where the sterilizer is to be used with cycles other than the make-safe of discard, a load-temperature probe should be provided within the chamber. This is a temperature sensor attached to a flex and designed to be inserted into load items (such as bottles) to monitor the temperature during an operating cycle. The reading is displayed on a temperature recorder as described in paragraph 14.24. Means should be provided to stow the probe in a safe position within the chamber when it is not in use.

Steam generators

14.30 Where steam is supplied from a generator within the sterilizer (Types 2 and 3 of BS 2646: Part 1: 1993), condensate from the steam which comes into contact with any discard load should not be returned to the boiler.

14.31 Where the sterilizer chamber is used as a water reservoir (Type 4), the water should enter the chamber after the start of the cycle and be drained before the end of the cycle.

14.32 Reservoirs may accumulate solidified agar and should de designed so that they can be cleaned easily.

Chamber drain

14.33 The chamber drain should be designed to minimise the risk of its becoming blocked with solidified agar or similar material.

14.34 Where the temperature of the effluent is high, for example for free steaming, means should be provided to prevent vapour being discharged into the plantroom or the loading area. Further information on drainage may be found in Chapter 6.

Top-loading sterilizers

14.35 Top-loading sterilizers are difficult to load safely without the use of mechanical aids. Loading systems should be designed to protect the operator from the risk of injury caused by lifting and hot surfaces and should comply with the requirements of the Manual Handling Operations Regulations 1992 and the Lifting Operation and Lifting Equipment Regulations 1998 (see Chapter 4 and Part 1 of this SHTM).

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Operating cycles

14.36 BS 2646 recognises only three distinct operating cycles which it denotes as make-safe, liquids sterilization, and equipment and glassware sterilization. The range of operating cycles recommended for NHS use, and the materials they are designed to process, are described below and specified in Table 12. Where the table gives a choice of sterilization temperatures, the highest temperature should normally be specified. The performance class listed for each cycle is explained in Table 5. If heat-sensitive loads are likely to be processed, then additional lower-temperature cycles may be required. The complete set of cycles to be provided on each machine, including any non-standard cycles not shown here, should be agreed with the manufacturer before the contract is placed.

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Table 12: Operating cycles for laboratory sterilizers

Name of operating cycle	Thermal door lock(80°C)	Air-removal method	Cooling and drying method	Sterilization temperature [°C][a]	Typical performance class[b]
Make-safe of small plastic discard	Yes	Active	None	134	5
				126	6
				121	6
		Passive	None	134	9
				126	9
				121	9
Make-safe of contained fluid discard	Yes	Passive	Natural	134	12
				126	12
				121	12
			Dry assisted	134	9
				126	9
				121	9
Sterilization of culture media (pre-set cycle)	Yes	Passive	Natural	121	12
				115	12
			Dry assisted	121	8
				115	9
			Wet assisted	121	5
				115	6
Sterilization of culture media (variable cycle)	Yes	Passive	Dry assisted	102 - 134	10
Disinfection of fabrics	No	Active	None	134	3
				126	4
				121	5
Sterilization of glassware and equipment	No	Active	Vacuum	134	3
				126	3
				121	4
		Passive	None	134	4
				126	5
				121	6
Free steaming (variable cycle)	Yes	Passive	Dry assisted	102 - 104	10

These are the most common combinations for operating cycles. Others are possible.

[a] See Table 4 for full sterilization conditions.

[b] See Table 5 for definitions of performance classes.

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14.37 Operating cycles are normally automatic and preset and cannot be adjusted by the operator. For some processes, however, such as the sterilization of culture media and free steaming, it may be desirable to have a variable cycle with controls for adjusting the sterilization temperature and holding time within a preset range. This feature should normally be provided as a separate cycle.

Make-safe of small plastic discard

14.38 This cycle corresponds to the “make-safe” cycle specified in BS 2646. It is designed to sterilise infected material held in plastic containers not exceeding 50 ml. Examples of such containers include Petri dishes, specimen bottles and other small plastic items intended either for disposal or for reuse.

14.39 Although the containers would normally be unsealed, the limits on volume ensure that any fluid held in a sealed container does not present an explosion hazard when the door is opened at the end of the cycle. Glass containers and larger plastic containers should be processed with the make-safe cycle for contained fluid discard (paragraph 14.42).

14.40 If the workload is heavy, an active air removal system (paragraph 14.15b) is recommended to shorten the cycle time.

14.41 Discard boxes as specified in paragraph 14.60 will be required.

Make-safe of contained fluid discard

14.42 This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646. It is designed to make-safe infected material in sealed glass containers of any size or sealed plastic containers of volume greater than 50 ml.

14.43 While essentially the same as the culture media cycle (paragraph 14.45), a sterilization temperature of 126°C is normally used to protect the glass. Lower sterilization temperatures should only be used if plastic containers are to be processed.

14.44 Discard boxes as specified in paragraph 14.60 will be required.

Sterilization of culture media

14.45 This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646. It is designed to sterilise culture media in open or sealed containers.

14.46 Since culture media are normally damaged by sterilization at 134°C the maximum sterilization temperature is set at 121°C.

14.47 A variable cycle, in which combinations of sterilization temperature and holding time can be set by the operator, may be desirable for certain products and, if required, should be specified as a separate cycle.

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14.48 The culture media cycle is also suitable for disinfecting unwrapped equipment such as tubing sets.

Disinfection of fabrics

14.49 This cycle is a variant of the “glassware and equipment” cycle specified in BS 2646. It is designed to disinfect (but not sterilise) fabric materials such as towels, clothing, wrapped animal bedding, and other porous materials.

14.50 If the fabrics are required to be sterile and dry at the end of the cycle, a machine complying with the performance requirements for a clinical porous-load sterilizer will be necessary (see Chapter 8).

14.51 The cycle differs from the glassware and equipment cycle (14.53) in that more pressure pulses will be required to remove air from the load.

14.52 The fabrics cycle is also suitable for sterilising empty glassware without caps and for disinfecting wrapped tubing and wrapped filters (see paragraph 14.54).

Sterilization of glassware and equipment

14.53 This cycle corresponds to the “glassware and equipment” cycle specified in BS 2646. It is designed to sterilise clean, empty glassware (without caps) and equipment such as tubing and filters. Loads must not contain any fluids.

14.54 Some microbiological filter membranes may be damaged by the rapid fluctuations in pressure used by an active air-removal system, and it may be necessary to provide a separate filter cycle.

Free steaming

14.55 This cycle is not specified in BS 2646. It is designed to melt solidified agar by exposing it to steam near atmospheric pressure. It is normally a variable cycle. If the workload is heavy, this will not be a cost-effective way of using a sterilizer and a Köch steamer may be more suitable.

Culture media preparators

14.56 Many of the problems which relate to sterilising culture media can be solved by the use of small sterilizers in which the media constituents are placed directly into the chamber, thus avoiding the use of glass containers and their attendant hazards. Since these small machines have a unique function, their design is specialised in comparison with other laboratory sterilizers and BS 2646 is not applicable.

14.57 A culture media preparator consists of two or three modules incorporated into a system designed to provide controlled preparation, sterilization, cooling and dispensing of culture media with a minimum of attention by the

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operator. The system may also include a module which automatically stacks the completed culture plates.

14.58 The sterilizer module consists of a pressure vessel which contains the medium, surrounded by a jacket (which may itself be a pressure vessel) containing a heat transfer fluid (usually water) or separate heating elements and coils. Throughout the preparation and sterilising part of the process heat is transmitted from the jacket to the culture medium to attain a controlled temperature between 80°C and 130°C in order to dissolve the constituents and sterilise the resultant culture medium. After a predetermined time at the sterilization temperature the medium is rapidly cooled to a controlled dispensing temperature between 40°C and 60°C. Cooling is usually achieved by circulating cold water. Provision is also made for adding solutions to the sterilized cooled medium before possible reheating, cooling and final dispensing.

14.59 The sterilizer module of these systems should conform with the UK Health Departments' specifications set out in *Performance and safety specification for culture media sterilizers* (STB 3A/85/12) with the following modifications:

a. both inner and outer vessels must have a pressure relief valve; these must be dedicated safety valves set to prevent the vessel being over-pressurised and not have any other function. They must be positioned so that in the event of the valves operating the discharge will not be expelled into the immediate working area;

b. port covers should be made of a material, such as stainless steel, which will not distort under normal operating conditions.

Discard boxes

14.60 When a sterilizer intended for use with make-safe cycles is purchased, suitable boxes will need to be specified for receiving discard material, transporting it from the laboratory bench to the sterilizer, and containing the load during the sterilization process. Enough boxes to load the chamber fully should be provided.

14.61 The sterilizer manufacturer will have used a certain type of discard box in determining the cycle time. If other types are used for routine production, the cycle time may differ considerably.

14.62 The design of the box can greatly affect the overall cycle time, varying between 45 minutes and two hours when the process incorporates an active air-removal system, and between two and six hours for processes based on passive displacement. Figure 3 illustrates a typical commercially available discard box.

14.63 The box should be designed to facilitate the removal of air from the load and the penetration of steam into the load.

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14.64 The box material should be impervious, conduct heat well, be robust, resistant to puncturing, easily cleanable and able to withstand the sterilization process without damage. Stainless steel, aluminium and plastic are the most common materials:

a. stainless steel, preferably coated with polytetrafluoroethylene (PTFE), is the material of choice. Its principal advantages are resistance to distortion at sterilization temperatures, good heat transfer and “non-stick” properties;

b. aluminium is lighter than other metals but is prone to metal fatigue and cracking, and so has a shorter life expectancy;

c. plastic boxes are cheaper than those made of metal but conduct heat poorly, increasing energy consumption and lengthening cycle times. Where inserts are used to segregate solid from liquid discard, a plastic box may distort and prevent the discard or insert from being withdrawn.

14.65 Where small discard is to be made safe, the box should contain a trivet to support the load before sterilization and allow any liquids to drain to the bottom of the box during the cycle. This will make it easier to separate solid and liquid residues for disposal.

14.66 Discard should be enclosed when the box is being moved. Loose-fitting lids are satisfactory for transport within a laboratory. Alternatively, the discard material may be placed in a discard bag (see paragraph 14.67) inside an open box, providing the neck of the bag is closed. Whenever discard material is transported outside the laboratory suite, a sealed and locked lid should be fitted. Where the lid can affect the efficacy of the sterilization process, it should be opened or removed before the cycle begins and sterilized along with the box.

14.67 Bags, usually plastic, are available with identification markings for discard material. The bags are often manufactured in a material which will melt at 134°C to assist air removal. Discard bags should always be contained in a discard box and opened wide before sterilization.

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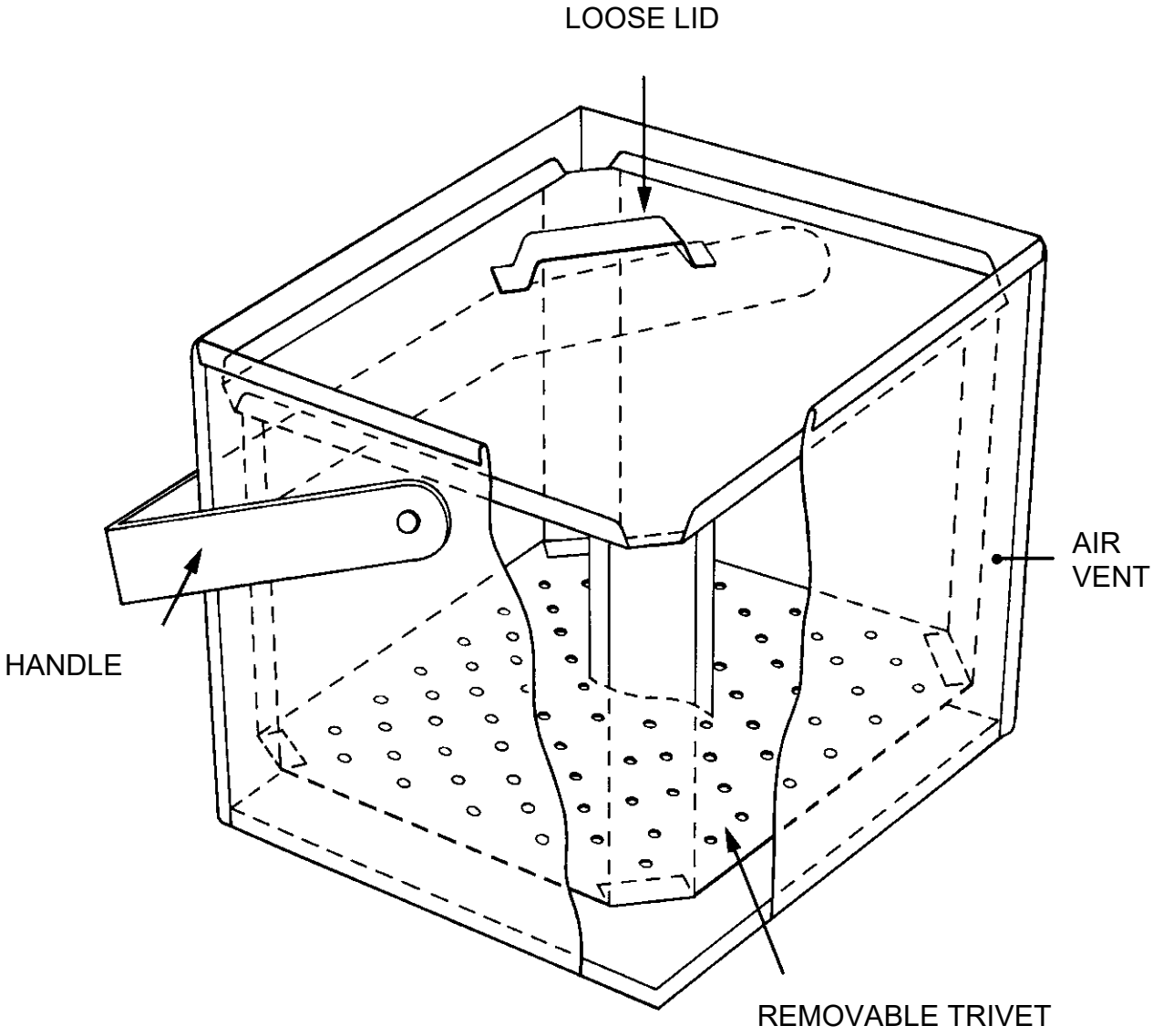
Figure 3: An example of a laboratory discard container



Typical size: 250 mm high

310 mm x 310 mm base

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Glossary

The following list of definitions has been adopted in SHTM 2010 and used in Part 2. Certain pressure terms have been modified to comply with the requirements of BS EN 764. Cross references to other terms are shown in bold type.

absolute pressure	pressure for which the zero value is associated with absolute vacuum.
aeration	a part of the **sterilization process** during which **sterilant gas** and/or its reaction products desorb from the **load** until predetermined levels are reached. See **degassing** and **flushing**.
air detector	a device used to determine that sufficient air or other **non-condensable gases** have been removed from the **chamber**.
allowable pressure	of a pressure vessel, a limit to the **operating pressure** specified for safety reasons. See **design pressure**.
automatic controller	a device that, in response to predetermined **cycle variables**, operates the **sterilizer** sequentially through the required stages of the **operating cycle**.
batch process record (BPR)	a permanent record of one or more **cycle variables recorded** during a complete **operating cycle** by instruments fitted permanently to the **sterilizer**.
biological indicator	a device, consisting of an inoculated carrier contained within a primary pack, designed to test the efficacy of an **operating cycle**.
Bowie-Dick test	a test, used mainly with porous load sterilizers, to show whether or not steam penetration into a **standard test pack** is even and rapid.
cartridge	in **EO sterilizers**, a portable, single-use, simple vessel containing **sterilant** gas under pressure from which the gas is delivered by puncturing the cartridge.
chamber	the part of the **sterilizer** in which the **load** is placed.
chamber exhaust ventilation (CEV)	a ventilation system designed to extract gas from the **chamber** of an **EO sterilizer** supplied from a **cartridge**.

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chamber furniture	shelves, pallets, loading trolleys and other fixed or movable parts that support the **load** within the **chamber**.
chamber temperature	the lowest temperature prevailing in the **chamber**.
chemical indicator	a device designed to show, usually by change of colour, whether specified values of one or more **cycle variables** have been attained.
clinical sterilizer	a **sterilizer** designed to process **medical devices** or **medicinal products** to be used in the clinical care of patients.
commissioning	the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with the equipment specifications and that it functions within predetermined limits when operated in accordance with the operational instructions.
conditioning	in **EO sterilizers**, the treatment of a **load** within the **operating cycle**, but prior to **sterilization**, to attain a predetermined temperature and humidity throughout the load.
contained fluid discard	discard material held in sealed glass containers or sealed plastic containers of volume greater than 50 ml (see **small plastic discard**).
cooling stage	the period of the **operating cycle**, after the **holding time** has been completed, during which the **load** remains in the **chamber** while the load cools to a safe temperature.
culture media preparator	a specialised **laboratory sterilizer** designed for the **sterilization** and dispensing of culture media.
cycle complete	recognition by the **automatic controller** that the preset values for the **cycle variables**, necessary for a successful **operating cycle**, have been attained and that the sterilized **load** is ready for removal from the **chamber**.
cycle variables	the physical properties, for example time, temperature, pressure, humidity and gas concentration, that influence the efficacy of the **operating cycle**.
dedicated steam supply	a supply of steam produced by a generator for the exclusive use of a **sterilizer** or group of sterilizers.

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degassing	1. in **LTSF** and **EO sterilizers**, an **aeration** procedure in which **sterilant** gas and its reaction products are desorbed from the **load** by defined treatment outside the **sterilizer** after completion of the **operating cycle**. 2. a pre-heating treatment of boiler feed-water to reduce the amount of **non-condensable gases** in the steam supply.
design pressure	of a pressure vessel, the pressure chosen for the design calculations. See **operating pressure**, **allowable pressure**.
discard	laboratory material which is, or may be, infected by micro-organisms and is to be made safe before disposal.
discard bag	a bag, usually of plastic, designed to receive solid **discard** material before being placed in a **discard box** for processing by a **make-safe** cycle.
discard box	a box designed to contain discard material for processing by a make-safe cycle.
disinfection	a process used to reduce the number of viable micro-organisms in a **load** but which may not necessarily inactivate some viruses and bacterial spores.
disinfector	an apparatus designed to achieve **disinfection**.
double-ended sterilizer	a **sterilizer** in which there is a door at each end of the **chamber**.
dry-heat sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to hot dry air near atmospheric pressure.
dryness value	a dimensionless quantity, approximating to the dryness fraction, derived to determine whether steam is of the correct dryness for **sterilization** purposes. A dryness value of 1.0 represents dry **saturated steam**.
EO sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to **ethylene oxide** gas or EO gas mixtures.
equilibration time	the period which elapses between the attainment of the **sterilization temperature** in the **chamber** and the attainment of the sterilization temperature in all parts of the **load**.

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ethylene oxide (EO)	**sterilant** gas used to sterilise items that would be damaged by exposure to heat or moisture. Chemical formula CH_2CH_2O.
F_O	a quantity, measured in minutes, used to determine the efficacy of an **operating cycle** and equivalent to a continuous period at a temperature of 121°C.
fail-safe	an attribute of **sterilizer** design whereby failure of any component or its associated services does not create a safety hazard.
fault	the recognition by the **automatic controller** that the preset **cycle variables** for the **operating cycle** have not been attained and that **sterilization** or **disinfection** has been jeopardised.
flash sterilizer	a device designed to achieve **sterilization** by exposing the **load** to a very high temperature steam for a few seconds.
fluid sterilizer	a **clinical sterilizer** designed to sterilise fluids in sealed containers by exposure to **high-temperature steam** under pressure.
flushing	in **LTSF** and **EO sterilizers,** an **aeration** procedure by which remaining **sterilant** gas is removed from the **load** within the **chamber** by the passage of air or other inert gas.
formaldehyde	**sterilant** gas used in combination with **low-temperature steam** to sterilise items that would be damaged by exposure to **high-temperature steam.** Chemical formula HCHO. Also known as methanal.
formalin	formaldehyde Solution BP. A 38% aqueous solution of **formaldehyde** stabilised with 10% w/v ethanol, commonly used as the primary material for generating formaldehyde gas.
free steaming	a process, used in **laboratory sterilizers,** in which the **load** is exposed to steam near atmospheric pressure.
free-standing	of a **sterilizer,** installed in a room which is not separated into a **plantroom** and a **loading area**.
full load	a specified **load,** used in thermometric tests, to represent the maximum size and mass of load which the **sterilizer** is designed to process.

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gas exposure time	in **EO sterilizers,** the time for which the **chamber** is maintained at the specified temperature, gas concentration, pressure and humidity.
gauge pressure	pressure equal to the difference between the **absolute pressure** and local atmospheric pressure.
high-temperature steam	steam at a temperature above the boiling point of water at local atmospheric pressure.
holding time	the period during which the temperature in all parts of the **chamber, load** and any coolant fluid is held within the **sterilization temperature band.** It follows immediately after the **equilibration time**.
hot-air sterilizer	see **dry-heat sterilizer**.
indicated	an indicated value is that shown by a dial or other visual display fitted permanently to the **sterilizer** (see **recorded** and **measured**).
installation checks	a series of checks performed by the contractor to establish that the **sterilizer** has been provided and installed correctly, is safe to operate, does not interfere with nearby equipment and that all connected services are satisfactory and do not restrict the attainment of conditions for **sterilization**.
installation tests	a series of tests performed by the contractor after the **installation checks** to demonstrate that the **sterilizer** is working satisfactorily.
integral steam supply	a supply of steam produced in a sterilizer **chamber** or in a generator directly connected to it. The pressure in the sterilizer chamber is equal to that in the generator.
Köch steamer	a laboratory apparatus designed to expose a **load** to steam near atmospheric pressure and commonly used for melting solidified agar.
laboratory sterilizer	a **sterilizer** designed to sterilise, disinfect or **make-safe** laboratory materials and equipment.
load	collectively, all the goods, equipment and materials that are put into a **sterilizer** or **disinfector** at any one time for the purpose of processing it by an **operating cycle**.
load item	one of several discrete containers, packs or other units that together constitute a **load**.

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load-temperature probe	a movable temperature sensor fitted within the **sterilizer chamber** and designed to record the temperature inside selected **load items**.
loading area	the room or area in front of the **sterilizer** in which the operator works and from which the sterilizer is loaded and unloaded. It is commonly separated by a fascia panel from the **plantroom**.
loading condition	a specified combination of the nature and number of **load items,** the items of **chamber furniture,** and their distribution within the **chamber**.
loading factor	the average fraction of the **usable chamber space** occupied by a load during normal operation.
local exhaust ventilation (LEV)	a ventilation system designed to extract small amounts **EO** or **formaldehyde** vapour released during normal operation of a **sterilizer** and its ancillary equipment.
low-temperature steam (LTS)	steam at a temperature below the boiling point of water at local atmospheric pressure.
LTS disinfector	a clinical **disinfector** designed to disinfect **loads** by exposure to **low-temperature steam** at sub-atmospheric pressure.
LTSF sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to **low-temperature steam** and **formaldehyde** gas at sub-atmospheric pressure.
mains steam supply	the supply of steam produced for distribution to a range of steam-consuming equipment by an independent common boiler.
make-safe	a process, used in **laboratory sterilizers,** to reduce the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard or environmental contamination.
master process record (MPR)	a **batch process record** obtained from a thermometric **commissioning** or **performance qualification** test and annotated to show the permitted tolerances for **cycle variables** during subsequent testing and routine production.

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measured	a measured value is that shown on a test instrument, such as a thermometric recorder or a test pressure gauge, attached to the **sterilizer** for test purposes **(see indicated** and **recorded)**.
medical device	any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC.)
medicinal product	any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product. (Source: EU Council Directive 65/65/EEC.)
module	a standard unit of **chamber** size being a rectangular box measuring 300 x 300 x 600 mm of volume 54 litres.
non-condensable gases (NCGs)	gases which cannot be liquefied by compression under the range of conditions of temperature and pressure used during the **operating cycle**.
noted	a noted value is that written down by the operator, usually as the result of observing an **indicated**, **recorded** or **measured** value.
operating cycle	the set of stages of the **sterilization** or **disinfection** process carried out in sequence and regulated by the **automatic controller.** It is synonymous with the terms “sterilization cycle” for **sterilizers** and “disinfection cycle” for **disinfectors**.
operating pressure	the pressure in the **chamber** during the **plateau period** of an **operating cycle**. See **allowable pressure**, **design pressure**.

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override	a system by which the progress of the **operating cycle** can be interrupted or modified as necessary.
paraformaldehyde	a mixture of polymethylene glycols formed by the reaction of **formaldehyde** with water.
performance class	an integer, from 1 to 20, related to the total cycle time for a **sterilizer** with a **full load**.
performance qualification (PQ)	the process of obtaining and documenting evidence that the equipment, as commissioned, will produce acceptable product when operated in accordance with the process specification.
performance requalification (PRQ)	the process of confirming that the evidence obtained during **performance qualification** remains valid.
periodic tests	a series of tests carried out at daily, weekly, quarterly and yearly intervals.
personal protective equipment (PPE)	equipment, including clothing, which is intended to be worn or held by a person at work, which protects against one or more risks to his or her health and safety.
plant history file	a file containing **validation**, maintenance and other engineering records for each **sterilizer**.
plantroom	the room or area to the rear of the **sterilizer** in which services are connected and which provides access for maintenance. It is commonly separated by a fascia panel from the **loading area**.
plateau period	the **equilibration time** plus the **holding time**.
porous-load sterilizer	a **clinical sterilizer** designed to process, by exposure to **high-temperature steam** under pressure, porous items such as towels, gowns and dressings, and also **medical devices** that are wrapped in porous materials such as paper or fabrics.
preconditioning	treatment of a **load** to attain predetermined conditions, such as temperature and humidity, before the start of an **operating cycle**.
pressure ballasting	a technique used in **fluid sterilizers** by which the pressure in the **chamber** is maintained at or near to the pressure inside the **load** containers during all or part of the **operating cycle**.

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pressure vessel	a collective term describing the sterilizer **chamber,** jacket (if fitted), door(s) and components that are in permanent open connection with the chamber.
priming	of a steam generator, the delivery of steam containing water in suspension due to violent boiling or frothing.
process indicator	a **chemical indicator** used to distinguish between processed and unprocessed load items.
pyrogen	a bacterial toxin that causes a rise in body temperature and which is not destroyed by steam **sterilization**.
recommissioning	a procedure to confirm that operational data established during **commissioning** remain valid.
recorded	a recorded value is that shown on the output of a recording instrument fitted permanently to the **sterilizer** (see **indicated** and measured).
revalidation	a procedure to confirm an established **validation,** consisting of **recommissioning** followed by **performance requalification**.
safety hazard	a potentially detrimental effect on persons or the surroundings arising directly from either the **sterilizer** or its **load.**
saturated steam	steam whose temperature, at any given pressure, corresponds to that of the vaporisation curve of water.
small load	a specified **load,** used in thermometric tests, to represent the minimum size and mass of load which the **sterilizer** is designed to process.
small plastic discard	**discard** material comprising or held in plastic containers not exceeding 50 ml in volume.
sterilant	an agent used to effect **sterilization,** such as steam, hot air or a sterilising gas.
sterile	condition of a **load item** that is free from viable micro-organisms. See BS EN 556 for the requirements for a **medical device** to be labelled “sterile”.
sterilization	a process undertaken to render a **load sterile**.

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sterilization conditions	the ranges of the **cycle variables** which may prevail throughout the **chamber** and **load** during the **holding time**.
sterilization process	the complete set of procedures required for **sterilization** of a **load,** including the **operating cycle** and any treatment of the load before or after the operating cycle.
sterilization temperature	minimum acceptable temperature of the **sterilization temperature band**.
sterilization temperature band	the range of temperatures which may prevail throughout the **load** during the **holding time.** These temperatures are expressed as a minimum acceptable (the **sterilization temperature)** and a maximum allowable and are stated to the nearest degree Celsius.
sterilizer	an apparatus designed to achieve **sterilization**.
sterilizer process log	a log, kept by the User, which contains records for each production cycle.
superheated steam	steam whose temperature, at any given pressure, is higher than that indicated by the vaporisation curve of water.
thermal door lock	an interlock fitted to certain **sterilizers** to prevent the door from being opened until the temperature in the **chamber** and **load** falls below a preset value.
transportable	requiring no permanent connections or installation and capable of being moved manually without mechanical assistance. Synonymous with “bench-top”.
type tests	a series of tests conducted by the manufacturer to establish the working data for a **sterilizer** type.
usable chamber space	the space inside the **chamber** which is not restricted by **chamber furniture** and which is consequently available to accept the **load**.
utilisation factor	the fraction of the open hours for which a sterilizer is available to process loads.
validation	a documented procedure for obtaining, recording and interpreting data required to show that a **sterilization process** will consistently comply with predetermined specifications.

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works tests	a series of tests to establish the efficacy of each **sterilizer** at the manufacturer's works.

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Abbreviations

BPR	batch process record
BS	British Standard
°C	degree Celsius
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CEV	chamber exhaust ventilation
COSHH	Control of Substances Hazardous to Health (Regulations)
dBA	decibel, A-weighted
EMC	electromagnetic compatibility
EN	European Standard (Europäische Norm)
EO	ethylene oxide
EU	European Union (formerly European Community)
GGMP	EU, *Guide to good manufacturing practice for medicinal products*
h	hour
HBN	Health Building Note
HDN	Hospital Design Note
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HTM	Health Technical Memorandum (UK)
ISO	International Organisation for Standardisation
kW	kilowatt
l	litre
LEV	local exhaust ventilation
LTMEL	long-term maximum exposure limit
LTS	low-temperature steam
LTSF	low-temperature steam and formaldehyde
µm	micrometre (micron, 10^{-6} m)
m	metre
mbar	millibar (10^{-3} bar)
MCA	Medicines Control Agency
MDA	Medical Devices Agency
mg	milligram (10^{-3} g)
min	minute
ml	millilitre (10^{-3} l)
mm	millimetre (10^{-3} m)
mmol	millimole (10^{-3} mole)
MPR	master process record
NCG	non-condensable gas
PES	programmable electronic system
ppm	parts per million
PQ	performance qualification
PRQ	performance requalification
RH	relative humidity
s	second

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SHPN	Scottish Hospital Planning Note
SHTM	Scottish Health Technical Memorandum
SSD	sterile services department
STMEL	short-term maximum exposure limit
UK	United Kingdom

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NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

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	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
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Publication ID	Title	Publisher	Date	Notes
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	Part 5: Methods of testing for function and performance		1993	
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BS 4275	**Guide to implementing an effective respiratory protective device programme**	BSI Standards	1997	
BS 5164	**Specification for indirect acting electrical indicating and recording instruments and their accessories**		1975	
BS 5295	**Environmental cleanliness in enclosed spaces** **Part 1:** Specification for clean rooms and clean air devices		1989	
BS 5304	**British standard code of practice for safety of machinery**	BSI Standards	1988	
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BS 6068	**Water quality** **Sect.1.2** Glossary	BSI Standards	1997	
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BS 6257	**Specification for paper bags for steam sterilization for medical use**		1989	
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	Phosphorus and silicon in waters, effluents and sludges 1992	HMSO	1993	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
LG 2	Lighting guide: hospitals and healthcare buildings	Chartered Institution of Building Services Engineers	1989	
	Sterilization and disinfection of heat-liable equipment	Central Sterilizing Club	1986	

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Appendix 1: Useful addresses

Medicines Control Agency,
Market Towers,
1 Nine Elms Lane,
London SW8 5NQ.
Tel. 0171-273 3000.

Medical Devices Agency,
14 Russell Square,
London WC1 B 5EP.
Tel. 0171-972 2000.

Scottish Executive Health Department
St Andrew's House,
Edinburgh EH1 3DG.
Tel. 0131-556 8400.

NHSScotland, Property and Environment Forum Executive,
4th Floor,
St Andrew House,
141 West Nile Street,
Glasgow, G1 2RN.
Tel. 0141 404 3737

Public Health Laboratory Service,
Central Public Health Laboratory,
61 Colindale Avenue,
London NW9 5HT.
Tel. 0181-200 4400.

Health and safety

Health and Safety Executive,
375 West George Street,
Glasgow, G2 4LW.
Tel. 0141 275 3000

Belford House
59 Belford Road,
Edinburgh, EH4 3UE.
Tel. 0131 247 2000

Health and Safety Executive Information Line
Tel. 0870 154 5500

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Standards organisations

British Standards Institution
Head office: 2 Park Street,
London W1A 2BS .

Publications:
Linford Wood,
Milton Keynes MK14 6LE.
Tel. 01908-221 166.

European Committee for Standardization,
Rue de Stassart 36, B-1050 Brussels

Other organisations

Association of Consulting Engineers,
Alliance House, 12 Caxton Street,
London SW1 H 0QL.
Tel. 0171-222 6557.

Institute of Healthcare Engineering and Estate Management ,
2 Abingdon House, Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1 DS.
Tel. 02392-823186.

Institution of Electrical Engineers,
Publication Sales Department, PO Box 26,
Hitchin,
Hertsfordshire SG5 1SA.
Tel. 01438-742792.

Institution of Mechanical Engineers, Publication Sales Department,
PO Box 24, Northgate Avenue,
Bury St Edmunds,
Suffolk IP32 6BW.
Tel. 01284-763277.

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Appendix 2: Information to be supplied by the manufacturer

A2.1 The following information should be supplied by the manufacturer of the sterilizer at or before the time the sterilizer is delivered.

Standards

A2.2 Statements of compliance with relevant British and European Standards and documentary evidence to demonstrate such compliance.

Instruction manual

A2.3 The manual should contain complete instructions including:

a. simplified operating instructions in a durable form suitable for fixing next to the sterilizer;

b. guidance on the types of load that may be processed in the sterilizer and their recommended packaging;

c. operational limits including design pressure, maximum permissible working pressure and maximum permissible working temperature.

Instruments and controls

A2.4 The manual should include a description of each instrument and control fitted to the sterilizer including:

a. the scale ranges of each and the limits of accuracy;

b. evidence that the calibration of each instrument has been verified and that the instrument is reading correctly within its stated limits of accuracy.

A2.5 Where an air detector is fitted, the manual should give:

a. the setting of the sensitivity of the air detector;

b. the level of the signal from the airdetector which will trigger automatic controller to abort the cycle and indicate a fault;

c. the vacuum leak rate that will cause this level to be exceeded.

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Operating cycles

A2.6 The manual should give a description of each operating cycle available on the sterilizer specifying:

a. the sterilization temperatures available;

b. graphical representation of cycle variables (temperature, pressure, etc.) as a function of elapsed time for each sterilization temperature;

c. the maximum rate of change for each cycle variable;

d. the range of variation of any adjustable, preset cycle variables;

e. the cycle time and performance class for the thermometric tests for a full load described in Part 3 of this SHTM;

f. copies of the cycle records obtained during any type tests or works tests.

Services

A2.7 The manual should give a description of all the engineering services required by the sterilizer, specifying:

a. values of the fluctuating demands placed on each service during the course of a normal operating cycle;

b. the maximum and minimum safe supply pressures, temperatures and voltages.

Safety

A2.8 Safety information should include:

a. descriptions of any safety hazards that may arise in the normal operation of the sterilizer and recommended precautions to avoid them;

b. descriptions of all safety devices including their recommended settings and any means provided to override and reset them.

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Chamber

A2.9 Information about the chamber should include the following:

a. the total volume of the chamber;

b. the dimensions of the usable chamber space and its capacity expressed both in litres and as an integral number of sterilization modules;

c. sufficient information to enable the user to identify, for an empty chamber:

(i) the parts of the usable chamber space that are the fastest and the slowest to attain the sterilization temperature;

(ii) the parts of the usable chamber space that are the hottest and the coolest during the sterilization holding time;

(iii) for sterilizers with a thermal door lock, the part of the usable chamber space that is the slowest to cool to a preset safe temperature (normally 80°C).

Maintenance manual

A2.10 Two copies should be provided. It should include:

a. a planned preventative maintenance programme consistent with the principles outlined in Part 4 of this SHTM together with detailed instructions for the procedures contained within it;

b. a list of any information to enable the user to identify, for an empty and testing;

c. diagrams of all electrical, steam, compressed air, water and gas systems;

d. a complete list of spare parts, indicating all parts which should be held in stock and that may require replacement during the normal working life of the sterilizer together with their likely usage rates;

e. guidance on tracing and rectifying likely causes of malfunction;

f. procedures for door safety control checks together with the sequence of operation;

g. method of calibrating the pressure, temperature and humidity indicating and recording systems.

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Scottish Health Technical Memorandum 2010

(Part 3 of 6)

Validation and verification

Sterilization

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NHSScotland, P&EFEx, June 2001

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Preface

SHTM 2010 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the following types of sterilizer in use in the National Health Service:

a. clinical sterilizers:
   (i) high-temperature steam sterilizers used for processing porous loads (including instruments and utensils wrapped in porous materials);
   (ii) high-temperature steam sterilizers used for processing aqueous fluids in sealed containers;
   (iii) high-temperature steam sterilizers used for processing unwrapped solid instruments and utensils;
   (iv) dry-heat sterilizers (hot-air sterilizers);
   (v) ethylene oxide (EO) sterilizers;

b. laboratory sterilizers:
   (i) high-temperature steam sterilizers used with one or more specialised operating cycles;
   (ii) culture media preparators

Sterilization by irradiation is not covered.

NOTE: Despite their name LTSF sterilizers are disinfectors.

This SHTM is intended primarily as a guide for technical personnel, whether specialists in sterilizers and sterilization procedures or those responsible for maintenance and testing. It is also intended for those responsible for the day-to-day running of sterilizers, and will also be of interest to supplies officers, architects, estates managers and others in both the public and private sectors.

Detailed information on the planning and design of a sterile services department, including the level of provision of sterilizers, is given in Scottish Hospital Planning Note 13; *Sterile services department*. Guidance for laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

Although this edition of SHTM 2010 reflects established sterilizer technology, it is recognised that considerable scope exists for the utilisation of emerging technology in the management of sterilizers. This will be kept under review with the aim of introducing recommendations for such technology at the earliest opportunity so that the procedures essential for the efficient, safe and effective operation of sterilizers can be optimised.

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The sterilizers described in this SHTM may not be suitable, without modification, for safely processing articles infected with Hazard Group 4 pathogens nor agents, such as those associated with transmissible spongiform encephalopathies, which are unusually resistant to sterilization. Design considerations for sterilizers intended to process articles infected with such organisms are discussed in Part 2.

NOTE: Information about Hazard Groups may be found in the HSC document 'Categorisation of pathogens according to hazard and categories of containment' (4th edition, 1995) compiled by the Advisory Committee on Dangerous Pathogens.

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1. Introduction

General

1.1 This part of SHTM 2010 covers the validation and periodic testing of the various sterilization processes used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in sterilization has long been inconsistent and occasionally ambiguous. This SHTM introduces a set of terms consistent with European Standards (see paragraph 1.4) which, it is hoped, will in time be adopted by sterilization workers in the NHS. The Glossary contains definitions referred to in this part. A fuller list of terms will be found in Part 5, 'Good practice guide'.

1.3 The Reference section contains full references for all the documents referred to in this part and for selected documents of which the reader should be aware. A fuller list of references relevant to sterilization will be found in Part 5.

European Standards

1.4 Part 1 of this SHTM discusses the three European Union Directives on the manufacture and supply of medical devices, active implantable medical devices and in-vitro diagnostic medical devices, which were implemented in the UK in stages from 1993 onwards. The Directives do not cover sterilization of medicinal products, as this is governed by other legislation (see Part 1).

1.5 To support the Directives, the European Committee for Standardisation (Comité Européen de Normalisation, CEN) prepared draft European Standards on operational procedures for different methods of sterilization of medical devices. Compliance with the relevant standard is considered to be a legal presumption of compliance with the sterilization requirements of the Directive it supports. The standards require that persons responsible for sterilization operate a quality system and that part of that system is validation and routine testing of the process.

1.6 The following Standards on the validation and routine control of sterilization processes are relevant to this part of SHTM 2010:

a. BS EN 550 covers ethylene oxide sterilization;

b. BS EN 554 covers all "moist heat" sterilization. This includes porous load and fluid sterilizers (except where used for medicinal products), and sterilizers for unwrapped instruments and utensils;

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c. BS EN 556 sets out the requirements for medical devices to be labelled “sterile”.

1.7 While the guidance given here is designed to be broadly consistent with the standards, SHTM 2010 should not be regarded as a substitute for the standards themselves when ascertaining compliance with EU Directives or the UK Regulations that implement them.

Personnel

1.8 The following personnel are referred to in this part of SHTM 2010. Further information, including qualifications and areas of responsibility, can be found in Part 1.

1.9 **Management** is defined as the owner, occupier, employer, general manager, chief executive or other person of similar authority who is ultimately accountable for the sole operation of the premises.

1.10 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small, autonomous installations the user may take on this function.

1.11 The **user** is defined as the person designated by the executive manager to be responsible for the management of the sterilizer.

1.12 In a hospital the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the production manager (see paragraph 1.20) in charge of the entire manufacturing process.

1.13 The **competent person (pressure vessels)** is defined as a person or organisation designated by management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a sterilizer described in the Pressure Systems Safety Regulations 2000 (see Part 1). The shorter term “competent person” is used in this SHTM.

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1.14 The **authorised person (sterilizers)** is defined as a person designated by management to provide independent auditing and advice on sterilizers and sterilization and to review and witness documentation on validation. The shorter term “authorised person” is used in this SHTM.

1.15 A list of suitably qualified authorised persons (sterilizers) is maintained by the Institution of Healthcare Engineering and Estate Management (see Appendix 1).

1.16 The **test person (sterilizers)** is defined as a person designated by the executive manager to carry out validation and periodic testing of sterilizers, The shorter term “test person” is used in this SHTM.

1.17 The **maintenance person (sterilizers)** is defined as a person designated by the executive manager to carry out maintenance duties on sterilizers. The shorter term “maintenance person” is used in this SHTM.

1.18 The **microbiologist (sterilizers)** is defined as a person designated by the executive manager to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. The shorter term “microbiologist” is used in this SHTM.

1.19 The **production manager** is defined as a person designated by the executive manager to be responsible for the production of medicinal products.

1.20 The **quality controller** is defined as a person designated by the executive manager to be responsible for quality control of medicinal products with authority to establish, verify and implement all quality control and quality assurance procedures.

1.21 The **laboratory safety officer** is defined as a person designated by the executive manager to be responsible for all aspects of laboratory safety including equipment, personnel and training relating to safety issues, and ensuring compliance with safety legislation and guidelines.

1.22 An **operator** is defined as any person with the authority to operate a sterilizer, including the noting of sterilizer instrument readings and simple housekeeping duties.

1.23 The **manufacturer** is defined as a person or organisation responsible for the manufacture of a sterilizer.

1.24 The **contractor** is defined as a person or organisation designated by the executive manager to be responsible for the supply and installation of the sterilizer, and for the conduct of the installation checks and tests. The contractor is commonly the manufacturer of the sterilizer.

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Safety

1.25 Extensive guidance on the safe operation of the various types of sterilizer is given in Part 4, 'Operational management'. As far as testing is concerned, normal safety precautions are adequate except in the case of sterilizers used to process infectious materials, and sterilizers using gaseous sterilants, as described below. Users are recommended to operate a permit-to-work system to ensure that such sterilizers are declared safe to work on, and that personnel working on them have documented authority to do so.

Infectious materials

1.26 All sterilizers have the potential to process infectious materials, but attention is drawn to certain laboratory sterilizers with cycles expressly designed for the routine making-safe of discard material that is or may be contaminated with pathogenic micro-organisms. Note also that laboratory sterilizers without a make-safe cycle may be occasionally used to process infected material in the event of the designated machine being out of service. The user should therefore ensure that personnel working on laboratory sterilizers wear appropriate protective clothing and are fully informed of any hazards that may be present. Further guidance may be found in the HSC document 'Safe working and the prevention of infection in clinical laboratories: model rules for staff and visitors', compiled by the Health Services Advisory Committee.

Gaseous sterilants

1.27 Low-temperature steam and formaldehyde (LTSF) sterilizers and ethylene oxide (EO) sterilizers both use toxic gases in the sterilization process. Occupational exposure to formaldehyde and EO is controlled by the Control of Substances Hazardous to Health (COSHH) Regulations (see Part 1). Maximum exposure limits are set out in the annual Guidance Note EH40, 'Occupational exposure limits', published by the Health and Safety Executive (HSE) (see References). The limits shown in Table 1 are as at 2001. These limits are statutory maxima but should not be regarded as representing a safe working exposure; employers have a legal obligation to ensure that the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

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Table 1: Maximum exposure limits for atmospheric formaldehyde and ethylene oxide

	Short term exposure limit		Long term exposure limit	
Gas	[ppm]	[mg m^{-3}]	[ppm]	[mg m^{-3}]
Formaldehyde	2	2.5	2	2.5
Ethylene oxide	-	-	5	9.2

The short-term exposure limit (STEL) is the average over any 15-minute period.

The long-term exposure limit (LTEL) is the exposure over any 24-hour period expressed as a single uniform exposure over an 8-hour period.

COSHH does not specify a STEL for EO. In such cases the STEL is deemed to be three times the LTEL in accordance with the recommendations of the Health and Safety Executive.

(Source: HSE Guidance Note EH40 (2001)

1.28 Certain tests in this document require that the sterilant gases be replaced with a suitable non-hazardous substitute:

a. for LTSF sterilizers, the primary material for generating formaldehyde (usually formalin) should be replaced with water;

b. for EO sterilizers where the gas is supplied from cylinders, the sterilant gas should be replaced with a suitable non-toxic, non-flammable gas or gas mixture admitted to the chamber through the EO supply system (including the vaporiser). Air may be used if the system is known to be free of residual traces of EO sufficient to cause an explosive or fire hazard (see paragraph 6.54 for a specification for a suitable monitoring instrument), but nitrogen is recommended as being safe in all circumstances;

c. for EO sterilizers where the gas is supplied from cartridges contained within the chamber, no substitute is normally necessary because of the small amounts of EO present in the system. If a substitute is thought to be desirable, nitrogen cartridges may be used.

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2. Testing of sterilizers

Introduction

2.1 Sterilization is a process whose efficacy cannot be verified retrospectively by inspection or testing of the product. For this reason sterilization processes have to be validated before use, the performance of the process routinely monitored, and the equipment maintained.

2.2 Means of assuring that a sterilizer is fit for its Intended purpose will include tests and checks carried out during the various stages of manufacture, after delivery, during validation and periodically thereafter. Tests will also be required before a sterilizer is returned to service after modification.

2.3 The philosophy of testing and maintenance embodies three main principles to ensure that required standards of performance and safety are attained and sustained:

a. all sterilizers are subject to a planned programme of tests to monitor their performance;

b. all sterilizers are subject to a planned programme of preventive maintenance irrespective of whether or not a preventive maintenance scheme is being operated on the premises generally;

c. expertise on all aspects of the testing of sterilizers should be available at two levels; these are represented by the authorised person (sterilizers) and the test person.

2.4 The scheduled test programmes include simple procedures undertaken by the user, as well as more complex tests undertaken by the test person to demonstrate that the equipment is functioning satisfactorily.

2.5 Schedules for installation checks, validation tests and periodic tests are presented in Chapters 3, 4 and 5, and discussed below. Where appropriate, the schedules refer to detailed test procedures described in later chapters.

2.6 Maintenance of sterilizers is dealt with in Part 4 of this SHTM.

Responsibilities for validation

2.7 Sterilizers should be commissioned on site using the procedures described in this SHTM. The purchaser, manufacturer and contractor have distinct responsibilities.

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Purchaser

2.8 Management should nominate an authorised person (sterilizers) to provide advice on validation.

2.9 The test person should witness the installation checks and tests carried out by the contractor, and arrange for test loads to be supplied as required.

2.10 The test person should carry out the commissioning tests and performance qualification tests. (Some of the performance qualification tests on LTSF and EO sterilizers are the responsibility of the user.)

Manufacturer

2.11 The manufacturer should ensure that the sterilizer is designed, manufactured and tested within a quality system such as that given in BS 5750. The extent of testing will depend on whether the manufacturer has obtained a current certificate of compliance to a relevant British or European Standard by means of a type test for the particular type and size of sterilizer:

a. where a certificate is available, the manufacturer may limit the works tests to those which demonstrate compliance with the specification;

b. when a certificate is not available, such as for a one-off design, works tests should (except for the sound pressure test) include those listed as commissioning tests in Tables 2 and 3 (see Chapter 4). This option is expensive.

Contractor

2.12 The contractor (who may also be the manufacturer) should complete the installation checks and tests specified in Chapter 3 to the satisfaction of the test person before the sterilizer can be accepted for use in accordance with the contract.

2.13 The contractor should provide the test instruments and equipment (but not the test loads, see paragraph 2.9) required for the installation checks and tests, and should satisfy the authorised person that their accuracy, calibration and condition meet the requirements for test instruments specified in Chapter 6, and that the calibration of each instrument has been checked on site and is satisfactory.

The validation process

2.14 Validation is defined as a documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications. Validation is considered as a total process which consists of commissioning followed by performance qualification (Figure 1).

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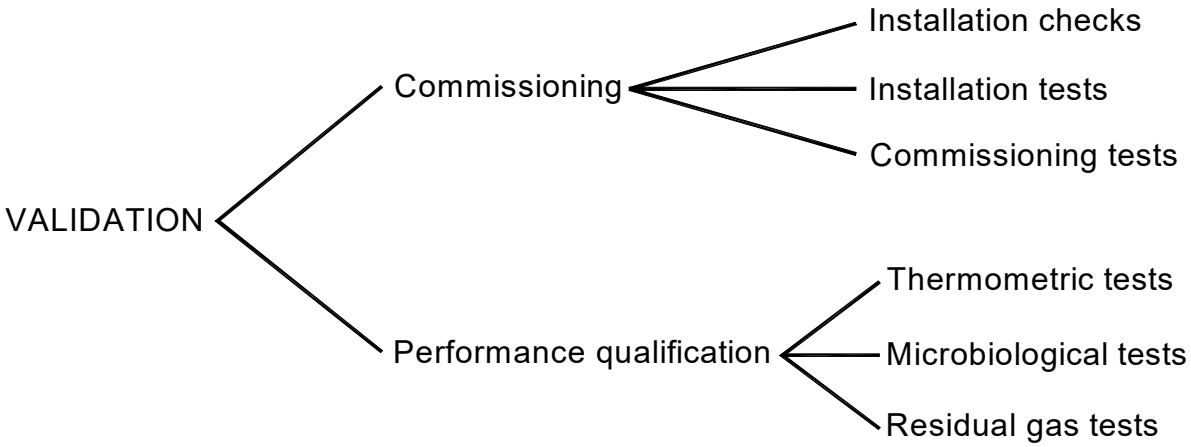
Figure 1: The validation process



Commissioning

2.15 Commissioning is defined as the process of obtaining and documenting evidence that the equipment has been provided and installed in accordance with its specifications, and that it functions within predetermined limits when operated in accordance with operational instructions.

2.16 Commissioning consists of a series of installation checks and installation tests (often identified as “installation qualification” and “equipment qualification”) to be carried out by the contractor, and a series of commissioning tests to be carried out by the test person.

Installation checks

2.17 On delivery of the sterilizer, the contractor should carry out the required installation checks to establish that the sterilizer has been provided and installed correctly, is safe to operate, does not interfere with nearby equipment and that all connected services are satisfactory and do not restrict the attainment of conditions for sterilization.

2.18 Ancillary equipment, such as service supplies and ventilation systems, should be checked by the contractor responsible for their installation.

2.19 The schedule for installation checks is set out in Chapter 3.

Installation tests

2.20 When the installation checks have been completed, the contractor should carry out the required installation tests to demonstrate that the sterilizer is working satisfactorily. The contractor is not required to carry out any thermometric tests unless previously specified in the contract. Any assistance required from the department in which the sterilizer is installed should be agreed between the contractor and the purchaser.

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2.21 If any maintenance or modification work is carried out on the steam, water or piped gas services after the installation tests have been completed, the tests should be repeated by the test person before the commissioning tests commence.

2.22 The schedule for installation tests is set out in Chapter 4.

Commissioning tests

2.23 When the sterilizer has been accepted, the test person should carry out a sequence of commissioning tests to evaluate basic performance and safety. Some of these commissioning tests are identical to those specified as installation tests, and need not be repeated if commissioning follows within seven days of the installation tests.

2.24 The schedule for commissioning tests is set out in Chapter 4.

Performance qualification

2.25 Performance qualification (PQ) is defined as the process of obtaining and documenting evidence that the equipment as commissioned will produce an acceptable product when operated according to process specification.

2.26 PQ consists of tests designed to show that sterilization conditions are attained throughout a production load. A thermometric test is sufficient for most sterilizers but an additional microbiological test is required for sterilizers using gaseous sterilants, and may be necessary for any sterilizer where loading conditions cannot be validated solely by thermometric methods.

2.27 In principle, a PQ test is required for each loading condition that the sterilizer is intended to process. In practice, a test on a single “reference load” may be valid for a range of less demanding loading conditions and in some cases, notably porous loads, the tests specified for commissioning will often provide sufficient evidence for performance qualification.

2.28 The schedule for performance qualification tests is set out with the commissioning tests in Chapter 4. Further information and detailed procedures for performance qualification are given in Chapter 8.

Documentation

2.29 Accurate and efficient keeping of records is an essential part of the management of a sterilizer. A recommended system, based on a plant history file and a sterilizer process log, is described in Part 4 of this SHTM.

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Summary sheets

2.30 On the completion of the validation process, and before leaving the premises, the test person should prepare summary sheets for the user containing the results of the commissioning and PQ tests, and essential working data. At the request of the user the test person should also supply graphical representations of cycle variables obtained from the thermometric tests. The sheets should be signed by the test person and countersigned by the user to certify that the sterilizer is fit for use. Summary sheets should be kept in the sterilizer process log for ready reference by the user. A set of model summary sheets is given in Appendix 3.

2.31 At the same time the test person should provide the user with copies of any master process records (see paragraph 8.58) required for routine production.

Validation report

2.32 Within one month of the completion of the validation process the test person should prepare a full validation report. It should include the following:

a. all the data, supplied by the contractor, collected during the installation checks specified in Chapter 3 and the installation tests specified in Chapter 4, with written confirmation from the contractor that they meet the manufacturer's specifications;

b. written confirmation from the contractor that the calibration of all instruments and gauges fitted to the sterilizer has been verified;

c. all the data collected during the commissioning tests specified in Chapter 4, with written confirmation from the test person that they meet the requirements of the tests;

d. data showing the correlation between the performance of the instruments fitted on the sterilizer and the test instruments used for commissioning and performance qualification;

e. all the data collected during the performance qualification tests in the form of PQ reports (see paragraph 8.54), with written confirmation from the test person and the user and (for medicinal products) the quality controller of the loading conditions (see paragraph 8.7) which may be satisfactorily processed in the sterilizer.

2.33 If any of the data is in the form of electronic data files, the report should include copies of disks or tapes containing the data in a format agreed with the user, and a print-out of each disk or tape directory showing clearly where the data for each test are to be found.

2.34 The test person should certify that all tests and checks have been carried out and that the results are satisfactory. The microbiologist should sign the records of any microbiological tests. The complete validation report should be examined and countersigned by the authorised person.

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2.35 The validation report should be given to the user for the plant history file and a copy retained by the test person. Copies should be sent to the authorised person and, on request, to the quality controller and the microbiologist.

Periodic tests

2.36 After the validation process has been completed, and the sterilizer is passed into service, it is subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals. These tests are the shared responsibility of the user and the test person.

2.37 The yearly test schedule is essentially a revalidation schedule. It provides for performance requalification (PRQ) tests to confirm that data collected during performance qualification remain valid.

2.38 The schedule of periodic tests is set out in Chapter 5.

Revalidation

2.39 Revalidation is the process of confirming that the operational data acquired during validation remain valid. It consists of recommissioning followed by performance requalification. Revalidation is required on the following occasions:

a. when modifications or engineering work are carried out which could affect the performance of the sterilizer, for example:
   (i) when a sterilizer is to be returned to service after the repair of a serious defect (see Part 4);
   (ii) when the inspection of a sterilizer pressure vessel by the competent person requires the removal of components which could affect the performance of the sterilizer (if the inspection immediately precedes a yearly test, recommissioning is not necessary);
   (iii) when the preset values of cycle variables have been modified;
   (iv) when the software in a computer control system has been upgraded or otherwise modified;

b. when the sterilizer is to be returned to service after investigation and correction of unacceptable deviations from performance data established during validation, for example:
   (i) when the pattern of a batch process record is outside the limits specified on the master process record;
   (ii) when the sterilizer fails a periodic test;

c. when there is a demand for revalidation by an authorised inspectorate or licensing authority;

d. whenever the user or authorised person advises that revalidation is necessary.

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2.40 The revalidation procedure is identical to that prescribed for the yearly tests set out in Chapter 5.

Repeat validation

2.41 On occasions, usually rare, it will be necessary to repeat the validation procedure to obtain a new set of commissioning and performance qualification data to replace the set originally obtained during validation. Repeat validation is required on the following occasions:

a. when the sterilizer is subject to modifications of such a nature that the validation data must be presumed to be no longer valid, for example:
   (i) when a sterilizer, other than a transportable, has been moved and installed at a new site;
   (ii) when a sterilizer has been dismantled or extensively overhauled or modified;
   (iii) when a new operating cycle has been introduced;
b. when revalidation or a yearly test fails to confirm the validity of the original validation data and no obvious cause can be found;
c. whenever the authorised person advises that repeat validation is necessary;
d. when there is a demand for repeat validation by an authorised inspectorate or licensing authority.

2.42 The authorised person should advise on which elements of the validation process need be repeated. For example, it will not be necessary to repeat all of the installation checks.

Types of test

2.43 Although many tests are listed in the schedules, they fall into a few basic categories as follows.

2.44 **Automatic control tests** are designed to show that the operating cycle functions correctly as evidenced by the values of the cycle variables indicated and recorded by the instruments fitted permanently to the sterilizer.

2.45 **Thermometric tests** use accurate measuring equipment to monitor temperatures and pressures independently of the instruments fitted to the sterilizer. They provide the assurance that the temperature requirements for sterilization are met:

a. thermometric tests for a **small load** are designed for two purposes. In sterilizers with an active air removal system they demonstrate that the sterilizer is capable of removing air from a small load in which air from a near-empty chamber has been retained. In cycles for fluid loads they

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demonstrate that sufficient condensate will be collected for cooling purposes, and that the initial temperature overshoot is kept within acceptable limits;

b. thermometric tests for a **full load** are designed to show that sterilization conditions are present in a test load of specified maximum mass and of sufficient size to fill the usable chamber space. In certain circumstances they may also serve as PQ tests for loading conditions which present a lesser challenge to the operating cycle than the specified full load (see paragraph 8.7).

2.46 **Microbiological tests** are designed to show that sterilization conditions are attained where thermometric methods are inadequate, that is, for LTSF and EO sterilizers and for exceptional loading conditions in other sterilizers.

2.47 Other tests, specific to certain types of sterilizer, are designed to show that the steam supply is suitable, the sterilizer does not produce too much noise, the chamber is airtight, gaseous sterilants are not released into the environment, and safety devices are functioning correctly.

Procedure on failure of a test

2.48 A correctly installed and maintained sterilizer should have no difficulty in complying with either the validation tests or the periodic tests. As a rule, a failure of a test implies that the sterilizer is not working to specification, and it should be withdrawn from service and the failure investigated. In practice the immediate action to be taken is a matter for judgement based on the nature of the failure and experience gained in using the sterilizer. In some cases it may be acceptable for the sterilizer to continue in service under restricted operating conditions until the failure can be investigated. The authorised person and the user should agree in advance on how to handle test failures.

2.49 **It should be emphasised that the user has the ultimate responsibility for certifying that the sterilizer is fit for use.**

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3. Schedule of installation checks

Introduction

3.1 On delivery of the sterilizer the contractor should carry out the installation checks set out in this chapter and included in the contract to establish that the sterilizer has been provided and installed correctly, is safe to operate, does not interfere with other equipment and that all connected services are satisfactory and do not restrict the attainment of conditions for sterilization.

3.2 Installation checks on services and other ancillary equipment should be carried out by the contractor responsible for their installation. These checks should be completed satisfactorily before starting the checks on the sterilizer itself.

3.3 Any checks specified here which are not included in the contract should be completed by the test person before commissioning begins.

3.4 As a safety precaution, checks on LTSF sterilizers should be carried out on the LTS cycle only. Checks on EO sterilizers should be carried out using a non-hazardous substitute for the sterilant as described in Chapter 1.

Checks on ancillary equipment

3.5 Ancillary equipment should ideally be installed and commissioned before the validation procedure for the sterilizer begins. Where the checks require the sterilizer to be operating, the test person should carry them out in cooperation with the sterilizer contractor. The sterilizer contractor is not responsible for the correct functioning of services and other ancillary equipment unless agreed in the contract.

Engineering services

3.6 Check that the following requirements are met:

a. the engineering services are installed correctly, they are adequate to meet the demands of the sterilizer, and they do not leak;

b. drains remove effluent effectively when all plant in the vicinity, including the sterilizer, is connected and operating;

c. the water economy system (if fitted) operates correctly;

d. for EO sterilizers supplied from cylinders, the system complies with the requirements of Part 2, and all gas lines are free of leaks.

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Additional checks for LTSF and EO sterilizers

3.7 LTSF and EO sterilizers require further checks to the ventilation and safety systems because of the use of toxic gases.

3.8 For both LTSF and EO, check that the ventilation systems within the loading area, plantroom and manifold room meet the requirements of Part 2. Pay particular attention to the following:

a. they meet the manufacturer's specification;

b. air flow is from the operator towards the sterilizer, and air does not flow from the plantroom into the loading area;

c. exhaust systems are non-recirculating and their discharges comply with safety regulations;

d. if the air flow is insufficient to cause a minimum of 10 air changes an hour:

(i) a warning is given;

(ii) the door cannot be opened at the end of the operating cycle;

(iii) a new cycle cannot be started.

3.9 Check that the local exhaust ventilation system meets the requirements of Part 2. Pay particular attention to the following:

a. air flow is from the operator towards the sterilizer, and air does not flow from the plantroom into the loading area;

b. the rate of flow complies with that specified in Part 2;

c. the exhaust discharge complies with safety regulations specified in Part 2.

3.10 Check that the drain from the sterilizer to the drainage system is trapped, sealed and vented to a safe position, as described in Part 2.

Additional checks for EO sterilizers

3.11 Check that the local exhaust ventilation system meets the following requirements in addition to those in paragraph 3.9:

a. manual control switches are located in prominent, easily accessible positions, such as in the EO cylinder change area;

b. the system operates whenever any one of the manual switches is operated;

c. it operates automatically at the end of an operating cycle and before the door is opened;

d. it operates whenever any of the gas detectors sense that the atmospheric concentration of EO exceeds the short-term exposure limit specified in Table 1.

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3.12 Check that EO safety installations meet the requirements of Part 2. Pay particular attention to the following:

a. notices concerning emergency procedures, safety and restricted access are displayed in prominent positions;

b. where gas is supplied from cylinders:

(i) environmental alarm and emergency systems are installed and operate in accordance with the specification;

(ii) emergency protective equipment is provided and stored in designated areas.

Checks on the sterilizer

3.13 The following checks presume that engineering services and other ancillary equipment are functioning correctly.

Preliminary checks

3.14 After the sterilizer has been installed, check that the following requirements are met:

a. the manufacturer has supplied all the documents specified in the contract;

b. the sterilizer has been supplied and installed in accordance with the contract;

c. calibration verification certificates for the temperature and pressure instruments and controllers are supplied;

d. no defects are apparent from a visual inspection of the sterilizer;

e. all supports, bases, and fixing are secure and without imposed strain from service connections;

f. thermal insulation is in good condition and securely attached;

g. security and settings of door safety switches and door-locking components are in compliance with data provided by the manufacturer;

h. keys, codes or tools required to operate locked controls are supplied and operate satisfactorily. Each key, code or tool unlocks only the control for which it is intended, and cannot unlock controls on other sterilizers in the vicinity;

i. loading trolleys and other aids are effective and safe in use.

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3.15 Check that the electrical equipment on the sterilizer is correctly connected to the electrical service. Carry out the following electrical tests:

a. insulation resistance;

b. phase sequence (for three-phase installations);

c. polarity;

d. bonding and earth continuity;

e. emergency stop.

Functional checks

3.16 During an operating cycle with an empty chamber, check that the following requirements are met (several cycles may be necessary to complete all the checks):

a. the selection of automatic or manual control is by key, code or tool. When the controller is in manual mode, the automatic control is inactivated. When the controller is in automatic mode, the manual control is inactivated;

b. under automatic control, steam, compressed air, formaldehyde or EO cannot be admitted into the chamber, and the operating cycle cannot start, until the door is locked and sealed. Under manual control, the operator can advance the cycle only sequentially through each stage. Any stages designed to remove formaldehyde or EO from the chamber and load cannot be circumvented;

c. throughout the cycle, indicated and recorded steam, water, air and gas pressures are within the limits specified by the manufacturer;

d. throughout the cycle, there are no leaks of steam, water, air, gas or effluent;

e. there is no evidence of interference to or from other equipment connected to the same services;

f. there is no evidence of electromagnetic interference to or from other equipment;

g. operation and readings of all instruments appear satisfactory, including return to zero (this may not be achievable with combined pressure and vacuum gauges);

h. the temperature of surfaces routinely handled by the operator does not exceed that specified in Part 2;

i. the effluent temperature does not exceed that specified in Part 2.

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3.17 At the end of a cycle check that the following requirements are met:

a. the door opening system cannot be operated until the chamber vent valve is open, and the chamber pressure is within 200 mbar of atmospheric;

b. door retaining parts cannot be released until the seal between the door and chamber has been broken, and the chamber is effectively vented to atmospheric pressure;

c. the door interlock system is either fail-safe or is fitted with at least two independent interlocks. Failure of one interlock, or any one service, does not allow the door to be opened when conditions within the chamber would cause a hazard, for example, pressure in excess of 200 mbar, unacceptable level of sterilant gas, or temperature of fluid in sealed containers above 80°C (glass) or 90°C (plastic);

d. for EO sterilizers, the operating cycle automatically returns to either the gas removal stage or the flushing stage if the door has remained sealed for more than 15 minutes after the admission of air;

e. the automatic controller has operated in accordance with the specification.

Response to external faults

3.18 It is necessary to check that the sterilizer reacts correctly and safely when exposed to a number of external fault conditions, that is, a safety hazard is not created and a false indication of cycle complete is not obtained. During each stage of an operating cycle, check the response of the sterilizer to the following simulated faults (where appropriate to the type of sterilizer):

a. operation of the emergency stop button;

b. power failure;

c. steam pressure too low;

d. steam pressure too high;

e. water pressure too low;

f. compressed air pressure too low;

g. failure of sterilant gas supply (LTSF and EO);

h. failure of room ventilation (LTSF and EO).

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4. Schedule of validation tests

Introduction

4.1 Installation tests are carried out by the contractor to demonstrate compliance with specifications, and may be repeated by the test person if required. Commissioning and performance qualification tests are carried out by the test person.

4.2 The schedules for the tests are set out for each type of clinical sterilizer in Table 2 and for laboratory sterilizers in Table 3. Each test is cross-referenced to a detailed description of the test procedure in a later chapter. The tests should be carried out with the sterilizer at normal working temperature (a warming-up cycle may be needed) and completed in the order shown.

4.3 The laboratory machine known as a Köch steamer is not listed here. Where it is used primarily for melting agar, validation tests are not required. Where it is to be used for the disinfection of a product, the thermometric tests prescribed in Table 3b for the culture media cycle should be followed.

4.4 The calibration of thermometric test equipment should be checked before and after the thermometric tests as described in paragraphs 6.32-39.

4.5 In principle, performance qualification tests should be carried out after the commissioning tests have been completed. However, for sterilizers with an active air removal system, thermometric PQ tests may be performed while the sensors used in the commissioning tests are still in place and before any final vacuum leak test. This is provided for in the schedules. Where tests on EO sterilizers require EO gas to be in the chamber, however, sensors should either be removed from the chamber or else disconnected from the recorder and the wires grounded to the body of the sterilizer (see note (d) to Table 2f).

4.6 Chapter 8 describes general procedures for conducting performance qualification tests and generating master process records.

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Table 2: Schedule of validation tests for clinical sterilizers

Table 2a: Validation tests for porous load sterilizers

		Ref
	Installation tests – contractor	
1.	Vacuum leak test	11.2
2.	Verification of calibration of sterilizer instruments	6.32
3.	Automatic control test	12.1
	Commissioning tests – test person	
1.	Steam non-condensable gas test	9.4
2.	Steam superheat test	9.20
3.	Steam dryness test	9.30
4.	Vacuum leak test	11.2
5.	Vacuum leak test (temperature and pressure sensors connected)	11.2
6.	Automatic control test	12.1
7.	Verification of calibration of sterilizer instruments*	12.2
8.	Chamber wall temperature test	13.3
9.	Air detector performance test for a small load	11.45
10.	Air detector performance test for a full load	11.53
11.	Thermometric test for a full load	13.15
12.	[Load dryness test]*	13.25
13.	Thermometric test for a small load	13.7
14.	[Load dryness test]*	13.25
15.	Thermometric test for a small load (to check consistency with test 13)	13.7
	Performance qualification tests (see below)	
16.	Vacuum leak test (sensors removed)	11.2
17.	Air detector function test	11.60
18.	Bowie-Dick test for steam penetration	13.3
19.	[Sound pressure test]	10.1
	Performance qualification tests – test person	
1.	Thermometric tests for performance qualification as required by the user[a]	8.13
2.	Hospital load dryness check	13.25

* May be done at the same time as the preceding test.
[ ] Optional test, to be done at the user's discretion.
a. Not normally required for loads processed in a sterile services department (SSD) (see paragraph 8.7).

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Table 2b: Validation tests for fluid sterilizers

		Ref
	Installation tests – contractor	
1.	Verification of calibration of sterilizer instruments	6.32
2.	Heat exchanger integrity test	14.4
3.	Automatic control test	12.1
	Commissioning test – test person	
1.	Automatic control test	12.1
2.	Verification of calibration of sterilizer instruments*	12.2
3.	Chamber temperature profile	7.21
4.	Thermometric test for a small load	14.21
5.	Thermometric test for a full load	14.10
6.	Coolant quality test	14.32
7.	[Sound pressure test]	10.1
	Performance qualification tests – test person	
1.	Thermometric tests for performance qualification as required by the user and the quality controller (for medicinal products) or by the user (other loads).	8.13

* May be done at the same time as the preceding test.
[ ] Optional test, to be done at the user's discretion.

Table 2c: Validation tests for sterilizers for unwrapped instruments and utensils

		Ref
	Installation tests – contractor[a]	
1.	Verification of calibration of sterilizer instruments	6.32
2.	Automatic control test	12.1
	Commissioning tests – test person	
1.	Automatic control test	12.1
2.	Verification of calibration of sterilizer instruments*	12.2
3.	Chamber temperature profile	7.21
4.	Chamber overheat cut-out test[b]	15.3
5.	Thermometric test for a small load	15.7
6.	Thermometric test for a full load	15.13
7.	Thermometric test for a small load (to check consistency with test 5)	15.7
8.	[Sound pressure test][a]	10.1
	Performance qualification tests – test person	
1.	Thermometric tests for performance qualification as required by the user	8.13

* May be done at the same time as the preceding test.
[ ] Optional test, to be done at the user's discretion.
a. Not required for transportable sterilizers.
b. Not required where steam is supplied from a source external to the chamber.

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Table 2d: Validation tests for dry-heat sterilizers

		Ref
	Installation tests – contractor	
1.	Verification of calibration of sterilizer instruments	6.32
2.	Automatic control test	16.4
	Commissioning tests – test person	
1.	Automatic control test	16.4
2.	Verification of calibration of sterilizer instruments*	12.2
3.	Chamber temperature profile	7.21
4.	Chamber overheat cut-out test	16.8
5.	Air filter integrity test	16.13
	Performance qualification test (see below)	
6.	[Thermometric test for a full load]	16.33
	Performance qualification tests – test person	
1.	Thermometric tests for performance qualification as required by the user and the quality controller (medicinal products) or by the user (other loads)	16.22

* May be done at the same time as the preceding test.
[ ] Optional test to be done at the user's discretion. The full-load test need be done only if the sterilizer fails a PQ test.

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Table 2e: Validation tests for LTS disinfectors and LTSF sterilizers

		Ref
	Installation tests – contractor	
1.	Vacuum leak test	11.2
2.	Verification of calibration of sterilizer instruments	6.32
3.	Automatic control test	12.1
4.	Vacuum leak monitor test	11.19
	Commissioning tests – test person	
1.	Steam non-condensable gas test	9.4
2.	Steam superheat test	9.20
3.	Steam dryness test	9.30
4.	Vacuum leak test	11.2
5.	Vacuum leak test (temperature and pressure sensors connected)	11.2
6.	Automatic control test	12.1
7.	Verification of calibration of sterilizer instruments*	12.2
8.	Vacuum leak monitor test	11.19
9.	Chamber temperature profile	7.21
10.	Chamber overheat cut-out test	17.4
11.	Chamber wall temperature test	17.10
12.	Thermometric test for a small load	17.15
13.	[Load dryness test]*	13.25
14.	Thermometric test for a full load (LTS)	17.23
15.	Thermometric test for a small load (to check consistency with test 12)	17.15
16.	Microbiological test for basic performance (LTSF)	17.40
17.	Environmental formaldehyde vapour test (LTSF)	17.32
	Performance qualificaton tests (see below)	
18.	Vacuum leak test (sensors removed)	11.2
19.	[Sound pressure test]	10.1
	Performance qualification tests – test person	
1.	Thermometric tests for performance qualification as required by the user	8.13
2.	Microbiological tests for performance qualification as required by the user (LTSF)	17.50
3.	Environmental gas tests (LTSF)*	8.37
	Performance qualification tests – user	
1.	Tests for degassing time (LTSF)	8.46

* May be done at the same time as the preceding test.

[ ] Optional test, to be done at the user's discretion

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Table 2f: Validation tests for ethylene oxide sterilizers

		Ref
	Installation tests – contractor	
1.	Verification of calibration of sterilizer instruments	6.32
2.	Vacuum leak test	11.2
3.	Pressure leak test[a]	11.24
4.	Automatic control test	12.1
	Commissioning tests – test person	
1.	Vacuum leak test	11.2
2.	Pressure leak test[a]	11.24
3.	Vacuum leak test (temperature, pressure and RH sensors connected)	11.2
4.	Pressure leak test[a]	11.24
5.	Automatic control test	12.1
6.	Verification of calibration of sterilizer instruments*	12.2
7.	Vacuum leak monitor test	11.19
8.	Chamber temperature profile	7.21
9.	Chamber overheat cut-out test	18.4
10.	Chamber space temperature test	18.11
11.	Chamber wall temperature test	18.16
12.	Gas circulation test[b, d]	
13.	Microbiological test for gas exposure time[c, d]	18.20
	Performance qualification tests (see below)	
14.	Vacuum leak test (sensors removed)	11.2
15.	Pressure leak test[a]	11.24
16.	[Sound pressure test]	10.1
	Performance qualification tests – test person	
1.	Thermometric tests for performance qualification as required by the user	18.36
2.	Microbiological tests for performance qualification as required by the user[d]	18.49
3.	Environmental gas tests*	8.37
	Performance qualification test – user	
1.	Tests for degassing time	8.46

* May be done at the same time as the preceding test.
[ ] Optional test, to be done at the user's discretion.
a. Required only where the sterilizer operates above atmospheric pressure.
b. Required only where a circulating fan is fitted. Instrumentation is used to demonstrate that pressures and flows specified by the manufacturer are obtained.
c. May be omitted if test data are provided by the manufacturer.
d. To avoid risk of sparking, tests using EO gas should not be done while temperature sensors are in the chamber. Providing safe operating procedures are not compromised, it may be acceptable to disconnect the sensors from the recorder and ground the wires to the body of the sterilizer.

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Table 3: Schedule of validation tests or laboratory sterilizers

Table 3a: Validation tests for high temperature steam sterilizers

		Ref
	Installation tests – contractor	
1.	Vacuum leak test[a]	11.2
2.	Verification of calibration of sterilizer instruments	6.32
3.	Automatic control test for each operating cycle	12.1
4.	Thermal door-lock override test	19.64
	Commissioning tests	
1.	Vacuum leak test[a]	11.2
2.	Vacuum leak test (temperature and pressure sensors connected)[a]	11.2
3.	Automatic control test for each operating cycle	12.1
4.	Verification of calibration of sterilizer instruments*	12.2
5.	Chamber temperature profile	7.21
6.	Tests for make-safe of small plastic discard	
	(i) Thermometric test for a small load	19.16
	(ii) Thermometric test for a full load	19.7
7.	Tests for make-safe of contained fluid discard	
	(i) Thermometric test for a small load	19.37
	(ii) Thermometric test for a full load	19.24
8.	Tests for sterilization of culture media	
	(i) Thermometric test for a small load	19.37
	(ii) Thermometric test for a full load	19.24
9.	Tests for disinfections of fabrics	
	(i) Thermometric test for a small load	13.7
10.	Tests for sterilization of glassware and equipment	
	(i) Thermometric test for a small load	19.61
	(ii) Thermometric test for a full load	19.52
11.	Tests for free steaming	
	(i) Thermometric test for a full load	19.24
	Performance qualification tests (see below)[b]	
12.	Vacuum leak test (sensors removed)[a]	11.2
13.	[Sound pressure test]	10.1
	Performance qualification tests – test person	
1.	Thermometric tests for each operating cycle as required by the user	8.13

* May be done at the same time as the preceding test.
[ ] Optional test, to be done at the user's discretion.
a. For sterilizers with an active air removal system.
b. For sterilizers with an active air removal system, the PQ tests may be done at this point.

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Table 3b: Validation tests for culture media preparators

		Ref
	Commissioning tests – test person[a]	
1.	Automatic control test	12.1
2.	Verification of calibration of sterilizer instruments*	12.2
3.	Thermometric test for a full load	19.71
4.	Reheat and dispensing test	19.78

* May be done at the same time as the preceding test.

a. The commissioning tests may be omitted if test data is supplied by the manufacturer.

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5. Schedule of periodic tests

Introduction

5.1 Periodic tests are carried out at daily, weekly, quarterly and yearly intervals. They are the shared responsibility of the test person and the user.

5.2 The yearly test schedule is identical to that carried out on revalidation (see paragraph 2.39). It contains tests for both recommissioning and performance requalification.

5.3 Tests should be performed on completion of planned maintenance tasks as described in Part 4. The schedules for the tests are set out for each type of clinical sterilizer in Table 4 and for laboratory sterilizers in Table 5. Each test is cross-referenced to a detailed description of the test procedure in a later chapter. The tests should be carried out with the sterilizer at normal working temperature (a warming-up cycle may be needed) and completed in the order shown.

5.4 The calibration of thermometric test equipment should be checked before and after the thermometric tests as described in Chapter 6.

5.5 Where tests on EO sterilizers require EO gas to be in the chamber, sensors should either be removed from the chamber or else disconnected from the recorder and the wires grounded to the body of the sterilizer (see note (d) to Table 4f).

5.6 The results of the tests done by the test person should be kept in the plant history file. The results of the tests done by the user should be kept in the sterilizer process log. (See Part 4 for guidance on record-keeping.)

Weekly safety checks

5.7 The test person should make the following safety checks before starting the sequence of weekly tests:

a. examine the door seal;

b. check the security and performance of door safety devices;

c. check that safety valves, or other pressure-limiting devices, are free to operate;

d. make any other checks required by the competent person in connection with the written scheme of examination for the pressure vessel.

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Yearly safety checks

5.8 In order to ensure the safe functioning of the sterilizer, the test person should conduct a sequence of safety checks before starting the yearly tests. The installation checks (Chapter 3) should be used as a basis for these, but it will not be necessary to repeat them all. In selecting which checks to include in the yearly schedule, consideration should be given to conditions which affect safety and to those which may have changed over the course of time. It will not be necessary, for example, to check again that the sterilizer has been supplied in accordance with specification, but it will be necessary to check that the engineering services remain adequate and are connected safely. The authorised person should advise on which checks will need to be included.

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Table 4: Schedule of periodic tests for clinical sterilizers

Table 4a: Periodic tests for porous load sterilizers

		Ref
	Daily test – user	
1.	Bowie-Dick test for steam penetration	13.39
	Weekly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test	11.2
3.	Air detector function test	11.60
4.	Automatic control test	12.1
5.	Bowie-Dick test for steam penetration*	13.39
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test	11.2
3.	Vacuum leak test (temperature and pressure sensors connected)	11.2
4.	Automatic control test	12.1
5.	Verification of calibration of sterilizer instruments*	12.2
6.	Thermometric test for a small load*	13.7
7.	Vacuum leak test (sensors removed)	11.2
8.	Air detector function test	11.60
9.	Bowie-Dick test for steam penetration	13.39
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Steam non-condensable gas test	9.4
3.	Steam superheat test	9.20
4.	Steam dryness test	9.30
5.	Vacuum leak test	11.2
6.	Vacuum leak test (temperature and pressure sensors connected)	11.2
7.	Automatic control test	12.1
8.	Verification of calibration of sterilizer instruments*	12.2
9.	Air detector test for a small load	11.45
10.	Air detector test for a full load	11.53
11.	Thermometric test for a small load	13.7
12.	Tests for performance requalification as required by the user	8.64
13.	Vacuum leak test (sensors removed)	11.2
14.	Air detector function test	11.60
15.	Bowie-Dick test for steam penetration	13.39

* May be done at the same time as the preceding test.

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Table 4b: Periodic tests for fluid sterilizers

		Ref
	Weekly tests – test person	
1.	Weekly safety checks	5.7
2.	Heat exchanger integrity test[a,b]	14.4
3.	Automatic control test	12.1
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Heat exchanger integrity test[a]	14.4
3.	Automatic control test	12.1
4.	Verification of calibration of sterilizer instruments*	12.2
5.	Simplified thermometric test for performance requalification	14.27
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Heat exchanger integrity test	14.4
3.	Automatic control test	12.1
4.	Verification of calibration of sterilizer instruments*	12.2
5.	Tests for performance requalification as required by the user and the quality controller (for medicinal products) or by the user (other loads)	8.64
6.	Coolant quality test	14.32

* May be done at the same time as the preceding test.

a. Not required where the heat exchanger is designed and constructed in a fail-safe fashion so that the coolant in the secondary circuit cannot become contaminated in any circumstances.

b. Not required where the pressure in the secondary circuit exceeds the pressure in the primary circuit throughout the operating cycle.

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Table 4c: Periodic tests for sterilizers for unwrapped instruments and utensils

		Ref
	Daily test – user	
1.	Automatic control test - observe and note the reading on the cycle counter,if visible to the user	12.1
	Weekly tests – test person[a]	
1.	Weekly safety checks	5.7
2.	Automatic control test	12.1
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Automatic control test	12.1
3.	Verification of calibration of sterilizer instruments*	12.2
4.	Thermometric test for a small load	15.7
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Automatic control test	12.1
3.	Verification of calibration of sterilizer instruments*	12.2
4.	Chamber overheat cut-out test[b]	15.3
5.	Thermometric test for a small load	15.7
6.	Thermometric test for a full load	15.13
7.	Tests for performance requalification as required by the user	8.64

* May be done at the same time as the preceding test.

a. For transportable sterilizers, the weekly tests may be done by the user by agreement with the test person.

b. Not required where the steam is supplied from a source external to the chamber.

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Table 4d: periodic tests for dry-heat sterilizers

		Ref
	Weekly tests – test person	
1.	Weekly safety checks	5.7
2.	Automatic control test[a]	16.4
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Automatic control test	16.4
3.	Verification of calibration of sterilizer instruments*	12.2
4.	Simplified thermometric test for performance requalification	16.26
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Automatic control test	16.4
3.	Verification of calibration of sterilizer instruments*	12.2
4.	Chamber overheat cut-out test	16.8
5.	Air filter integrity test	16.13
6.	Tests for performance requalification as required by the user and the quality controller (medicinal products) or by the user (other loads)	8.64

* May be done at the same time as the preceding test.

a. Not required where the previous week's batch process records are jointly reviewed by the user and the test person and, within specified limits, are comparable with previous records.

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Table 4e: Periodic tests for LTS disinfectors and LTSF sterilizers

		Ref
	Daily tests – user	
1.	Vacuum leak test[a]	11.2
2.	During the holding time of the first production cycle of the day, observe and note the reading on the cycle counter, chamber temperature indicator and chamber pressure indicator	
3.	Routine microbiological test for each production cycle (LTSF)	17.58
	Weekly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test	11.2
3.	Automatic control test	12.1
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test	11.2
3.	Vacuum leak test (temperature and pressure sensors connected)	11.2
4.	Automatic control test	12.1
5.	Verification of calibration of sterilizer instruments*	12.2
6.	Vacuum leak monitor test	11.19
7.	Thermometric test for a small load	17.15
8.	Vacuum leak test (sensors removed)	11.2
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Vacuum leak test	11.2
3.	Vacuum leak test (temperature and pressure sensors connected)	11.2
4.	Automatic control test	12.1
5.	Verification of calibration of sterilizer instruments*	12.2
6.	Vacuum leak monitor test	11.19
7.	Chamber overheat cut-out test	17.4
8.	Chamber wall temperature test	17.10
9.	Thermometric test for a small load	17.15
10.	Thermometric test for a full load (LTS)	17.23
11.	Microbiological test for basic performance (LTSF)	17.40
12.	Environmental formaldehyde vapour test (LTSF)	17.32
13.	Thermometric tests for performance requalification as required by the user	8.13
14.	Microbiological tests for performance requalification as required by the user (LTSF)	8.29
15.	Vacuum leak test (sensors removed)	11.2
	Yearly and revalidation tests – user	
1.	Tests for degassing time (LTSF, performance requalification)	8.46

* May be done at the same time as the preceding test.
a. Not required where a vacuum leak monitor is fitted.

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Table 4f: Periodic tests for ethylene oxide sterilizers

		Ref
	Daily tests – user	
1.	Routine microbiological test for each production cycle	18.58
	Weekly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test	11.2
3.	Pressure leak test[a]	11.24
4.	Automatic control test[b]	12.1
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test	11.2
3.	Pressure leak test[a]	11.24
4.	Vacuum leak test (temperature and pressure sensors connected)	11.2
5.	Pressure leak test[a]	11.24
6.	Automatic control test	12.1
7.	Verification of calibration of sterilizer instruments*	12.2
8.	Vacuum leak monitor test	11.19
9.	Chamber space temperature test	18.11
10.	Vacuum leak test (sensors removed)	11.2
11.	Pressure leak test[a]	11.24
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Vacuum leak test	11.2
3.	Pressure leak test[a]	11.24
4.	Vacuum leak test (temperature, pressure and humidity sensors connected)	11.2
5.	Pressure leak test[a]	11.24
6.	Automatic control test	12.1
7.	Verification of calibration of sterilizer instruments	12.2
8.	Vacuum leak monitor test	11.19
9.	Chamber overheat cut-out test	18.4
10.	Chamber wall temperature test	18.16
11.	Chamber space temperature test	18.11
12.	Gas circulation test[c,d]	
13.	Microbiological test for basic performance[d]	18.30
14.	Thermometric tests for performance requalification as required by the user	18.36
15.	Microbiological tests for performance requalification as required by the user[b]	18.49
16.	Environmental gas tests*[,d]	8.37
17.	Vacuum leak test (sensors removed)	11.2
18.	Pressure leak test[a]	11.24
	Yearly and revalidation tests – user	
1.	Tests for degassing time (performance requalification)	8.46

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* May be done at the same time as the preceding test.
a. Required only when the sterilizer operates above atmospheric pressure.
b. Not required when the previous week's batch process records are jointly reviewed by the user and the test person and, within specified limits, are comparable with previous records.
c. Required only when a circulating fan is fitted. instrumentation is used to demonstrate the pressures and flows specified by the manufacturer are obtained.
d. To avoid risk of sparking, tests using EO gas should not be done while temperature sensors are in the chamber. Providing safe operating procedures are not compromise, it may be acceptable to disconnect the sensors from the recorder and ground the wires to the body of the sterilizer.

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Table 5: Schedule of periodic tests for laboratory sterilizers

Table 5a: Periodic tests for high-temperature steam sterilizers

		Ref
	Daily tests – user	
1.	During the holding time of the first production cycle of the day, observe and note the reading on the cycle counter, chamber temperature indicator and chamber pressure indicator	
	Weekly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test[a]	11.2
3.	Automatic control test[b]	12.1
	Quarterly tests – test person	
1.	Weekly safety checks	5.7
2.	Vacuum leak test[a]	11.2
3.	Vacuum leak test (temperature and pressure sensors connected)[a]	11.2
4.	Automatic control test for each operating cycle	12.1
5.	Verification of calibration of sterilizer instruments*	12.2
6.	Thermometric test for a small load (small plastic discard, or fabrics, or glassware and equiptment)[c]	19.16, 13.7, 19.61
7.	Simplified thermometric test for performance requalification (contained fluid discard, or culture media, or free steaming)[c]	19.46
8.	Vacuum leak test (sensors removed)[a]	11.2
9.	Thermal doorlock override test	19.64
	Yearly and revalidation tests – test person	
1.	Yearly safety checks	5.8
2.	Vacuum leak test[a]	11.2
3.	Vacuum leak test (temperature and pressure sensors connected)[a]	11.2
4.	Automatic control test for each cycle	12.1
5.	Verification of calibration of sterilizer instruments*	12.2
6.	Thermometric test for a small load (small plastic discard, or fabrics, or glassware and equipment)[c]	19.16, 13.7, 19.61
7.	Thermometric test for a full load (contained fluid discard, or culture media, or free steaming)[c]	19.24
8.	Tests for performance requalification as required by the user	8.64
9.	Vacuum leak test (sensors removed)[a]	11.2
10.	Thermal door-lock override test	19.64

* May be done at the same time as the preceding test

a. Required only for sterilizers with an active air removal system.

b. The cycle should be chosen on a rotating basis from the cycles in routine use.

c. Required only for the first cycle listed in brackets that is available on the sterilizer.

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Table 5b: Periodic tests for culture media preparators

		Ref
	Weekly tests – user or test person	
1.	Weekly safety checks	5.7
2.	Automatic control test	12.1
	Yearly tests – test person	
1.	Yearly safety checks	5.8
2.	Automatic control test	12.1
3.	Verification of calibration of sterilizer instruments*	12.2
4.	Thermometric test for a full load	19.71
5.	Reheat and dispensing test	19.78

* May be done at the same time as the preceding test.

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6. Test equipment

Introduction

6.1 This chapter discusses the portable test equipment required to carry out the test procedures described in this document. Specifications for instruments fitted permanently to sterilizers are given in the relevant British and European Standards discussed in Part 2 of this SHTM.

6.2 With the rapid advance in instrumentation technology, it is becoming increasingly difficult (and undesirable) to set detailed specifications for the equipment to be used in testing sterilizers. For example, a clear trend is for much of the testing to be under the control of a computer which can automatically take the desired measurements, check that they meet the requirements of the tests in this SHTM, and report the results. The object of this chapter is twofold. First, to ensure that the traditional measurement methods are adequately supported; and second, to make clear the essential requirements for test equipment that apply for old and new technology alike. Where it is proposed to use measurement and recording techniques that are not explicitly covered here, the advice of the authorised person should be sought.

6.3 Access to standard laboratory equipment and supplies is assumed.

Calibration and sources of error

6.4 The errors produced in temperature and pressure measurement will arise from a number of factors. Some are inherent in the design, age and condition of the measuring equipment, and others are due to loose terminals, imperfect plug and socket connections, and the change of environmental temperature around the instrument. Variations in thermocouple alloys, preparation of thermocouple hot junctions, the method of introducing sensors into the chamber, and their location within the load will add to the error in temperature measurement. Temperature fluctuations within pressure-sensing elements will lead to errors in pressure measurement.

6.5 Every effort should be made to eliminate or minimise these errors by attention to detail, location of instruments, effective maintenance, and skill in the application, handling and use of the instruments. Systematic errors can be reduced by careful calibration.

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6.6 Instruments should be maintained and calibrated as recommended by the manufacturer as part of a planned maintenance programme. Each instrument should be labelled with the calibration date and a reference to its certificate. The calibration of all test instruments should be verified yearly by using reference instruments with a valid certificate of calibration traceable to a national standard. A history record should be kept for each instrument.

6.7 All electronic test instruments should be allowed a period of time to stabilise within the test site environment. They should be located in a position protected from draughts, and should not be subjected to rapid temperature variations. The manufacturer's instructions should be followed.

Recorders

6.8 Test recorders are required to measure temperature and pressure in all types of sterilizer, and humidity in EO sterilizers. They should be designed for use with the appropriate sensors, independent of those fitted to the sterilizer, as described later in this chapter. Most of the tests in this SHTM may be conducted with a single recorder combining temperature and pressure functions, preferably showing both records on the same chart or print-out. For EO sterilizers, a third function, for humidity, is desirable but not essential.

6.9 Twelve temperature channels are sufficient for all the tests on each type of sterilizer in this SHTM, though more may be convenient for determining chamber temperature profiles (see paragraph 7.21). One pressure channel is required for all sterilizers except fluid sterilizers which require up to three. The pressure channel for a dry-heat sterilizer is required to measure the small differential pressure (no more than 10 mbar) across the air filter. Two relative-humidity channels are desirable for EO sterilizers.

6.10 Analogue recorders (conventional pen and chart recorders) should comply with the display requirements of BS 3693. If they use potentiometric techniques, they should comply with BS 5164.

6.11 Digital recorders (data loggers) are rapidly coming into use and have many advantages over traditional pen recorders. They measure the variables electronically and store the values in digital form suitable for computer processing. Data may be presented graphically or as a numerical list, or as a combination of both. Parts of the operating cycle, such as the plateau period, can be expanded and replotted for closer examination. The record should quantify all turning points in the data, and distinguish by colour, print format or separate list, measurements which are within the sterilization temperature band for the operating cycle under test. The recorder should have the facility for downloading data onto tape or disk which can then be removed and kept securely. Software used with digital recorders should be developed under a quality system (such as BS 5750) and validated before use.

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6.12 The detailed specification for a test recorder will depend upon the range of sterilizers with which it is to be used. In all cases the recorder and its sensors should be capable of measuring cycle variables to considerably greater accuracy than the instruments fitted to the sterilizer.

6.13 The accuracy with which a variable can be read from the recorder will be affected not only by the sources of error discussed above (see paragraph 6.4), but also by the precision of the calibration, the scale range selected, the integration time, the sampling interval and the intrinsic accuracy of the recorder itself. Digital recorders will invariably register measurements to a precision greater than the accuracy of the system as a whole, and care should be taken in interpreting such measurements.

6.14 The intrinsic accuracies quoted by recorder manufacturers are measured under controlled reference conditions and do not include errors from temperature, pressure or humidity sensors. Temperature measurement errors due to ambient temperature changes should not exceed 0.04°C per °C rise.

6.15 The scale ranges should include the expected maximum and minimum values of the cycle variables throughout the operating cycle, with sufficient leeway to accommodate any deviations resulting from a malfunctioning sterilizer. (Note that in some sterilizers the temperature in the chamber free space will considerably exceed the upper limit of the sterilization temperature band for a short time at the start of the plateau period.)

6.16 The most critical stage of the operating cycle is the plateau period (the equilibration time plus the holding time, see paragraph 7.11) during which the load becomes exposed to the sterilization conditions. It is during this period that the values of the cycle variables are at their most critical and the recorder should be capable of measuring them to sufficient accuracy to confirm that the sterilization conditions have been attained. The criteria are as follows:

a. for digital recorders, the sampling interval should be short enough for the holding time to contain at least 180 independent measurements in each recording channel. This corresponds to a sampling interval of one second for the shortest holding time (3 minute, high-temperature steam sterilizers) and 40 seconds for the longest (120 minute, dry-heat sterilizers). For pen recorders, the chart speed should be fast enough to allow fluctuations on that scale to be clearly resolved. The duration of the holding time should be measurable to within 1%;

b. the integration time of the recorder (the response time) should be short enough to enable the output to follow significant fluctuations in the cycle variables and to ensure that successive measurements are independent of each other, It should not be longer than the sampling interval;

c. the width of the sterilization temperature band (see paragraph 7.14) varies from 3°C (high-temperature steam sterilizers) to 10°C (dry-heat sterilizers). The recorder must be accurate enough to show clearly whether the measured temperatures are within the band or not. For all

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the types of sterilizer covered by this SHTM, the repeatability of the recorder should be ± 0.25°C or better, and the limit of error of the complete measurement system (including sensors) should be no more than 0.5°C;

d. for pressure measurement, the limit of error should be no more than 0.5% of the absolute pressure during the plateau period;

e. for humidity measurement, the limiting factor is likely to be the performance of the sensor (see paragraph 6.47).

6.17 A recorder chosen to meet these criteria for the plateau period will have more than enough performance for the preceding and following stages of the operating cycle.

6.18 If a fluid sterilizer is fitted with an F_0 integrating system (see Part 4 for a discussion of the use of F_0 in controlling operating cycles), then the recorder should be capable of computing and printing values of F_0 for each channel with integration times no greater than 2 s (see BS 3970: Part 2).

Temperature measurement

Temperature sensors

6.19 Temperature sensors are required to sense the temperature in locations in the chamber and load as specified in the tests. They may be either platinum resistance elements or thermocouples.

6.20 Platinum resistance elements should comply with Class A of BS EN 60751.

6.21 Thermocouples should conform to BS EN 60584-1 (nickel-chromium/ nickel-aluminium) or Part 5 (copper/constantan). The calibration accuracy should be Tolerance Class 1 as specified in BS EN 60584: Part 2 (formerly BS 4937: Part 20). The tolerance on Part 4 thermocouples (± 1.5°C) is high when compared with that allowed for those in Part 5 (± 0.5°C), and for this reason copper/constantan thermocouples are usually preferred for the test recording system.

6.22 Thermocouple wire is available which is marked to show the limits of variation of the reel from the figures given in the British Standard. The variation will have been established by the manufacturer by testing samples from both ends of the full reel. Selected rather than standard wire should be used. For selected wire this variation is typically (for copper/constantan) of the order of 0.015 mV which is equivalent to 0.4°C at 20°C and 0.3°C at 134°C.

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6.23 The wire should be single-strand, not exceeding 0.7 mm diameter over the covering of one core of a twin cable. Twin-core cable is usually preferred because it is easier to handle and more durable than single-core wire. The width of the cable should not exceed 2 mm. If bulkier cable is used, the tracking of steam along the outside of the cable may invalidate certain tests, such as those which require temperatures to be measured in the centre of a standard test pack (see paragraph 7.27).

6.24 Thermocouples may be argon arc-welded or micro-welded. However, experience has shown that provided the wires are cleaned, they may be satisfactorily twisted together to form the hot junction. Brazing, silver brazing and welding with filler rods may be no more reliable in respect of accuracy than freshly twisted wires. Particular attention should be given to the condition of copper/constantan thermocouples when testing LTSF sterilizers. Thermocouples should not be fitted with a heat sink.

Use of sensors

6.25 A typical method of introducing sensors into a sterilizer chamber is illustrated in Figure 2. Methods which prevent the removal of individual sensors are to be discouraged. In older machines having no dedicated entry port, entry may be made via a tee which can usually be inserted into a service entry pipe to the chamber (for example the steam supply pipe). Sensors should not be introduced through the door seal. The test schedules for sterilizers employing active air removal systems provide for a vacuum leak test to be done after temperature sensors have been introduced into the chamber, and again after they have been removed, to ensure that the chamber remains gas-tight.

6.26 Many of the tests require a temperature sensor to be placed in the active chamber discharge of the sterilizer. This is a drain or vent which permits the controlled flow of air and condensate (a drain) or of air alone (a vent), such that the temperature within the discharge is the same as the chamber temperature.

The preferred locations are as follows:

a. in the drain, if it is active throughout the operating cycle;

b. otherwise in a vent, if it is active throughout the operating cycle;

c. otherwise in the coldest part of the usable chamber space.

6.27 The sensor should be placed in the drain or vent in steam phase boundary conditions in a position where overheat cannot be detected. This will normally require at least 10 mm insertion depth. The sensors connected to the sterilizer temperature indicator and recorder, and to the automatic controller, are normally in this position also. Care should be taken to ensure that the sensor does not touch any metal parts. (Contact between the hot junction and metal surfaces can cause induced electromotive forces (EMFs) leading to inaccurate readings.)

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6.28 Figure 3 shows several methods for inserting sensors into glass or plastic containers filled with fluid or powders. It is important that the sensor is firmly supported and that the container does not leak. For rigid containers the sensor should be located on the vertical axis and inserted to a depth of 85-5% of the height of the container. For flexible containers, such as plastic bags, the sensor should be located as near as practicable to the centre of the fluid and supported in this position throughout the operating cycle.

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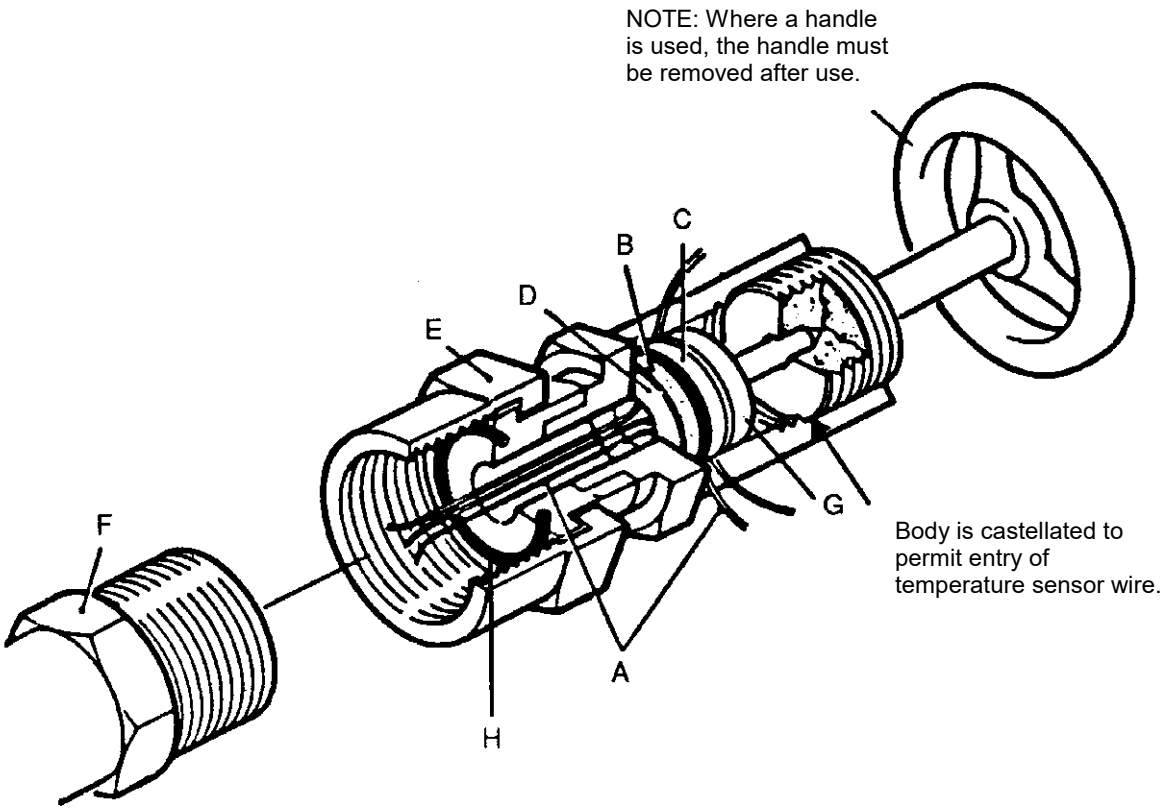
Figure 2: A method of introducing temperature sensors into a sterilizer chamber



A	Temperature sensor wire
B	Silicone rubber washer
C	Silicone rubber disc
D	Metal thrust washer
E	Metal body
F	Adaptor
G	Metal thrust spigot
H	O-ring

The illustration shows a fitting designed for a sterilizing chamber having a male gland and an 'O' ring seal. When the gland is a female thread an adaptor will be required (F). Other methods of introducing temperature sensors into a sterilizer chamber and which guarantee a gas-tight seal are equally acceptable.

6.29 When sensors are used in fluid containers, steam or fluid may be forced along the wire between the core and the sheath. To prevent damage to the recorder, the outer sheath should be either punctured a few centimetres from the end or stripped back for a similar distance to ensure that droplets forming where the sheath has been punctured or terminated fall clear of the recorder.

6.30 If the load item is a solid object, the sensor should be held securely in good thermal contact with the object.

6.31 Where required, sensors may be attached to the chamber walls by means of masking tape.

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Verification of calibration

6.32 The recorder should incorporate mechanical or electrical calibration facilities. The manufacturer of the recorder will normally calibrate it without the use of temperature sensors or transducers.

6.33 An independent temperature reference source (a “hot source”) is required, with a pocket to accommodate up to 12 temperature sensors. The temperature gradient within the pocket should not exceed 0.2°C and the control accuracy should be within ± 0.1°C over the relevant sterilization temperature band.

6.34 The temperature of the hot source should be measured either by a mercury-in-glass laboratory thermometer conforming to BS 593 or other temperature measurement system of similar or greater accuracy. The supplier should be asked to provide a certified calibration curve traceable to the national primary standard. Note that all the thermometric measurements required by this SHTM will ultimately depend upon the accuracy of this calibration; an uncertified laboratory thermometer will not be accurate enough to ensure that the sterilizer is working correctly and may give dangerously misleading results. The following types of mercury-in-glass thermometers are suitable:

a. F 75C/100 (24°C to 78°C) for EO sterilizers;
b. F 100C/100 (48°C to 102°C) for LTS disinfectors and LTSF sterilizers;
c. F 150C/100 (98°C to 152°C) for high-temperature steam sterilizers;
d. F 200C/100 (148°C to 202°C) for dry-heat sterilizers.

6.35 Mercury-in-glass thermometers should be used only in the hot source and must never be placed inside a sterilizer chamber. Note that mercury-in-glass thermometers are not permitted to be taken into pharmaceutical production facilities.

6.36 Before a recorder is taken to site, verify the calibration of the system by inserting the test sensors into the hot source at a temperature within the sterilization temperature band. Adjust the recorder in accordance with the manufacturer s instructions until the mean temperature measured by the sensors is the same as the temperature indicated on the thermometer. The calibration is satisfactory if the temperatures measured by individual sensors do not differ from the mean by more than 0.5°C. This test should be carried out at an ambient temperature as close as practicable to that expected at site.

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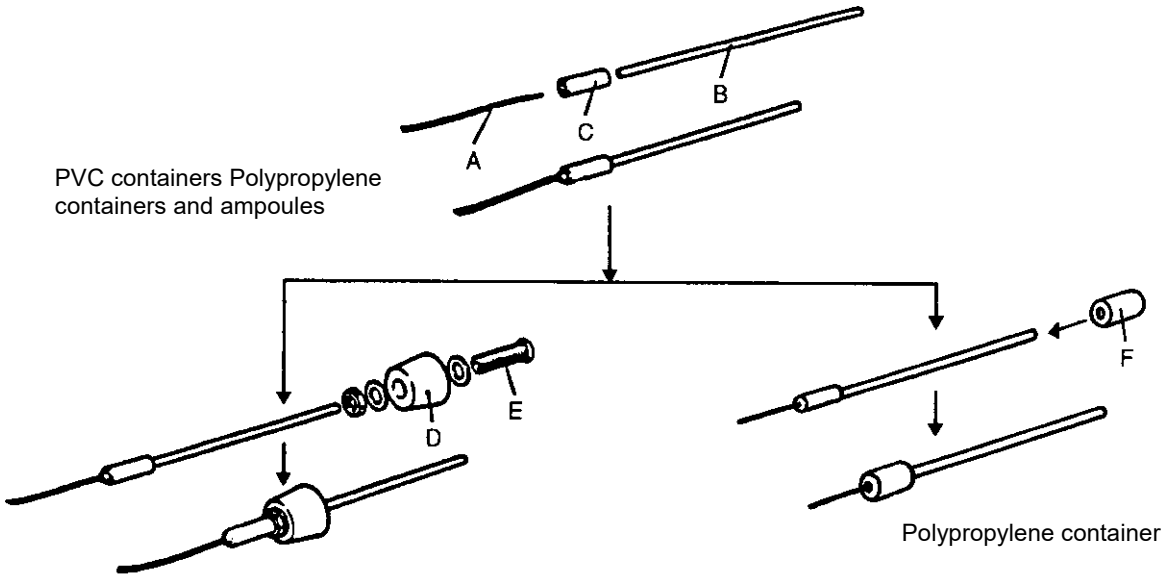
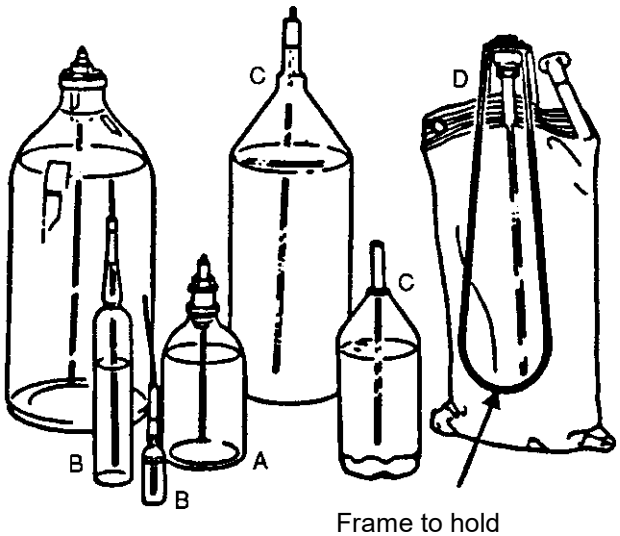
Figure 3: Methods of inserting temperature sensors into load containers



A - Temperature sensor, wire 2mm O/D
B - Needle tubing, 12 SWG, sealed at one end only
C - Silicone tubing, 4.5mm O/D x 1mm I/D
D - No. 21 rubber stopper (BS2775) with 8mm diameter bore (used for DIN containers)
E - Gland assembly (M8 x 25mm bolt with 5mm bore)
F - Silicone tubing (to suit container)

Examples

A - DIN standard glass
B - Glass ampoules
C - Rigid plastic container
D - Flexible plastic container



Frame to hold the temperature sensor tube in a central position

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6.37 If the hot source is not to be taken to site, connect a millivolt source to one channel of the recorder, and adjust it until the measured temperature is within 2°C of that obtained with the sensors connected. Note the measured temperature and the voltage indicated on the millivolt source. Also note the ambient air temperature near the source.

6.38 After arriving at site, and before starting any thermometric tests, check the calibration using either the hot source or the millivolt source.

a. If the hot source is used, adjust the temperature to correspond with that used off-site. Check that each sensor is measuring the same temperature as before;

b. If the millivolt source is used, ensure that the ambient temperature is similar to that measured off-site. Connect the millivolt source to the recorder, apply the voltage obtained off-site and check that the same temperature is measured. Bundle all the sensors together, place them in the chamber and expose them to an operating cycle. Check that the temperatures measured during the holding time are consistent with those obtained off-site with the hot source.

6.39 Repeat the check after the tests have been completed.

Pressure measurement

6.40 Pressures are required to be measured over a range from 20 mbar absolute (in vacuum leak testing) to typically 3.8 bar absolute at the working pressure of a high-temperature steam sterilizer and 7 bar absolute at the working pressure of a sterilizer using EO gas diluted with carbon dioxide.

Transducers

6.41 Transducers for use with pressure recorders should conform with BS 6447, be suitable for the purpose, certified and no less accurate than the gauges specified below. The natural frequency of the sensor and connected tubing should not be less than 10Hz, and the time constant for rising pressure (0-63%) should not be greater than 0.04s.

Gauges

6.42 Pressure gauges are required where the pressure recorder is unsuitable or for calibrating pressure instruments fitted to the sterilizer. Four gauges will normally be required to cover the whole pressure range for all sterilizers and these are specified in Table 6.

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Table 6 Pressure gauges for test purposes

Scale range [bar]	Mark interval [mbar]	Calibration	Application
0 to 0.160 (abs)	1	Gas	Vacuum leak testing
-1 to 0	10	Gas	LTS, LTSF + pure EO cycles
0 to 4	50	Liquid	High-temp stream, EO + HFC cycles
0 to 10	200	Gas	EO + CO_2 cycles

6.43 Pressure gauges should be temperature-compensated and, except for the absolute gauge, be Bourdon-tube test gauges conforming to BS EN 837-1 of nominal size 150 mm and accuracy class 0.25 (that is, the error should not exceed 0.25% of the maximum scale range). For pressure leak testing on EO sterilizers, gauges should be of accuracy class 1 or, better, over a range within 10% of the gas exposure pressure.

6.44 Gauges not designed for direct connection to steam at 2.8 bar should be connected via a syphon or similar device to ensure that the accuracy of the gauge is maintained over the temperature range associated with changing steam pressure. If the low-pressure gauge used for vacuum leak testing cannot withstand the pressure in the chamber during sterilization an automatic valve should be provided to protect it.

6.45 Gauges should be tested yearly by a recognised testing laboratory as described in BS EN 837-1.

6.46 The very low differential pressure across the air filter in a dry-heat sterilizer can be measured with a water manometer with a range of up to 10 mbar.

Humidity measurement

6.47 Humidity is a critical cycle variable in the control of EO processes. The level of humidity in the chamber and load at the end of the conditioning stage is ideally measured during validation by test instruments calibrated for relative humidity (RH) at atmospheric pressure. The accuracy of measurement should not be less than ±10% RH over the range 30-80% RH.

6.48 In practice, the measurement of relative humidity within the chamber of an EO sterilizer is difficult. Although the new European Standard on EO sterilizers will require RH sensors to be fitted, such sensors are still rare in the UK and the NHS has little experience in their use. If suitable test sensors are not available, then the chamber humidity may be validated by calculation as discussed in Appendix 2.

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6.49 There is no British Standard for humidity sensors, but it is recommended that test sensors should function at temperatures of 10-60°C and at pressures from vacuum up to 7 bar absolute.

6.50 The sensitivity and accuracy of electrically operated humidity sensors is often compromised by exposure to EO. The tests described in this SHTM require humidity to be measured only during cycles where an inert substitute for EO is used. The measurement can then be extrapolated to production cycles provided the other cycle variables are the same. If it becomes necessary to measure the humidity during cycles using EO gas, sensors should normally be replaced, degassed and recalibrated after each cycle.

Other instruments

Sound level meter

6.51 An integrating-averaging sound level meter is required for the sound pressure test. It should comply with Type 2 of BS EN 60804. Ten microphones are required for a single sterilizer.

Air flow metering device

6.52 A metering device (such as a needle valve) is required to admit air into the sterilizer chamber for the air detector tests, and vacuum and pressure leak tests. The device should be capable of controlling the flow of air into an evacuated chamber. It should be adjustable and have a range which includes a flow of 0-5 ml min^{-1} per litre volume of the sterilizer chamber. The error in repeatability between 10% and 90% of the setting range should not exceed ± 5%. The device is connected to the chamber by a valved port provided by the sterilizer manufacturer.

Balance

6.53 A laboratory balance is required for steam dryness tests, load dryness tests and coolant quality tests. It should be capable of measuring the mass of loads up to 2 kg to an accuracy of 0.1 g (dryness tests), and up to 100 g to an accuracy of 0.1 mg (coolant quality test).

Gas monitoring instrument

6.54 A gas monitoring instrument, such as an infrared spectrophotometer, is required for tests on LTSF and EO sterilizers.

6.55 The formaldehyde instrument should be suitable for measuring formaldehyde concentration in air with an accuracy of ± 10% at 2ppm.

6.56 The ethylene oxide instrument should be suitable for measuring ethylene oxide concentration in air with an accuracy of ± 10% at 15ppm.

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6.57 The scale ranges should include the appropriate short-term exposure limits specified in Table 1, and extend to at least ten times the exposure limit. The two functions may be combined in one instrument.

Aerosol generator

6.58 An aerosol generator is required for tests on dry-heat sterilizers.

6.59 The device should be capable of generating a polydisperse aerosol with particles having the size distribution shown in Table 7.

Table 7: Particle size distribution for aerosol generator

Particle size [μm]	Fraction by mass [%]
<0.5	>20
<0.7	>50
<1.0	>75

Source: BS 5295: Part 1

Photometer

6.60 A photometer is required for tests on dry-heat sterilizers.

6.61 The device should be suitable for estimation or comparison of mass concentration of airborne particles as defined in Table 7. It should have an accuracy of better than ±5% over the range of a five-expandable, six-decade resolution (that is, 0.01% to 100% of the test cloud) as specified in Appendix C of BS 5295: Part 1.

6.62 The photometer should have a minimum threshold sensitivity of 0.0001μg l^{-l} and should be capable of measuring aerosol concentration in the range 80-120μg l^{-1}

6.63 The sample flow rate should be 0.40 ± 0.05ls^{-1} and sampling should be via a suitable probe device.

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7. Testing methods

Introduction

7.1 This chapter discusses general principles and methods that are used in the thermometric and microbiological tests described in this SHTM.

Terminology

7.2 For the purposes of this SHTM the following definitions have been adopted.

Cycle variables

7.3 The **cycle variables** are the physical properties, such as time, temperature, pressure, humidity and sterilant gas concentration, that influence the efficacy of the sterilization process. Most of the tests described in this SHTM require the values of cycle variables to be determined experimentally and then compared with standard values.

7.4 An **indicated** value is that shown by a dial or other visual display fitted permanently to the sterilizer.

7.5 A **recorded** value is that shown on the output of a recording instrument fitted permanently to the sterilizer.

7.6 A **measured** value is that shown on a test instrument, such as a thermometric recorder or a test pressure gauge, attached to the sterilizer for test purposes.

7.7 A **noted** value is that written down by the operator, usually as the result of observing an indicated, recorded or measured value.

Sterilization conditions

7.8 Most operating cycles have a stage in which the load is exposed to the sterilization (or disinfection) conditions for a specified length of time. This period is known as the **holding time**.

7.9 The **sterilization conditions** are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

7.10 The holding time is preceded by a period in which the sterilization conditions are present in the chamber but not yet present throughout the load. This is known as the **equilibration time**.

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7.11 Together, the equilibration time and the holding time constitute the plateau period. While the **plateau period** can always be determined from the recorded chamber temperature, the equilibration and holding times cannot be distinguished unless the temperature in the part of the load that is slowest to reach the sterilization temperature is also being recorded or measured.

7.12 Certain LTSF sterilizers may achieve sterilization by exposing the load to a series of pulses of formaldehyde rather than a single holding time.

7.13 For EO sterilizers the plateau period is equivalent to the **gas exposure time**. The holding time cannot be determined by thermometry and is therefore of no practical interest.

7.14 For steam and dry-heat sterilizers, the sterilization conditions are specified by a **sterilization temperature band**, defined by a minimum acceptable temperature, known as the **sterilization temperature**, and a maximum allowable temperature. A sterilization temperature band can also be quoted for LTSF and EO sterilizers, but since these processes depend primarily upon chemical action such a band is not a complete specification of the sterilization conditions. Bands for the different types of sterilizer are listed in Table 8.

Table 8: Sterlization temperature bands

	High-temperature steam				Dry heat			LTS	LTSF	Ethylene oxide
Sterilization temperature (°C)[a]	115	121	126	134	160	170	180	71[b]	71	30-56
Maximum allowable temperature (°C)	118	124	129	137[c]	170	180	190	80	80	[d]
Minimum holding time (min)	30	15	10	3	120	60	30	10	180[e]	[f]

Notes:

a. The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.

b. Disinfection temperature.

c. British Standards permit 138°C.

d. For EO, the maximum allowable temperature will normally be 4°C above the sterilization temperature.

e. For LTSF, the sterilization conditions may specify either a continuous holding time or the number of pulses for formaldehyde required to achieve sterilization.

f. For EO, the “gas exposure time” is determined for each sterilizer by microbiological methods during commissioning but is typically 2-7 hours depending upon sterilization temperature and gas concentration.

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Interpretation of thermometric measurements

7.15 Figure 4 shows in schematic form the kind of data that are typically obtained in a thermometric test using measuring equipment as described in Chapter 6. In practice there may be more or fewer temperature traces depending on the number of sensors used. The detailed behaviour before and after the plateau period is dependent on the nature of the operating cycle and is not shown here.

7.16 The equilibration time begins when the temperature in the coolest part of the chamber (normally the active chamber discharge, see paragraph 6.26) first attains the sterilization temperature. It ends when the holding time begins.

7.17 The holding time begins when the temperature in the part of the load that is the slowest to heat up first attains the sterilization temperature. It ends at the start of the cooling stage, when the temperature in the coolest part of the chamber falls below the sterilization temperature.

7.18 The **fluctuation** in a trace over a given interval is $\pm T$ °C if the difference between the maximum and minimum values is $2T$.

7.19 The **drift** in a trace over a given interval is the change in the mean value of the trace over that interval.

7.20 The **difference** between two traces is the difference in their values at a given instant. A trace is said to be **within** T °C of a given value or another trace if the difference between them at any instant over a given interval is no more than T.

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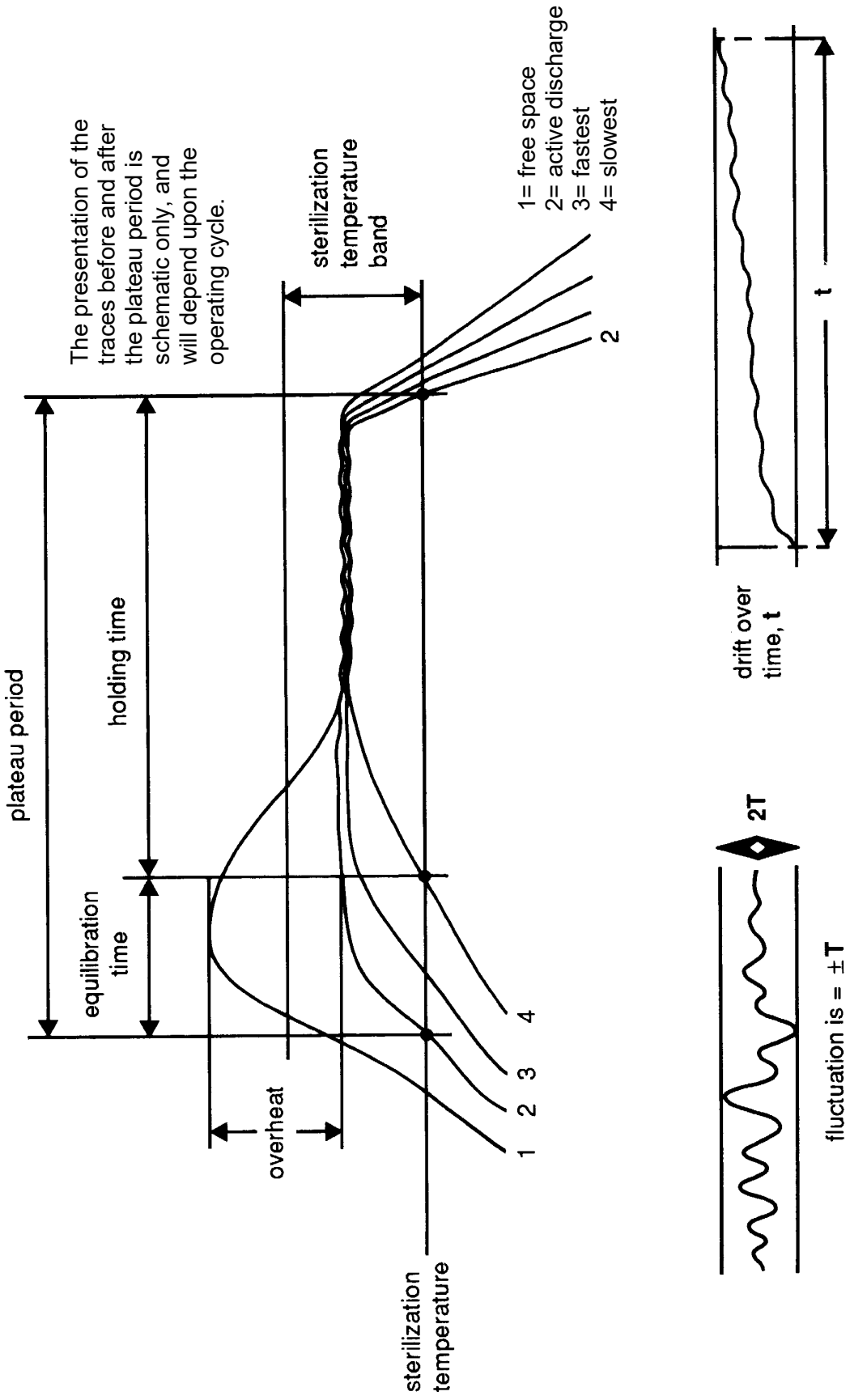
Figure 4: Interpretation of thermometric recording



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Chamber temperature profile

7.21 Many of the tests require temperature sensors (or biological or chemical indicators) to be placed in the parts of the load known to be the most difficult to sterilize. To make this assessment, it is necessary to know the hottest and coolest parts of the chamber, and the parts that are the fastest and slowest to attain the sterilization temperature.

7.22 This procedure is not required for porous load sterilizers since compliance with the small-load, full-load and air detector tests ensures that the penetration of steam is effectively instantaneous.

7.23 Place temperature sensors on a grid pattern throughout the usable chamber space. The number of sensors should be at least as many as that specified for the relevant full-load test. If the test recorder has too few channels it will be necessary to run through more than one operating cycle to collect data from a sufficient number of points. If so, at least two sensors should remain in the same positions (including one in an active chamber discharge) to establish the correlation between successive cycles.

7.24 If a choice of operating cycles is available, select the cycle with the highest sterilization temperature. This will normally be 134°C for high-temperature steam sterilizers. Start the cycle.

7.25 At the end of the cycle, examine the measured temperatures and note the following:

a. the parts of the usable chamber space that are the fastest and the slowest to attain the sterilization temperature;

b. the parts of the usable chamber space that are the hottest and the coolest during the sterilization holding time;

c. for sterilizers with a thermal door interlock, the part of the usable chamber space that is the slowest to cool to 80°C.

7.26 Users should be aware that the temperature profile derived in this way is valid only for an empty chamber. The presence of a load will disturb the profile, although the positions determined in paragraph 7.25 will be accurate enough for most practical purposes. However, where the sterilizer is to be used to process medicinal products, the positions will need to be confirmed for each loading condition as part of the performance qualification procedure (see paragraph 8.17).

Standard test pack

7.27 In order to ensure that tests are carried out under repeatable conditions, European Standards require the use of a standard test pack for all sterilizers designed to process porous loads. As well as porous load sterilizers

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themselves, the standard test pack is used for tests on LTS disinfectors, LTSF sterilizers and laboratory sterilizers with a cycle for the disinfection of fabrics.

7.28 The standard test pack is used to check that, at the levels at which the cycle variables are set, rapid and even penetration of steam into the pack is attained. The pack is chosen to represent the maximum density of porous load material which a sterilizer conforming to British and European Standards should be able to process. It may be used with other materials to form a full load.

7.29 The test pack is composed of plain cotton sheets complying with BS 5815: Part 1, each bleached to a good white and having an approximate size of 90 cm x 120 cm. The number of threads per centimetre in the warp should be 30 ± 6 and in the weft 27 ± 5.

7.30 The sheets should be washed but not subjected to any conditioning agent. (Conditioning agents may affect the characteristics of the fabric and may contain volatile substances which will contribute to the non-condensable gases in the chamber.)

7.31 The sheets should be dried and then aired for at least one hour at a temperature of 15-25ºC and a relative humidity of 30-70%. Failure to observe this protocol can result in the test giving a pass result when it should have been a failure. Sheets which have become excessively dehydrated may cause superheating in the pack, which might also produce misleading results.

7.32 After airing, the sheets should be folded to approximately 22 cm x 30 cm and stacked to a height of approximately 25 cm. After being compressed by hand, the pack should be wrapped in similar fabric and then secured with tape no more than 25 mm wide. The total weight of the pack should be 7.0 ± 0.7 kg. The sheets will become compressed after the pack has been used. If the weight of sheets needed to form a stack 25 cm high exceeds 7.7 kg, the sheets should be discarded.

7.33 Packs which are not used within one hour of preparation may be stored, providing the environmental conditions are maintained within those specified above for airing.

7.34 Non-standard test packs made of different materials (including huckaback towels TL5 or TL6 complying with BS 1781) and of different sizes and weights may be used, provided they comply with BS 7720. These packs may also be useful for small chambers (see paragraph 7.35).

7.35 The standard test pack should not be used where the usable chamber space is less than five times the volume of the pack. In these cases a smaller version of the pack may be constructed. This should be of cubic form with a volume about one-fifth of the usable chamber space, and made of similar materials to the standard test pack.

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Use of chemical indicators

7.36 Chemical indicators are designed to show by a change of colour whether specified sterilization conditions have been attained. They should, however, always be regarded as supplementary to definitive thermometric, microbiological or (for EO) hygrometric results. Whenever a cycle variable is outside its specified limits an operating cycle should always be regarded as unsatisfactory, irrespective of the results obtained from any chemical indicators.

7.37 Chemical indicators are manufactured for a range of sterilization processes and cycle variables. They should not be used for any process other than that specified by the manufacturer. The use of an inappropriate indicator may give dangerously misleading results.

7.38 Specifications for chemical indicators for sterilization processes are given in EN 867 which is currently in preparation (1994). Two classes are applicable to the tests covered in SHTM 2010.

7.39 Class A indicators (“process indicators”) are intended for use with individual packs of product to demonstrate that the pack has been exposed to the sterilization process. They have a defined end-point reaction, in which a visible change occurs after exposure to the specified variables at a level equal to or greater than that specified for the indicator. Class A indicators are used alongside biological indicators in tests on LTSF and EO sterilizers to provide an early visual indication of the efficacy of gas penetration. If a chemical indicator shows a failure, then it is normal for the test to be abandoned and the cause investigated. If all chemical indicators are satisfactory, then the biological indicators should be incubated as described in the relevant test. Chemical indicators by themselves are insufficient to demonstrate the efficacy of gaseous sterilization processes. Class A indicators are specified in BS EN 867: Part 2.

7.40 Class B indicators are designed for use in the Bowie-Dick test for steam penetration (see paragraph 13.37). They may have either a defined end-point or a graduated response in which a progressive change occurs on exposure to one or more process variables allowing assessment of the level achieved. Class B indicators are specified in BS EN 867: Part 3.

7.41 Other classes of indicator are available but are not required for the tests in this SHTM.

7.42 The performance of chemical indicators may be affected by the conditions of storage before use, the methods of use and the conditions of storage after exposure to the process. For these reasons the recommendations of the manufacturer for storage and use should be followed precisely. Indicators should not be used beyond any expiry date stated by the manufacturer.

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Use of biological indicators

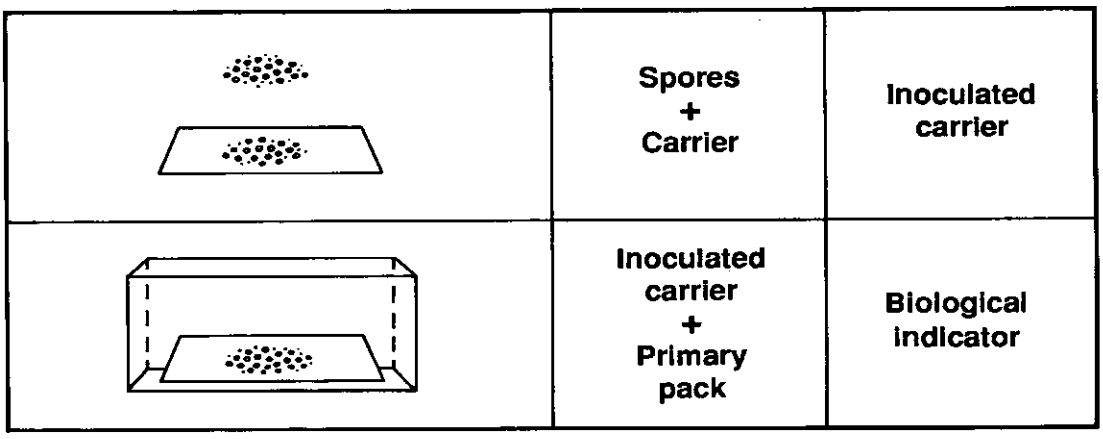
7.43 Biological indicators are designed to show by the survival of test micro-organisms whether specified sterilization conditions have been attained. The absence of growth of a test micro-organism after exposure to a sterilization process demonstrates that a specified level of microbiological inactivation has been delivered. Survival of a test micro-organism subjected to a sterilization process indicates that the process has failed. Biological indicators are required for tests on LTSF and EO sterilizers to confirm that sterilization conditions have been attained. On rare occasions they may be required for PQ tests on other types of sterilizer (see paragraph 8.9).

7.44 Terminology adopted in this SHTM conforms to that given in BS EN 866. An **inoculated carrier** is defined as a piece of supporting material on which a defined number of test organisms has been deposited. A **biological indicator** is defined as an inoculated carrier contained within its primary pack ready for use. The relationship between the components is shown in Figure 5.

7.45 Biological indicators are manufactured for a range of sterilization processes and cycle variables. They should not be used for any process other than that specified by the manufacturer. The use of an inappropriate indicator may give dangerously misleading results.

7.46 The performance of biological indicators may be affected by the conditions of storage before use, the methods of use and the techniques employed after exposure to the process. For these reasons the recommendations of the manufacturer for storage and recovery conditions should be followed. Biological indicators should be transferred to the specified recovery conditions as soon as possible after exposure to the process and in any case within 2 hours of the end of the cycle. Indicators must not be used beyond any expiry date stated by the manufacturer.

Figure 5: Component of a biological indicator



Adapted from BS EN 866: Part 1

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7.47 Control of biological indicators should be the responsibility of the microbiologist. Incubation of indicators should be carried out by an accredited laboratory registered with CPA (UK) Ltd (see Appendix 1).

Specifications

7.48 Specifications for biological indicators for sterilization processes are given in the several parts of BS EN 866. The standard draws a distinction between indicators designed for routine monitoring and indicators designed for validation tests. For routine monitoring, BS EN 866 specifies both the minimum number of organisms on the carrier and also a minimum D-value. For validation, no such limits are set. As a consequence, indicators manufactured in accordance with BS EN 866 for routine monitoring will always be suitable for validation, but the reverse will not necessarily be true.

7.49 The following organisms are recommended in BS EN 866 for the microbiological tests specified in this SHTM. Other strains or organisms may be used provided they are demonstrated to be of equivalent performance. Addresses for culture collections may be found in Appendix 1:

a. for LTSF sterilizers, Bacillus stearothermophilus as specified in BS EN 866: Part 5. B stearothermophilus strains NCIMB 8224 and NCTC 10003 have been found to be suitable;

b. for EO sterilizers, Bacillus subtilis var niger as specified in BS EN 866: Part 2. B subtilis var niger strains ATCC 9372, CIP 7718 and NCTC 10073 have been found to be suitable.

7.50 Although not normally required for the tests in this SHTM, the following organisms may be used where the need arises:

a. for high-temperature steam sterilizers, Bacillus stearothermophilus as specified in BS EN 866: Part 3. B stearothermophilus strains ATCC 7953, ATCC 12980, CIP 5281 and NCTC 10003 have been found to be suitable;

b. for dry-heat sterilizers, Bacillus subtilis as specified in BS EN 866: Part 6. B subtilis strains ATCC 9372 and CIP 7718 have been found to be suitable.

Line-Pickerell helix

7.51 The Line-Pickerell helix (Line and Pickerell, 1973) is a process challenge device used in microbiological tests on LTSF and EO sterilizers and designed to simulate the worst-case penetration conditions for sterilization by gas. The device is so constructed that an inoculated carrier can be placed within it in a position most difficult for the gas to reach.

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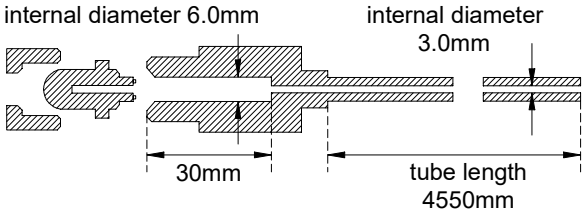
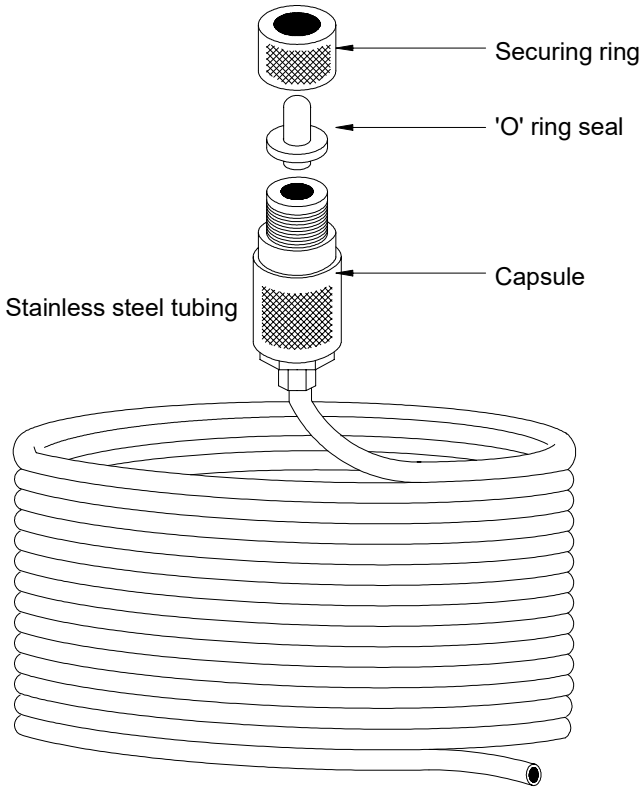
7.52 The device consists of stainless steel tubing with a gas-tight metal capsule for the biological indicator at one end (Figure 6). The capsule is in two parts which fit together against an O-ring seal and are secured by a knurled nut. The capsule body is sealed to the stainless steel tube so that the only entry into the assembled capsule is via the whole length of the tube. The nominal dimensions of the tube are 4.55 m in length and 3.0 mm in internal diameter, presenting a single-ended system with a length-to-bore ratio of approximately 1500:1. The total internal volume of the assembly is approximately 32 ml, of which 0.85 ml comprises the capsule. For compactness, the tube is formed into a helix of nominal 115 mm diameter. The tail of the helix is turned out slightly for ease of connection to air or water services for cleaning.

7.53 Before placing an inoculated carrier in the capsule, ensure that the helix is clear by blowing oil-free compressed air through it. Check the seal for damage or deterioration. Tighten the capsule and test it for leakage by submerging the helix in water and pressurising it with oil-free air at approximately 0.15 bar.

Figure 6: Line-Pickerell helix



Test helix capsule



The test helix

$$\text{Bore/length ratio} = \frac{\text{3mm bore}}{\text{4550mm long}}$$

$$= \frac{1}{1500}$$

The figure has been reproduced from the Journal of Clinical Pathology.

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Preparation of recovery medium

7.54 The recovery medium should be tryptone soya broth demonstrated as capable of recovering 10-100 viable spores of the test organism. Documentary evidence of performance should be provided by the manufacturer for each batch of dehydrated medium supplied.

7.55 The made-up medium should be prepared in accordance with the producer s recommendation. If no recommendation is available, proceed as follows.

7.56 Each batch should be dispensed in volumes of 15-20 ml in screw-capped bottles of at least 25 ml capacity and sterilized at a sterilization temperature of 121°C. The bottles should be stored at 2-10°C and used within 12 months.

7.57 The microbiologist should test each batch for sterility at each of the incubation temperatures at which it will be used. Select at least 2% of the bottles at random and incubate them for seven days at 52-56°C (for bottles intended for use with *B stearothermophilus*) or 30-32°C (for bottles intended for use with *B subtilis*). The batch should be considered satisfactory for use at that incubation temperature if none of the bottles shows growth. If one or more bottles does show growth, the entire batch should be regarded as not sterile.

7.58 The microbiologist should test each batch for its ability to promote growth. Test organisms which are damaged but not killed in the sterilization process may not outgrow if cultural conditions are not ideal. The following method is recommended.

7.59 Remove the inoculated carriers from two biological indicators of the type to be used with the recovery medium. Place the carriers in 10 ml of quarter-strength Ringer's solution. Agitate to release the test organisms from the carriers; this may be done by ultrasonication, shaking with glass beads, or another appropriate validated method.

NOTE: Ringer's solution (full strength) is made from 9.0g sodium chloride, 0.42g potassium chloride, 0.48g calcium chloride and 0.2g sodium bicarbonate, in 1000ml of distilled water. Source: Bacteriological tests for graded milk (Ministry of Health, 1937).

7.60 Dilute the solution to make a suspension with a count of 500 test organisms per ml.

7.61 Select 20 bottles at random from the sterilized batch of recovery medium. Add 0.1ml of the suspension to each bottle. Incubate the bottles for seven days at 52-56°C (for *B stearothermophilus*) or 30-32°C (for *B subtilis*). Confirm the recovery of the test organism by subculture as described in paragraph 7.71.

7.62 The batch of recovery medium should be considered satisfactory if all 20 bottles show growth. If one or more bottles does not show growth, the entire batch should be discarded.

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General procedure for microbiological tests

7.63 All biological indicators used in any one test should be taken from the same batch.

7.64 Except where specified otherwise (in certain EO tests), all the microbiological tests in this SHTM require biological indicators to be used in the form of unprotected inoculated carriers without their primary packs. They should therefore be handled aseptically to avoid contamination.

7.65 Biological indicators should be positioned as described in the relevant test procedure. If chemical indicators are to be used, they should be placed alongside the biological indicators to form biological/chemical indicator pairs.

7.66 Indicators should be cultured in accordance with the manufacturer s recommendations. The use of an inappropriate recovery system can give dangerously misleading results. If no recommendation is available, proceed as follows.

7.67 Within 2 hours of the end of the cycle, aseptically transfer each inoculated carrier to a bottle of recovery medium at a temperature of 15-25°C. Fit the caps to the bottles loosely (for *B stearothermophilus*) or tightly (for *B subtilis*).

7.68 Prepare control bottles of recovery medium as follows:

a. at least three bottles (for validation tests) or at least one bottle (for periodic tests), each containing an unexposed inoculated carrier, to demonstrate that the indicators are viable;

b. at least three bottles containing recovery medium only, to demonstrate that the medium is not contaminated.

7.69 Incubate the test bottles together with the controls under the conditions shown in Table 9.

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Table 9: Recommended incubation conditions for biological indicators

Organism	*B stearothermophilus*	*B subtils*
Incubation temperature	52-56°C	30-32°C
Incubation time:		
for validation tests (commissioning and performance qualification)	14 days[a]	7 days
for routine tests (production cycles)	7 days	7 days

a. For validation of LTSF cycles it is recommended that biological indicators are incubated for 14 days to allow outgrowth of organisms which may have been damaged but not inactivated by exposure to the process. Once the validation tests have been successfully completed, incubation times of seven days are acceptable for subsequent routine tests.

7.70 Inspect the bottles periodically for signs of growth. After inspection, gently shake the bottles to aerate the medium. Control bottles should be handled in the same way as test bottles.

7.71 As soon as one or more of the test bottles becomes turbid, confirm the isolation of the test organism as follows. Take a sample from each turbid test bottle and from each positive control bottle and streak them on to tryptone soya agar on vented plates. *B stearothermophilus* should be incubated at 52-56°C in an airtight container (such as a plastic bag) to prevent the agar drying out. *B subtilis* should be incubated at 30-32°C. If there is no growth on the test plates after 18-24 hours, the cloudiness is not due to microbial growth. The positive control plate should show characteristic colonies of the test organism as described in *A colour atlas of Bacillus species* (Parry, Turnbull and Gibson, 1983).

7.72 The test should be considered satisfactory if the following requirements are met:

a. chemical indicators show a uniform colour change at the end of the cycle;

b. all bottles containing an inoculated carrier exposed to the sterilization process show no growth at the end of the incubation time;

c. all control bottles containing an unexposed inoculated carrier show growth of the test organism within 24 hours;

d. all control bottles without an inoculated carrier show no growth at the end of the incubation time.

7.73 All culture results should be noted, whether satisfactory or not.

7.74 Where growth has resulted from an organism other than the test organism, the test is inconclusive and should be repeated.

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7.75 Note the following:

a. as a rough guide, the earlier the growth appears during the incubation period, the less efficacious is the sterilization process;

b. consistent failures in one position in the chamber may indicate problems of gas distribution (for example, stratification);

c. failure in a helix with no failures in the chamber free space may indicate poor gas penetration possibly due to inadequate air removal, excessively wet steam, or (for EO) low humidity;

d. for LTSF sterilizers, failure in the chamber with no failure in a helix may indicate low humidity due to the chamber wall being too hot or the steam being superheated.

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8. Performance qualification

Introduction

8.1 Performance qualification (PQ) is defined as the process of obtaining and documenting evidence that the sterilizer, as commissioned, will produce acceptable goods when operated in accordance with the operational instructions. PQ tests are performed as part of the initial validation procedure, as part of any repeat validation procedure, and whenever the user judges that a new loading condition calls for a new PQ test.

8.2 Performance qualification should not be attempted on any sterilizer that falls to meet the requirements of the commissioning tests specified in Chapters 4 and 5.

8.3 Thermometric PQ is required for all sterilizers. Additional microbiological PQ tests, and PQ tests for environmental gas and load degassing times, are required for LTSF and EO sterilizers.

8.4 Information gathered from the PQ test is filed in a PQ report which specifies the standard of performance expected with a particular operating cycle and loading condition (see paragraph 8.7). The report includes a master process record, employed by the user to validate routine production loads, together with thermometric and (where required) microbiological data used for subsequent performance requalification.

8.5 Performance requalification (PRQ) is the process of confirming that the sterilizer continues to meet the performance standards established during performance qualification, and that the working data collected during performance qualification remain valid. It is carried out once a year as part of the yearly test schedule, as part of any revalidation process, or whenever the user requests such confirmation.

8.6 PQ and PRQ tests should normally be preceded by the basic performance tests specified in the commissioning and yearly test schedules.

Loading conditions and reference loads

8.7 A **loading condition** is a specified combination of the nature and number of load items, the items of chamber furniture, and their distribution within the chamber. For example, a load placed on the top shelf of the chamber constitutes a different loading condition from an identical load placed on the bottom shelf. In principle, validation is not complete until a PQ test has been performed for each loading condition that the sterilizer is expected to process. In practice, loading conditions specified in the thermometric tests for small and full loads carried out during commissioning are designed to be representative of

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the nature of production loads, and to present a greater challenge to the process than most production loads. In these cases PQ data may be taken from the commissioning tests and PQ tests may not be necessary.

8.8 Guidance on the design of loading conditions to achieve efficient sterilization can be found in Part 4 of this SHTM.

8.9 PQ tests are indicated in the following circumstances:

a. where the loading condition presents a greater challenge to the process than that presented by the commissioning tests. For example, while porous load sterilizers rarely need PQ tests, such tests will be required if the density of the porous material exceeds that of the standard test pack (see paragraph 7.27) or if narrow lumens restrict air removal and steam penetration;

b. where the nature of the load is not represented by the commissioning tests. For example, certain loads may be damaged by exposure to the normal sterilization temperature. In these cases, the settings of cycle variables and their permitted tolerances should ensure not only that the load is sterilized, but also that it is not unacceptably degraded by long exposure to high temperatures.

8.10 Where PQ tests are required it is often possible to select a production load that is known to present a greater challenge to the process than any of the others, This **reference load** can then serve as a worst case and allow one PQ test to be valid for a range of less demanding loading conditions.

8.11 A microbiological PQ test is required for LTSF and EO sterilizers in addition to the thermometric test. It may also be required for other sterilizers where air removal and steam penetration are difficult, and a thermometric test does not provide sufficient assurance that the sterilization conditions have been attained throughout the load.

8.12 Responsibility for deciding which loading conditions require PQ tests is exercised as follows in doubtful cases advice should be sought from the authorised person:

a. sterilizers to be used for medicinal products – jointly by the user, the quality controller and the test person;

b. LTSF and EO sterilizers – jointly by the user, the microbiologist and the test person;

c. all other sterilizers - jointly by the user and the test person.

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Thermometric test for performance qualification

8.13 This test is suitable for all steam sterilizers, that is, porous loads, fluids, unwrapped instruments and utensils, LTS, LTSF and laboratory sterilizers. (See Chapter 16 for dry-heat sterilizers, and Chapter 18 for EO sterilizers.)

8.14 The production load under test will normally consist of discrete items such as packs, bottles or other containers. Place temperature sensors in the following positions:

a. one in each of three items known to be the slowest to attain the sterilization temperature;

b. one in each of three items known to be the fastest to attain the sterilization temperature;

c. if the sterilizer has a thermal door interlock, one in each of three items known to be the slowest to cool to 80°C.

8.15 If the load consists of less than six items, then place a sensor in each item.

8.16 The sensors should be in good thermal contact with the fluid or device which they are monitoring, and placed, If possible, in or on the part of the item slowest to heat up. (See Chapter 6 for guidance on the use of temperature sensors.)

8.17 The fastest and slowest items should have been identified as part of the design of the loading condition as described in Part 4. It may be desirable to confirm that the correct items have been selected by placing additional sensors in neighbouring items and running one or more preliminary operating cycles to verify that the selected items are indeed the fastest and slowest.

8.18 Place a sensor either in an active chamber discharge (see paragraph 6.26) or in the coolest part of the chamber. (This will normally be close to the sensor connected to the sterilizer recording instrument.)

8.19 Insert any load temperature probes provided in the chamber into the positions they will normally occupy in the load. If a probe is required to occupy the same position as a sensor, then the sensor should be moved to a neighbouring load item if they cannot both be accommodated in the same load item.

8.20 Note the loading condition and the positions of the sensors and probes in sufficient detail for the test to be replicated on any future occasion.

8.21 If the sterilizer has a pressure instrument, connect a pressure recorder (or test gauge) to the chamber.

8.22 Select the operating cycle that will be used for the production load. Start the cycle.

8.23 Ensure that a batch process record is made by the recording instrument fitted to the sterilizer. This will serve as the basis for a master process record for the

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loading condition under test (see paragraph 8.58). If the sterilizer does not have a recorder (such as some machines for unwrapped instruments and utensils), note the elapsed time, indicated chamber temperatures and pressures at all significant points of the operating cycle, for example the beginning and end of each stage or sub-stage.

8.24 At the approximate mid-point of the plateau period, note the elapsed time and indicated chamber temperature and pressure.

8.25 For fluid loads, during the cooling stage wait for the temperature in the containers to fall to 90°C (plastic containers) or 80°C (glass). Wearing protective visor and gloves, attempt to open the door. As soon as the cycle is complete, but before opening the door, note the recorded temperature in the containers.

8.26 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. the holding time, as determined from the measured temperatures, is not less than that specified for the appropriate sterilization temperature band in Table 8;

c. during the holding time:

(i) the measured temperatures are within the sterilization temperature band specified for the operating cycle;

(ii) the indicated and recorded chamber temperatures are within 2°C of the temperature measured in the active chamber discharge;

(iii) the temperature measured in each load item does not fluctuate more than ± 1°C, and does not differ from that in other load items by more than 2°C;

(iv) the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure;

d. at the end of the cycle:

(i) the temperature sensors have remained in position;

(ii) the items containing sensors are intact;

(iii) the temperature measured in any fluid containers is not greater than 90°C (plastic) or 80°C (glass).

8.27 If the test is satisfactory, it should be performed two more times to check for reproducibility and to establish permitted tolerances (see paragraph 8.47). A master process record should then be made as described below (see paragraph 8.58).

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8.28 If, having completed the commissioning tests, the sterilizer fails to meet the above requirements then it is possible that the sterilizer is not capable of processing the load. Advice should be sought from the authorised person.

Microbiological test for performance qualification

8.29 This test is designed to be used in exceptional circumstances as an additional PQ test for steam and dry-heat sterilizers. (See Chapter 17 for LTSF sterilizers, and Chapter 18 for EO sterilizers.)

8.30 The microbiological test should follow a satisfactory thermometric test, and use the identical loading condition and operating cycle. (See Chapter 7 for information on the use of biological and chemical indicators.)

8.31 Put a biological indicator and a chemical indicator together in each of the six load items that carried temperature sensors in the thermometric test. Place the items in as nearly as possible the same positions they occupied in the thermometric test.

8.32 Select and start the operation cycle.

8.33 Ensure that a batch process record is made by the recording instrument fitted to the sterilizer. If the sterilizer does not have a recorder (such as some machines for unwrapped instruments and utensils), observe and note the elapsed time, indicated chamber temperatures and pressures at all significant points of the operating cycle, for example the beginning and end of each stage or sub-stage.

8.34 At the approximate mid-point of the plateau period, note the elapsed time and indicated chamber temperature and pressure.

8.35 At the end of the cycle, remove the indicators from the load items. Check that the chemical indicators show a uniform colour change. If so, place each of the inoculated carriers in a bottle of recovery medium and incubate them with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-75).

8.36 The test should be considered satisfactory if the following requirements are met:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during the thermometric PQ test;

b. the requirements for microbiological tests set out in paragraph 7.72 are met.

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Environmental gas test

8.37 This PQ test is designed to determine the concentration of formaldehyde or EO gas discharged into the loading area from the chamber and load at the end of a cycle. The concentration will vary with the type of load, wrapping material and environmental ventilation and temperature.

8.38 This test should follow a satisfactory thermometric PQ test. The loading condition, preconditioning process and operating cycle should be identical. The test may be combined with the microbiological PQ test.

8.39 A gas monitoring instrument as described in Chapter 6 is required.

8.40 Load the chamber as for the microbiological test for performance qualification.

8.41 Select the operating cycle used in the microbiological test. Start the cycle.

8.42 At the end of the cycle, measure the concentration of gas discharged from the chamber into the air when the door starts to open. The sample should be taken 80-120 mm in front of the gap at a height of 1.4-1.6 m. Continue to monitor the gas concentration for the next 15 min.

8.43 Determine the average concentration of gas over the 15 min period.

8.44 The test should be considered satisfactory if the average concentration of gas over the 15 min period does not exceed the short-term exposure limit specified in Table 1.

8.45 The data from the test should be used to establish a permitted upper limit for subsequent performance requalification. This should be as low as reasonably practicable, and in any case lower than the short-term exposure limit (see paragraph 1.28).

Test for degassing time

8.46 Loads from LTSF and EO sterilizers require a further PQ test to determine the minimum degassing time required before a load may be released for clinical use. It is the responsibility of the user to establish this period for the area in which sterilized loads are stored. Procedures for determining the levels of residual EO are described in BS EN 30993: Part 7; a standard for formaldehyde is under development.

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Permitted tolerances

8.47 It is the purpose of performance qualification to establish the standard of performance expected with a particular operating cycle and loading condition, so that subsequent production cycles can be judged by that standard. The evidence for this performance is provided by the indicated, recorded and measured cycle variables, and it is necessary to determine how much each variable will be permitted to vary from cycle to cycle while still conforming to that standard.

8.48 A starting point is the limits prescribed for the cycle variables in the commissioning and PQ tests described in this SHTM. Other than in exceptional circumstances, these limits should be regarded as absolute, and a failure to meet them implies a failure of the test and a gross failure of the sterilizer. These limits originate from European and British Standards and from operational experience. They are set to accommodate a wide range of sterilizer models and designs of operating cycles. However, an individual sterilizer should be able to repeat a cycle well within these limits, and the permitted tolerances for PQ purposes should be correspondingly smaller.

8.49 It is important that the tolerances are set with careful consideration of the likely range of variation from cycle to cycle. If set too tight, acceptable production loads may be erroneously rejected as non-sterile, and automatic control and PRQ tests may fail unnecessarily. However, it would be a mistake to set an over-generous tolerance, since that may disguise variations signalling a developing malfunction of the sterilizer. The following paragraphs give guidance on determining the permitted tolerances. The authorised person should be consulted in cases of doubt.

8.50 PQ tests (or commissioning tests providing PQ data) collect indicated, recorded and measured data (see paragraph 7.2-7.20 for an explanation of these terms). The three sets of data serve different purposes and may require different tolerances:

a. **indicated data** are available to the user for production cycles on all types of sterilizer, but cannot be regarded as definitive. Except for sterilizers without a recorder, PQ tests require indicated values to be noted only during the holding time to ensure that they comply with the sterilization conditions;

b. **recorded data** are available to the user for production cycles on most types of sterilizer and can be regarded as definitive for routine production control. The permitted tolerances are normally marked on a master process record (see paragraph 8.58). The user should be aware of any calibration error in the recorder, but since production cycles are validated by direct comparison of the batch process record (BPR) with the master process record (MPR), such errors can be ignored in determining the permitted tolerances;

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c. **measured data** are not available for production cycles and so play no part in routine monitoring. However, they are to be regarded as definitive for the purposes of performance requalification. Measured variables are more reliable than Indicated or recorded values, and the permitted tolerances should reflect this.

8.51 A further consideration is the intended use of the PQ data:

a. **PQ data valid for a single loading condition**: where the PQ data are to be used for one loading condition only, the variation between cycles is essentially random (that is, due to uncontrolled variables or the intrinsic performance limits of the sterilizer) and the permitted tolerances can be tight. This is appropriate, as such cases are often used for loads which would be damaged if the limits were broader. The tolerances should be set by experience of the sterilizer and of the cycle. The three replicate thermometric PQ tests (see paragraph 8.13) will give some indication of what variation to expect;

b. **PQ data valid for a range of loading conditions**: where the PQ data for a single loading condition is judged to be valid for a range of loading conditions, the variation between cycles will contain a systematic variation related to the differing loading conditions and therefore the permitted tolerances will be greater. The choice of loading conditions for which the data is valid should take into account whether this greater tolerance is acceptable;

c. **PQ data obtained from commissioning tests**: for many loads, especially on porous load sterilizers, PQ tests are not normally necessary and data from the thermometric commissioning tests are used to establish performance standards for a wide range of loading conditions. In these cases, data from the small-load and full-load tests can be used to establish the limits of variation for production loads which fall between these two extremes. The permitted tolerances will be broader than either (a) or (b).

8.52 Note that the permitted tolerances during the holding time of an operating cycle will generally be tighter than those allowed during the preceding and following stages. In no circumstances should these tolerances permit the cycle variables to depart from the sterilization conditions specified in Table 8, unless the operating cycle has been designed with that intention.

8.53 Tolerances are normally expressed as a permitted variation either side of a central value, either in absolute terms or as a percentage. In some cases the tolerances may be expressed as an upper or lower limit, with the variables permitted to take any value on the safe side of the limit.

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PQ report

8.54 All the data collected during PQ tests should be filed in a PQ report, a copy of which should be kept with the plant history file. The report should contain or refer to the complete specification for the sterilization process. The specification should be detailed enough to allow the loading condition, the operating cycle and the test itself to be replicated on any future occasion. The report should include the following:

a. a specification of the loading condition, defined either by the nature and number of load items, items of chamber furniture, and their distribution within the chamber, or by a coded reference to a detailed specification held elsewhere;

b. a specification of the operating cycle, defined either by the settings for the cycle variables or by a coded reference to a detailed specification held elsewhere;

c. a specification of any preconditioning, conditioning and degassing process (this is essential for EO sterilizers);

d. all the indicated, recorded and measured data from the test, drawing attention to the values and permitted tolerances of elapsed time and of the indicated, recorded and measured cycle variables at all significant points of the operating cycle, for example at the beginning and end of each stage or sub-stage (the tolerances in recorded variables should also be marked on the master process record);

e. for loads which require the removal of air before sterilization, the method used to verify whether the minimum conditions of steam penetration into the load are attained (for porous load sterilizers, this is by use of the air detector);

f. the original of the master process record derived from the test.

8.55 EO sterilizers require extensive additional data for safety and quality control purposes and these are listed in Table 11.

8.56 Immediately following the PQ tests, the test person should prepare PQ summary sheets (see Appendix 3) and working copies of any necessary master process records. These should be given to the user and kept with the sterilizer process log.

8.57 If PQ tests are not required, the PQ summary sheet should contain data from the thermometric test for a full load and be marked accordingly.

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Preparation of a master process record

8.58 A master process record (MPR) is a record of the values and permitted tolerances of cycle variables for a correctly functioning operating cycle against which test and production cycles can be checked. (The term master temperature record was used in previous editions of HTM 10.) It is derived either from the batch process record (BPR) obtained during a thermometric PQ test or, if no PQ test has been deemed necessary, from the BPR obtained from a full-load thermometric test carried out during commissioning. (A further MPR may be required to validate automatic control tests with an empty chamber.) It may be a one-to-one transparent copy of the BPR, a template derived from the BPR, or data stored in a computer control system and compared automatically.

8.59 An MPR is primarily intended for production control on sterilizers used to process medicinal products, but it is also used for test purposes on all types of sterilizer.

8.60 When required for production purposes, a sufficient number and variety of MPRs should be prepared so that there is a suitable MPR for each loading condition or for the appropriate reference load (see paragraph 8.10).

8.61 To prepare an MPR, the appropriate thermometric test should be carried out as described above (see paragraph 8.13). If all three cycles are satisfactory, the BPR showing the shortest holding time should be used for producing the MPR. It should be marked with the following information:

a. an MPR reference number and reference to the PQ report;

b. sufficient information to identify the sterilizer uniquely (by a unique reference number; by the name of the manufacturer, the model of sterilizer and the serial number; or by any sufficient combination of these);

c. a specification of the loading condition as in paragraph 8.54a and other loading conditions for which the MPR is valid;

d. a specification of the operating cycle as in paragraph 8.54b;

e. the permitted tolerances for the cycle variables during each stage of the operating cycle (these are best shown graphically);

f. for fluid loads, the point during the cycle at which the temperature of the fluid in the hottest container falls to 80^{o}C (glass) or 90^{o}C (plastic);

g. date of test;

h. signatures of the test person and the user.

8.62 When the BPR has been annotated it may be endorsed “master process record” and a transparency obtained. An example of an MPR is shown in Figure 7.

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Figure 7: Example of Master Process Record (analogue)

Reference
15-26-03-85

Site & Dept
Western General Pharmacy

P.Q. report reference
SDE/3/X

Make of sterilizer & serial number
DAB – FC/378/93

Type of sterilizer
Fluid Mk4 RCF

Loading concentration reference
P/326

Location of load temperature probe
Lower front centre

Operating cycle reference
OC/31

Chart Speed
1 cm = 2 minutes

Test Person
J Stern
26 January 1993

User
T Pear
26 January 1993

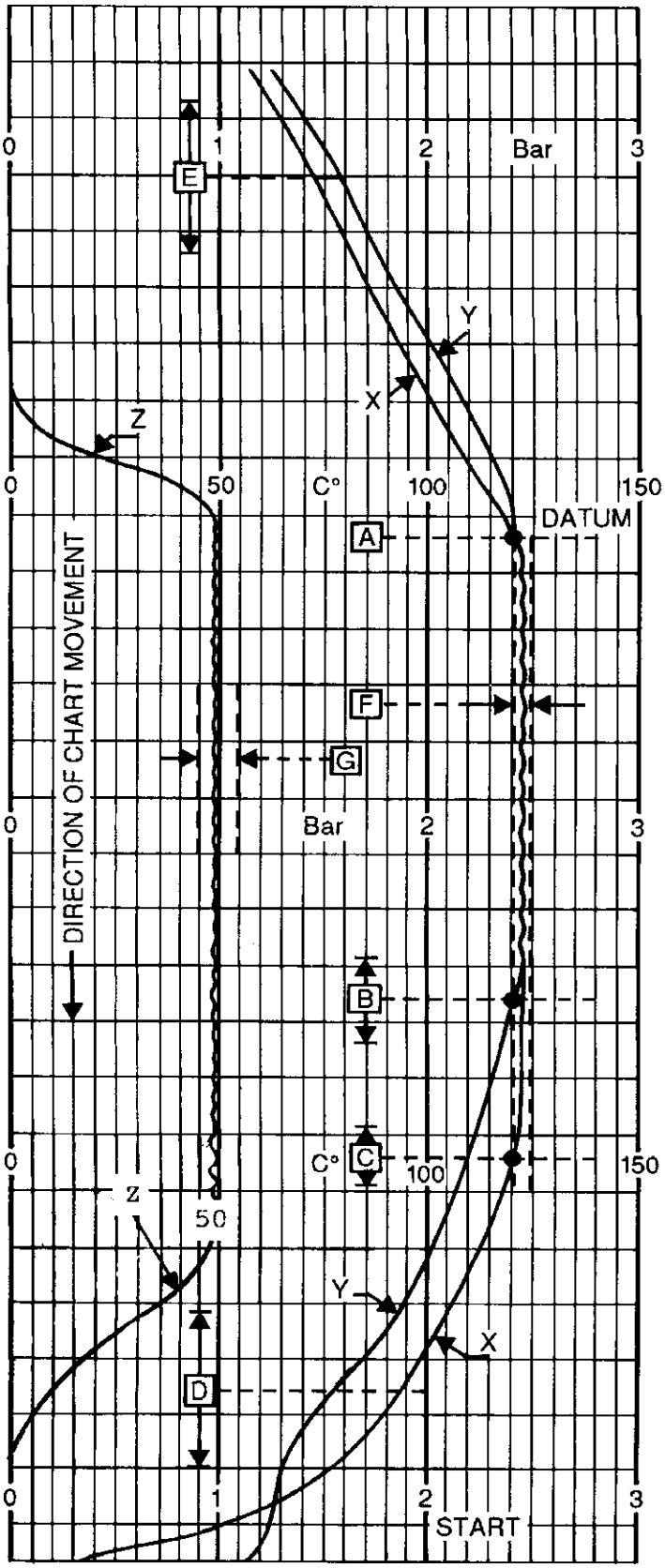

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Figure 8: Example of Master Process Record

Reference	-	***15-26-3-85***
Site and department	-	***Western General / Pharmacy***
PQ report references	-	***SDE/3/X***
Make of sterilizer and serial number	-	***DAB FC/378/93***
Type of sterilizer	-	***Fluid Mk4 RCF***
Loading condition reference	-	***P/326***
Location of load temperature probe	-	***Lower front centre***
Operating cycle reference	-	***OC/31***
Sterilization temperature	-	***121°C***
Sterilizer temperature band (F)	-	***3°C***
Sterilization pressure band	-	***0.15 bar***
Holding time	-	***15 Minutes***

Stage	Time mins/sec	Temperature°C		Pressure m bar	F(O) mins
		Drain	Load		
Heating	0.00	22.2	20.0	996	0.0
(D)	5.15	110.0	80.1	1450	0.0
(C)	14.45	121.1	110.2	2060	0.0
Holding Time (B)					
	21.15	122.1	121.1	2155	5.6
	22.00	122.1	121.2	2161	6.5
	22.45	122.1	121.4	2165	7.2
	23.30	122.1	121.5	2163	6.6
	24.15	122.3	121.7	2163	8.9
	25.00	122.1	121.7	2177	9.8
	23.45	122.3	121.8	2147	10.6
	26.30	122.3	121.9	2167	11.5
	27.15	122.3	121.9	2187	12.4
	28.00	122.3	122.1	2160	13.4
	28.45	122.4	122.1	2171	14.2
	29.30	122.3	122.0	2173	15.2
	30.15	122.3	122.1	2182	16.2
	31.00	122.4	122.1	2162	17.2
	31.45	122.4	122.1	2151	18.0
	32.30	122.4	122.1	2166	18.9
	33.15	122.4	122.1	2166	19.8
	34.00	122.4	122.2	2171	20.9
	34.45	122.4	122.2	2151	21.8
	35.30	122.4	122.2	2153	22.7
	36.15	122.5	122.3	2156	23.7
(A)	37.00	115.6	121.0	2260	24.2
Cooling	37.45	113.6	120.1	2270	24.4
(E)	98.15	39.2	80.0	2271	24.8
	101.00	35.4	76.3	2216	24.8
	103.15	31.1	75.2	846	24.8
Venting	104.00	31.1	75.2	846	24.8
	104.45	26.1	74.8	995	24.8
End	-	-	-	-	-

8.63 If the BPR is in the form of numerical data, the MPR should be presented in a similar form to the BPR to permit ready comparison. As a minimum

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requirement, it should list the cycle variables at each turning point of the cycle and contain a plot generated from the data. An example of a digital MPR is shown in Figure 8.

Tests for performance requalification

8.64 PRQ tests are performed once a year to ensure that the sterilization conditions are still met. They should follow the yearly schedule of checks and tests listed in Chapter 5. For a given operating cycle it is normally necessary only to perform the PRQ test for a reference load for which a PQ report exists. The cycle can then be assumed to be effective for less demanding loads also. The need for PRQ tests on other loads should be agreed between the user and the test person.

8.65 The procedure for the PRQ test is similar to that for the PQ test. The operating cycle and the loading condition should be identical to those used for the original PQ test. The test should be considered satisfactory if the values of the measured cycle variables are within the tolerances stated in the PQ report.

8.66 For dry-heat sterilizers, fluid sterilizers and certain fluid cycles on laboratory sterilizers, a simplified PRQ test is required at quarterly intervals, and this is provided for in the schedules (see Tables 4 and 5).

8.67 Results of PRQ tests should be appended to the relevant PQ report.

8.68 Providing the yearly test programme has been completed satisfactorily, the sterilizer should pass the PRQ test. If the PRQ test is not satisfactory, the advice of the authorised person should be sought.

Notes to Figures 7 and 8

Figure 7 shows a typical master process record (MPR) for a fluid sterilizer. This is based on a batch process record made during a performance qualification test at a sterilization temperature of 121°C.

X Temperature recorded in the active chamber discharge.

Y Temperature recorded in the load item slowest to attain the sterilization temperature.

Z Chamber pressure.

A The end of the holding time is taken as the datum point from which intervals are measured.

B Start of the holding time, with permitted tolerance

C Start of the plateau period, with permitted tolerance.

D Temperature in the load item attains 80°C.

E Temperature in the load item falls to 80°C. The door may be opened at this point.

F Sterilization temperature band.

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G Sterilization pressure, with permitted tolerance.

The following deviations from the MPR are considered acceptable:

interval A-B, ± 10%;

interval A-C, ± 10%;

interval A-E, ± 20%;

interval B-D, ± 20%.

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9. Steam quality tests

Introduction

9.1 A continuous supply of saturated steam is required for steam sterilization and for humidification in certain EO sterilizers. Too high a level of non-condensable gases will prevent the attainment of sterilizing conditions; too little moisture carried in suspension may allow the steam to become superheated during expansion into the chamber, while excess moisture may cause damp loads.

9.2 For all these tests, the steam should be sampled from the steam service pipe to each sterilizer. The measurements are taken during a period of maximum steam demand, when steam is first admitted to the sterilizer chamber.

9.3 Silicone rubber tubing is porous to steam and should not be used to carry steam in these tests.

Non-condensable gas test

9.4 This test is used to demonstrate that the level of non-condensable gases in the steam will not prevent the attainment of sterilization conditions in any part of the load. (Possible sources of non-condensable gases are discussed in Part 2 of this SHTM.) The method described should be regarded not as measuring the exact level of non-condensable gas, but a method by which the provision of acceptable steam quality can be demonstrated.

9.5 The apparatus is shown and described in Figure 9. All sizes are nominal.

9.6 Connect the needle valve to the steam service pipe as shown in Figure 9.

9.7 Assemble the apparatus so that condensation will drain freely from the long rubber tube into the sampling pipe. If the tube is too short, copper or stainless steel tubing may also be used.

9.8 Fill the container with cold water until it overflows. Fill the burette and funnel with cold water, invert them and place them in the container. Draw out any air that has collected in the burette.

9.9 With the steam sampling pipe out of the container, open the needle valve and allow steam to purge the air from the pipe. Place the pipe in the container, locate the end within the funnel, and add more cold water until it flows through the overflow pipe.

9.10 Place the empty measuring cylinder under the container overflow.

9.11 Adjust the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of steam hammer to be heard. Ensure that

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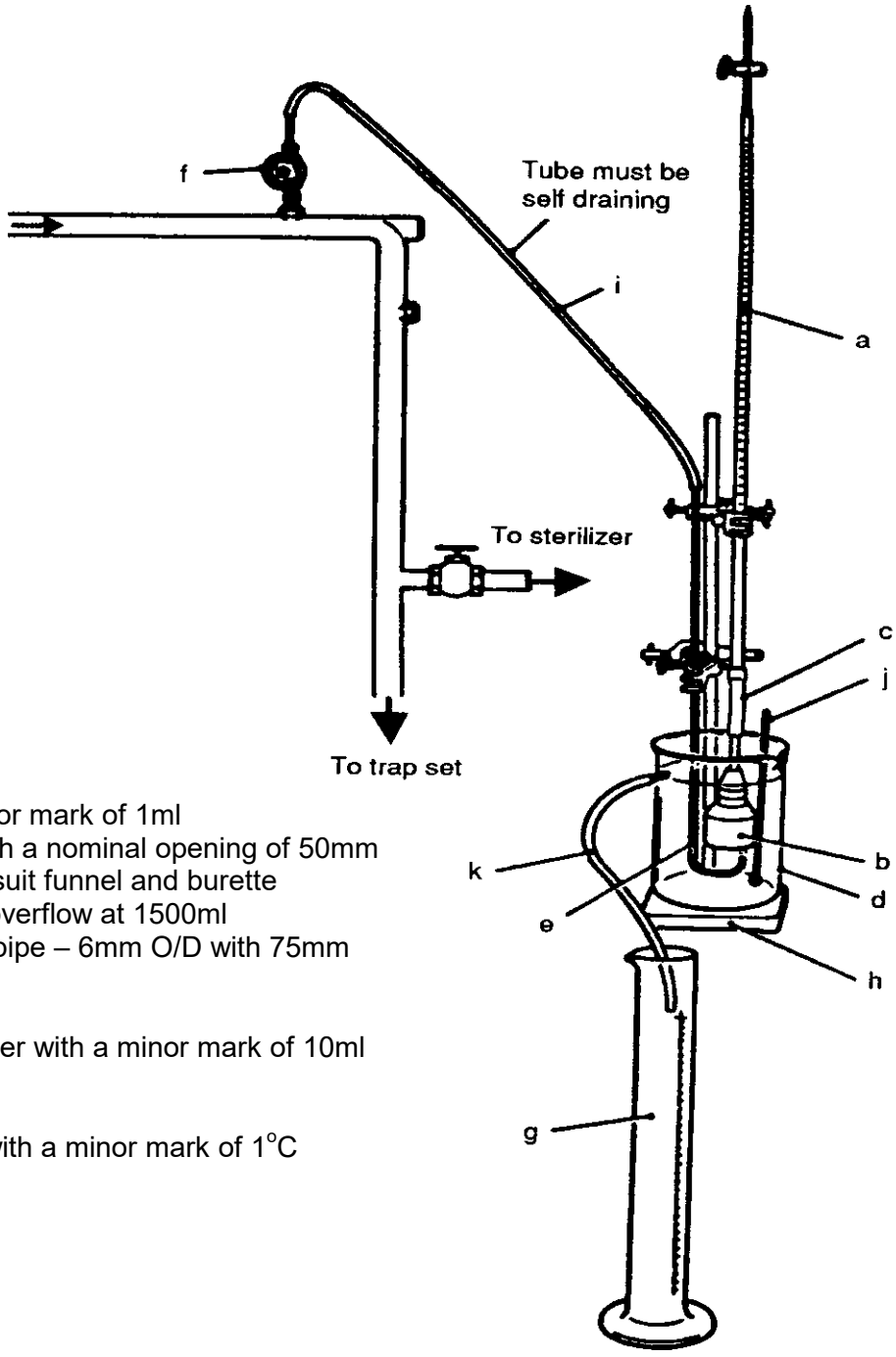
all the steam is discharged into the funnel and does not bubble out into the container. Note the setting of the needle valve. Close the valve.

9.12 Ensure that the container is topped up with cold water and that the measuring cylinder is empty. Draw out any air present in the burette

Figure 9: Apparatus for non-condensable gas test



a 50ml burette with a minor mark of 1ml
b parallel-sided funnel with a nominal opening of 50mm
c rubber tubing – size to suit funnel and burette
d 2000ml container with overflow at 1500ml
e steam sample delivery pipe – 6mm O/D with 75mm upturn
f ¼“ BSP needle valve
g 250ml measuring cylinder with a minor mark of 10ml
h burette stand
i rubber tubing
j thermometer 0-100°C with a minor mark of 1°C
k overflow pipe

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9.13 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

9.14 When the steam supply to the chamber first opens, open the needle valve to the previously noted setting, allowing a continuous sample of steam into the funnel sufficient to cause a small amount of steam hammer to be heard.

9.15 Allow the steam sample to condense in the funnel. Any non-condensable gases will rise to the top of the burette. Overspill formed by the condensate and the water displaced by the gases will collect in the measuring cylinder.

9.16 When the temperature of the water in the container reaches 70-75°C, close the needle valve. Note the volume of gas collected in the burette (V_b) and the volume of water collected in the measuring cylinder (V_c).

9.17 Calculate the fraction of non-condensable gases as a percentage as follows:

$$\text{Fraction of non-condensable gases} = 100 \times (V_b/V_c).$$

9.18 The test should be considered satisfactory if the fraction of non-condensable gases does not exceed 3.5%.

9.19 The test should be done two more times to check consistency. If the results of the three tests differ significantly, then the cause should be investigated before proceeding further.

Superheat test

9.20 This test is used to demonstrate that the amount of moisture in suspension with steam from the service supply is sufficient to prevent the steam from becoming superheated during expansion into the chamber.

9.21 The method described here uses a low-volume sample, continuously taken from the centre of the steam service pipe. The level of superheat determined by this method cannot be regarded as indicative of the true dryness of the steam in the pipe since condensate flowing along the inner surface is not collected. However, devices designed to separate free condensate are incorporated into the steam delivery system to the chamber and therefore the level determined by this method is representative of steam conditions likely to prevail within the chamber during the plateau period.

9.22 This test should normally follow a satisfactory test for non-condensable gases.

9.23 This test, and the subsequent dryness value test, require a pitot tube as shown in Figure 10. The rest of the apparatus is shown and described in Figure 11. All sizes are nominal.

9.24 Fit the pitot tube concentrically within the steam service pipe as shown in Figure 11.

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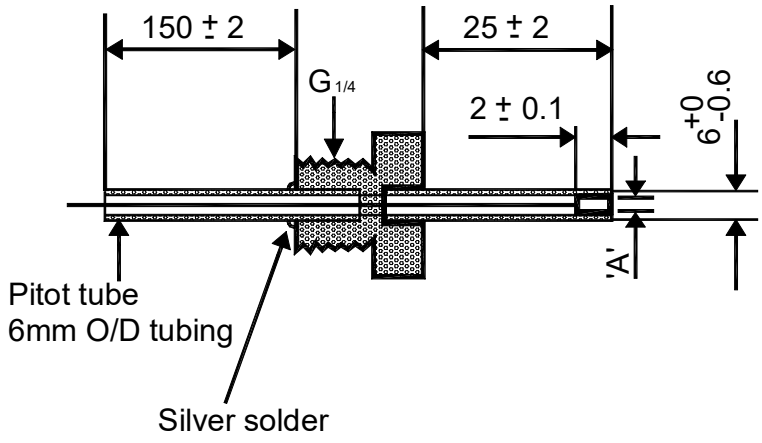
9.25 Fit the sensor entry gland to the steam service pipe. Insert one of the sensors through the gland and position it on the axis of the pipe.

9.26 Insert the second sensor through the gland in the expansion tube and position it on the axis of the pipe. Wrap lagging around the expansion tube. Push the tube on to the pitot.

Figure 10: Pitot tube



Steam pressure bar	Bore 'A' mm ± 0.02
up to 3	0.08
up to 4	0.06
up to 7	0.04

9.27 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

9.28 From the measured temperatures, note the temperature in the steam service pipe (for use in the dryness test) and in the expansion tube (T_e) when the steam supply to the chamber first opens. Calculate the superheat in °C from the following equation:

$$Superheat = T_e - T_o$$

where T_o is the boiling point of water at local atmospheric pressure.

9.29 The test should be considered satisfactory if the superheat measured in the expansion tube does not exceed 25°C.

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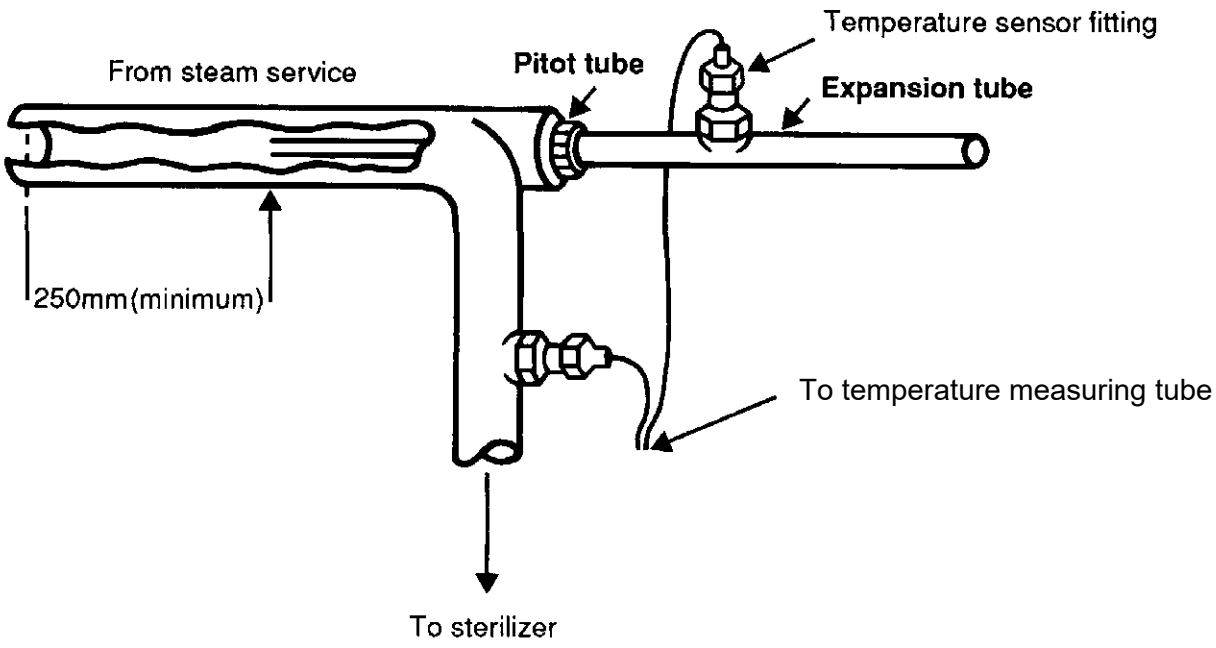
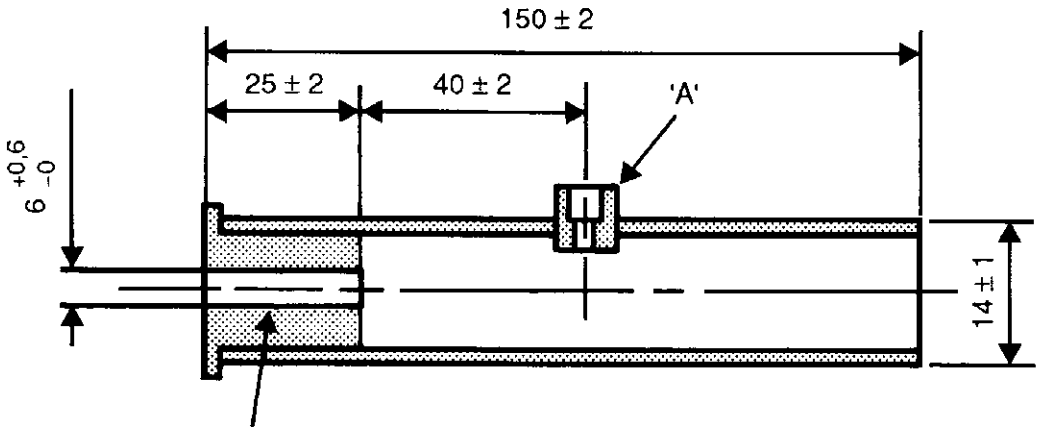
Figure 11: Apparatus for superheat test



Expansion tube



Nylon bush
Push fit into
the tube

'A' – Suitable fitting for locating a temperature sensor into the tube. To minimise heat transfer between the fitting and temperature sensor, insulation may be required.

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Dryness test

9.30 The accurate measurement of the percentage of moisture content in the steam is difficult, and the traditional methods where constant steam flow is required are not suitable for sterilizers. This test should be regarded not as measuring the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated. Possible sources of excess moisture are discussed in Part 2 of this SHTM.

9.31 The test is conveniently carried out immediately after the superheat test.

9.32 This test requires a pitot tube as shown in Figure 10. The apparatus is shown and described in Figure 12. All sizes are nominal. A laboratory balance is also required, capable of weighing a load up to 2 kg with an accuracy of 0.1 g or better.

9.33 If it is not already fitted, fit the pitot tube concentrically within the steam service pipe as shown in Figure 12.

9.34 If it is not already fitted, fit the sensor entry gland to the steam service pipe. Insert a temperature sensor through the gland and position it on the axis of the pipe.

9.35 Connect the rubber tube to the longer of the pipes in the stopper, place the stopper in the neck of the vacuum flask, weigh the whole assembly and note the mass (M_1).

9.36 Remove the stopper and tube assembly and pour 650 ± 50 ml of cold water (below 27°C) into the flask. Replace the stopper and tube assembly, weigh the flask and record the mass (M_2).

9.37 Support the flask close to the pitot, and ensure that the rubber tube and flask are protected from excess heat and draughts. Do not connect it to the pitot tube yet.

9.38 Introduce the second temperature sensor through the shorter of the two pipes in the stopper and into the water in the flask. Note the temperature of the water in the flask (T_o).

9.39 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

9.40 When the steam supply to the chamber first opens, connect the rubber tube to the pitot discharge and wrap lagging around it. Arrange the rubber tube to permit condensate to drain freely into the flask. Note the temperature in the steam service pipe (T_s).

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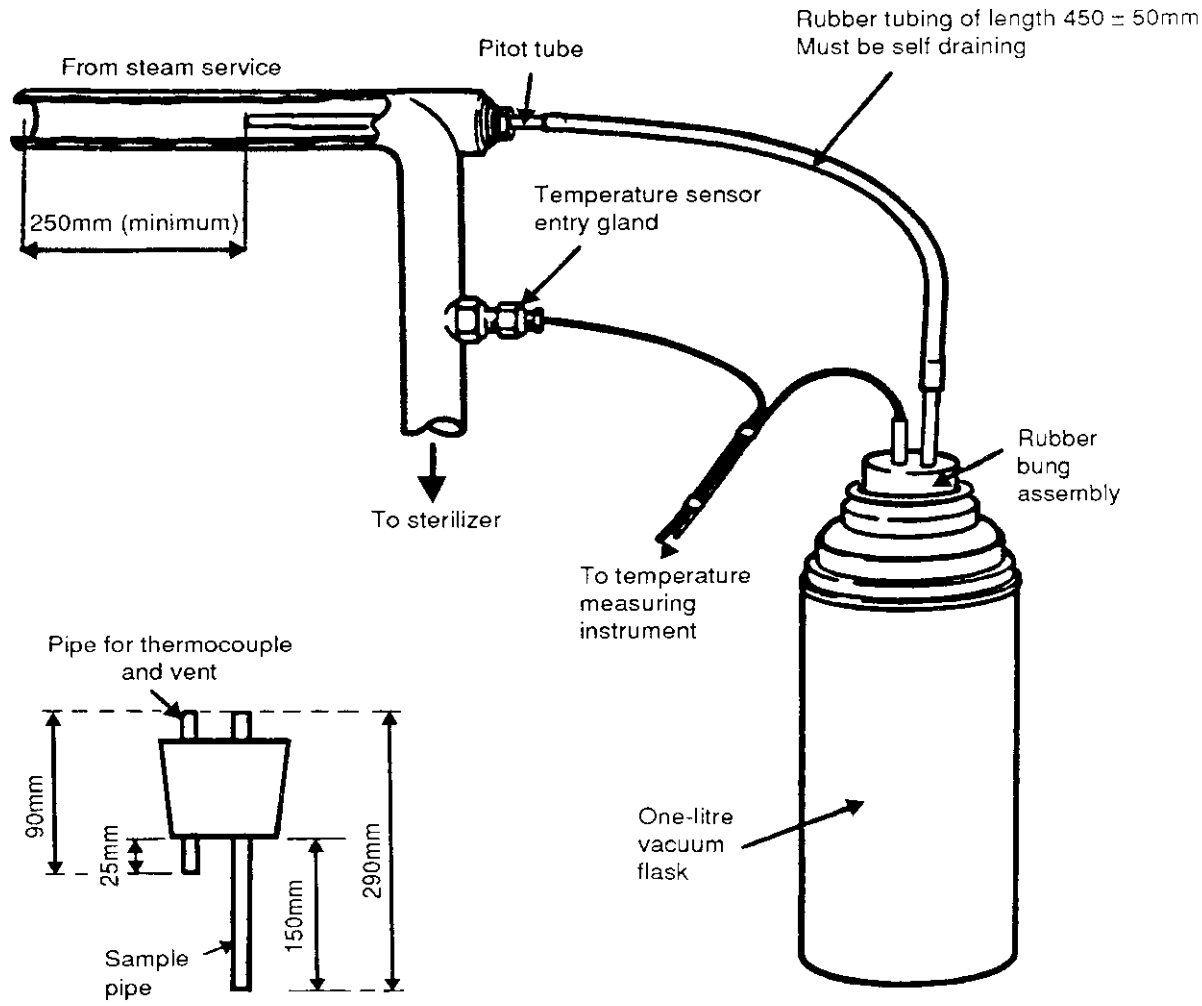
Figure 12: Apparatus for dryness test



Rubber bung assembly
Glass pipes have 6mm outside diameter

9.41 When the temperature of the water in the flask is approximately 80°C, disconnect the rubber tube from the pitot, agitate the flask so that the contents are thoroughly mixed, and note the temperature of the water (T_1).

9.42 Weigh the flask and stopper assembly and note the mass (M_3).

9.43 The initial mass of water in the flask is given by $M_w = M_2 - M_1$.

9.44 The mass of condensate collected is given by $M_c = M_3 - M_2$.

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9.45 Calculate the dryness value of the steam from the following equation:

$$D = \frac{(T_1 - T_0)(4.18M_W + 0.24)}{LM_C} - \frac{4.18(T_s - T_1)}{L}$$

where :

T_o = initial temperature of the water in the flask (°C);

T_1 = final temperature of the water and condensate in the flask (°C);

T_s = average temperature of the steam delivered to the sterilizer (°C);

M_w = initial mass of water in the flask (kg);

M_c = mass of condensate collected (kg);

L = latent heat of dry saturated steam at temperature T_s (kJ kg^{-1}).

9.46 A derivation of this equation, and a discussion of the assumptions implicit within it, can be found in Appendix 2.

9.47 The test should be considered satisfactory if the following requirements are met:

a. the dryness value is not less than 0.90 (if metal loads are to be processed, the dryness value should not be less than 0.95);

b. throughout the operating cycle, the temperature measured in the steam service pipe is within 3°C of that measured during the superheat test.

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10. Sound pressure test

Introduction

10.1 British and European Standards require the manufacturer to carry out a sound power test as a type test for the sterilizer. This test, which measures the total radiated sound power from a sterilizer, must be performed in a suitably equipped test room and it is not necessary or practicable to repeat the test once a sterilizer has been installed.

10.2 Of more practical concern is the perceived level of noise in the immediate vicinity of the sterilizer. This quantity, the A-weighted sound pressure level, depends not only upon the sound power, but also upon the acoustic properties of the environment and other sources of noise. It must therefore be determined on site with the sterilizer installed and working normally. It follows that a failure of the sound pressure test need not imply that the sterilizer is faulty. It is possible that the machine is installed in a room with insufficient sound insulation. Information about sound-reducing measures may be found in Part 2 of this SHTM.

10.3 The sound pressure test described in this chapter should be carried out according to the detailed instructions in BS EN ISO 3746. The additional information given here is by itself not sufficient to permit the test to be completed by personnel unfamiliar with the requirements of this standard.

Test procedure

10.4 A precision sound-level meter is required as described in paragraph 6.51 The sound pressure levels are determined from a number of microphone positions. Where the measuring instrument has insufficient input channels, additional instruments or repeated operating cycles will be required.

10.5 The test determines the A-weighted sound pressure levels using a rectangular measurement surface. For the purpose of this test, the “reference surface” defined in BS EN ISO 3746 is to be drawn as follows:

a. for a single sterilizer, the reference surface is the smallest rectangular box that just encloses the sterilizer, with a width and depth measured from the outside of the vessel lagging, and a height measured from the floor to the top of the vessel lagging. The box does not include pipes and valves used to connect the sterilizer to its services;

b. for a group of sterilizers treated as a single source, the reference surface is the smallest rectangular box that just encloses the reference surfaces of the individual sterilizers.

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10.6 Noise sources which contribute to the sound pressure level in the room in which the sterilizer is installed (including sources in adjacent rooms) should be operating during the test. In particular, all the building services in the area surrounding the room containing the sterilizer should be working normally, under their design conditions.

10.7 Sterilizers should be regarded as “large sound sources” as defined in BS EN ISO 3746. The measurement distance, *d*, should be 1.0 ± 0.1 m or half the distance from the sterilizer to an adjacent wall, whichever is less. It should not be less than 150 mm. Microphones should be placed in the following positions:

a. where a single sterilizer is the only major noise source in the room, place ten microphones as shown in Figure 13a. (If the sterilizer is recessed into a wall or partition, three of these microphones will be in the loading area and the remainder in the plantroom.) The microphone above the sterilizer may be omitted for safety reasons or if preliminary measurements show that its exclusion does not significantly affect the calculated value of the mean sound pressure level;

b. where several sterilizers are installed, they should be treated as a single large source and the reference surface drawn as described in paragraph 10.5b. Place ten microphones as shown in Figure 13b. If any dimension of the reference surface exceeds 5.0 m, intermediate microphone positions will be required as described in BS EN ISO 3746.

10.8 Load the sterilizer with a full load as described in the appropriate chapter of this SHTM.

10.9 If there is a choice of operating cycle, select the cycle with the highest sterilization temperature. Ensure that the pressure and flow from the steam and water services are set to normal working levels. Start the operating cycle.

10.10 Integrate the sound pressure level throughout the operating cycle or, if the cycle exceeds 30 minutes, over a 30-minute period known to contain the loudest sounds.

10.11 Using the procedure described in BS EN ISO 3746, for both the plantroom and the loading area, determine the following:

a. the mean A-weighted surface sound pressure level;

b. the peak A-weighted surface sound pressure level.

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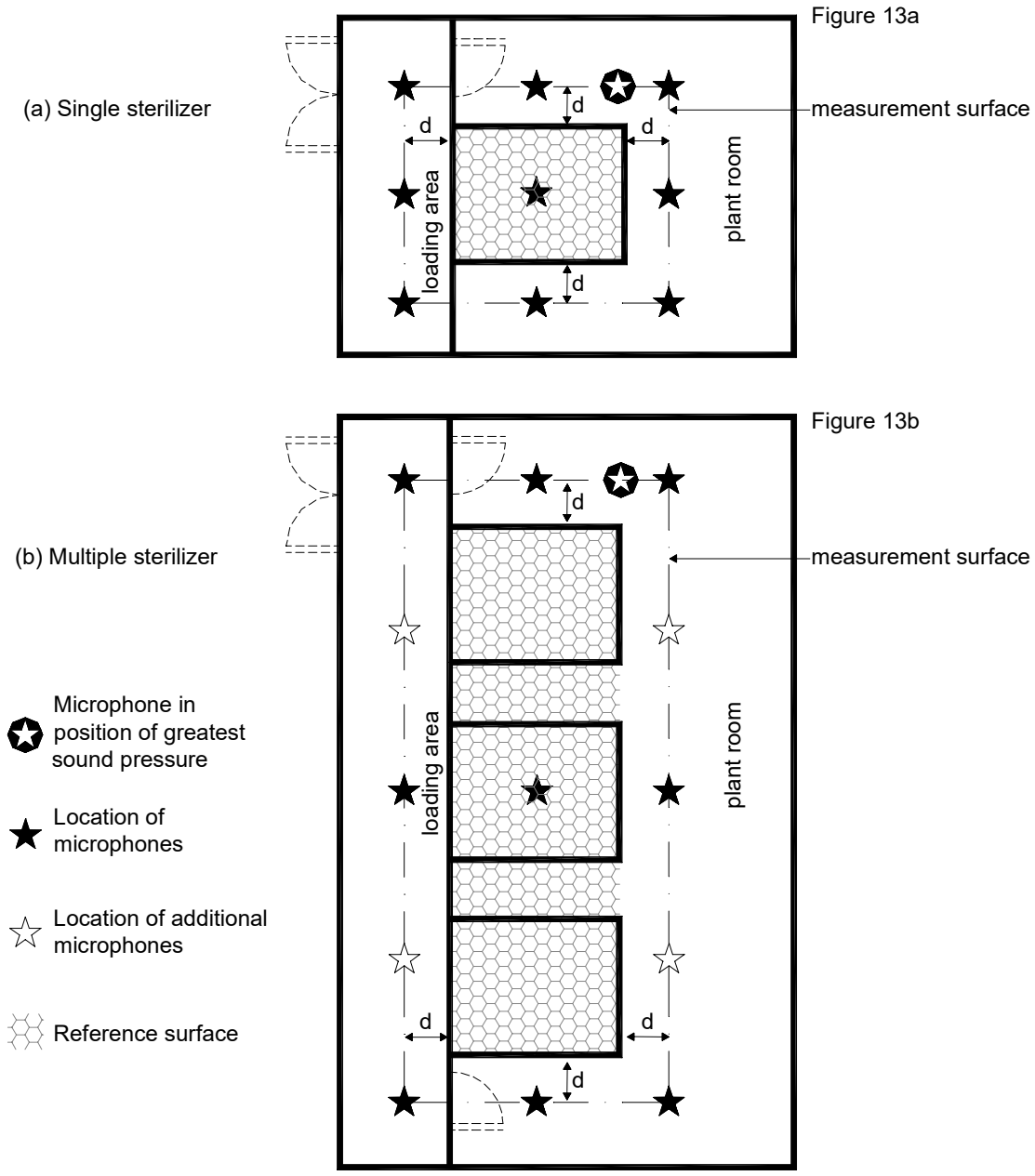
Figure 13: Location of microphones for sound pressure test



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10.12 The test should be considered satisfactory if the following requirements are met:

a. in the loading area, the mean A-weighted surface sound pressure level does not exceed:
   (i) 55 dBA for a sterilizer installed in an operating suite, pharmacy, treatment room or other noise-sensitive area;
   (ii) 70 dBA for a sterilizer installed in a sterile services department;
   (iii) 85 dBA for a sterilizer installed in an area that is not noise-sensitive;
b. in the plantroom, the mean A-weighted surface sound pressure level does not exceed 85 dBA;
c. in both the loading area and the plantroom, the peak A-weighted surface sound pressure level does not exceed the mean A-weighted surface sound pressure level by more than 15 dBA.

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11. Chamber integrity tests

Introduction

11.1 These tests are designed to show that the sterilizer chamber does not leak either under vacuum or under pressure, and that the devices used to monitor leakage and the presence of air are functioning correctly.

Vacuum leak test

11.2 The vacuum leak test is applicable to any sterilizer which employs vacuum to remove air from the load, that is, porous load sterilizers, LTS disinfectors, LTSF sterilizers, EO sterilizers and some laboratory sterilizers.

11.3 Leakage of air into the chamber at a rate greater than that specified below (see paragraph 11.15) is unacceptable for three reasons:

a. the presence of air inhibits penetration of the load by the sterilant (steam or gas) and prevents sterilization;

b. air leaking into the chamber during the drying and air admission stages will not have passed through the bacteria-retentive filter, and therefore there is a risk of recontamination of the load;

c. the presence of air may cause an explosive hazard in EO sterilizers

11.4 A vacuum leak test is required to establish that permissible limits are not exceeded.

11.5 The test is performed by measuring the change of vacuum in the chamber when all valves leading to it have been closed and the vacuum source isolated. If the test is conducted as part of a programme including thermometric tests, it will be necessary to repeat it with the temperature sensors and any test pressure gauge in place, and again when they have been removed, to ensure that there is no leakage through the ports. These tests are specified in the appropriate schedules in Chapters 4 and 5.

11.6 The test may either be part of the air removal stage or be performed at the end of the drying stage. It is designed to be carried out either automatically or semi-automatically, and in either case selected by a switch or data entry point located on the front fascia. It should be performed with an empty chamber.

11.7 If the sterilizer is not fitted with a vacuum leak test instrument, connect a 0-160 mbar absolute pressure gauge (Table 6) to the chamber.

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11.8 For the test to be accurate, the chamber temperature should be stable. For example, in a closed vessel at 40 mbar absolute, the pressure changes by approximately 1 mbar for each 10°C change in temperature over the range 20-140°C. At 70 mbar the change is approximately 2 mbar. The test could be compromised if the temperature changes by more than 10°C during the period in which the chamber pressure is monitored. Stabilise the temperature of the chamber by one of the following methods:

a. If the vessel incorporates a heated jacket, carry out an operating cycle with the chamber empty;

b. if there is no heated jacket, ensure that the temperature of the chamber is no greater than 20°C from ambient.

11.9 When the temperature has stabilised, start the vacuum leak test cycle. For automatic systems the following steps are performed automatically, and the vacuum leak rate is displayed as a pressure rise in mbar min^{-1}. For semi-automatic systems, the pressures should be read and noted by the operator.

11.10 When the pressure in the chamber drops below 50 mbar absolute (or the maximum vacuum attained in an EO cycle), close all the valves connected to the chamber and stop the vacuum pump. Note the time and the absolute pressure (P_1).

11.11 Wait for 5 minutes (± 10 s), and then note the pressure again (P_2).

11.12 Wait for a further 10 minutes (± 10 s), and then note the pressure for a third time (P_3).

11.13 Restore the operating cycle, and allow it to proceed normally.

11.14 Calculate the vacuum leak rate for the 10-minute period from:

$$Vacuum\ \ leak\ \ rate = (p_3 - p_2)/10 mbar \min^{-1}$$

11.15 For chambers with a capacity of 250-600 l, the test should be considered satisfactory if the following requirements are met:

a. the absolute pressure (P_2) at the start of the 10-minute period is:
   (i) less than 70 mbar for porous load sterilizers, LTS disinfectors, LTSF sterilizers and laboratory sterilizers;
   (ii) as specified by the manufacturer for EO sterilizers;

b. the vacuum leak rate does not exceed:
   (i) 1.3 mbar min^{-1} for porous load sterilizers and laboratory sterilizers;
   (ii) 0.5 mbar min^{-1} for LTS disinfectors and LTSF sterilizers;
   (iii) 1.0 mbar min^{-1} for EO sterilizers.

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11.16 For chambers outside the range 250-600 l, the test should be considered satisfactory if the pressure P_2 and the vacuum leak rate are as specified by the manufacturer.

11.17 Considerable care must be applied in the interpretation of the results of leak tests. On a typical test on a porous load sterilizer the pressure may rise by 20 mbar or more ($P_2 – P_1$) in the first 5 minutes of the test due to the evaporation of moisture remaining in the chamber and connecting pipework. Such a result does not necessarily indicate a leak.

11.18 A machine which fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.

Vacuum leak monitor test

11.19 For LTS disinfectors, and LTSF and EO sterilizers, the air removal stage is followed by an automatic check on the leakage of air into the chamber. The vacuum leak monitor test ensures that when the monitoring device is challenged with a specified leak rate the operating cycle is aborted and a fault is indicated.

11.20 Connect an air flow metering device (see paragraph 6.52) to the chamber.

11.21 Follow the procedure for the vacuum leak test, adjusting the metering device to cause a leak rate over the 10-minute test period of:

a. 5.0 ± 0.2 mbar min^{-1} for LTS disinfectors and LTSF sterilizers;

b. 3.0 ± 0.2 mbar min^{-1} for EO sterilizers.

11.22 For LTS disinfectors and LTSF sterilizers, place a standard test pack (see paragraph 7.27) in the chamber. For EO sterilizers, leave the chamber empty. Start the operating cycle.

11.23 The test should be considered satisfactory if the operating cycle is aborted after the air removal stage and a fault is indicated at the end of the cycle.

Pressure leak test

11.24 The pressure leak test is applicable to sterilizers which use EO or EO gas mixtures to sterilize products in chambers pressurised above atmospheric pressure.

11.25 Leakage of EO from the chamber at a rate greater than that specified below (see paragraph 11.35) is unacceptable because the gas is toxic and flammable. The maximum exposure limits are listed in Table 1. A pressure leak test is required to establish that leakage from the sterilizer will not cause these limits to be exceeded.

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11.26 The test is performed by measuring the change of pressure in the chamber when all valves leading to it have been closed and the pressurising source has been isolated. If the test is conducted as part of a programme which includes thermometric tests, it will be necessary to repeat it with the temperature sensors and any test pressure gauge in place, and again when they have been removed, to ensure that there is no leakage through the ports. These tests are specified in the appropriate schedules in Chapters 4 and 5.

11.27 The test is performed using an inert gas as described in paragraph 1.29 and the measurements taken during the gas exposure stage. The test is designed to be carried out either automatically or semi-automatically, and in either case is selected by a switch or data entry point located on the front fascia. It should be performed with an empty chamber, immediately following a vacuum leak test.

11.28 If the sterilizer is not fitted with a pressure leak test instrument, connect a test gauge to the chamber. Thus should have a accuracy of 1% or better over a range of ± 10% of the gas exposure pressure.

11.29 Start the pressure leak test cycle. This is similar to a normal operating cycle except that an inert gas is used instead of EO. For automatic systems the following steps are performed automatically and the pressure leak rate is displayed as a pressure fall in mbar/min. For semi-automatic systems, the pressures are noted by the operator.

11.30 When the working pressure is attained, the gas will continue to be injected intermittently for a further 5 minutes to allow the pressure and temperature in the chamber to stabilise.

11.31 Close the valves connected to the chamber, and stop the pressure source. Observe and note the time and the pressure (P_1).

11.32 Wait for 60 ±1 minutes and then observe and note the pressure again (P_2).

11.33 Restore the operating cycle, and allow it to proceed normally.

11.34 Calculate the pressure leak rate for the 60-minute period from:

$$\textit{pressure leak rate} = (p_1 - p_2)/60 \ \textit{mbar} \ \text{min}^{-1}$$

11.35 The test should be considered satisfactory if the following requirements are met:

a. for chambers with a capacity of 250-600 l, the pressure leak rate does not exceed 1.0 mbar min^{-1};

b. for chambers outside the range 250-600 l, the pressure leak rate is as specified by the manufacturer.

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11.36 A machine which fails to meet the requirements of this test should not be used until the fault has been rectified.

Air detector tests

11.37 An air detector is fitted to certain sterilizers which employ vacuum as a means of removing air from the load before sterilization. It is currently required for porous load sterilizers and may also be fitted to LTS disinfectors, LTSF sterilizers and some laboratory sterilizers. It is used to determine whether any air or non-condensable gas present in the chamber is sufficient to impair the sterilizing process. The air detector should cause a fault to be indicated if the amount of air or gas in the chamber at the start of the plateau period is sufficient to depress the temperature in the centre of the load more than 2°C below the temperature in the active chamber discharge.

11.38 A correctly adjusted air detector will contribute to product security but should not be regarded as an alternative to effective maintenance.

11.39 The procedure for setting an air detector is lengthy and complex if prior information is not available. The manufacturer will have established the correct settings for the air detector and should supply the following information:

a. the setting of the sensitivity of the air detector;

b. the level of the signal from the air detector (the “trigger point”), which will trigger the automatic controller to abort the cycle and indicate a fault;

c. the vacuum leak rate that will cause this level to be exceeded.

11.40 The three air detector tests are designed to demonstrate compliance with the manufacturer’s specifications. Several operating cycles will be required to complete the tests satisfactorily.

11.41 The three tests - for small load, full load and function - should be performed in sequence after it has been established that the vacuum leak rate of the sterilizer is acceptable.

11.42 Before starting the tests, connect an air-flow metering device (see paragraph 6.52) to the chamber by means of the valved port provided by the sterilizer manufacturer. It will normally be necessary to conduct a sequence of vacuum leak tests to establish the relationship between the setting on the metering device and the induced vacuum leak rate. The relationship should be recorded in the plant history file for each sterilizer.

11.43 If the sterilizer is not fitted with a leak test instrument, connect a 0-160 mbar absolute pressure test gauge (Table 6) to the chamber.

11.44 The two air detector performance tests require temperatures to be recorded by independent measuring equipment as described in Chapter 6.

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Performance test for a small load

11.45 This test is designed to determine the setting for the air detector so that, with a small load, it will respond to a leak rate sufficient to depress the temperature in the test pack by no more than 2°C.

11.46 The procedure for the small-load test is set out in the flow chart in Figure 14. If the air detector is correctly set, the test should proceed rapidly down the left-hand branch and be complete in two cycles.

11.47 Select the operating cycle with the highest sterilization temperature and standard drying time.

11.48 Place a standard test pack (see paragraph 7.27) in the chamber, with the bottom of the pack supported 100-200 mm above the centre of the chamber base, and two temperature sensors placed in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one at the approximate centre of the test pack (the wire from the sensor should be carefully arranged to prevent steam tracking along it).

11.49 A fresh test pack is required for each cycle. In practice, three test packs will be enough, provided that two are unfolded and left to air while the other is in the chamber.

11.50 At the start of the test ensure that the air detector sensitivity is set to the value recommended by the manufacturer. The detector can be disabled by adjusting the automatic controller so that it will not recognise a fault. This may be done by setting the trigger point, in accordance with the manufacturer s instructions, to a level that will not be attained during normal operation (see paragraph 11.39(b)).

11.51 During the air removal stage, admit air into the chamber by means of the metering device. From the measured temperatures, determine the temperature depression at the start of the plateau period:

Depression, $\Delta T = T_c - T_p$ where:

T_c = temperature measured in the active chamber discharge;

T_p = temperature measured in the centre of the test pack.

11.52 When the small-load test is complete, proceed immediately to the full-load test.

Performance test for a full load

11.53 This test is designed to show that an air detector set to respond correctly during the small-load test will also respond correctly with a full load. It is normally carried out immediately after a satisfactory completion of a small-load test.

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11.54 The procedure for the full-load test is set out in the flow chart in Figure 15. If the air detector has been correctly set, the test should proceed rapidly down the left-hand branch and be complete in two cycles.

11.55 Select the operating cycle used for the small-load test.

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Figure 14: Procedure for air detector small-load test

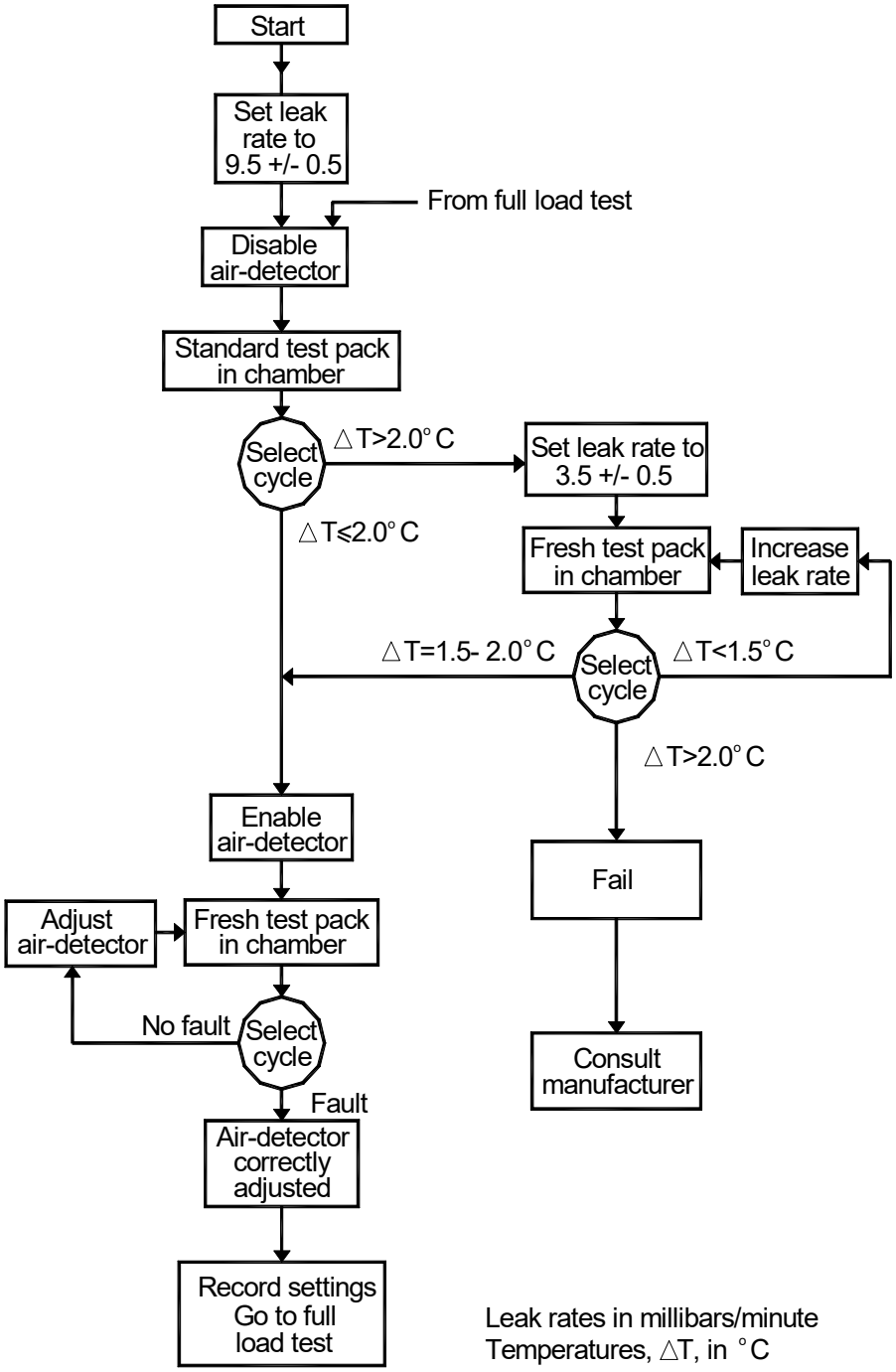

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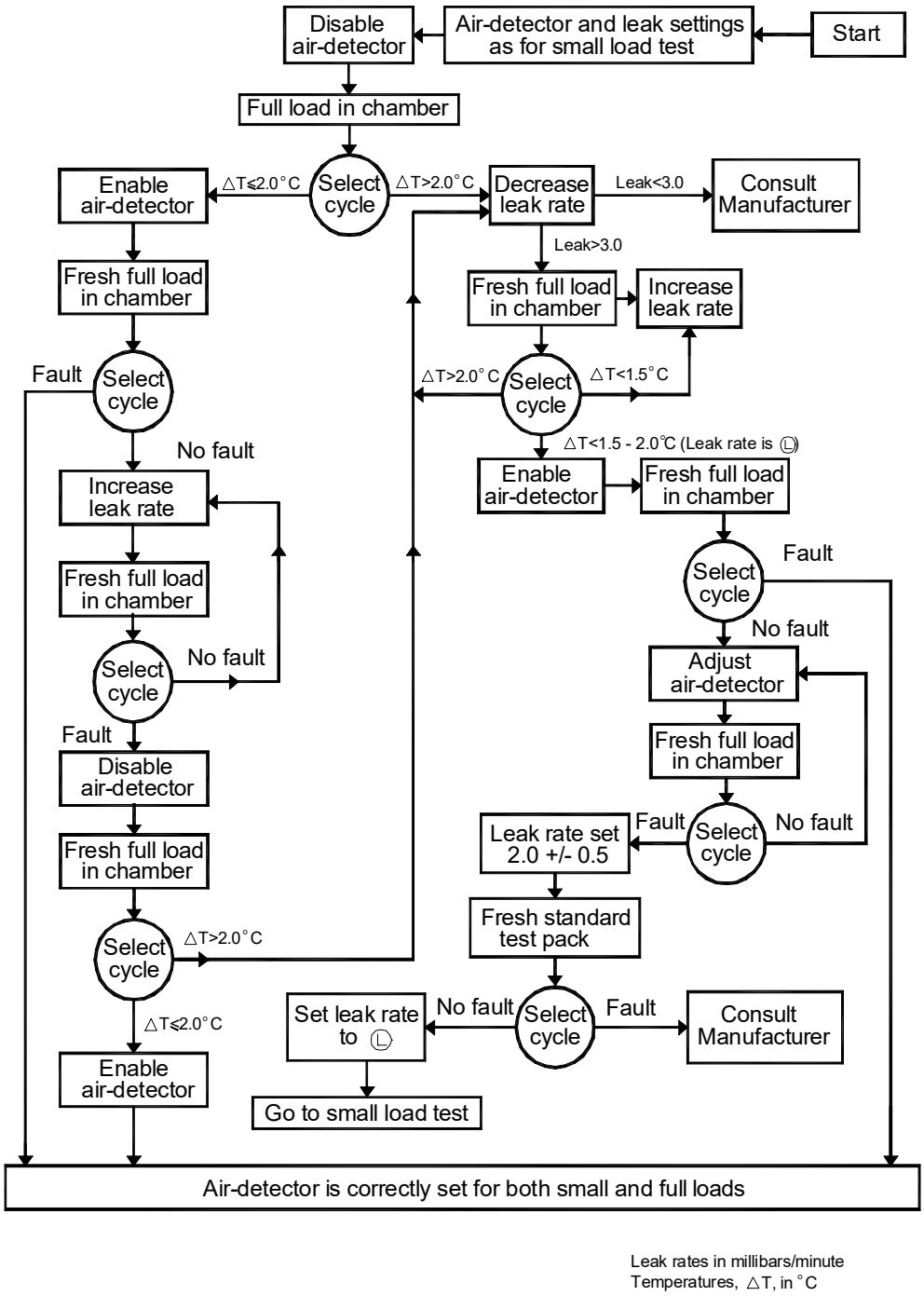
Figure 15: Procedure for air detector full load



11.56 The load is a standard test pack placed in the chamber in a position identified by the manufacturer as the most difficult to sterilize, with the remaining usable chamber space filled with a full load appropriate to the type of sterilizer under test (see the procedure for the relevant thermometric test for a full load). Place temperature sensors as for the small-load test.

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11.57 A fresh load is required for each cycle. In practice, three loads will be enough provided that two are unfolded and left to air while the other is in the chamber.

11.58 At the start of the test ensure that the air detector sensitivity and leak rate settings are identical to those established in the small-load test.

11.59 If, during the test, it becomes necessary to readjust the air detector, the procedure requires the small-load test to be repeated from the point indicated in Figure 13.

Function test

11.60 This test is designed to confirm that the air detector is functioning correctly during a normal operating cycle.

11.61 Set the air-flow metering device to the setting established during the small-load test.

11.62 Place a standard test pack in the chamber, with the bottom of the pack supported 100-200 mm above the centre of the chamber base.

11.63 Select and start the operating cycle.

11.64 The test should be considered satisfactory if the operating cycle is aborted and a fault is indicated. If the cycle is not aborted, then the advice of the manufacturer should be sought.

11.65 When the air detector tests are complete, the settings of the air detector sensitivity, the automatic controller trigger point, and the air-flow metering device and induced vacuum leak rate should be noted in the test report.

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12. Automatic control test

Introduction

12.1 The automatic control test is designed to show that the operating cycle functions correctly as evidenced by the values of the cycle variables indicated and recorded by the instruments fitted to the sterilizer. It is carried out once a week on most sterilizers, and is the main test for ensuring that the sterilizer continues to function correctly.

12.2 During the commissioning, yearly and quarterly test programmes the temperature and pressure sensors for subsequent thermometric tests will be connected to the chamber during this test. If one sensor is placed in the active chamber discharge (see paragraph 6.26) the calibration of the sterilizer instruments may conveniently be checked during the holding time of the automatic control test.

Test procedure

12.3 For porous load sterilizers, LTS disinfectors and laboratory sterilizers (fabrics cycle), place a standard test pack (see paragraph 7.27) in the chamber, with the bottom of the pack supported 100-200 mm above the centre of the chamber base.

12.4 For sterilizers for unwrapped instruments and utensils, leave the chamber empty except for the usual chamber furniture.

12.5 For fluid, dry-heat, LTSF, EO and laboratory sterilizers:

a. for installation and commissioning tests, leave the chamber empty except for the usual chamber furniture;

b. for periodic tests, load the chamber with a production load of a type for which a record has been established during performance qualification. If the test proves satisfactory, the sterilized load may be released for normal use.

12.6 Sterilizers designed for fluid loads (fluid sterilizers, dry-heat sterilizers and certain laboratory sterilizers) are equipped with one or two probes to record the temperature of the load. If a production load is being processed, insert the probes into the load in the positions they would normally occupy. Otherwise stow the probes on the bracket provided in the chamber. Do not insert probes into discard material to be processed in laboratory make-safe cycles.

12.7 If an LTSF or EO sterilizer is being tested with an empty chamber, ensure that the sterilant is replaced with an inert substitute (see paragraph 1.29).

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12.8 Select the sterilization temperature for the operating cycle to be tested. As a rule, this should be the highest temperature compatible with the load. If a production load is being used, select the temperature at which it would normally be sterilized. Start the cycle.

12.9 Ensure that a batch process record is made by the recording instrument fitted to the sterilizer. If the sterilizer does not have a recorder (such as some machines for unwrapped instruments and utensils), observe and note the elapsed time, indicated chamber temperatures and pressures at all significant points of the operating cycle, for example the beginning and end of each stage or sub-stage, and the maximum values during the holding time.

12.10 At the approximate mid-point of the plateau period, note the elapsed time and indicated chamber temperature and pressure.

12.11 For fluid loads, during the cooling stage wait for the temperature in the containers to fall to 95°C (plastic containers) or 85°C (glass). Wearing protective visor and gloves, attempt to open the door.

12.12 For fluid loads, as soon as the cycle is complete, but before opening the door, observe and note the recorded temperature in the containers.

12.13 The test should be considered satisfactory if the following requirements are met:

a. a visual display of cycle complete is indicated;

b. during the whole of the cycle the values of the cycle variables as shown on the batch process record are either within the limits established by the manufacturer as giving satisfactory results, or, for production loads, within the permitted tolerances marked on a master process record subsequently established during performance qualification;

c. during the plateau period determined from the recorded chamber temperature:

   (i) the indicated and recorded chamber temperatures are within the appropriate sterilization temperature band specified in Table 8;

   (ii) the difference between the indicated and recorded chamber temperature does not exceed 2°C;

   (iii) the difference between the indicated and recorded chamber pressure does not exceed 0.1 bar;

d. the holding time determined from any load temperature probes is not less than that specified in Table 8;

e. during the holding time, any temperatures recorded in the load are within the appropriate sterilization temperature band specified in Table 8;

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f. the door cannot be opened until the cycle is complete;

g. for fluid loads, at the end of the cycle the temperature recorded in the containers is not greater than 90°C (plastic) or 80°C (glass);

h. the person conducting the test does not observe any mechanical or other anomaly.

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13. Porous load sterilizers

Introduction

13.1 This chapter contains detailed procedures for tests specific to sterilizers designed to process porous loads. Schedules prescribing which tests are to be carried out, and when, are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests).

13.2 Unless specified otherwise, all the tests should be performed at each of the sterilization temperatures available on the sterilizer.

Chamber wall temperature test

13.3 This test is designed to show that temperature variations across the chamber walls do not exceed 2°C at the sterilization temperature. Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6. The test is performed with an empty chamber.

13.4 Place 12 temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. five on each of the two chamber side walls (one at the approximate centre and four adjacent to the corner positions of the usable chamber space);

c. one on the plane of the usable chamber space (not on the wall), at a point nearest to the steam inlet port.

13.5 If a jacket is fitted, ensure that it is heated. Select and start the operating cycle.

13.6 The test should be considered satisfactory if, at the start of the plateau period, the measured temperatures are within 2°C of each other.

Thermometric test for a small load

13.7 This test is used to demonstrate that after the air removal stage of the operating cycle, sterilizing conditions are obtained within the chamber and standard test pack. The more air there is to remove, the more exacting will be the test; that is why the pack is used by itself in an otherwise empty chamber.

13.8 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

13.9 Place a standard test pack (see paragraph 7.27) in the chamber with the bottom of the pack supported 100-200 mm above the centre of the chamber base.

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13.10 Place three temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one at the approximate centre of the test pack (the wire from the sensor should be carefully arranged to prevent steam tracking along it);

c. one placed in the free space 50 ± 5 mm above the approximate centre of the upper surface of the test pack.

13.11 Connect a pressure recorder (or test gauge) to the chamber.

13.12 Start the operating cycle, with standard drying time, and take readings as described for the automatic control test (see paragraph 12.9).

13.13 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

13.14 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. during the plateau period the temperature measured above the test pack does not exceed the temperature measured in the active chamber discharge by more than 5°C for the first 60 s and 2°C for the remaining period;

c. the equilibration time determined from the measured temperatures does not exceed 15 seconds for chambers up to 800 l and 30 seconds for larger chambers;

d. the holding time determined from the measured temperatures is not less than that specified in Table 8;

e. during the holding time the temperatures measured in the active chamber discharge and in the centre of the test pack:

(i) are within the appropriate sterilization temperature band specified in Table 8;

(ii) do not fluctuate by more than ± 1°C;

(iii) do not differ from one another by more than 2°C;

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f. during the holding time:

   (i) the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge;

   (ii) the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure;

g. for sterilizers using vacuum as the sole method of drying:

   (i) the duration of the drying stage is not less than 3 minutes;

   (ii) the chamber pressure at the end of the stage does not exceed 40 mbar absolute;

h. at the end of the cycle the sheets are sensibly dry.

Thermometric test for a full load

13.15 The full-load test is designed to demonstrate that, at the levels at which cycle variables are set, rapid and even penetration of steam into the centre of a load occurs, and the sterilizing condition is achieved in a test load of specified maximum mass and of sufficient size to fill the usable chamber space.

13.16 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

13.17 The load is made up of a standard test pack (see paragraph 7.27) and additional folded sheets designed to represent the maximum mass of textiles which may be processed in the sterilizer. Each sheet should contain at least 50% m/m of cotton fibre and have a surface density of approximately 200 g m^{-2}. They should be washed and aired as for the standard test pack (see paragraphs 7.30-31). After airing, the sheets should be folded to approximately 25 cm x 50 cm and laid one on top of the other to form stacks of mass 7.5 ± 0.5 kg.

13.18 Place the standard test pack within the chamber in a position identified by the manufacturer as the most difficult to sterilize. This will normally be in the approximate centre of the chamber.

13.19 Place three temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one at the approximate centre of the test pack (the wire from the sensor should be carefully arranged to prevent steam tracking along it);

c. one below the approximate centre of the top sheet of the test pack.

13.20 Load the rest of the usable chamber space with stacks of sheets. (The mass of fabric in the load should be equivalent to 7.5 ± 0.5 kg for a unit volume 300 mm x 300 mm x 600 mm.)

13.21 Connect a pressure recorder (or test gauge) to the chamber.

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13.22 Start the operating cycle, with standard drying time, and take readings as described for the automatic control test (see paragraph 12.9).

13.23 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

13.24 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. the equilibration time determined from the measured temperatures does not exceed 15 s for chambers up to 800 l and 30 s for larger chambers;

c. the holding time determined from the measured temperatures is not less than that specified in Table 8;

d. during the holding time:

   (i) the measured temperatures are within the appropriate sterilization temperature band specified in Table 8;

   (ii) the measured temperatures do not fluctuate by more than ± 1°C;

   (iii) the measured temperatures do not differ from one another by more than 2°C;

   (iv) the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge;

   (v) the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure;

e. the total cycle time is within the performance class stated by the manufacturer;

f. at the end of the cycle the sheets are sensibly dry.

Load dryness test

13.25 This test is used to demonstrate that the operating cycle, without extended drying, will not cause an increase in moisture in a standard test pack sufficient for there to be uncertainty about the dryness of loads routinely processed.

13.26 Three polythene bags, at least 35 cm x 25 cm and of polythene at least 250µm thick, and a balance capable of weighing loads up to 2 kg with an accuracy of 0.1 g or better, are required.

13.27 Allow the sheets which will comprise the standard test pack to air as described in paragraph 7.31.

13.28 Mark three of the sheets and similarly mark each of the polythene bags so that each sheet is identified with a bag.

13.29 Weigh each of the polythene bags and note the mass (M_1).

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13.30 Place each sheet in a polythene bag, weigh each bag with its enclosed sheet and note the mass (M_2).

13.31 Remove the sheets from the bags and assemble the standard test pack with one of the sheets in the centre of the pack and one in the second position from each end of the pack.

13.32 Place the test pack in the approximate centre of the sterilizer chamber and start the operating cycle within one minute. (Extended drying should not be used.)

13.33 Not more than one minute after the cycle has finished, remove the test pack from the chamber. Remove the three sheets from the test pack and put them quickly into their marked bags. Seal each bag by turning its open end over several times. This operation should be completed as quickly as possible to reduce evaporation of retained moisture and in any case within three minutes of the end of the cycle.

13.34 Weigh each bag with its enclosed sheet and note the mass (M_3).

13.35 Calculate the percentage gain in mass of each sheet from the formula:

$$\textit{percentage gain in mass} = 100 \times \frac{(M_3 - M_2)}{(M_2 - M_1)}$$

13.36 The test should be considered satisfactory if the average gain in mass of each of the three bagged sheets is not more than 1%.

Hospital load dryness check

13.37 Process a production load which is known to present the greatest challenge to the operating cycle. Extended drying may be required.

13.38 The check should be considered satisfactory if a “cycle complete” indication is obtained and the load is sensibly dry.

Bowie-Dick test for steam penetration

13.39 Sterilization is achieved by the rapid and even penetration of steam into all parts of the load and the maintenance of these conditions for the specified holding time. To ensure this, it is essential to remove air from the chamber and load, and to provide a steam supply which contains a minimal volume of non-condensable gases. Any residual air and non-condensable gases will become concentrated as a bubble in the load and inhibit steam penetration.

13.40 The Bowie-Dick test shows whether or not steam penetration of the test pack is even and rapid, and thus by implication that air or other non-condensable gases are not present. It does not confirm that the sterilization conditions in the load have been achieved.

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Principle of the test

13.41 The test, as originally conceived and described in earlier editions of HTM 10 (Bowie, Kelsey and Thomson, 1963), is based on the use of a chemical indicator in the form of an adhesive tape stuck to a piece of suitable paper to form a St Andrew's cross. This indicator paper is placed at the centre of a test pack of folded huckaback towels and then subjected to an operating cycle. The indicator tape shows a change of colour in response to a combination of time, temperature and moisture.

13.42 If no air is present in the chamber, steam will penetrate rapidly and completely, and the indicator will show a uniform colour change. If air is present, it will collect within the pack as a bubble. The indicator in the region of the bubble will be of a different colour than elsewhere on the paper, because of a lower temperature, lower moisture level or both.

13.43 The modern Bowie-Dick test uses a Class B chemical indicator conforming to BS EN 867: Part 3 (see paragraph 7.40) contained within a standard test pack (see paragraph 7.27). The indicator is distributed over an A4 paper sheet in the form of a geometric pattern.

13.44 When used in conjunction with a standard test pack, Class B indicators are designed to show a failure either if, at the start of the holding time, the temperature at the centre of the test pack is 2°C or more below the temperature in the active chamber discharge; or if the indicator is exposed to insufficient moisture. Both conditions are usually caused by the presence of air or other non-condensable gases (see paragraph 13.56). Because of the tolerances necessary in the manufacture of chemical indicators, users should be aware that in order to detect a temperature difference of 2°C the indicator may show signs of failure with a smaller temperature difference.

Test procedure

13.45 The Bowie-Dick test is normally preceded by a warm-up cycle. This cycle is necessary because the effectiveness of air removal may depend on all parts of the sterilizer being at working temperature. A satisfactory sterilizer may give a fail result if this is not done.

13.46 Remove the wrapping from a standard test pack and place the indicator paper in the sheet located nearest to the centre of the pack. Reassemble and secure the pack and replace the wrapping.

13.47 Place the test pack in the chamber with the bottom of the pack supported 100-200 mm above the centre of the chamber base.

13.48 Select the Bowie-Dick test cycle. Ensure that the holding time will not be longer than that specified in Table 10. If this time is exceeded, the indicator may change in such a way as to make it difficult to detect the variations that would indicate a fail condition. Start the operating cycle.

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Table 10: Holding times for the Bowie-Dick test cycle

Sterilization temperature	Holding time	
[°C]	minimum [min]	maximum [min]
134	3.3	3.5
126	10.8	11.0
121	16.8	17.0

13.49 During the holding time, note the reading on the cycle counter, the chamber temperature indicator and the chamber pressure indicator.

13.50 When the cycle is complete, remove the indicator paper from the test pack.

13.51 The test should be considered satisfactory if the following requirements are met:

a. there is a uniform change throughout the indicator;

b. the automatic controller indicates that a Bowie-Dick test cycle has just been completed.

13.52 It is important to compare the colour of the indicator at the corners of the paper with that at the centre so that any difference can be clearly seen. If there is any discernible difference the test should be recorded as failed, and the paper marked accordingly. A large area of unchanged indicator points to a gross failure.

13.53 The indicator paper should be marked with the result and kept for reference for at least three months. The chemical reaction continues during this time and the paper may be discarded when the indicator becomes unreadable. The associated batch process record should be kept for at least 11 years.

13.54 An unsatisfactory test result indicates that the machine should not be used until the fault has been rectified. It is important to realise that if a sterilizer fails to pass the Bowie-Dick test it cannot be made safe simply by increasing the holding time until a uniform colour change is produced. A failed sterilizer is in urgent need of skilled attention.

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13.55 Several factors may inhibit steam penetration and cause the test to fail Common causes of failure include the following:

a. an inefficient air removal stage;

b. an air leak during the air removal stage;

c. the presence of non-condensable gases in the steam supply.

13.56 A subsequent thermometric test for a small load (see paragraph 13.7) will assist in diagnosing the cause of failure:

a. if the test reveals a temperature depression at the centre of the test pack, the problem is likely to be inefficient air removal or an air leak into the chamber. Air remaining in the centre of the test pack is inhibiting the penetration of steam and the correct temperature is not being attained. The sterilizer should not be returned to service until it has been subjected to a vacuum leak test (see paragraph 11.2) and an air detector function test (see paragraph 11.60);

b. if the test fails to reveal a temperature depression, the problem is almost certainly air or other non-condensable gases in the steam supply. In this case the correct temperature is being attained but the steam is diluted, and insufficient moisture is present to change the indicator. The sterilizer should not be returned to service until the steam supply has been tested for the presence of non-condensable gases (see paragraph 9.4).

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14. Fluid sterilizers

Introduction

14.1 This chapter contains detailed procedures for tests specific to sterilizers to process aqueous fluids in sealed containers. Schedules prescribing which tests are to be carried out and when are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests).

14.2 Unless specified otherwise, all the tests should be performed at each of the sterilization temperature available on the sterilizer.

14.3 For the thermometric tests the containers should be filled with the volume of water. The volumes of the fluid in each container should not differ from their mean by more than 5%. At the start of the cycle the temperature of the fluid in each container should be 20 ± 5°C.

Heat exchanger integrity test

14.4 This test is designed to check the integrity of the heat exchanger used to heat and cool the circulating coolant (air or water) in the sterilizer chamber. The circuit which is directly heated is called the primary circuit. Water in the primary circuit must be assumed to be non-sterile. The circuit which exposes coolant to the load is called the secondary circuit. In recent models of fluid sterilizers the secondary circuit is designed to operate at a higher pressure than the primary to prevent leakage of contaminated water into the chamber.

14.5 Where the heat exchanger is designed and constructed in a fail-safe fashion so that the secondary coolant cannot become contaminated under any circumstances, the test is required only for commissioning and yearly tests.

14.6 Attach a pressure recorder (or test gauge) to the primary circuit. The range should include the maximum pressure to which the circuit is to be pressurised.

14.7 Charge the primary circuit with water and pressurise it to either 1.5 times its maximum working pressure or twice the maximum pressure in the secondary circuit, whichever is less. This should be done in accordance with the manufacturer's instructions, and in some cases may require additional ports and valves to be fitted.

14.8 Close the inlet and outlet valves, and allow the pressure to stabilise over a period of 10 min. Observe and note the measured pressure. Wait for a further 10 min. Observe and note the pressure again.

14.9 The test should be considered satisfactory if the measured pressure has not fallen over the 10 min period.

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Thermometric test for a full load

14.10 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

14.11 Load the chamber with one-litre bottles (nominal capacity), each filled with 1 l of water, at the minimum spacing recommended by the manufacturer. The bottles and chamber furniture should fill the usable chamber space. If the sterilizer is not designed to process one-litre bottles, the largest size recommended by the sterilizer manufacturer should be used.

14.12 Place 10 or 11 temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);
b. one in each of the three bottles that are the slowest to attain the sterilization temperature;
c. one in each of the three bottles that are the fastest to attain the sterilization temperature;
d. one in each of the three bottles that are the slowest to cool to 90°C (plastic) or 80°C (glass);
e. one in the coolest part of the coolant spray system (if fitted).

14.13 Insert the load temperature probe into a bottle adjacent to the bottle identified as the slowest to attain the sterilization temperature. If a second probe is provided, insert it into a bottle adjacent to the bottle identified as the fastest to attain the sterilization temperature.

14.14 Connect a pressure recorder (or test gauge) to the chamber and, for sterilizers fitted with a spray pump, to the spray pump discharge. Where the heat exchanger secondary circuit is designed to operate at a higher pressure than the primary circuit, connect a third sensor to measure the differential pressure between the circuits.

14.15 Select and start the operating cycle and take readings as described for the automatic control test (see paragraph 12.9).

14.16 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

14.17 As soon as the cycle is complete, note the measured temperature in the bottles before opening the door.

14.18 If required, collect a sample of coolant for a subsequent coolant quality test (see paragraph 14.32).

14.19 If the coolant is derived from a water or steam service, and is intended to come into contact with the load containers, the operating cycle must expose the coolant to sufficient heat to ensure that it is free of microbial contamination by the end of the holding time. This is checked by calculating an F_0 value (see

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Part 4 for a discussion of the use of F_0) that is equivalent to the time in minutes at a sterilization temperature of 121°C. If the test recorder is not capable of calculating F_0 (see paragraph 6.16), proceed as follows:

a. from the measured temperatures, identify the point during the heat-up time at which the coolant temperature first reaches 108°C. Note the temperature (T°C) at subsequent one-minute intervals until the end of the holding time;

b. for each measurement, calculate the incremental F_0 (ΔF_0) from the following equation:

$$\Delta Fo = log_{10}\left(\frac{T-121}{10}\right) minutes;$$

c. the F_0 value is the sum of all ΔF_0

14.20 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (paragraph 12.13) are met;

b. the holding time is not less than that specified for the appropriate sterilization temperature band in Table 8;

c. during the holding time:

(i) the measured temperatures are within the appropriate sterilization temperature band specified in Table 8;

(ii) the measured temperatures are within 1°C of each other;

(iii) the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge;

(iv) the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure;

(v) the recorded chamber pressure is within 0.05 bar of saturated steam pressure or, if a partial pressure system is used, as specified by the manufacturer;

d. at the end of the cycle:

(i) the temperature sensors have remained in position;

(ii) the bottles containing sensors have not leaked, burst or broken;

(iii) not more than one of the other bottles (or 1%, whichever is the greater) has burst or broken;

(iv) the temperature measured in the bottles is not greater than 90°C (plastic) or 80°C (glass);

e. throughout the cycle:

(i) the coolant spray pressure complies with the manufacturer's specifications;

(ii) the pressure in the heat exchanger secondary circuit is greater than that in the primary circuit (if appropriate);

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f. F_0 for the coolant is not less than 8 minutes;

g. the total cycle time is within the performance class stated by the manufacturer.

Thermometric test for a small load

14.21 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

14.22 Place 25 vials or ampoules of 5-ml nominal capacity, each containing 5 ml of water, in each of two wire baskets. Support one basket in the upper rear half of the usable chamber space and the other in the lower front half. Use the upper and lower shelves if provided. If the sterilizer is not designed to process vials or ampoules of this size, the smallest size and number of containers recommended by the sterilizer manufacturer should be used. Where the sterilizer is to be used to process one size of container only, the test load may be a single container of this size, filled with the nominal volume of water and supported in a position known to be the slowest to attain the sterilization temperature.

14.23 Place temperature sensors and load temperature probes as described for the full-load test.

14.24 Connect a pressure recorder (or test gauge) to the chamber and other pressure sensors as described for the full-load test.

14.25 Follow the procedure for the full-load test.

14.26 The test should be considered satisfactory if, except for paragraph 14.20 (g), the requirements of the full-load test (see paragraph 14.20) are met.

Simplified thermometric test for performance requalification

14.27 This test is not a substitute for a full PRQ test, but is used quarterly to check that the sterilization conditions continue to be met. Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

14.28 Prepare a production load known to present the greatest challenge to the operating cycle and for which there is a PQ report. (This will normally be the reference load used in the yearly PRQ tests.)

14.29 Place three or four temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one in a container that is the slowest to attain the sterilization temperature;

c. for chambers of capacity of 800 l and above, one in a container that is the fastest to attain the sterilization temperature;

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d. one in a container that is the slowest to cool to 80°C (glass) or 90°C (plastic).

14.30 Place the load in the chamber as described in the PQ report. Select and start the operating cycle.

14.31 The test should be considered satisfactory if the requirements listed in the PQ report are met.

Coolant quality test

14.32 This test measures the concentration of particulates and dissolved solids in the coolant. It is carried out after a satisfactory operating cycle, normally at the end of a full-load, small-load or PQ test.

14.33 Rinse a one-litre bottle with purified water BP immediately before use and discard the rinsings.

14.34 Use the bottle to collect a test sample of cooling water from the coolant system immediately after an operating cycle but before the final discharge to waste.

14.35 Take a dish or beaker, made of silica or borosilicate glass, of capacity at least 150 ml. Dry the dish for 2 h in an oven at a temperature of 110 ± 2°C. Put it in a desiccator and allow it to cool to ambient temperature. Weigh it to the nearest 0.1 mg and note the mass (M_1).

14.36 Ensuring that the test sample is well mixed, measure 100 ml of the test sample into the dish and evaporate it over a boiling-water bath until apparently dry.

14.37 Repeat with two further 100 ml of test sample transferred into the same dish.

14.38 Put the dish into the oven and heat at a temperature of 110 ± 2°C for about 2 h. Put it in the desiccator and allow it to cool to ambient temperature. Weigh it to the nearest 0.1 mg and note the mass (M_2).

14.39 Repeat paragraph 14.38 until the difference between two consecutive weighings does not exceed 0.2 mg.

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14.40 Calculate the concentration of residue in milligrams per litre of cooling water.

$$Concentration\ of\ residue = \frac{(M_2 - M_1)}{V} mg\,l^{-1}$$

where:

M_1 = mass of dry dish (mg);

M_2 = final mass of dish and residue (mg);

V = volume of sample water evaporated (normally 300 ml).

14.41 The test should be considered satisfactory if the concentration of residue does not exceed 40 mg l^{-1}

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15. Sterilizers for unwrapped instruments and utensils

Introduction

15.1 This chapter contains detailed procedures for tests specific to sterilizers designed to process unwrapped solid instruments and utensils. Schedules, prescribing which tests are to be carried out and when, are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests). Except where stated otherwise, the tests in this chapter apply equally to fixed and transportable sterilizers.

15.2 Unless specified otherwise, all the tests should be performed at each of the sterilization temperatures available on the sterilizer.

Chamber overheat cut-out test

15.3 This test applies only to sterilizers where the steam is generated within the chamber. The test is done with an empty chamber and with insufficient water charge for a complete cycle. Temperatures should be recorded by independent measuring equipment as described in Chapter 6.

15.4 Attach a temperature sensor to the chamber wall in a position identified by the manufacturer as attaining the highest temperature.

15.5 Select the operating cycle with the highest sterilization temperature. (Only one cycle is normally provided.) Start the cycle.

15.6 The test should be considered satisfactory if the following requirements are met:

a. a boil-dry condition occurs before the end of the cycle;

b. the overheat cut-out operates, and the heaters are isolated from the electricity supply;

c. the chamber wall temperature does not exceed the temperature specified by the manufacturer.

Thermometric test for a small load

15.7 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

15.8 Place a pair of forceps (for example 5-inch artery forceps) in the approximate centre of the chamber.

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15.9 Place three temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one trapped between the jaws of the forceps;

c. where steam is supplied from outside the chamber, one in the upper third of the free chamber space;

d. where steam is generated within the chamber, one either in the reservoir or, if water is retained in the chamber, in the water.

15.10 Connect a pressure recorder (or test gauge) to the chamber.

15.11 Select and start the operating cycle.

15.12 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. during the first minute of the plateau period the temperature measured in the chamber free space does not exceed the temperature measured in the active chamber discharge by more than 5°C;

c. after the first minute of the plateau period:

(i) the temperature measured in the chamber free space does not exceed the temperature measured in the active chamber discharge by more than 2°C;

(ii) the temperature measured in the jaws of the forceps is within 1°C of the temperature measured in the active chamber discharge;

d. the holding time determined from the measured temperatures is not less than that specified in Table 8;

e. during the holding time:

(i) the measured temperatures are within the appropriate sterilization temperature band specified in Table 8;

(ii) the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge;

(iii) the indicated and recorded chamber pressures are within 0.05 bar of the measured chamber pressure;

f. at the end of the cycle the temperature of any water left in the chamber or in the reservoir is less than the boiling point of water at local atmospheric pressure.

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Thermometric test for a full load

15.13 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

15.14 Place a pair of forceps as for the small-load test in the approximate centre of the chamber, and add further instruments and utensils up to the maximum total mass which the sterilizer is designed to process.

15.15 Place four temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one trapped between the jaws of the forceps;

c. where steam is supplied from outside the chamber, one in the free space between the load items;

d. where steam is generated within the chamber, one either in the reservoir or, if water is retained in the chamber, in the water.

15.16 Connect a pressure recorder (or test gauge) to the chamber.

15.17 Select and start the operating cycle.

15.18 The test should be considered satisfactory if the requirements for the small-load test are met, and the total cycle time is within the performance class stated by the manufacturer.

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16. Dry-heat sterilizers

Introduction

16.1 This chapter contains detailed procedures for tests specific to dry-heat sterilizers. Schedules, prescribing which tests are to be carried out and when, are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests).

16.2 For these tests it is essential that load items are packaged and positioned in a manner which will permit the circulation of air to all parts of the chamber and pack surfaces.

16.3 Unless specified otherwise, all the tests should be performed at each of the sterilization temperatures available on the sterilizer.

Automatic control test

16.4 Follow the general procedure for the automatic control test given in Chapter 12 with the following amendments.

16.5 Where the chamber is pressurised during the cooling stage, note the differential pressure across the air filter after the start of the cooling stage and shortly before the end.

16.6 As soon as the cycle is complete, and before opening the door, note any recorded temperatures in the load containers.

16.7 The test should be considered satisfactory if the following requirements are met:

a. a visual indication of “cycle complete” is obtained;

b. during the whole of the cycle the values of the cycle variables as shown on the batch process record are either within the limits established by the manufacturer as giving satisfactory results, or within the permitted tolerances marked on a master process record subsequently established during performance qualification;

c. during the plateau period determined from the recorded chamber temperature:

(i) the indicated and recorded chamber temperatures are within the appropriate sterilization temperature band specified in Table 8;

(ii) the difference between the indicated and recorded chamber temperature does not exceed 5°C;

(iii) the recorded chamber temperature does not drift by more than 2°C;

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d. the holding time determined from any load temperature probes is not less than that specified in Table 8;

e. during the holding time, the recorded temperature in the load containers is within 5°C of the recorded chamber temperature;

f. during the cooling stage, the differential pressure indicated across the air filter is in the range specified by the manufacturer;

g. the door cannot be opened until the cycle is complete;

h. at the end of the cycle the temperature recorded in any load containers is not greater than 90°C;

i. the person conducting the test does not observe any mechanical or other anomaly.

Chamber overheat cut-out test

16.8 This test is designed to show that the thermal cut-out will prevent the temperature in the chamber from exceeding 200°C. The test should be done with an empty chamber. Temperatures should be recorded by independent measuring equipment as described in Chapter 6.

16.9 Place a temperature sensor in the hottest part of the chamber free space.

16.10 Inactivate the chamber temperature control to allow the temperature to rise. This should be done in accordance with the manufacturer's instructions.

16.11 Select and start the operating cycle.

16.12 The test should be considered satisfactory if the measured chamber temperature does not exceed 200°C during the cycle.

Air filter integrity test

16.13 This test is designed to show whether the high-efficiency particulate filter fitted to a dry-heat sterilizer is intact and working correctly. It is based on the test given in Appendix C of BS 5295: Part 1.

16.14 A test aerosol generator and a photometer are required as described in Chapter 6.

16.15 The sterilizer should be at room temperature with the chamber door open. In accordance with the manufacturer s instructions, arrange for the chamber pressurising fan to be drawing air through the filter at its normal rate.

16.16 Set up the aerosol generator outside the chamber so that a uniform concentration of particles is dispersed across the intake of the air filter and its sealing frame. Ensure that this concentration is maintained throughout the test.

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16.17 Using the photometer, measure the concentration of particles as close as possible to the intake of the filter and ideally not more than 150 mm from the filter face. Adjust the photometer (and the aerosol generator if necessary) to give a stable reading of 100%.

16.18 Inside the chamber, use the photometer to scan all of the downstream face of the filter including the sealing device. Hold the sampling probe approximately 25 mm away from the area being tested, and pass it over the entire area in slightly overlapping strokes at a traverse rate of no more than 50 mm s^{-1}. Make separate passes around the entire periphery of the filter, along the bond between the filter pack and the frame, and around the seal between the filter and retaining device.

16.19 Note the location of any steady, repeatable reading of the photometer.

16.20 The test should be considered satisfactory if any steady and repeatable reading does not exceed 0.001%.

16.21 A filter that fails the test should be replaced. It is not possible to repair the high-efficiency filters installed in dry-heat sterilizers.

Thermometric test for performance qualification

16.22 Temperatures should be recorded by independent measuring equipment.

16.23 Follow the procedure for the thermometric test for performance qualification given in Chapter 8 (see paragraph 8.13), but instead of placing a temperature sensor in an active chamber discharge place two sensors as follows:

a. one (sensor A) in thermal contact with the sensor connected to the sterilizer temperature recorder;

b. one (sensor B) in thermal contact with the sensor connected to the sterilizer temperature indicator.

16.24 Where the chamber is pressurised during the cooling stage, connect a pressure recorder to measure the differential pressure across the air filter. Measure the differential pressure during the cooling stage.

16.25 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 16.7) are met;

b. the holding time, as determined from the measured temperatures, is not less than that specified in Table 8;

c. during the holding time:

(i) the measured temperatures are within the appropriate sterilization temperature band specified in Table 8;

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(ii) the indicated chamber temperature is within 1°C of the temperature measured by sensor B;

(iii) the recorded chamber temperature is within 1°C of the temperature measured by sensor A;

(iv) the temperatures measured by each sensor in the load and by sensor B are within 5°C of the temperature measured by sensor A;

(v) the temperature measured by sensor A does not drift more than 2°C;

d. during the cooling stage the differential pressure measured across the air filter is in the range specified by the manufacturer;

e. at the end of the cycle:

(i) the temperature sensors have remained in position;

(ii) the items containing sensors are intact;

(iii) the temperature measured in any item is not greater than 90°C.

Simplified thermometric test for performance requalification

16.26 This test is not a substitute for a full PRQ test, but is used quarterly to check that the sterilization conditions continue to be met. Temperatures should be recorded by independent measuring equipment.

16.27 Prepare a production load known to present the greatest challenge to the operating cycle and for which there is a PQ report. (This will normally be the reference load used in the yearly PRQ tests.)

16.28 Place the load in the chamber as described in the PQ report with temperature sensors in the following positions:

a. one (sensor A) in thermal contact with the sensor connected to the chamber temperature recorder;

b. one (sensor B) in thermal contact with the sensor connected to the chamber temperature indicator;

c. one in the item of the load which is the slowest to attain the sterilization temperature.

16.29 Where the chamber is pressurised during the cooling stage, connect a pressure recorder to measure the differential pressure across the air filter.

16.30 Ensure that the operating cycle corresponds with that used for the performance qualification test for the load. Start the cycle.

16.31 During the cooling stage, measure the differential pressure across the air filter.

16.32 The test should be considered satisfactory if the requirements listed in the PQ report are met.

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Thermometric test for a full load

16.33 This test will have been carried out by the manufacturer as a type test. It need be repeated only if the sterilizer fails to meet the requirements of the thermometric test for performance qualification (see paragraph 16.22).

16.34 The test is adapted from the former BS 3421 (now withdrawn). Temperatures should be recorded by independent measuring equipment as described in Chapter 6. For chambers with more than two shelves, two or more cycles may be required to measure the temperature at all the required points.

16.35 The test load should comprise the largest number of open-topped glass jars, nominally 12 cm high and 6 cm in diameter, which can be placed in the usable chamber space subject to the following conditions:

a. the shelves should be of the type provided for use with the sterilizer. The number of shelves should be the maximum that can be placed in the chamber such that the distances between the top of each layer of jars and the surface above (shelf or roof of chamber) is not less than 3 cm. For the purposes of this test, it is permissible to arrange the shelves on temporary supports;

b. on each shelf the number of jars should be the maximum that can be placed in rows parallel to and at right angles to the front of the chamber with at least 1 cm separating jars in adjacent rows.

16.36 Place 100 ml of a suitable heat-stable, non-volatile liquid in each of the four jars at the corners of each shelf and in the jar nearest to the centre of each shelf. The remaining jars should be empty. Suitable liquids for this purpose are silicone oils which remain liquid under the conditions of the test. Alternative liquids may be used providing they have a similar thermal behaviour.

16.37 Place temperature sensors in the following positions:

a. one (sensor A) in thermal contact with the sensor connected to the chamber temperature recorder;

b. one (sensor B) in thermal contact with the sensor connected to the chamber temperature indicator;

c. one in the centre of the liquid in each of the jars.

16.38 Select a sterilization temperature of 160°C. Adjust the timer to give a holding time of at least 2½h (this is longer than the recommended minimum). Start the cycle.

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16.39 At the end of the cycle, examine the recording of the chamber temperature measured by sensor A:

a. determine the mean temperature during the first 30 min of the holding time. If the temperature at any time before the start of the holding time is higher than this mean, the difference between the maximum temperature attained and this mean is the overheat;

b. determine the mean temperature during a 30-min period commencing 120 min after the start of the holding time. The difference between this mean and the mean determined for the start of the holding time is the temperature drift during a 2h period.

16.40 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 16.7) are met;

b. the temperature overheat does not exceed 2°C;

c. the holding time determined from the measured temperatures is not less than that specified in Table 8;

d. during the holding time:

(i) the measured temperatures are within the appropriate sterilization temperature band specified in Table 8;

(ii) the recorded chamber temperature is within 1°C of the temperature measured by sensor A;

(iii) the indicated chamber temperature is within 1°C of the temperature measured by sensor B;

(iv) the temperatures measured by each sensor in the load are within 5°C of the temperature measured by sensor A;

(v) the temperature measured by sensor A does not drift by more than 2°C over a 2-h period;

(vi) the temperature measured by sensor A does not fluctuate by more than 1°C;

e. the total cycle time is within the performance class stated by the manufacturer.

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17. LTS disinfectors and LTSF sterilizers

Introduction

17.1 This chapter contains detailed procedures for tests specific to machines designed to process loads by exposure to low-temperature steam (LTS disinfectors) or low-temperature steam and formaldehyde (LTSF sterilizers). Schedules, prescribing which tests are to be carried out and when, are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests).

17.2 Machines are usually designed for both LTS and LTSF. These processes have similar characteristics and a machine incapable of meeting the LTS requirements will not normally meet the LTSF requirements. Note that some LTSF machines expose the load to a series of pulses of sterilant rather than a continuous holding time.

17.3 Attention is drawn to the safety Information presented in Chapter 1 and the detailed safety precautions discussed in Part 4.

Chamber overheat cut-out test

17.4 This test is designed to show that the overheat cut-out mechanisms for the chamber and jacket will prevent the temperature of the chamber walls and free space from exceeding 80°C. Where two temperature control mechanisms are fitted (for the jacket and the chamber) the test should be done twice, with each mechanism inactivated alternately.

17.5 Temperatures should be recorded by independent measuring equipment as described in Chapter 6. If an LTSF sterilizer is being tested, the LTS cycle should be selected. If an LTS cycle is not available, the primary material for generating formaldehyde should be replaced with an inert substitute (see paragraph 1.29). The chamber should be empty except for the usual chamber furniture.

17.6 Place 12 temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. five on each of the two chamber side walls (one at the approximate centre and four adjacent to the corner positions of the usable chamber space);

c. one on the plane of the usable chamber space (not on the wall) at a point nearest to the steam inlet port.

17.7 Inactivate the chamber or jacket temperature control in accordance with the manufacturer's instructions.

17.8 Select and start the LTS operating cycle.

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17.9 The test should be considered satisfactory if the following requirements are met:

a. the cut-out device operates and causes the heat source to be isolated from the machine and the operating cycle to advance to the drying stage;

b. none of the measured temperatures exceeds 80°C;

c. at the end of the cycle the door remains locked and a fault is indicated.

Chamber wall temperature test

17.10 This test is designed to show that the air removal stage will not start until the chamber walls are heated to within 2°C of the selected operating temperature. If an LTSF sterilizer is being tested, the LTS cycle should be selected. If an LTS cycle is not available, the primary material for generating formaldehyde should be replaced with an inert substitute (see paragraph 1.29).

17.11 Temperatures should be recorded by independent measuring equipment as described in Chapter 6. The chamber should be empty except for the usual chamber furniture.

17.12 Place 12 temperature sensors in the positions described for the chamber overheat cut-out test (see paragraph 17.6).

17.13 Select and start the LTS operating cycle.

17.14 The test should be considered satisfactory if the following requirements are met:

a. the air removal stage of the operating cycle does not start until the temperatures measured by the 10 sensors attached to the chamber side walls are within 2°C of the selected operating temperature;

b. after the first 5 min of the holding time all the temperatures measured in the chamber are within –0°C + 5°C of the temperature measured in the active chamber discharge.

Thermometric test for a small load

17.15 If an LTV sterilizer is being tested, the LTS cycle should be selected. If an LTS cycle is not available, the primary material for generating formaldehyde should be replaced with an inert substitute (see paragraph 1.29).

17.16 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

17.17 Place a standard test pack (see paragraph 7.27) in the chamber with the bottom of the pack supported 100-200 mm above the centre of the chamber base.

17.18 Place three temperature sensors in the following positions:

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a. one in an active chamber discharge (see paragraph 6.26);

b. one at the approximate centre of the test pack (the wire from the sensor should be carefully arranged to prevent steam tracking along it);

c. one placed 50 ± 5 mm above the approximate centre of the upper surface of the test pack.

17.19 Connect a pressure recorder (or test gauge) to the chamber.

17.20 Select the LTS cycle. Ensure that the process temperature is set to 73°C (corresponding to a sterilization temperature of 71°C). Start the cycle.

17.21 If a test gauge is being used, measure and note the chamber pressure at the approximate mid-point of the holding time.

17.22 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. the holding time, determined from the measured temperatures, is not less than that specified in Table 8;

c. during the holding time:

(i) the measured temperatures are within the temperature band specified in Table 8;

(ii) the temperature measured above the test pack is within 4°C of the temperature measured in the active chamber discharge;

(iii) the temperature measured in the centre of the test pack is within 2°C of the temperature measured in the active chamber discharge;

(iv) the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge;

(v) the indicated and recorded chamber pressures are within 0.05 bar of the measured pressure;

d. for sterilizers using vacuum as the sole method of drying:

(i) the duration of the drying stage is not less than 3 min;

(ii) the chamber pressure at the end of the stage does not exceed 50 mbar absolute;

e. at the end of the cycle the sheets are sensibly dry.

Thermometric test for a full load

17.23 This test applies to LTS disinfection cycles only. It is not required when the machine is to be used solely with an LTSF sterilization cycle.

17.24 The load is made up of a standard test pack (see paragraph 7.27) and additional folded sheets designed to represent the maximum mass of textiles

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which may be processed in the machine, and is used to demonstrate that, at the levels at which cycle variables are set, rapid and even penetration of steam into the centre of a load occurs and disinfecting conditions are achieved.

17.25 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

17.26 Place a standard test pack within the chamber in a position identified by the manufacturer as the most difficult to disinfect. This will normally be in the approximate centre of the chamber. Load the rest of the usable chamber space with stacks of sheets as described for porous load sterilizers (see paragraphs 13.17, 13.20).

17.27 Place three temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one at the approximate centre of the test pack (the wire from the sensor should be carefully arranged to prevent steam tracking along it);

c. one below the approximate centre of the top sheet of the test pack.

17.28 Connect a pressure recorder (or test gauge) to the chamber.

17.29 Ensure that the LTS operating cycle is set to an operating temperature of 73°C. Start the cycle.

17.30 If a test gauge is being used, measure and note the chamber pressure at the approximate mid-point of the holding time.

17.31 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. during the holding time:

(i) the measured temperatures are within the temperature band specified in Table 8;

(ii) the temperature measured in the centre of the test pack is within 2°C of the temperature measured in the active chamber discharge;

c. at the end of the test the sheets are sensibly dry;

d. the total cycle time is within the performance class stated by the manufacturer.

Environmental formaldehyde vapour test

17.32 This test is designed to determine the concentration of formaldehyde vapour discharged into the environment from the chamber and test load at the end of an LTSF cycle. A gas monitoring instrument is required as specified in paragraphs 6.54-56.

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17.33 Line two modular cardboard instrument trays (or similar), approximately 600 mm x 300 mm x 50 mm, with a 12- mm thickness of high-density, open-cell polyurethane foam.

17.34 Place two stainless steel rods, each 400 ± 2 mm long by 10 ± 0.5 mm in diameter, in each tray and fit the lids. If the trays are smaller than specified above, the rods may be 250 mm long.

17.35 Place the trays side by side in the centre of the chamber.

17.36 Select the LTSF operating cycle. Ensure that the concentration of formaldehyde used for the test is that to be used for the microbiological test for basic performance. Start the cycle.

17.37 At the end of the cycle, measure the concentration of formaldehyde gas discharged from the chamber when the door starts to open. The sample should be taken 80-120 mm in front of the gap at a height of 1.4-1.6 m. Continue to sample the gas for the next 15 min.

17.38 Determine the average concentration of gas over the 15-min period.

17.39 The test should be considered satisfactory if the atmospheric concentration of formaldehyde gas over the 15-min period does not exceed the short-term exposure limit specified in Table 1.

Microbiological test for basic performance

17.40 Since the efficacy of LTSF sterilization cannot be assured by the measurement of cycle variables, the only definitive performance test currently available for LTSF sterilizers is microbiological. This test is designed to demonstrate the distribution and penetration of formaldehyde gas within the chamber. Chemical indicators are used to give an early indication of the efficacy of gas penetration but by themselves are not sufficient to validate the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators.

17.41 Place 27 inoculated carriers in the chamber arranged on fine thread to the pattern shown in Figure 16. (If the usable chamber space is less than 200 l fewer carriers may be used. The authorised person will advise on this.) Place a chemical indicator alongside each of the inoculated carriers.

17.42 Place an inoculated carrier and a chemical indicator in each of four Line-Pickerill helices (see paragraph 7.51). Double-wrap two of the helices in paper bags (that is, bag in bag) conforming to BS 6257.

17.43 Place the wrapped helices in diametrically opposite corners of the sterilizer chamber; one in the upper rear of the usable chamber space, and the other in the lower front. Place one unwrapped helix in the front half of the usable chamber space and one in the rear half. All these positions are shown in Figure 16.

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17.44 Ensure that the cycle variables are set to the values specified by the manufacturer. The concentration of formaldehyde is normally 15 g m^{-3} of chamber volume per pulse which can be achieved by the vaporisation of 40 ml of formal in per cubic metre of chamber volume. Start the operating cycle.

17.45 At the end of the cycle, remove the inoculated carriers and chemical indicators from the chamber and the helices. Check that the chemical indicators show a uniform colour change. If so, place each of the inoculated carriers in a bottle of recovery medium, and incubate them with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-75).

17.46 If the chemical indicators do not show a uniform colour change, then the test should be abandoned.

17.47 The test should be considered satisfactory if the requirements given in paragraph 7.72 are met.

17.48 The test should be performed two more times to ensure that similar results are obtained.

17.49 The test should be reported in the format shown in Figure 17.

Microbiological test for performance qualification

17.50 This test is designed to follow a thermometric test for performance qualification. The loading condition and operating cycle should be identical. Chemical indicators are used to give an early indication of the efficacy of gas penetration but by themselves are not sufficient to validate the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators.

17.51 Put an inoculated carrier and a chemical indicator together in each of the six load items that carried temperature sensors in the thermometric test. Place the items in as nearly as possible in the same positions they occupied in the thermometric test. Put a biological indicator and a chemical indicator together in a Line-Pickerell helix (see paragraph 7.51) and place the helix in a position known to be the most difficult to sterilize (normally the coolest part of the chamber).

17.52 Select and start the operating cycle.

17.53 Ensure that a batch process record is made by the recording instrument fitted to the sterilizer.

17.54 At the approximate mid-point of the plateau period, note the elapsed time and indicated chamber temperature and pressure.

17.55 At the end of the cycle, remove the indicators from the load items and the helix. Check that the chemical indicators show a uniform colour change. If so, place each of the inoculated carriers in a bottle of recovery medium and incubate

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them with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-75).

17.56 If the chemical indicators do not show a uniform colour change, then the test should be abandoned.

17.57 The test should be considered satisfactory if the following requirements are met:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during the thermometric PQ test;

b. the requirements for microbiological tests set out in paragraph 7.72 are met.

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Figure 16: Layout of indicators for the microbiological test for basic performance (LTSF)

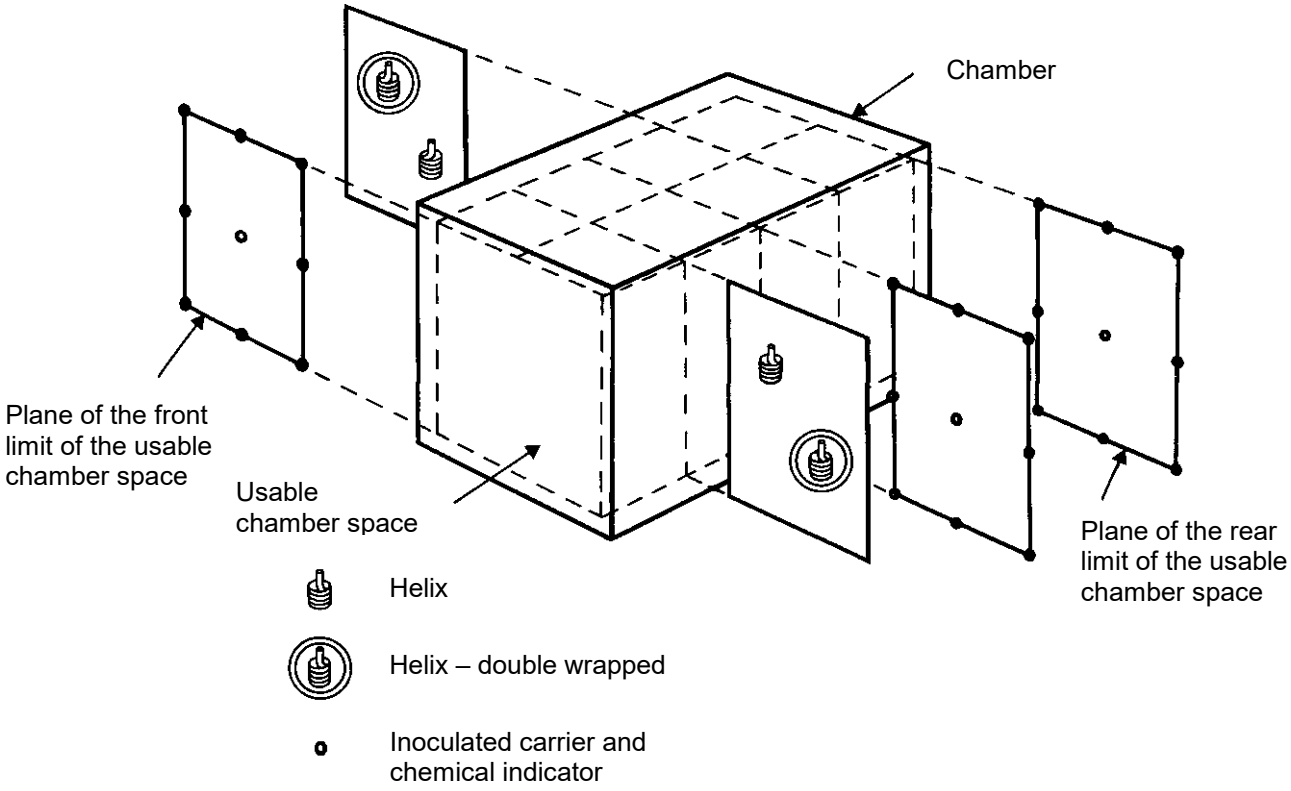

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Figure 17: Report of microbiological test for basic performance (LTSF)

LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER
REPORT OF MICROBIOLOGICAL TEST FOR BASIC PERFORMANCE

Automatic controller settings for plateau: Temperature_____°C Time_____ mins_____ s
Primary material for generating formaldehyde_____ batch no._____ Expiry date_____
Mass of primary material used in the cycle: Setting_____ gram Measured_____ gram
CHEMICAL INDICATORS: Manufacturer _____ Batch no _____ Expiry date_____
BIOLOGICAL INDICATORS: Manufacturer _____ organism _____ Strain _____
Manufacturer's declared number of recoverable spores on each indicator_____
Batch no. _____ Expiry date_____

LOCATION OF CHEMICAL AND BIOLOGICAL INDICATORS

Location	No	Chemical	Biological	No	Chemical	Biological	No	Chemical	Biological
Rear plane	1	Pass/Fail	Pass/Fail	2	Pass/Fail	Pass/Fail	3	Pass/Fail	Pass/Fail
	4	Pass/Fail	Pass/Fail	5	Pass/Fail	Pass/Fail	6	Pass/Fail	Pass/Fail
	7	Pass/Fail	Pass/Fail	8	Pass/Fail	Pass/Fail	9	Pass/Fail	Pass/Fail
Centre plane	10	Pass/Fail	Pass/Fail	11	Pass/Fail	Pass/Fail	12	Pass/Fail	Pass/Fail
	13	Pass/Fail	Pass/Fail	14	Pass/Fail	Pass/Fail	15	Pass/Fail	Pass/Fail
	16	Pass/Fail	Pass/Fail	17	Pass/Fail	Pass/Fail	18	Pass/Fail	Pass/Fail
Front plane	19	Pass/Fail	Pass/Fail	20	Pass/Fail	Pass/Fail	21	Pass/Fail	Pass/Fail
	22	Pass/Fail	Pass/Fail	23	Pass/Fail	Pass/Fail	24	Pass/Fail	Pass/Fail
	25	Pass/Fail	Pass/Fail	26	Pass/Fail	Pass/Fail	27	Pass/Fail	Pass/Fail
Line Pickerell helices:		Wrapped		1	Pass/Fail	Pass/Fail	2	Pass/Fail	Pass/Fail
		Unwrapped		3	Pass/Fail	Pass/Fail	4	Pass/Fail	Pass/Fail

BIOLOGICAL CONTROLS

Unexposed BI	1	Growth/No Growth	2	Growth/No Growth	3	Growth/No Growth
No BI	4	Growth/No Growth	5	Growth/No Growth	6	Growth/No Growth

Test Person: Name _____ Signature _____ Date_____
Microbiologist: Name _____ Signature _____ Date_____

Routine microbiological test

17.58 A routine microbiological test is required for every production load. Chemical indicators are used to give an early indication of the efficacy of gas penetration but by themselves are not sufficient to monitor the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators. Conditions under which the load may be released as sterile are discussed in Part 4.

17.59 Place an inoculated carrier and a chemical indicator in a Line-Pickerill helix (see paragraph 7.51). Double-wrap the helix in paper bags (that is, bag in bag) conforming to BS 6257. Put it in the chamber with the normal production load.

17.60 Select and start the operating cycle.

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17.61 At the end of the cycle, remove the inoculated carrier and chemical indicator from the helix. Check that the chemical indicator shows a uniform colour change. If so, place the inoculated carrier in a bottle of recovery medium and incubate it with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-75).

17.62 If the chemical indicator does not show a uniform colour change, then the test should be abandoned.

17.63 The test should be considered satisfactory if the requirements for microbiological tests set out in paragraph 7.72 are met.

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18. Ethylene oxide sterilizers

Introduction

18.1 This chapter contains detailed procedures for tests specific to sterilizers designed to process loads by exposure to ethylene oxide gas (EO). Schedules, prescribing which tests are to be carried out and when, are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests).

18.2 Attention is drawn to the safety information presented in Chapter 1 and the detailed safety precautions discussed in Part 4.

18.3 Humidity is the most critical cycle variable in EO sterilization but also the most difficult to measure and control. In several of these tests it is necessary to determine the humidity in the sterilizer chamber during the conditioning stage. The ideal method is to use humidity sensors calibrated for RH (see paragraphs 6.47-50), but if these are not available the RH should be calculated using the method given in Appendix 2. Because of the large errors in both methods, and the variation within the chamber, the new EN permits a relatively broad range of 40-85% RH and that is the value given here. Users should aim, however, to attain an ideal true value of 50-60% RH to ensure that no part of the chamber is allowed to reach the dangerous extremes of <30% RH or >95% RH.

Chamber overheat cut-out test

18.4 This test is designed to show that the overheat cut-out mechanisms for the chamber and jacket will prevent the temperature of the chamber free space from exceeding the gas exposure temperature by more than 6°C. Where cycles with different gas exposure temperatures are available, the test should be done for each cycle. Where two temperature control mechanisms are fitted (for the jacket and the chamber) the test should be done with each mechanism inactivated alternately.

18.5 The dimensions of the usable chamber space need to be known for this test. The space is assumed to be a rectangular box. If the usable chamber space is cylindrical, the planes referred to below are those of the smallest box that can contain it (see Figure 18).

18.6 Temperatures should be recorded by independent measuring equipment as described in Chapter 6. The chamber should be empty except for the usual chamber furniture. EO gas should be replaced with an inert substitute (see paragraph 1.29).

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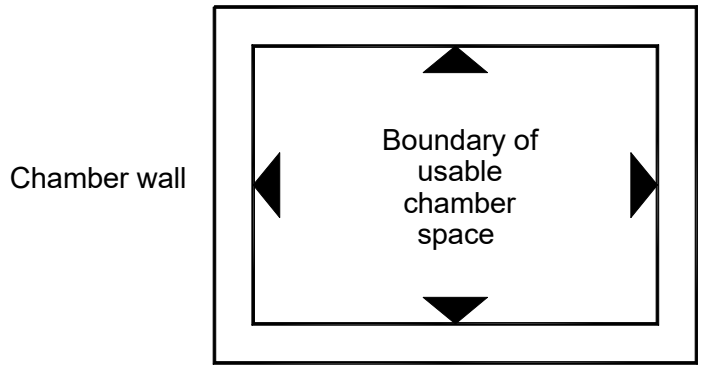
18.7 Place 12 temperature sensors in the following positions:

a. one in thermal contact with the sensor connected to the temperature recorder fitted to the sterilizer;

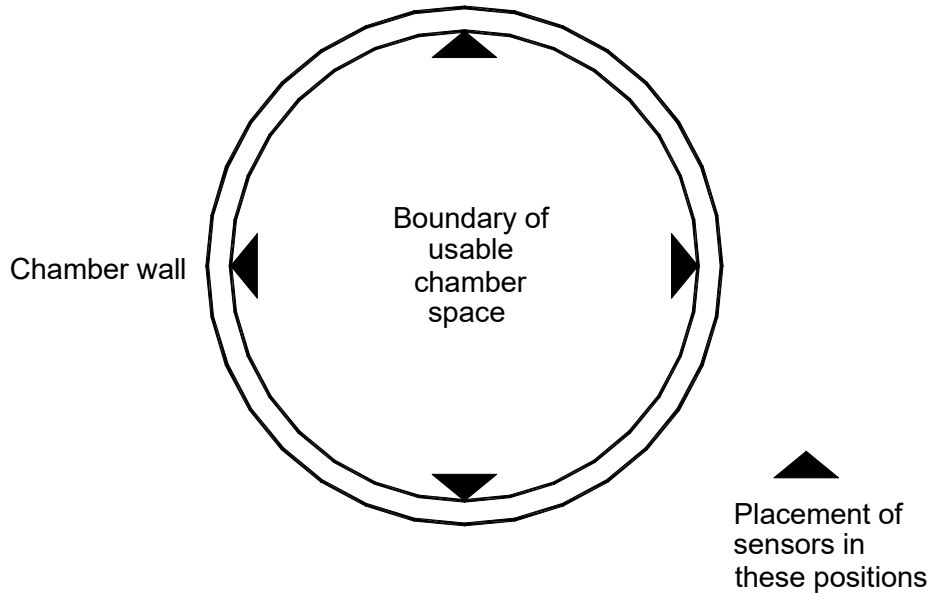
b. two on each of the planes of the usable chamber space, excluding doors (one at the approximate centre of the plane and one in a position known to be the hottest);

c. one on the plane of the usable chamber space at a point nearest to the steam inlet port.

Figure 18: Location of sensors for EO chamber overheat cut-out and chamber space temperature test



(a) Rectangular chamber



(b) Cylindrical chamber

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18.8 Inactivate the chamber or jacket temperature control in accordance with the manufacturer's instructions.

18.9 Select and start the operating cycle.

18.10 The test should be considered satisfactory if the following requirements are met:

a. the cut-out device operates and causes the heat source to be isolated from the machine and the operating cycle to advance to the gas removal stage;

b. none of the measured temperatures exceeds the preset gas exposure temperature by more than 6°C;

c. at the end of the cycle a fault is indicated.

Chamber space temperature test

18.11 This test is designed to show that the temperature of the chamber free space is within 2°C of the preset gas exposure temperature at the start of the gas exposure stage.

18.12 Temperatures should be recorded by independent measuring equipment as described in Chapter 6. The chamber should be empty except for the usual chamber furniture. EO gas should be replaced by an inert substitute (see paragraph 1.29).

18.13 Place 12 temperature sensors in the positions described for the chamber overheat cut-out test (see paragraph 18.7).

18.14 Select and start the operating cycle.

18.15 The test should be considered satisfactory if the following requirements are met:

a. at the start of the gas exposure stage the measured temperatures are within 2°C of the preset gas exposure temperature;

b. after the first 5 min of the gas exposure stage the temperatures measured in the chamber are within 2°C of the temperature measured by the sensor adjacent to the temperature recorder sensor.

Chamber wall temperature test

18.16 Temperatures should be recorded by independent measuring equipment as described in Chapter 6. The chamber should be empty except for the usual chamber furniture. EO gas should be replaced by an inert substitute (see paragraph 1.29).

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18.17 Place 12 temperature sensors in the following positions:

a. one in thermal contact with the sensor connected to the temperature recorder fitted to the sterilizer;

b. two on each of the chamber surfaces, excluding doors (one at the centre of the surface and one in a position known to be the hottest);

c. one on the plane (not on the wall) of the usable chamber space at a point nearest to the steam inlet port.

18.18 Select and start the operating cycle.

18.19 The test should be considered satisfactory if, after the first 5 min of the gas exposure stage, the temperatures measured in the chamber are within 5°C of the temperature measured by the sensor adjacent to the temperature recorder sensor.

Microbiological test for gas exposure time

18.20 Since the efficacy of EO sterilization cannot be assured by the measurement of cycle variables, the only definitive performance test currently available for EO sterilizers is microbiological. This test is designed to demonstrate the penetration of EO gas within the chamber and to determine the duration of the gas exposure stage for routine production. Chemical indicators are used to give an early indication of the efficacy of gas penetration but by themselves are not sufficient to validate the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators.

18.21 During the conditioning stage it will be necessary to determine the relative humidity in the chamber. Humidity may be indicated or recorded by the instrument fitted to the sterilizer, calculated (Appendix 2) or referenced to a test in which an identical loading condition has been tested with an inert gas.

18.22 Place an inoculated carrier and a chemical indicator in each of four Line-Pickerill helices (see paragraph 7.51). Triple-wrap the helices in paper bags (that is, bag in bag in bag) conforming to BS 6257. Seal the bags and allow them to equilibrate in an environment of 20 ± 5°C and 60 ± 20% RH for at least one hour.

18.23 Place two helices towards the front of the usable chamber space and two towards the rear, in positions known to be the slowest to attain the gas exposure temperature.

18.24 Select the operating cycle. The EO concentration in the chamber will normally be 250-1000 mg l^{-1}. The duration of the gas exposure stage should be considerably less than one-third of that anticipated for routine production, and insufficient to inactivate all the biological indicators. The authorised person will advise on what this period should be. Start the cycle.

18.25 At the end of the cycle remove the inoculated carriers and chemical indicators from the helices.

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18.26 Repeat the cycle several times with fresh inoculated carriers and chemical indicators and the gas exposure time increased in each cycle. The gas exposure time for the final cycle should be sufficient to inactivate all the inoculated carriers. The behaviour of the chemical indicators may be used to estimate when this time is attained. The authorised person will advise on how many cycles are required and the time increment for each one.

18.27 Place each of the inoculated carriers in a bottle of recovery medium and incubate them with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-7.75).

18.28 The test should be considered satisfactory if the following requirements are met:

a. at the end of the conditioning stage of each cycle the humidity in the chamber is in the range 40-85% RH (see paragraph 18.3);

b. at the end of the incubation period:

   (i) one or more of the bottles with inoculated carriers exposed to the EO process shows growth for the shortest gas exposure time, but none shows growth for the longest gas exposure time;

   (ii) control bottles with no inoculated carrier show no growth;

c. control bottles with unexposed inoculated carriers show growth within 24 h.

18.29 Note the shortest gas exposure time for which no growth is observed. Perform the test for a further two cycles at this exposure time. If all three cycles are satisfactory, the gas exposure time determined by this procedure (the critical gas exposure time) should be regarded as one-third of the minimum time required for production loads representing less of a challenge than the load used in this test.

Microbiological test for basic performance

18.30 This test is designed to demonstrate the penetration of EO gas within the chamber and confirm the duration of the gas exposure stage for routine production. Chemical indicators are used to give an early indication of the efficacy of gas penetration, but by themselves are not sufficient to validate the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators.

18.31 Prepare and position four Line-Pickerell helices as described in the microbiological test for gas exposure time (see paragraphs 18.22-18.23).

18.32 Select the operating cycle. Set the duration of the gas exposure stage to the critical gas exposure time determined during commissioning (see paragraph 18.29). Start the cycle.

18.33 At the end of the cycle remove the inoculated carriers and chemical indicators from the helices. Examine the chemical indicators and check whether they

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show a uniform colour change. If so, place each inoculated carrier in a bottle of recovery medium and incubate them with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-7.75).

18.34 If the chemical indicators do not show a uniform colour change, then the test should be abandoned.

18.35 The test should be considered satisfactory if the following requirements are met:

a. at the end of the conditioning stage the humidity in the chamber is in the range 40-85% RH (see paragraph 18.3);

b. the requirements for microbiological tests set out in paragraph 7.72 are met.

Thermometric test for performance qualification

18.36 The load used for this test should be one of the production loads processed in the sterilizer. To serve as a reference load it should present to the process the greatest challenge on the basis of moisture absorbency, gas absorbency and the attainment of the gas exposure temperature throughout the load. If the load presents a greater challenge than the test load used in the microbiological test for basic performance, then that test will need to be repeated with the new load in order to confirm the gas exposure time.

18.37 Table 11 indicates the information that will need to be noted for the PQ report. See Chapter 8 for general Information about PQ tests and reports.

18.38 Temperatures, pressures and humidities should be recorded by independent measuring equipment as described in Chapter 6. If humidity sensors are not available, humidity should be calculated as described in Appendix 2. EO gas should be replaced with an inert substitute (see paragraph 1.29).

18.39 Package each item of the load in accordance with the procedure to be used for routine production. Note the type of load and method of packaging.

18.40 Ensure that the preconditioning procedure is identical to that which will be used for production. This should normally be for at least 1 h in an environment having a temperature of 15-25°C and a humidity of 40-85% RH.

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18.41 Place 12 temperature sensors in the following positions:

a. one in thermal contact with the sensor connected to the chamber temperature recorder fitted to the sterilizer (sensor A);
b. one in the gas entry port to the chamber;
c. one in the primary heat source to the gas preheater (if fitted);
d. one in each of five load items known to be the slowest to attain the gas exposure temperature and placed in the coolest part of the chamber;
e. one in a load item in the hottest part of the chamber;
f. one in the coolest part of the chamber free space;
g. one on the hottest part of the chamber;
h. one on the coolest part of the chamber surface.

18.42 If available, place two humidity sensors in the following positions:

a. one alongside the temperature sensor in the load item in the hottest part of the chamber (see paragraph 18.41 (e));
b. one alongside the temperature sensor in the coolest part of the chamber free space (see paragraph 18.41(f)).

18.43 Connect a pressure recorder (or test gauge) to the chamber.

18.44 Select the operating cycle that will be used for the production load. The cycle variables should be set as determined in the microbiological test for gas exposure time, although the duration of the flushing stage may need to be adjusted to satisfy the requirements of the environmental gas test (see paragraph 8.37) and the test for degassing time (see paragraph 8.46). Start the cycle.

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Table 11: Performance qualification data for EO sterilizers

The PQ report for EO sterilizers should include the values and permitted tolerances of the following variables:

1 ***preconditioning*** (in separate areas, if used):

a. time, temperature and humidity;

b. minimum temperature of product permitted to enter preconditioning;

c. maximum elapsed time between removal of the load from preconditioning and the start of the conditioning stage of the operating cycle.

2 ***conditioning*** (in sterilizer chamber):

a. temperature and humidity in the chamber and within the load at the beginning and end of the conditioning stage;

b. if the humidity indicator or recorder is not fitted to the sterilizer, the critical parameters necessary for the attainment of the specified humidity of the load – the parameters chosen will depend on the method used to humidify the load.

3 ***sterilization****:*

a. chamber pressure;

b. chamber temperature;

c. gas exposure time;

d. temperature of the load;

e. EO concentration, estimated from pressure change (see Appendix 2) or (exeptionally) by direct analysis of chamber atmosphere.

4 ***flushing*** (in sterilizer chamber):

a. time, temperature and pressure changes;

b. rate of change of air or other gas;

c. temperature of the load.

5 ***degassing*** (in separate aeration cabinet and/or room):

a. time, temperature and pressure changes;

b. rate of change of air or other gas;

c. temperature of the load.

18.45 Ensure that a batch process record is made by the recording instrument fitted to the sterilizer. This will serve as the basis for a master process record (see paragraph 8.58) for the loading condition under test.

18.46 At the end of the conditioning stage, note the readings from the humidity sensors, including the sterilizer humidity indicator (if fitted).

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18.47 At the approximate mid-point of the gas exposure stage, note the elapsed time and the indicated chamber temperature and pressure.

18.48 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. after the first 5 min of the gas exposure time the temperatures measured on the chamber walls are within 5°C of the temperature measured by sensor A;

c. after the first 5 min of the gas exposure time, and until its end, all the measured temperatures, except in the gas pre-heater and on the chamber walls, are within 2°C of the temperature measured by sensor A;

d. at the end-of the conditioning stage:

(i) the humidity is in the range 40-85% RH (see paragraph 18.3);

(ii) the difference between the two RH measurements (if made) does not exceed 20% RH;

(iii) the reading on the sterilizer humidity indicator (if fitted) is not less than 40% RH;

e. after the first 15 min of the gas exposure time, and until its end, the peak-to-peak variation in the measured chamber pressure does not exceed 20% for cylinder systems and 25% for cartridge systems;

f. for cylinder systems, throughout the cycle the temperature measured in the primary heat source to the gas pre-heaters does not exceed 70°C.

Microbiological test for performance qualification

18.49 This test is designed to follow a thermometric test for performance qualification. The loading condition, preconditioning process and operating cycle should be identical. Chemical indicators are used to give an early indication of the efficacy of gas penetration but by themselves are not sufficient to validate the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators.

18.50 Assemble 20 biological indicators and 20 chemical indicators to form 20 biological-chemical indicator pairs. Place them in the following positions:

a. one pair in each of the six load items which carried temperature sensors in the thermometric test (see paragraphs 19.41 (d), (e));

b. 14 pairs distributed throughout the remaining load items.

18.51 Select the operating cycle used in the thermometric test. The concentration of EO used for the test should be the same as will be used for production cycles. This is normally 250-1000 mg l^{-1}. Start the cycle.

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18.52 Ensure that a batch process record is made by the recording instrument fitted to the sterilizer.

18.53 At the end of the conditioning stage, note the indicated chamber temperature, pressure and humidity. Where a humidity instrument is not fitted, RH may be assumed to be the same as that determined during the thermometric test provided that all the cycle variables are identical within the permitted tolerances.

18.54 At the approximate mid-point of the gas exposure stage, note the elapsed time and the indicated chamber temperature, pressure and humidity.

18.55 At the end of the cycle, remove the indicators from the load items. Check whether the chemical indicators show a uniform colour change. If so, place each of the inoculated carriers in a bottle of recovery medium and incubate them with controls as described in the general procedure for microbiological tests (see paragraphs 7.63-7.75).

18.56 If the chemical indicators do not show a uniform colour change, then the test should be abandoned.

18.57 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;
b. the humidity values at the end of the conditioning stage, whether indicated, measured or calculated, are consistent with those obtained during the thermometric test;
c. the requirements for microbiological tests set out in paragraph 7.72 are met.

Routine microbiological test

18.58 A routine microbiological test is required for every production load. Chemical indicators are used to give an early indication of the efficacy of gas penetration but by themselves are not sufficient to monitor the sterilization process. See Chapter 7 for advice on the use of biological and chemical indicators. Conditions under which the load may be released as sterile are discussed in Part 4.

18.59 Assemble ten biological indicators and ten chemical indicators to form ten biological-chemical indicator pairs. Distribute the pairs evenly in the spaces between the load items.

18.60 Select and start the operating cycle.

18.61 At the end of the cycle, remove the indicators from the load. Check that the chemical indicators show a uniform colour change. If so, place each of the inoculated carriers in a bottle of recovery medium and incubate them with

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controls as described in the general procedure for microbiological tests given in Chapter 7.

18.62 If the chemical indicators do not show a uniform colour change, then the test should be abandoned.

18.63 The test should be considered satisfactory if the requirements for microbiological tests set out in paragraph 7.72 are met.

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19. Laboratory sterilizers

Introduction

19.1 This chapter contains detailed procedures for tests specific to laboratory sterilizers. Schedules, prescribing which tests are to be carried out and when, are set out in Chapter 4 (for validation tests) and Chapter 5 (for periodic tests). The tests in this chapter apply to laboratory sterilizers equipped with one or more of the following operating cycles:

a. make-safe of small plastic discard;

b. make-safe of contained fluid discard;

c. sterilization of culture media (preset or variable cycle);

d. disinfection of fabrics (see paragraph 13.7 for the small-load test);

e. sterilization of glassware and equipment;

f. free steaming;

g. culture media preparator.

19.2 Attention is drawn to the safety information presented in Chapter 1 and the detailed safety precautions discussed in Part 4.

19.3 Unless specified otherwise, all the tests should be performed at each of the sterilization temperatures available on the sterilizer.

Make-safe of small plastic discard

19.4 These tests apply to laboratory sterilizers with an operating cycle designed to make-safe plastic discard material where no one item contains more than 50 ml of aqueous fluid.

19.5 If by agreement with the laboratory safety officer, the user authorises the use of the sterilizer with the thermal door-lock override selected, then these tests should be conducted both with and without the override selected.

NOTE: Information about Hazard Groups may be found in the HSC document Categorisation of pathogens according to hazard and categories of containment (4th edition, 1995) compiled by the Advisory Committee on Dangerous Pathogens.

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19.6 Containers should be held in the discard boxes recommended by the manufacturer. Discard boxes holding containers into which temperature sensors are to be inserted should not contain infected material. Material infected with Hazard Group 2 organisms may be used to make up other boxes in the test load. At no time should any material known to contain Hazard Group 3 or 4 organisms be used.

Thermometric test for a full load

19.7 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

19.8 Prepare sufficient Petri dishes to fill two discard boxes when the dishes are stacked vertically. Each dish should contain approximately 15ml of agar gel.

19.9 Place one temperature sensor in the centre of each of six of the dishes. Put three of these test dishes in each box: one in the centre of the box, one one-third from the bottom and one one-third from the top, supported by the remaining dishes. If only one box will fit in the chamber, put all six test dishes in the box, two at each position.

19.10 Put the two test boxes in opposite corners of the chamber. Load the remaining chamber space with boxes filled with discard material such that the spacing between boxes is in accordance with the minimum recommended by the manufacturer.

19.11 Place a further five temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one in the chamber, alongside the sensing element of the load temperature probe, if it is fitted (the probe should be stowed on its bracket);

c. one in the centre of the free space between the bottom of each test box and its trivet (if fitted). (If the box does not have a trivet, the sensor should be placed in the free space between Petri dishes 15 mm above the centre of the bottom of the box);

d. one in the chamber free space.

19.12 Connect a pressure recorder (or test gauge) to the chamber.

19.13 Select and start the operating cycle.

19.14 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

19.15 The test should be considered satisfactory if the requirements listed in Table 12 are met, and the drain is not blocked with agar.

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Thermometric test for a small load

19.16 This test is not required if the sterilizer is designed to accommodate only one discard box. Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

19.17 Load the chamber with a single discard box filled with Petri dishes as described in the full-load test, with three temperature sensors located in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one in the centre of a dish located one-third from the bottom of the box;

c. one in the centre of a dish located in the approximate centre of the box.

19.18 Follow the procedure for the full-load test.

19.19 The test should be considered satisfactory if all but the cycle time condition of the requirements for the full-load test are met.

Cycles for fluid loads

19.20 These tests apply to laboratory sterilizers with cycles designed to process fluid discard in glass containers and large plastic containers (>50 ml), culture media (preset or variable cycles) and for free steaming.

19.21 Bottles into which temperature sensors are inserted should contain a solution of 10-15g of agar powder dissolved in 1000 ml of distilled water. Other bottles in the loads should be filled with water or water-based culture medium.

19.22 All bottles should be filled to 80% of their nominal capacity. The volumes of the fluid in each bottle should not vary from their mean by more than 5%. At the start of the cycle the temperature of the fluid in each bottle should be 20 ± 5°C and the media preparation in the liquid form.

19.23 The bottles may be either all sealed or all unsealed, according to the practice in the laboratory and the requirements of the schedules in Chapters 4 and 5. Sealed and unsealed bottles should not be mixed in the same load.

Thermometric test for a full load

19.24 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

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Table 12 General requirements for the full-load test (laboratory sterilizers)

The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (paragraph 12.13) are met;

b. the holding time, as determined from the measured temperatures, is not less than that specified for the appropriate sterilization temperature band listed in Table 12;

c. during the holding time:

   (i) the measured temperatures are within the appropriate sterilization temperature band listed in Table 12;

   (ii) except for discard cycles, the measured temperatures are within 1°C of each other;

   (iii) the indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active chamber discharge;

   (iv) the indicated and recorded chamber pressures are within 0.05 bar of the measured chamber pressure;

   (v) the measured chamber pressure is within 0.05 bar of saturated steam pressure or, if a partial pressure system is used, as specified by the manufacturer;

d. at the end of the cycle:

   (i) the temperature sensors have remained in position;

   (ii) items holding sensors remain intact;

   (iii) not more than one of the other items (or 1%, whichever is the greater) has burst or broken;

   (iv) the temperature measured in any fluid containers is not greater than 90°C (plastic) or 80°C (glass);

e. the total cycle time is within the performance class stated by the manufacturer.

19.25 Fill nine one-litre bottles with the test liquid as described in paragraph 19.21. Insert a temperature sensor into each one, ensuring that the tops are sealed or unsealed as required. Unsealed bottles should be capped loosely to prevent coolant water entering the bottle.

19.26 If unsealed bottles are used, weigh each of them and note their masses (M_1) to an accuracy of 1g.

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19.27 Place three of the bottles in positions known to be the slowest to attain the sterilization temperature, three in positions known to be the fastest to attain the sterilization temperature, and three in positions known to be the slowest to cool to 80°C.

19.28 Load the remaining chamber space with one-litre bottles, filled either with water or a water-based medium, at the minimum spacing recommended by the manufacturer.

19.29 Place a further temperature sensor in an active chamber discharge (see paragraph 6.26).

19.30 Connect a pressure recorder (or test gauge) to the chamber.

19.31 Select the operating cycle:

a. if a variable culture media cycle is being tested, set the sterilization temperature to 121°C with a minimum holding time of 15 min;

b. if a free steaming cycle is being tested, set the load temperature to 95-98°C for a minimum of 15 min.

19.32 Start the cycle.

19.33 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

19.34 As soon as the cycle is complete, and before opening the door, observe and note the measured temperatures in the bottles.

19.35 Within 5 min of the end of the cycle, weigh any unsealed test bottles again and note their masses (M_2). For each bottle, calculate the percentage loss in mass from:

$$percentage\ \ loss\ in\ mass = 100 \times \frac{(M_1 - M_2)}{M_1}$$

19.36 The test should be considered satisfactory if the requirements listed in Table 12 are met and the loss of fluid in any unsealed bottles does not exceed 2% by mass.

Thermometric test for a small load

19.37 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

19.38 Fill nine 5-ml bijou bottles with 4 ml of test liquid as described in paragraph 19.21. Insert a temperature sensor into each one, ensuring that the tops are sealed.

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19.39 Distribute them among two wire baskets, one supported in the upper rear of the usable chamber space and the other in the lower front. Each should contain a total of 25 bijou bottles, so that three test bottles are in positions known to be the slowest to attain the sterilization temperature, three in positions known to be the fastest to attain the sterilization temperature, and three in positions known to be the slowest to cool to 80°C.

19.40 If the sterilizer is not designed to process bottles of this size, the smallest size and number of containers recommended by the sterilizer manufacturer should be used.

19.41 Where the sterilizer is to be used to process one size of container only, the test load may be a single container of this size, filled with the nominal volume of test liquid and supported in a position known to be the slowest to attain the sterilization temperature.

19.42 Place a further temperature sensor in an active chamber discharge (see paragraph 6.26).

19.43 Connect a pressure recorder (or test gauge) to the chamber.

19.44 Follow the procedure for the full-load test.

19.45 The test should be considered satisfactory if, except for the cycle time condition, the requirements listed in Table 12 are met.

Simplified thermometric test for performance requalification

19.46 This test is not a substitute for a full PRQ test, but is used quarterly to check that the sterilization conditions continue to be met. Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

19.47 Prepare a production load known to present the greatest challenge to the operating cycle and for which there is a PQ report. (This will normally be the reference load used in the yearly PRQ tests.) Place temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);

b. one in a container known to be the slowest to attain the sterilization temperature;

c. one in a container known to be slowest to cool to 80°C.

19.48 Place the load in the chamber as described in the PQ report.

19.49 Select the operating cycle as specified in the PQ report. Start the cycle.

19.50 The test should be considered satisfactory if the requirements listed in the PQ report are met.

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Sterilization of glassware and equipment

19.51 These tests apply to laboratory sterilizers with a cycle designed to sterilize empty glassware without caps and other non-porous equipment. If caps are fitted, air will not be removed, and the glassware should be classed as disinfected but not sterilized.

Thermometric test for a full load

19.52 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

19.53 Fill four discard boxes with empty glass bijou bottles, without caps, arranged randomly. Place two temperature sensors in each box, one inserted into an inverted bottle in the centre of the box and one in an inverted bottle one-third from the bottom.

19.54 Where the full load is less than four boxes, the maximum load which the sterilizer is designed to process should be used. The eight temperature sensors should be distributed within the load.

19.55 Put these test boxes in the chamber and load the remaining chamber space with boxes of bijou bottles at the minimum spacing recommended by the manufacturer.

19.56 Place three further temperature sensors in the following positions:

a. one in an active chamber discharge (see paragraph 6.26);
b. one in the chamber located alongside the load temperature probe (if fitted);
c. one in the upper chamber free space.

19.57 Connect a test pressure recorder (or a test gauge) to the chamber.

19.58 Select and start the operating cycle.

19.59 If a test gauge is being used, measure the chamber pressure at the approximate mid-point of the holding time.

19.60 The test should be considered satisfactory if the requirements listed in Table 12 are met, and the load is visibly dry.

Thermometric test for a small load

19.61 Fill one discard box with bijou bottles with sensors placed as described for the full-load test and put it in the chamber. Place a further sensor in an active chamber discharge.

19.62 Follow the procedure for the full-load test.

19.63 The test should be considered satisfactory if, except for the cycle time condition, the requirements listed for the full-load test are met.

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Thermal door-lock override test

19.64 A thermal door-lock is fitted to certain laboratory sterilizers to prevent the door from being opened until the temperature in the chamber and load falls below 80°C. The override is intended for use by trained persons who wish to gain access at temperatures above 80°C to loads which will not present an explosive hazard.

19.65 For this test the sterilizer chamber should be empty.

19.66 Select and start the operating cycle to be tested.

19.67 Attempt to select the thermal door-lock override during the heat-up, sterilization (holding time) and cooling stages.

19.68 The test should be considered satisfactory if the following requirements are met:

a. the override operates only during the cooling stage of the cycle and causes the cooling stage to terminate;
b. the override switch resets automatically when released;
c. the thermal door-lock override indicator is Illuminated;
d. at the end of the cycle the door cannot be opened except by means of a key, code or tool which is unique to the sterilizer.

19.69 Where the sterilizer is intended to be used exclusively for make-safe of discard in small containers, compliance with (b) and (d) may be waived by agreement with the laboratory safety officer. In this case, the switch should reset automatically whenever a different operating cycle is selected or whenever the power supply is interrupted.

Culture media preparator

19.70 For these tests, the sterilizer vessel should be filled with the test liquid described in paragraph 19.21 to the nominal capacity specified by the manufacturer.

Thermometric test for a full load

19.71 Temperatures and pressures should be recorded by independent measuring equipment as described in Chapter 6.

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19.72 Place two temperature sensors in the following positions:

a. one at the bottom of the chamber in the space occupied by the minimum production volume stated by the manufacturer;

b. one in the approximate centre of the chamber.

19.73 Connect a pressure recorder (or test gauge) to the chamber.

19.74 Select and start the operating cycle.

19.75 If a test gauge is being used, measure the chamber pressure at the beginning, middle and end of the holding time.

19.76 When the cycle is complete, wait for the temperature in the chamber to fall to 85°C. Attempt to open the door safety hood. If the hood does not open, wait for the temperature to fall below 80°C. Attempt to open the hood again.

19.77 The test should be considered satisfactory if the following requirements are met:

a. the requirements of the automatic control test (see paragraph 12.13) are met;

b. the holding time, as determined from the measured temperatures, is not less than that specified for the appropriate sterilization temperature band listed in Table 13;

c. during the holding time:

(i) the temperatures measured in the medium are both within ± 2°C of the set temperature;

(ii) the indicated and recorded chamber temperatures are within 1°C of the lower of the two temperatures measured in the medium;

(iii) the indicated and recorded chamber pressures are within 0.05 bar of the measured chamber pressure;

d. the door safety hood cannot be opened until the higher of the two temperatures measured in the medium falls below 80°C.

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Table 13: Sterilization conditions for laboratory sterilizers

Name of operating cycle	Sterilization temperature [°C]	Maximum temperature [°C]	Minimum holding time [min]
Make safe of small plastic discard.	134 126 121	138 129 124	3 10 15
Make safe of contained fluid discard	134 126 121	138 129 124	3 10 15
Sterilization of culture media (pre-set cycle)	121 115	124 118	15 30
Sterilization of culture media (variable cycle)	102-134 121[a]	 124	Up to 60 15
Disinfection of fabrics	134 126 121	138 129 124	3 10 15
Sterilization of glassware and equipment	134 126 121	138 129 124	3 10 15
Free steaming (variable cycle)	102-104 95[a]	 98	Up to 60 15
Culture media preparator	121 115	124 118	15 30

a. Although the cycle is variable, this temperature band should be used for testing purpose

Reheat and dispensing test

19.78 This test follows immediately after the full-load test, using the same load. Temperature and pressure sensors should be removed.

19.79 Set the sterilizer to reheat the batch to a nominal reheat temperature of 100°C.

19.80 Five minutes after the medium attains the reheat temperature, allow it to cool to a nominal dispensing temperature of 55°C.

19.81 When the indicated chamber temperature reaches 55°C wait 10 min and begin dispensing the medium.

19.82 Note the indicated chamber temperature and pressure at the beginning, middle and end of the dispensing period.

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19.83 The test should be considered satisfactory if the following requirements are met:

a. during dispensing:

(i) the indicated chamber temperature is within ±2°C of the set dispensing temperature;

(ii) the indicated chamber pressure is zero;

(iii) the medium does not solidify;

b. the person conducting the test does not observe any mechanical or other anomaly.

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Glossary

The following list of definitions has been adopted in SHTM 2010 and used in Part 2. Certain pressure terms have been modified to comply with the requirements of BS EN 764. Cross references to other terms are shown in bold type.

absolute pressure	Pressure for which the zero value is associated with absolute vacuum.
active chamber discharge	The controlled flow of air, or of air and condensate, from the **chamber**, through either a drain or a vent, such that the temperature of the discharge is at the temperature of the chamber.
aeration	A part of the **sterilization process** during which **sterilant gas** and/or its reaction products desorb from the **load** until predetermined levels are reached. See **degassing** and **flushing**.
air detector	A device used to determine that sufficient air or other **non-condensable gases** have been removed from the **chamber**.
allowable pressure	Of a pressure vessel, a limit to the **operating pressure** specified for safety reasons. See **design pressure**.
automatic controller	A device that, in response to predetermined **cycle variables**, operates the **sterilizer** sequentially through the required stages of the **operating cycle**.
automatic control test	A device that, in response to predetermined **cycle variables**, operates the **sterilizer** sequentially through the required stages of the **operating cycle**.
A-weighted	Of sound level measurements, weighted to the frequency response of the human ear.
batch process record (BPR)	A permanent record of one or more **cycle variables recorded** during a complete **operating cycle** by instruments fitted permanently to the **sterilizer**.

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biological indicator	A device, consisting of an **inoculated carrier** contained within a primary pack, designed to test the efficacy of an **operating cycle**.
cartridge	In **EO sterilizers**, a portable, single-use, simple vessel containing **sterilant** gas under pressure from which the gas is delivered by puncturing the cartridge.
chamber	The part of the **sterilizer** in which the **load** is placed.
chamber exhaust ventilation (CEV)	A ventilation system designed to extract gas from the **chamber** of an **EO sterilizer** supplied from a **cartridge**.
chamber furniture	Shelves, pallets, loading trolleys and other fixed or movable parts that support the **load** within the **chamber**.
chamber temperature	The lowest temperature prevailing in the **chamber**.
clinical sterilizer	A **sterilizer** designed to process **medical devices** or **medicinal products** to be used in the clinical care of patients.
commissioning	The process of obtaining and documenting evidence that equipment has been provided and installed in accordance with the equipment specifications and that it functions within predetermined limits when operated in accordance with the operational instructions.
conditioning	In **EO sterilizers**, the treatment of a **load** within the **operating cycle**, but prior to **sterilization**, to attain a predetermined temperature and humidity throughout the load.
contained fluid discard	Discard material held in sealed glass containers or sealed plastic containers of volume greater than 50 ml (see **small plastic discard**).
cooling stage	The period of the **operating cycle**, after the **holding time** has been completed, during which the **load** remains in the **chamber** while the load cools to a safe temperature.
critical gas exposure time	For **EO sterilizers**, the shortest **gas exposure time**, determined during **commissioning**, for which all **biological indicators** are inactivated.

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culture media preparator	A specialised **laboratory sterilizer** designed for the **sterilization** and dispensing of culture media.
cycle complete	Recognition by the **automatic controller** that the preset values for the **cycle variables**, necessary for a successful **operating cycle**, have been attained and that the sterilized **load** is ready for removal from the **chamber**.
cycle variables	The physical properties, for example time, temperature, pressure, humidity and gas concentration, that influence the efficacy of the **operating cycle**.
dedicated steam supply	A supply of steam produced by a generator for the exclusive use of a **sterilizer** or group of sterilizers.
degassing	1. in **LTSF** and **EO sterilizers**, an **aeration** procedure in which **sterilant** gas and its reaction products are desorbed from the **load** by defined treatment outside the **sterilizer** after completion of the **operating cycle**. 2. a pre-heating treatment of boiler feed-water to reduce the amount of **non-condensable gases** in the steam supply.
design pressure	Of a pressure vessel, the pressure chosen for the design calculations. See **operating pressure**, **allowable pressure**.
discard	Laboratory material which is, or may be, infected by micro-organisms and is to be made safe before disposal.
discard bag	A bag, usually of plastic, designed to receive solid **discard** material before being placed in a **discard box** for processing by a **make-safe** cycle.
discard box	A box designed to contain discard material for processing by a make-safe cycle.
disinfection	A process used to reduce the number of viable micro-organisms in a **load** but which may not necessarily inactivate some viruses and bacterial spores.
disinfector	An apparatus designed to achieve **disinfection**.

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double-ended sterilizer	A **sterilizer** in which there is a door at each end of the **chamber**.
dry-heat sterilizer	A **clinical sterilizer** designed to sterilise **loads** by exposure to hot dry air near atmospheric pressure.
dryness value	A dimensionless quantity, approximating to the dryness fraction, derived to determine whether steam is of the correct dryness for **sterilization** purposes. A dryness value of 1.0 represents dry **saturated steam**.
D-value	Decimal reduction value (for **biological indicators**). The time in minutes required to secure inactivation of 90% of the test organisms under stated exposure conditions.
EO sterilizer	A **clinical sterilizer** designed to sterilise **loads** by exposure to **ethylene oxide** gas or EO gas mixtures (Chapter 13).
equilibration time	The period which elapses between the attainment of the **sterilization temperature** in the **chamber** and the attainment of the sterilization temperature in all parts of the **load**.
ethylene oxide (EO)	**Sterilant** gas used to sterilise items that would be damaged by exposure to heat or moisture. Chemical formula CH_2CH_2O.
F_O	A quantity, measured in minutes, used to determine the efficacy of an **operating cycle** and equivalent to a continuous period at a temperature of 121°C.
fault	An attribute of **sterilizer** design whereby failure of any component or its associated services does not create a safety hazard.
fail-safe	The recognition by the **automatic controller** that the preset **cycle variables** for the **operating cycle** have not been attained and that **sterilization** or **disinfection** has been jeopardised.
flash sterilizer	A device designed to achieve **sterilization** by exposing the **load** to a very high temperature steam for a few seconds.

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fluid sterilizer	A **clinical sterilizer** designed to sterilise fluids in sealed containers by exposure to **high-temperature steam** under pressure.
flushing	In **LTSF** and **EO sterilizers,** an **aeration** procedure by which remaining **sterilant** gas is removed from the **load** within the **chamber** by the passage of air or other inert gas.
formaldehyde	**Sterilant** gas used in combination with **low-temperature steam** to sterilise items that would be damaged by exposure to **high-temperature steam.** Chemical formula HCHO. Also known as methanal.
formalin	Formaldehyde Solution BP. A 38% aqueous solution of **formaldehyde** stabilised with 10% w/v ethanol, commonly used as the primary material for generating formaldehyde gas.
free steaming	A process, used in **laboratory sterilizers,** in which the **load** is exposed to steam near atmospheric pressure.
free-standing	Of a **sterilizer,** installed in a room which is not separated into a **plantroom** and a **loading area**.
full load	A specified **load,** used in thermometric tests, to represent the maximum size and mass of load which the **sterilizer** is designed to process.
gas exposure time	In **EO sterilizers,** the time for which the **chamber** is maintained at the specified temperature, gas concentration, pressure and humidity.
gauge pressure	Pressure equal to the difference between the **absolute pressure** and local atmospheric pressure.
high-temperature steam	Steam at a temperature above the boiling point of water at local atmospheric pressure.
holding time	The period during which the temperature in all parts of the **chamber, load** and any coolant fluid is held within the **sterilization temperature band.** It follows immediately after the **equilibration time**.
hot-air sterilizer	See dry-heat sterilizer.

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hot source	A temperature reference used to verify the calibration of a thermometric measurement system.
indicated	An indicated value is that shown by a dial or other visual display fitted permanently to the **sterilizer** (see **recorded** and **measured**).
inoculated carrier	A component of a **biological indicator**, comprising a piece of supporting material on which a defined number of test organisms are deposited.
installation checks	A series of checks performed by the contractor to establish that the **sterilizer** has been provided and installed correctly, is safe to operate, does not interfere with nearby equipment and that all connected services are satisfactory and do not restrict the attainment of conditions for **sterilization**.
installation tests	A series of tests performed by the contractor after the **installation checks** to demonstrate that the **sterilizer** is working satisfactorily.
integral steam supply	A supply of steam produced in a sterilizer **chamber** or in a generator directly connected to it. The pressure in the sterilizer chamber is equal to that in the generator.
Köch steamer	A laboratory apparatus designed to expose a **load** to steam near atmospheric pressure and commonly used for melting solidified agar.
laboratory sterilizer	A **sterilizer** designed to sterilise, disinfect or **make-safe** laboratory materials and equipment.
Line-Pickerell helix	A device containing an **inoculated carrier**, used in microbiological tests on **LTSF** and **EO sterilizers**, and are designed to stimulate the worst-case conditions for **sterilization** by gas.
load	Collectively, all the goods, equipment and materials that are put into a **sterilizer** or **disinfector** at any one time for the purpose of processing it by an **operating cycle**.
load item	One of several discrete containers, packs or other units that together constitute a **load**.

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load-temperature probe	A movable temperature sensor fitted within the **sterilizer chamber** and designed to record the temperature inside selected **load items**.
loading area	The room or area in front of the **sterilizer** in which the operator works and from which the sterilizer is loaded and unloaded. It is commonly separated by a fascia panel from the **plantroom**.
loading condition	A specified combination of the nature and number of **load items,** the items of **chamber furniture,** and their distribution within the **chamber**.
loading factor	The average fraction of the **usable chamber space** occupied by a load during normal operation.
local exhaust ventilation (LEV)	A ventilation system designed to extract small amounts **EO** or **formaldehyde** vapour released during normal operation of a **sterilizer** and its ancillary equipment.
low-temperature steam (LTS)	Steam at a temperature below the boiling point of water at local atmospheric pressure.
LTS disinfector	A clinical **disinfector** designed to disinfect **loads** by exposure to **low-temperature steam** at sub-atmospheric pressure.
LTSF sterilizer	A **clinical sterilizer** designed to sterilise **loads** by exposure to **low-temperature steam** and **formaldehyde** gas at sub-atmospheric pressure.
mains steam supply	The supply of steam produced for distribution to a range of steam-consuming equipment by an independent common boiler.
make-safe	A process, used in **laboratory sterilizers,** to reduce the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard or environmental contamination.
master process record (MPR)	A **batch process record** obtained from a thermometric **commissioning** or **performance qualification** test and annotated to show the permitted tolerances for **cycle variables** during subsequent testing and routine production.

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measured	A measured value is that shown on a test instrument, such as a thermometric recorder or a test pressure gauge, attached to the **sterilizer** for test purposes **(see indicated** and **recorded)**.
medical device	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC.)
medicinal product	Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product. (Source: EU Council Directive 65/65/EEC.)
module	A standard unit of **chamber** size being a rectangular box measuring 300 x 300 x 600 mm of volume 54 litres.
non-condensable gases (NCGs)	Gases which cannot be liquefied by compression under the range of conditions of temperature and pressure used during the **operating cycle**.
noted	A noted value is that written down by the operator, usually as the result of observing an **indicated, recorded** or **measured** value.
operating cycle	The set of stages of the **sterilization** or **disinfection** process carried out in sequence and regulated by the **automatic controller.** It is synonymous with the terms “sterilization cycle” for **sterilizers** and “disinfection cycle” for **disinfectors**.

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operating pressure	The pressure in the **chamber** during the **plateau period** of an **operating cycle**. See **allowable pressure**, **design pressure**.
override	A system by which the progress of the **operating cycle** can be interrupted or modified as necessary.
performance class	An integer, from 1 to 20, related to the total cycle time for a **sterilizer** with a **full load**.
performance qualification (PQ)	The process of obtaining and documenting evidence that the equipment, as commissioned, will produce acceptable product when operated in accordance with the process specification.
performance requalification (PRQ)	The process of confirming that the evidence obtained during **performance qualification** remains valid.
periodic tests	A series of tests carried out at daily, weekly, quarterly and yearly intervals.
permitted tolerance	A limit, determined during **performance qualification**, on how much a **cycle variable** is permitted to vary from a nominal value.
plant history file	A file containing **validation**, maintenance and other engineering records for each **sterilizer**.
plantroom	The room or area to the rear of the **sterilizer** in which services are connected and which provides access for maintenance. It is commonly separated by a fascia panel from the **loading area**.
plateau period	The **equilibration time** plus the **holding time**.
porous-load sterilizer	A **clinical sterilizer** designed to process, by exposure to **high-temperature steam** under pressure, porous items such as towels, gowns and dressings, and also **medical devices** that are wrapped in porous materials such as paper or fabrics.
PQ report	A report containing the data and results obtained from a **performance qualification** test.

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preconditioning	Treatment of a **load** to attain predetermined conditions, such as temperature and humidity, before the start of an **operating cycle**.
pressure ballasting	A technique used in **fluid sterilizers** by which the pressure in the **chamber** is maintained at or near to the pressure inside the **load** containers during all or part of the **operating cycle**.
pressure vessel	A collective term describing the sterilizer **chamber**, jacket (if fitted), door(s) and components that are in permanent open connection with the chamber.
priming	Of a steam generator, the delivery of steam containing water in suspension due to violent boiling or frothing.
pyrogen	A bacterial toxin that causes a rise in body temperature and which is not destroyed by steam **sterilization**.
recommissioning	A procedure to confirm that operational data established during **commissioning** remain valid.
recorded	A recorded value is that shown on the output of a recording instrument fitted permanently to the **sterilizer** (see **indicated** and measured).
reference load	A specified **load** made up to represent the most difficult combination of items to be sterilized.
repeat validation	A procedure to obtain a new set of **commissioning** and **performance qualification** data to replace the set originally obtained during **validation**.
revalidation	A procedure to confirm an established **validation,** consisting of **recommissioning** followed by **performance requalification**.
safety hazard	A potentially detrimental effect on persons or the surroundings arising directly from either the **sterilizer** or its **load**.
saturated steam	Steam whose temperature, at any given pressure, corresponds to that of the vaporisation curve of water.

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small load	A specified **load,** used in thermometric tests, to represent the minimum size and mass of load which the **sterilizer** is designed to process.
small plastic discard	**Discard** material comprising or held in plastic containers not exceeding 50 ml in volume.
Standard test pack	A pack representing the maximum density of porous material which a **porous load sterilizer** conforming to European Standards should be able to process.
sterilant	An agent used to effect **sterilization,** such as steam, hot air or a sterilising gas**.**
sterile	Condition of a **load item** that is free from viable micro-organisms. See BS EN 556 for the requirements for a **medical device** to be labelled “sterile”.
sterilization	A process undertaken to render a **load sterile**.
sterilization conditions	The ranges of the **cycle variables** which may prevail throughout the **chamber** and **load** during the **holding time**.
sterilization pressure band	The range of pressures which may prevail in the **chamber** during the **holding time**. For a steam **sterilizer**, the sterilization pressure band is directly related to the **sterilization temperature band**.
sterilization process	The complete set of procedures required for **sterilization** of a **load,** including the **operating cycle** and any treatment of the load before or after the operating cycle.
sterilization temperature	Minimum acceptable temperature of the **sterilization temperature band**.
sterilization temperature band	The range of temperatures which may prevail throughout the **load** during the **holding time.** These temperatures are expressed as a minimum acceptable (the **sterilization temperature)** and a maximum allowable and are stated to the nearest degree Celsius.
sterilizer	An apparatus designed to achieve **sterilization**.

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superheated steam	Steam whose temperature, at any given pressure, is higher than that indicated by the vaporisation curve of water.
thermal door lock	An interlock fitted to certain **sterilizers** to prevent the door from being opened until the temperature in the **chamber** and **load** falls below a preset value.
transportable	Requiring no permanent connections or installation and capable of being moved manually without mechanical assistance. Synonymous with “bench-top”.
type tests	A series of tests conducted by the manufacturer to establish the working data for a **sterilizer** type.
usable chamber space	The space inside the **chamber** which is not restricted by **chamber furniture** and which is consequently available to accept the **load**.
utilisation factor	The fraction of the open hours for which a sterilizer is available to process loads.
validation	A documented procedure for obtaining, recording and interpreting data required to show that a **sterilization process** will consistently comply with predetermined specifications.
working pressure	The pressure in the **chamber** during the **plateau period** of an **operating cycle**.
works tests	A series of tests to establish the efficacy of each **sterilizer** at the manufacturer’s works.

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Abbreviations

ATCC	American Type Culture Collection
BPR	batch process record
BS	British Standard
°C	degree Celsius
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CEV	chamber exhaust ventilation
CIP	Collection Institut Pasteur (France)
COSHH	Control of Substances Hazardous to Health (Regulations)
dBA	decibel, A-weighted
EMC	electromagnetic compatibility
EMF	electromotive force
EN	European Standard (Europäische Norm)
EO	ethylene oxide
EU	European Union (formerly European Community)
GGMP	EU, *Guide to good manufacturing practice for medicinal products*
h	hour
HBN	Health Building Note
HDN	Hospital Design Note
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HTM	Health Technical Memorandum (UK)
ISO	International Organisation for Standardisation
kW	kilowatt
l	litre
LEV	local exhaust ventilation
LTEL	long-term exposure limit
LTMEL	long-term maximum exposure limit
LTS	low-temperature steam
LTSF	low-temperature steam and formaldehyde
µm	micrometre (micron, 10^{-6} m)
m	minutes
mbar	millibar (10^{-3} bar)
MCA	Medicines Control Agency
MDA	Medical Devices Agency
mg	milligram (10^{-3} g)
min	minute(s)
ml	millilitre (10^{-3} l)
mm	millimetre (10^{-3} m)
mmol	millimole (10^{-3} mole)
M	metre
MPR	master process record
NCG	non-condensable gas
NCIMB	National Collections of Industrial and Marine Bacteria
NCTC	National Collection of Type Cultures

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PES	programmable electronic system
ppm	parts per million
PQ	performance qualification
PRQ	performance requalification
RH	relative humidity
s	second(s)
SHPN	Scottish Hospital Planning Note
SHTM	Scottish Health Technical Memorandum
SHTN	Scottish Health Technical Note
SSD	sterile services department
STMEL	short-term maximum exposure limit
UK	United Kingdom

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
	Health and Medicines Act	HMSO	1988	
	Registered Establishments (Scotland) Act	HMSO	1998	
	Water (Scotland) Act	HMSO	1980	
SI 3146	Active Implantable Medical Devices Regulations	HMSO	1992	
SI 1995	Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995	HMSO	1995	
SI 2179 & 187	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
SI 2092	Carriage of Dangerous Goods (Classification, Packaging & Labelling) and Use of Transportable Pressure Receptacles Regulations	HMSO	1996	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988	

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Publication ID	Title	Publisher	Date	Notes
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 1315	In Vitro Diagnostic Medical Devices Regulations 2000	HMSO	2000	
SI 3232	Ionising Radiations Regulations 1999	HMSO	1999	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 2051	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulation	HMSO	1992	

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Publication ID	Title	Publisher	Date	Notes
British Standards				
BS 593	**Specification for laboratory thermometers**		1989	
BS 1781	**Specification for linen and linen union textiles**		1981	
BS 2646	**Autoclaves for sterilization in laboratories**	BSI Standards		
	Part 1: Specification for design, construction, safety and performance		1993	
	Part 2: Guide to planning and installation		1990	
	Part 3: Guide to safe use and operation		1993	
	Part 4: Guide to maintenance		1991	
	Part 5: Methods of testing for function and performance		1993	
BS 2648	**Performance requirements for electrically heated laboratory drying ovens (PD2517,6/56)**	BSI Standards	1955	
BS 2775	**Specification for rubber stoppers and tubing for general laboratory use**		1987	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**		1992	
BS 3928	**Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors)**	BSI Standards	1969	

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Publication ID	Title	Publisher	Date	Notes
BS 3970	**Sterilizing and disinfecting equipment for medical products** **Part 1:** Specification for general requirements **Part 2:** Specification for steam sterilizers for aqueous fluids in sealed rigid containers **Part 3:** Specification for steam sterilizers for wrapped goods and porous loads **Part 4:** Specification for transportable steam sterilizers for unwrapped instruments and utensils **Part 5:** Specification for low temperature steam disinfectors **Part 6:** Specification for sterilizers using low temperature steam with formaldehyde	BSI Standards	1990 1991 1990 1990 1993	
BS 4196-0	**Sound power level of noise sources. Guide for the use of basic standards and for the preparation of noise test codes**	BSI Standards	1981	
BS 4275	**Guide to implementing an effective respiratory protective device programme**	BSI Standards	1997	
BS 5164	**Specification for indirect acting electrical indicating and recording instruments and their accessories**		1975	
BS 5295	**Environmental cleanliness in enclosed spaces** **Part 1:** Specification for clean rooms and clean air devices		1989	
BS 5304	**British standard code of practice for safety of machinery**	BSI Standards	1988	
BS 5815	**Sheets, sheeting, pillowslips, towels, napkins and continental quilts secondary covers** **Parts 1:** Specification for sheeting etc **Part 2**: specification for towels etc. **Part 3:** Specification for counterpanes etc.	BSI Standards	1989 1988 1991	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 6000	**Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots**	BSI Standards	1996	
BS 6001	**Sampling procedures for inspection by attributes**	BSI Standards	1991	
BS 6068	**Water quality** **Sect.1.2** Glossary	BSI Standards	1997	
	Sect 6.5 Guidance on sampling of drinking water and water used for food processing		1991	
	Sect. 6.7 Guidance on sampling of water and steam in boiler plants.		1994	
BS 6257	**Specification for paper bags for steam sterilization for medical use**		1989	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**		1984	
BS 7671	**Requirements for electrical installations. IEE wiring regulations**	BSI Standards	1992	16th edition
BS 7720	**Specification for non-biological sterilization indicators equivalent to the Bowie and Dick Test**		1995	
BS EN 134	**Respiratory protective devices. Nomenclature of components. Names of components in three CEN languages and diagrams for respiratory protective equipment**	BSI Standards	1998	
BS EN 285	**Sterilization, steam sterilizers, large sterilizers**	BSI Standards	1997	
BS EN 550	**Sterilization of medical devices. Validation and routine control of sterilization by ethylene oxide**	BSI Standards	1994	
BS EN 552	**Sterilization of medical devices. Validation and routine control of sterilization by irradiation**	BSI Standards	1994	
BS EN 554	**Sterilization of medical devices. Validation and routine control of sterilization by moist heat**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized medical devices to be labelled 'STERILE'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 764	**Pressure equipment. Terminology and symbols: pressure, temperature, volume**	BSI Standards	1995	
BS EN 837-1	**Bourdon tube pressure gauges: dimensions, metrology, requirements and testing**	BSI Standards	1998	
BS EN 866	**Biological systems for testing sterilizers and sterilization processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterilizers **Part 3:** Particular systems for use in moist heat sterilizers	BSI Standards	 1997 1998 1997	
BS EN 867	**Non-biological systems for use in sterilizers** **Part 1:** General requirements **Part 2:** Process indicators **Part 3:** Specification for Class B indicators for use in the Bowie and Dick test	BSI Standards	 1997	
BS EN 868	**Packaging materials and systems for medical devices which are to be sterilized. General requirements**	BSI Standards	1997	
BS EN 980	**Graphical symbols for the use in the labelling of medical devices**	BSI Standards	1997	
BS EN 1174	**Sterilization of medical devices. Estimation of population of micro-organisms on product**	BSI Standards	1996	
BS EN 1422	**Sterilizers for medical purposes – ethylene oxide sterilizers – specification**	BSI Standards	1998	
BS EN 22872	**Complete, filled transport packages. Method for determination of resistance to compression**	BSI Standards	1993	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 25667-1	**Water quality. Guidance on design of sampling programmes**	BSI Standards	1994	
BS EN 25667-2	**Water sampling . Guidance on sampling techniques**	BSI Standards	1993	
BS EN 30993	**Biological evaluation of medical devices**	BSI Standards		
	Part 3: Tests for genotoxicity, carcinotoxicity, and reproductive toxicity		1994	
	Part 4: Selection of tests for interaction with blood		1994	
	Part 5: Tests for cytotoxicity, in vitro methods		1994	
	Part 6: Tests for local effects after implantation		1995	
BS EN ISO 3746	**Acoustics. Determination of sound power levels of noise sources using sound pressure. Survey method using an enveloping measurement surface over a reflecting plane**	BSI Standards	1996	
BS EN 45003	**Calibration and testing laboratory accreditation systems, general requirements for operation and recognition**	BSI Standards	1995	
BS EN 45011	**General requirements for bodies operating product certification systems**	BSI Standards	1998	
BS EN 45012	**General requirements for bodies operating assessment and certification/registration of quality system**	BSI Standards	1998	
BS EN 45014	**General criteria for supplier's declaration of conformity**	BSI Standards	1993	
BS EN 45020	**Standardization and related activities**	BSI Standards	1998	
BS EN 46001	**Specification for the application of EN ISO9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for the application of EN ISO9002 to the manufacture of medical devices**	BSI Standards	1994	

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BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	1998 1995	
BS EN 60079-14	**Electrical apparatus for explosive gas atmospheres. Electrical installations in hazardous areas (other than mines)**	BSI Standards	1997	
BS EN 60581-2	**Thermocouples. Manufacturing tolerances**	BSI Standards	1996	
BS EN 60584-1	**Thermocouples reference table**	BSI Standards	1996	
BS EN 60651	**Specification for sound level meters**	BSI Standards	1994	
BS EN 60751	**Industrial platinum resistance thermometer sensors**		1996	
BS EN 60804	**Specification for integrating averaging sound level meters**		1994	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **-1:** General requirements **-2-041:** Particular requirements for autoclaves and sterilizers using steam for the treatment of medical materials and for laboratory processes **-2-042:** Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes **-2-043:** Particular requirements for autoclaves and sterilizers using either hot air or hot inert gas for the treatment of medical materials and for laboratory processes		1993 1997 1997 1998	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing**	BSI Standards	1994	
BS EN ISO 9002	**Quality systems. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	
European Union Directives				
65/65/EEC	Approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.	Official Journal of the European Communities (OJEC), no 22, 9/2/65, p 369		
75/107/EEC	Approximation of the laws of member states relating to bottles used as measuring containers.	Official Journal of the European Communities (OJEC), L42, 15/2/75		
90/385/EEC	Approximation of the laws of the Member States relating to active implantable medical devices.	Official Journal of the European Communities (OJEC), L189 20/7/90, p 17		
91/356/EEC	Laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.	Official Journal of the European Communities (OJEC). L193 17/7/91, p 30		
80/778/EEC	Quality of water intended for human consumption	Official Journal of the European Communities, 1980		
93/42/EEC	Medical Devices Directive	Official Journal of the European Communities (OJEC), L169 12/7/93, p 1		
98/79/EC	In Vitro Diagnostic Medical Devices Directive	Official Journal of the European Communities, (OJEC), L331 7/12/98		
Scottish Health Technical Guidance				
SHTM 2007	Electrical services supply and distribution	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2014	Abatement of electrical interference	P&EFEx	2001	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems	P&EFEx	2001	CD-ROM
SHTM 2023	Access and accommodation for engineering services	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilizers	P&EFEx	2001	CD-ROM
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHTM 2045	Acoustics	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	HMSO	1994	
SHPN 15	Accommodation for pathology services	HMSO	1994	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	EEF	1999	CD-ROM
SHTN 4	General Purposes Estates and Facilities Model Safety Permit-to-Work system	EEF	1998	CD-ROM
SHGN	'Safe' hot water and surface temperatures	EEF	1999	CD-ROM
	NHS in Scotland – PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
UK Health Technical Guidance				
HBN 29	Accommodation for pharmaceutical services	HMSO	1988	
HTM 67	Building components: laboratory fitting out system	HMSO	1993	
CONCODE	Contracts and commissions for the NHS estate – contract procedures	HMSO	1994	
MES	Model Engineering Specifications	NHS Estates	1997	As required
MES C14	Sterilizers	NHS Estates	1993	
HBN 13	Supplement 1 – Ethylene oxide sterilization section	HMSO	1994	
MES C02	Thermal insulation	NHS Estates	1993	
Health and Safety Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
HN(76)126	Hospital design note 4 (noise control): amendments to appendices II, IV and VII	DHSS	1976	
STB3A/85/12	Performance and safety specification for media sterilizers. Media devices directorate	DHSS	1985	
	Emmerson, A. M. *Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Committee to the Department of Health Medical Devices Directorate.* Medical devices directorate	Department of Health	1993	
	Biological tests for graded milk. Memo 139/Foods.	Ministry of Health	1937	
	Scottish Infection Manual Guidance on the core standards for the control of infection in hospitals, healthcare premises and at the community interface	The Scottish Office	1998	

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Publication ID	Title	Publisher	Date	Notes
	Programmable electronic systems in safety related applications: General technical guidelines	HSE	1987	
	Programmable electronic systems in safety related applications: an introductory guide	HSE	1987	
L 5	General COSHH ACOP (Control of substances hazardous to health) Carcinogens ACOP (Control of carcinogenic substances) and Biological agents ACOP (Control of biological agents) Control of Substances Hazardous to Health Regulations1999 Approved Code of Practice	HSE	1999	
L 22	Safe use of work equipment: Approved code of practice and guidance	HSE	1998	
L 23	Manual handling operations: guidance on regulations	HSE	1998	
L 24	Workplace health, safety and welfare: Approved code of practice and guidance	HSE	1992	
L25	Personal protective equipment at work at work: guidance on regulations		1992	
L113	Safe use of lifting equipment: Approved code of practice and guidance	HSE	1998	
L122	Safety of pressure systems: Pressure Systems Safety Regulations 2000. Approved Code of Practice	HSE Books	2000	
PM73	Safety at Autoclaves	HSE Books	1998	
	Precautions for work with human and animal. Transmissible Spongiform Encaphalopathies	HSE (ACDP)		
	Categorisation of pathogens according to hazard and categories of containment	HSE (ACDP)	1995	4th Edition
	Safe working and the prevention of infection in clinical laboratories	HSC (HSAC)		
HS(R)23	A guide to the 'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995	HSE	1995	

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Publication ID	Title	Publisher	Date	Notes
Miscellaneous References				
GGMP Volume IV	Guide to good manufacturing practice for medicinal products – The rules governing medicinal products in the European Community			
	Atomic absorption spectrophotometry 1979 version	HMSO	1979	(out of print)
	Cadmium in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Colour and turbidity of waters 1981	HMSO	1981	(out of print)
	Determination of anions and cations, transition metals, and other complex ions and organic acids and bases in water by chromatography 1990	HMSO	1990	
	Lead in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Lead and cadmium in fresh waters by atomic absorption spectrophotometry (second edition) a general introduction to electrothermal atomization atomic absorption spctrophotometry 1986	HMSO	1986	(out of print)
	Measurements of electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters.	HMSO		(out of print)
	Mercury in waters, effluents, soils and sediments etc, additional methods	HMSO	1985	(out of print)
	Phosphorus and silicon in waters, effluents and sludges 1992	HMSO	1993	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
LG 2	Lighting guide: hospitals and healthcare buildings	Chartered Institution of Building Services Engineers	1989	
	Sterilization and disinfection of heat-liable equipment	Central Sterilizing Club	1986	

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Appendix 1: Useful Addresses

Medicines Control Agency,
Market Towers,
1 Nine Elms Lane,
London SW8 5NQ.
Tel. 0171-273 3000.

Medical Devices Agency,
14 Russell Square,
London WC1 B 5EP.
Tel. 0171-972 2000.

Scottish Executive Health Department
St Andrew's House,
Edinburgh EH1 3DG.
Tel. 0131-556 8400.

NHSScotland, Property and Environment Forum Executive,
4th Floor,
St Andrew House,
141 West Nile Street,
Glasgow, G1 2RN.
Tel. 0141 404 3737

Public Health Laboratory Service,
Central Public Health Laboratory,
61 Colindale Avenue,
London NW9 5HT.
Tel. 0181-200 4400.

Health and safety

Health and Safety Executive,
375 West George Street,
Glasgow, G2 4LW.
Tel. 0141 275 3000

Belford House
59 Belford Road,
Edinburgh, EH4 3UE.
Tel. 0131 247 2000

Health and Safety Executive Information Line
Tel. 0870 154 5500

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Standards organisations

British Standards Institution
Head office: 2 Park Street,
London W1A 2BS.

Publications:
Linford Wood,
Milton Keynes MK14 6LE.
Tel. 01908-221 166.

European Committee for Standardization,
Rue de Stassart 36, B-1050 Brussels

Other organisations

Association of Consulting Engineers,
Alliance House, 12 Caxton Street,
London SW1 H 0QL.
Tel. 0171-222 6557.

Institute of Healthcare Engineering and Estate Management ,
2 Abingdon House, Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1 DS.
Tel. 02392-823186.

Institution of Electrical Engineers,
Publication Sales Department, PO Box 26,
Hitchin,
Hertsfordshire SG5 1SA.
Tel. 01438-742792.

Institution of Mechanical Engineers, Publication Sales Department,
PO Box 24, Northgate Avenue,
Bury St Edmunds,
Suffolk IP32 6BW.
Tel. 01284-763277.

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Appendix 2: Calculations

Derivation of the steam dryness value equation

A2.1 The equation given in Chapter 9 for the steam dryness value can be derived as follows.

A2.2 Steam supplied from the main will contain dry steam with a small amount of moisture carried as droplets in suspension at the same temperature.

The dryness fraction, D, is defined as:

$$D = \frac{M_{dry}}{M_{steam}} = \frac{M_{dry}}{M_{dry} = M_{wet}} \qquad \text{(A2-1)}$$

where a given mass M_{steam} of steam contains a mass M_{dry} of pure dry steam and M_{wet} of moisture. Dry saturated steam has a dryness fraction of 1.0.

A2.3 If dry saturated steam is allowed to condense in cold water, then the temperature rise of the water is related to the amount of latent heat given up by the condensing steam. If the steam contains moisture, then the latent heat (and the temperature rise) will be less than for the same mass of pure dry saturated steam. The dryness fraction may then be estimated (the estimate being known as the dryness value) by equating the heat gained by the water to the heat lost by the steam.

A2.4 At the start of the test the flask contains a mass M_w of water at a temperature of T_0 . At the end of the test the temperature has risen to T_1,

Heat gained by water = $(T_1 - T_0)cM_w$ (A2-2)

where c is the specific heat capacity of water at a representative temperature between T_0 and T_1.

A2.5 The heat lost by the steam is equal to the latent heat of condensation plus the heat lost from the condensate and moisture as they cool from T_s to T_1 .

Heat lost by Steam = $LM_{dry} + (T_s - T_1)cM_c = DLM_C + (T_s - T_1)cM_C$ (A2-3)

where L is the specific latent heat of condensation of steam at temperature T_s and $M_C = M_{steam}$ is the mass of condensate and moisture. Equating (A2-2) and (A2-3) and solving for D gives:

$$D = \frac{(T_1 - T_0)(cM_W + A)}{LM_C} - \frac{(T_S - T_1)c}{L} \qquad \text{(A2-4)}$$

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where the term *A* represents the effective heat capacity of the flask and other apparatus. For the apparatus specified in Chapter 9, A can be taken as 0.24 kJ K^{-1} (see Table AI). If the apparatus being used differs significantly from Table AI then the effective heat capacity should be recalculated.

A2.6 Example: In a dryness value test the temperature of the water in the flask rises from T_1 = 19°C to T_2 = 81°C. The average steam temperature during this time is T_s = 144°C. The initial mass of water in the flask is M_w = 632 g, and the mass of condensate is M_c = 77 g. From tables c ≈ 4.18 kJ kg^{-1} K^{-1}, and L ≈ 2130 kJ kg^{-1}. Then:

$$D = \frac{(81-19)(4.18\ x\ 0.632 + 0.24)}{2130\ x\ 0.077} - \frac{(144-81)4.18}{2130} = 1.089 - 0.124 = \mathbf{0.96}$$

Table A1 Effective heat capacity for steam dryness apparatus

Component [a]	Mass (g)	Heating factor (b)	Effective heat capacity (kJ K^{-1})
One-litre glass vacuum flask	355	0.5	0.119
Rubber bung	91	0.8	0.116
90-mm glass pipe	2.4	1.0	0.002
290-mm glass pipe	7.8	1.0	0.005
TOTAL			0.242

a. The rubber pipe is not included as it is assumed to be at steam temperature at the start of the test.

b. The heating factor is an estimate of the factor by which the component is heated from T_1 to T_2 during the test.

A2.7 It can be seen that the term for the heat capacity of the apparatus (0.24) contributes approximately 10% to the total dryness value.

Relative humidity in EO sterilizers

A2.8 Due to the difficulty in measuring relative humidity in the chamber of an EO sterilizer, it is usually better to calculate the RH from the measured or recorded rise in pressure as humidifying steam is introduced.

A2.9 At the start of the conditioning stage the chamber contains a small amount of air at pressure P_O and temperature *T*. During the conditioning stage steam is introduced into the chamber and the pressure rises to P_1 while the temperature remains at *T*. From the law of partial pressures we can identify the pressure change, $\Delta P = P_1 - P_0$,with the partial pressure of the water vapour, P_w.

A2.10 Relative humidity is defined as P_w/P_s where P_s is the saturated vapour pressure of water at temperature *T*, which can be obtained from steam tables.

Hence,

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Relative humidity, $RH = \Delta P/P_S$ (A2-5)

A2.11 *Example:* During a conditioning stage at a temperature of 55°C, the chamber pressure rises from P_O = 80 mbar to P_1 = 168 mbar, a rise of ΔP = 88 mbar (8.8 kPa). From the steam tables we find that at 55°C, P_s = 157 mbar. The relative humidity is then 88/157 0.56 = **56%**

Concentration of ethylene oxide

A2.12 The concentration of ethylene oxide (EO) in a sterilizer chamber may be calculated as follows.

A2.13 An ideal gas obeys the equation of state:

$$PV = \frac{Pm}{p} = RT \quad \text{(A2-6)}$$

where:

P = absolute pressure (Pa);

V = molar volume ($m^3\ mol^{-1}$);

m = molecular weight ($kg\ mol^{-1}$);

p = density ($kg\ m^{-3}$);

R = gas constant (8.3 14 $J\ K^{-1} mol^{-1}$);

T = absolute temperature (K).

A2.14 At the end of the conditioning stage, the chamber contains a mixture of air and water vapour at a pressure P_1 and temperature T. During the sterilant gas injection stage the pressure rises to P_2 while the temperature remains at T. From the law of partial pressures the pressure change, $\Delta P = P_2 - P_1$ can be identified with the partial pressure of the EO mixture:

$$\Delta P = P_{EO} + P_{DG} = RT\left(\frac{P_{EO}}{M_{EO}} + \frac{P_{DG}}{M_{DG}}\right) \quad \text{(A2-7)}$$

where the subscript EO refers to ethylene oxide and DG to the diluent gas. Rearranging for the EO density:

$$P_{EO} = M_{EO}\left(\frac{\Delta P}{RT} - \frac{P_{DG}}{M_{DG}}\right) \quad \text{(A2-8)}$$

A2.15 But from equation (A2.6):

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$$P_{DG} = W_{DGP} = W_{DG}\ \frac{\Delta P \overline{m}}{RT} \qquad \text{(A2-9)}$$

where $\overline{m}$ is the mean molecular weight of the EO mixture and $w_{DG}$is the proportion by mass of diluent gas such that $w_{EO} = w_{DG} = 1$.

A2.16 Inserting equation (A2-9) in equation (A2-8) gives the EO concentration:

$$P_{EO} = \frac{\Delta P}{RT} m_{EO} \left(1 - W_{DG} \frac{\overline{m}}{m_{DG}}\right) \qquad \text{(A2-10)}$$

A2.17 The mean molecular weight of a mixture of two gases, 1 and 2, is defined as:

$$\overline{m} = \frac{n_1 m + n_2 m_{21}}{n_1 + n_2} = \frac{p_1 + p_2}{p_1 / m_1 + p_2 / m_2} = \frac{(p_1 + p_2) m_1 m_2}{p_1 m_2 + p_2 m_1} = \frac{m_1 m_2}{w_1 m_2 + w_2 m_1} \qquad \text{(A2-11)}$$

where n_1 and n_2 are the number of molecules of each gas. Hence, for an EO mixture the mean molecular weight is given by:

$$\overline{m} = \frac{m_{EO} m_{DG}}{w_{EO} m_{DG} + w_{DG} m_{EO}} \qquad \text{(A2-12)}$$

A2.18 Inserting equation (A2-12) in equation (A2-10) and rearranging, the concentration of EO in the chamber is:

$$p_{EO} = \frac{\Delta P}{RT} w_{EO} \overline{m} \qquad \text{(A2-13)}$$

A2.19 *Example:* A sterilizer uses a mixture of 12% EO (molecular weight: 44g mol^{-1}) and 88% dichlorodifluoromethane (molecular weight: 121 g mol^{-1}). From equation (A2-12), the mean molecular weight of the mixture is then:

$$\overline{m} = \frac{44\ x\ 121}{0.12\ x\ 121 + 0.88\ x\ 44} = 100.0 g\ mol^{-1}$$

A2.20 During the gas injection stage the pressure is observed to rise by 1.48bar (1.48 x 10^5Pa) while the temperature remains at 55°C (328 K). From equation (A2-13) the concentration of EO in the chamber, in SI units, is then:

$$P_{EO} = \frac{1.48\ x\ 10^5\ x\ 0.12\ x\ \ 0.100}{8.31\ x\ 328} = 0.652\ kgm^{-3} = \mathbf{0.65\ g\ l^{-1}}$$

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A2.21 *Example:* A sterilizer uses a mixture of 10% EO and 90% carbon dioxide (molecular weight: 44 g mol^{-1}), giving an effective molecular weight of 44 (since both gases have the same molecular weight). During the gas injection stage the pressure rises by 5.16 bar (5.16 x 10^5Pa) while the temperature remains at 37°C (310 K). From equation (A2-13) the concentration of EO in the chamber is then 0.881 kg m^{-3}, or **0.88 g l^{-1}**.

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Appendix 3: Summary sheets

Summary sheets

A3.1 The summary sheets for commissioning, performance qualification and yearly or revalidation tests should be completed by the test person and given to the user as described in paragraph 2.30.

A3.2 They cover porous load sterilizers, fluid sterilizers, sterilizers for unwrapped instruments and utensils, dry-heat sterilizers, LTS disinfectors and LTSF sterilizers, EO sterilizers and laboratory sterilizers.

A3.3 The lists of tests are to be regarded as a record of which tests have been done, not a prescription for which tests ought to be done. Detailed schedules are given in Chapters 4 and 5. Tests which do not apply to the sterilizer under test should be marked N/A.

A3.4 Where fluid or dry-heat sterilizers are to be used for the sterilization of medicinal products the sheets should be signed by the quality controller as shown.

A3.5 Common sheets are used for LTS and LTSF machines since most of the tests are identical. The signature of the microbiologist is required only for LTSF sterilizers.

A3.6 The sheets for laboratory sterilizers are designed to be used with any of the following operating cycles: make-safe of small plastic discard, make-safe of contained fluid discard, sterilization of culture media (preset or variable cycle), disinfection of fabrics, sterilization of glassware and equipment, free steaming. They may also be used for a culture media preparator. For commissioning and performance qualification, a separate sheet should be completed for each operating cycle available on the machine, and the name of the cycle written clearly in the space provided.

NOTE: We acknowledge the support of Scottish Healthcare Supplies in providing the Test Forms. Complete Test logbooks containing the Forms are available from Scottish Healthcare Supplies, Trinity Park House, South Trinity Road, Edinburgh EH5 3SH; Telephone 0131 552 6255. The Forms marked Sample copy are copyright of Scottish Healthcare Supplies.

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Appendix 3

Reference ……./SC Page 1 of 2

POROUS LOAD STERILIZER – SUMMARY OF COMMISSIONING TESTS

Hospital …… Department…… Date(s) of tests……..

STERILIZER: Manufacturer ……Model ……Usable chamber space……litres

Serial number ……..Plant reference number ……

RESULT OF COMMISSIONING TESTS Data file reference …….

Test (as specified in SHTM 2010 * = optional)	Pass or fail	Cycle number	Start time h min s	Results
Steam non-condensable gas				Concentration of NCG (%)
Steam superheat				Superheat (°C)
Steam dryness				Dryness value
Automatic control				Sterilization temp (ST) selected (°C)
Instrument calibration				See below
Chamber wall temperature				Max temp attained (°C)
Air detector small load				Leak rate mbar/min
Air detector full load				Leak rate mbar/min
Thermometric full load				ST selected(°C) max temp (°C)
Load dryness*				Average gain in mass (%)
Thermometric small load				ST selected (°C) max temp (°C)
Load dryness*				Average gain in mass (%)
Vacuum leak (final)				Leak rate mbar/min
Hospital load dryness				
Air detector function				Air detector setting mbar or °C
				Type of test pack
				Loading area: mean dBA, peak dBA
				Plant room: mean dBA, peak dBA

Test equipment file references……

STERILIZER INSTRUMENT CALIBRATION

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time.

Sensor is measured reading – recorded/indicated error.

	Measured	Recorded	Indicator error
Chamber temperature	°C	°C	°C
Chamber pressure	bar	bar	bar

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Appendix 3

Reference……../SC Page 2 of 2

POROUS LOAD STERILISER – SUMMARY OF COMMISSIONING TESTS

SUMMARY OF THERMOMETRIC TESTS

Sterilization temperature (ST) selected……°C

Automatic controller settings for plateau period: Temperature……°C Time……min……..s

Event	Elapsed time		Chamber pressure	Temperature sensors		
	min	s	bar	Drain/ Vent °C	Test pack °C	Free space °C
SMALL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Equilibration time Holding time Total cycle time				No	No	No
FULL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Equilibration time Holding time Total cycle time				No	No	No

DECLARATION OF TEST PERSON (STERILIZERS)

1. The installation checks and tests have been completed and show that the sterilizer has been provided and installed in accordance with its specifications.
2. All test instruments have current calibration certificates.
3. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
4. The commissioning tests have been completed and show that the sterilizer functions correctly when operated in accordance with operational instructions.

Test Person: Name:……Signature:……..Date:……

DECLARATION OF USER

The sterilizer is fit for use. the first yearly tests are due no later than:

User: Name:……Signature:……Date:……..

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Appendix 3

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POROUS LOAD STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TEST

Hospital: ……..Department: ……Date(s) of tests ……

STERILIZER: Manufacturer……Model: ……. Usable chamber spaces ……litres

Serial Number:……Plant reference number:……..

Chamber shape: …….. Width:……mm Height…….mm Depth……mm

OPERATING CYCLE REFERENCE:……Sterilization temperature:……°C

LOADING CONDITION REFERENCE:……..Batch reference:……

NATURE OF LOAD: ……...

Sample Copy

LOCATION OF SENSORS FOR THERMOMETRIC PQ TEST

Enter positions of temperature sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor Number	Sensor Type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of sensor
1	T				Active chamber drain/vent
2	T				
3	T				
4	T				
5	T				
6	T				
7	T				
8	T				
9	T				
10	T				
11	T				
12	T				
13	P				Chamber pressure test port

(T = Temperature P = Pressure)

Test equipment file references……

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POROUS LOAD STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

SUMMARY OF THERMOMETRIC PQ TEST

Sterilisation temperature (ST) selected ……°C

Automatic controller setting for plateau period: Temperature…..°C Time….min…s

Identify sensors in the load which are the fastest and the slowest to attain the ST.
Enter elapsed times and measured chamber pressures and temperatures.

Sensor Number	Description	Sensor first attains ST		Sensor falls below ST		Time above ST Min s	Max Temp °C
		Time Min s	Press bar	Time Min s	Press bar		
	Drain/vent fastest slowest						

Equilibration time……mins…..s Holding time….min….s Total cycle time…mins…..s

Cycle number …… Master Process Record reference…….

Is a microbiological PQ test required for this loading condition? ……..

Result of microbiological test PASS/FAIL PQ report reference ……

DECLARATION OF TEST PERSON (STERILIZERS)

1. This test has been preceded by a satisfactory sequence of commissioning/yearly tests.
   Reference:……..
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person: Name: ……Signature:……..Date:……..

DECLARATION OF USER

The sterilizer is fit for use with the loading condition identified above. The first performance re-qualification test, due

User: Name ……Signature:……..Date……

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Appendix 3
Reference……../SY Page 1 of 1

POROUS LOAD STERILIZER – SUMMARY OF YEAR/REVALIDATION TESTS

Hospital:……Department:……Date (s) of tests:……
STERILIZER: Manufacturer…….Model:……Usable chamber space…litres
Serial number:……Plant reference number:……

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference ……

Test (as specified in SHTM 2010)	Pass or fail	Cycle number	Start time h min s	Results
Yearly safety checks Automatic control Instrument calibration Air detector small load Air detector full load Thermometric small load Vacuum leak (final) Air detector function Bowie-Dick				Sterilisation temp (ST) selected °C See below Leak rate ……mbar/min Leak rate……..mbar/min ST selected…..°C Max temp....°C Leak rate……mbar/min Air detector setting……mbar or °C Type of test pack……

PERFORMANCE RE-QUALIFICATION (if required)

				Thermometric			Microbio, (optional)	
PQ report reference	Loading condition ref	Operating cycle ref	ST °C	Pass or fail	Cycle number	Start time h min s	Pass or fail	

Test equipment file references ……

DECLARATION OF TEST PERSON (STERILIZERS)

1. All test instruments have current calibration certificates.
2. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The yearly/revalidation checks and tests have been completed and confirm that the sterilizer is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person: Name:……Signature:……Date:……

DECLARATION OF USER

The sterilizer is fit for use. The first yearly tests are due no later than:

User: Name:……..……Signature:……..Date:……..…….

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FLUID STERILIZER – SUMMARY OF COMMISSIONING TESTS

Hospital:……Department:……..Date(s) of tests……
Sterilizer: Manufacturer:……..Model:……..Usable chamber space ……...Litres
Serial number: ……Plant reference number:……

RESULTS OF COMMISSIONING TESTS Data file reference……

Test (as specified in SHTM 2010 *= optional		Pass or fail	Cycle number	Start time H mins s	Results
Heat exchanger integrity					Test pressure……bar
Automatic control					Sterilisation temp (ST) selected ..°C
Instrument calibration					See below
Chamber temp profile					Max temperature attained……°C
Thermometric small load					ST selected…..°C Max temp…….s Decontamination time….mins….. s
Thermometric full load					ST selected °C Max temp…….s Decontamination time……mins…….s
Coolant quantity					Concentration of residue…mg/litre
Sound pressure*					Loading area: mean dBA, peak….dBA
					Plant room: mean….dBA, peak…dBA

Test equipment file references……

STERILIZER INSTRUMENT CALIBRATION

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time.
Sense is measured reading = recorded/indicated error.

	Measured	Recorded error	Indicator
Chamber temperature	°C	°C	°C
Load temperature (1)	°C	°C	
Load temperature (2)	°C	°C	
Chamber pressure	bar	bar	bar

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Appendix 3
Reference……../SC Page 2 of 2

FLUID STERILIZER – SUMMARY OF COMMISSIONING TESTS

SUMMARY OF THERMOMETRIC TESTS
Sterilization temperature (ST) selected……°C

Automatic controller settings for plateau period: .Temperature…….°C Time…min….s
Door release temperature setting …….°C Fo setting ……min

				Temperature sensors		
Event	Elapsed time	Chamber pressure	Spray pressure			
	Min s	bar	bar	Drain/ Vent °C	Fast °C	Slow °C
SMALL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Fo value at end Equilibration time Holding time Total cycle time				No min	No min	No min

Temperature of hottest container when cycle complete……..^{0}C (sensor no. …….)

FULL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Fo value at end Equilibration time Holding time Total cycle time				No min	No min	No min

DECLARATION OF TEST PERSON (STERILIZERS)

1. The installation checks and tests have been completed and show that the sterilizer has been provided and installed in accordance with its specifications.
2. All test instruments have current calibration certificates.
3. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
4. The commissioning tests have been completed and show that the sterilizer functions correctly when operated in accordance with operational instructions.

Test Person: Name:……Signature:……..Date:……..

DECLARATION OF USER AND FOR MEDICINAL PRODUCTS QUALIFIED PERSON

The sterilizer is fit for use. The first yearly tests are due no later than:

User: Name:……Signature:……Date: ……
Qualified Person: Name:……Signature:……Date: ……

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Appendix 3
Reference……../SPQ Page 1 of 2

FLUID STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

Hospital: ……..Department: ……Date(s) of tests: …….

STERILIZER: Manufacturer: ……Model:……Usable chamber space ….litres

Serial number: ……Plant reference number: ……

Chamber shape: ……Width: ……mm Height: ….mm Depth: …mm

OPERATING CYCLE REFERENCE: ……Sterilization temperature: …….°C

LOADING CONDITION REFERENCE: ……Batch ref: ……

Nature of Load: ……

LOCATION OF SENSORS FOR THERMOMETRIC PQ TEST

Enter positions of temperature sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor number	Sensor type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of Sensor
1	T				Active chamber drain/vent
2	T				
3	T				
4	T				
5	T				
6	T				
7	T				
8	T				
9	T				
10	T				
11	T				
12	T				
13	P				Chamber pressure test port
14	P				Spray pressure test port

(T = Temperature P = Pressure)

Test equipment file reference……

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FLUID STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

SUMMARY OF THERMOMETRIC PQ TEST
Sterilization temperature (ST) selected ……..°C

Automatic controller setting for plateau period: Temperature: …..°C Time …….mins ……s

Door release temperature setting ……..°C F. setting ……..min

Identify sensors in the load which are the fastest and the slowest to attain the ST. Enter elapsed times and measured chamber pressures and temperatures.

		Sensor first attains ST		Sensor falls below ST				
Sensor Number	Description	Time Min s	Press bar	Time Min s	Press bar	Time above ST Min s	Max Temp °C	Fo Min
	Drain/vent fastest slowest							

Equilibration time ….min ……s Holding time …….min……s Total cycle time ….min….s

Temp of hottest bottle at end…..°C (Sensor…..) Coolant decontamination time …..min……s

Cycle number: ……Master Process Record reference: ……..

Is a microbiological PQ test required for this loading condition? ……

Result of microbiological test PASS/FAIL PQ report reference: ……

DECLARATION OF TEST PERSON (STERILIZERS)

1. This test has been preceded by a satisfactory sequence of commissioning/yearly tests.
   Reference……
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person: Name: ……Signature:……..Date: ……

DECLARATION OF USER AND FOR MEDICINAL PRODUCTS QUALIFIED PERSON

The sterilizer is fit for use with the loading condition identified above. The first performance re-qualification test, due…….

User: Name:……Signature:……..Date: ……

Qualified Person: Name:……Signature:……..Date:……..

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Appendix 3
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FLUID STERILIZER – SUMMARY OF YEARLY/REVALIDAITON TESTS

Hospital:……..Department:……Date (s) of tests:…….

STERILIZER: Manufacturer:……Model:……..Usable chamber space……litres

Serial number:……Plant reference number:……..

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference:…….

Test (as specified in SHTM 2010)	Pass or fail	Cycle number	Start time H min s	Results
Yearly safety checks Heat exchanger integrity Automatic control Instrument calibration Coolant quality				Test pressure bar Sterilization temp (ST) selected °C See below Concentration of residue mg/litre

PERFORMANCE REQUALIFICATION

				Thermometric			Micro (optional)	
PQ report Reference	Loading condition Ref	Operating fail	ST °C	Pass or fail	Cycle Number	Start time H min s	Pass or fail	

Test equipment file references:

DECLARATION OF TEST PERSON (STERILIZERS) AND USER

1. All test instruments have current calibration certificates.
2. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The yearly/revalidation checks and tests have been completed and confirm that the sterilizer is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person: Name:…….Signature:……..Date:…….

DECLARATION OF USER AND FOR MEDICINAL PRODUCTS QUALIFIED PERSON

The sterilizer is fit for use. The fist yearly tests are due no later than:

User: Name:……..Signature:……..Date:……...

Qualified Person: Name:……..Signature:……..Date:……..

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STERILIZER FOR UNWRAPPED INSTRUMENTS AND UTENSILS
SUMMARY OF COMMISSIONING TEST

Hospital:……..Department:…….Dates(s) of tests:……

Sterilizer: Manufacturer:……Model:……..……Usable chamber space…….litres

Serial number:…… Plant reference number:……

RESULTS OF COMMISSIONING TESTS Data file reference:……...

Test (as specified in SHTM 2010 *= optional)	Pass or fail	Cycle number	Start time H min s	Results
Automatic control Instrument calibration Chamber temp profile Chamber overheat cut-out Thermometric small load Thermometric full load Sound pressure *				Sterilization temp (ST) selected (°C) See below Max temp attained (°C) Max temp attained (°C) ST selected (°C) Max temp (°C) ST selected °C Max temp °C Loading area: mean dBA, peak dBA Plant room: mean dBA, peak dBA

Test equipment file references:

STERILIZER INSTRUMENT CALIBRATION:

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time.

Sensor is *measured reading – recorded/indicated error*

	Measured	Recorder error	Indicator error
Chamber temperature	°C	°C	°C
Chamber pressure	bar	bar	bar

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Appendix 3
Reference……../SC Page 2 of 2

STERILIZER FOR UNWRAPPED INSTRUMENTS AND UTENSILS
SUMMARY OF COMMISSIONING TEST

SUMMARY OF THERMOMETRIC TESTS

Sterilization temperature (ST) selected ……°C
Automatic controller settings for plateau period: Temperature…….°C Time ……min…s

Event	Elapsed time	Chamber	Temperature sensors		
	Min s	Bar	Drain/ Vent °C	Load °C	Free Space °C
SMALL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Equilibration time Holding time Total cycle time			No…….	No……	No…….
FULL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Equilibration time Holding time Total cycle time			No……	No…….	No…….

DECLARATION OF TEST PERSON (STERILIZERS)

1. The installation checks and tests have been completed and show that the sterilizer has been provided and installed in accordance with it specification.
2. All test instruments have current calibration certificates.
3. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
4. The commissioning tests have been completed and show that the sterilizer functions correctly when operated in accordance with operational instructions.

Test Person: Name: ……Signature: ……Date:…….

DECLARATION OF USER

The sterilizer is fit for use. The first yearly tests are due no later than:

User: Name: ……Signature: ……Date:…….

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STERILIZER FOR UNWRAPPED INSTRUMENTS AND UTENSILS
SUMMARY OF PERFORMANCE QUALIFICATION TESTS

Hospital: …….Department:……Date(s) of tests:…….
STERILIZER: Manufacturer:…….Model:……Usable chamber space……litres
Serial number: ……Plant reference number:……
Chamber shape:…….. Width……mm Height……..mm Depth……mm

OPERATING CYCLE REFERENCE: ……Sterilization temperature: …….°C

LOADING CONDITION REFERENCE:……Batch reference: ……

Nature of load: ……..

LOCATION OF SENSORS FOR THERMOMETRIC PQ TEST

Enter positions of temperature sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor number	Sensor type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of Sensor
1	T				Active chamber drain/vent
2	T				
3	T				
4	T				
5	T				
6	T				
7	T				
8	T				
9	T				
10	T				
11	T				
12	T				
13	P				Chamber pressure test port

(T = Temperature P = Pressure)

Test equipment file references……..

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STERILIZER FOR UNWRAPPED INSTRUMENTS AND UTENSILS
SUMMARY OF PERFORMANCE QUALIFICATION TESTS

SUMMARY OF THERMOMETRIC PQ TEST

Sterilisation temperature (ST) selected ……..…… °C

Automatic controller setting for plateau period: Temperature ……°C Time……min …….s

Identify sensors in the load which are the fastest and the slowest to attain the ST.
Enter elapsed times and measured chamber pressures and temperatures.

Sensor Number	Description	Sensor first attains ST		Sensor falls below ST		Time above ST Min s	Max Temp °C
		Time Min s	Press bar	Time Min s	Press bar		
	Drain/vent fastest slowest						

Equilibration time: …….mins……s Holding time: …..min…….s Total cycle time: ….mins……s

Cycle number: ……..Master Process Record reference:……

Is a microbiological PQ test required for this loading condition?……

Result of microbiological test PASS/FAILPQ report reference……

DECLARATION OF TEST PERSON (STERILIZERS)

1. This test has been preceded by a satisfactory sequence of commissioning/yearly tests.
   Reference ……
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person: Name: ……..Signature:……. Date……

DECLARATION OF USER

The sterilizer is fit for use with the loading condition identified above. The first performance re-qualification test, due…….

User: Name: ……. Signature:……. Date……..

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STERILIZER FOR UNWRAPPED INSTRUMENTS AND UTENSILS SUMMARY OF YEARLY/REVALIDATION TESTS

Hospital:……Department:……..Date (s) of tests:……

STERILIZER: Manufacturer:……...Model:……Usable chamber space……litres

Serial number: ……Plant reference number: ……..

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference: ……..

Test (as specified in SHTM 2010)	Pass or fail	Cycle number	Start time H min s	Results
Yearly safety checks Automatic control Instrument calibration Chamber overheat cut-out Thermometric small load Thermometric full load				Sterilization temp (ST) selected °C Max temp attained °C ST selected °C Max temp °C ST selected °C Max temp °C

PERFORMANCE REQUALIFICATION (as required by user)

				Thermometric			Micro (optional)	
PQ report Reference	Loading condition Ref	Operating cycle ref	ST °C	Pass or fail	Cycle Number	Start time H min s	Pass or fail	

Test equipment file references:

DECLARATION OF TEST PERSON (STERILIZERS) AND USER

1. All test instruments have current calibration certificates.
2. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The yearly/revalidation checks and tests have been completed and confirm that the sterilizer is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person: Name: ……Signature:……Date:…….

DECLARATION OF USER

The sterilizer is fit for use. The fist yearly tests are due no later than:

User: Name:……Signature:……Date:…….

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Appendix 3
Reference……../SC Page 1of 1

DRY HEAT STERILIZER – SUMMARY OF COMMISSIONING TESTS

Hospital:…….Department:…….Date (s) of tests:…….

STERILIZER: Manufacturer:…… Model:……. Usable chamber space……litres

Serial number: …… Plant reference number: ……

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference:……..

Test (as specified in SHTM 2010 *= optional)	Pass or fail	Cycle number	Start time H min s	Results
Automatic control Instrument calibration Chamber temp profile Chamber overheat cut-out Basic Performance*				Sterilization temp (ST) selected °C See below Max temperature °C Max temperature °C Heat-up time min Drift °C Overshoot °C Variation °C

Test equipment file references……..

STERILIZER INSTRUMENT CALIBRATION

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time. Sensor is *measured reading – recorded/indicated error.*

	Measured	Recorder error	Indicator error
Chamber temperature	°C	°C	°C
Load Temperature (1)	°C	°C	
Load Temperature (2)	°C	°C	

DECLARATION OF TEST PERSON (STERILIZERS) AND USER

1. The installation checks and tests have been completed and show that the sterilizer has been provided and installed in accordance with its specifications.
2. All test instruments have current calibration certificates.
3. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
4. The commissioning tests have been completed and show that the sterilizer functions correctly when operated in accordance with operational instructions.

Test Person: Name: …… Signature:…….Date: ……..

DECLARATION OF USER AND FOR MEDICINAL PRODUCTS QUALIFIED PERSON

The sterilizer is fit for use. The fist yearly tests are due no later than:

User: Name: …… Signature: …… Date: ……..

Qualified Person: Name: …… Signature: ……Date: ……

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Reference……/SPQ

DRY HEAT STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

Hospital …… Department …… Date(s) of tests ……

STERILIZER: Manufacturer …… . Model …… Usable chamber space …… litres

Serial number ……Plant reference number ……

Chamber shape …….. Width …..…… mm Height …….mm Depth …….mm

OPERATING CYCLE REFERENCE ……Sterilization temperature…… °C

LOADING CONDITION REFERENCE …… Batch reference ……..

Nature of load ……

LOCATION OF SENSORS FOR THERMOMETRIC PQ TEST

Enter positions of temperature sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor number	Sensor type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of sensor
1	T				On temperature recorder sensor
2	T				On temperature indicator sensor
3	T				
4	T				
5	T				
6	T				
7	T				
8	T				
9	T				
10	T				
11	T				
12	T				
13	P				Differential pressure across filter

(T = Temperature P = Pressure)

Test equipment file references ……

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DRY HEAT STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

SUMMARY OF THERMOMETRIC PQ TEST

Sterilization temperature (ST) selected ……. °C

Automatic controller setting for plateau period: Temperature ……..°C Time…….min…….s

Cooling temperature setting …… °C Fo setting* …… min

Identify sensors in the load which are the fastest and slowest to attain the ST. Enter elapsed times and measured chamber pressures and temperatures.

Sensor number	Description	Sensor first attains ST		Sensor falls below ST		Time above ST min s	Max temp °C	Fo* min
		Time min s	Press bar	Time min s	Press bar			
1. 2. ……. ……..	Temp recorder Temp indicator Fastest Slowest							

Equilibration time …….min…..s Holding time ……. min…….s Total cycle time ……..min……s

Cooling stage – minimum differential pressure across air filter: ……. millbars/pascals

Temp of hottest container at end …….. °C (sensor ……)

Cycle number …… Master Process Record reference ……..

Is a microbiological PQ test required for this loading condition ? …….

Result of microbiological test PASS/FAIL PQ report reference ……..

DECLARATION OF TEST PERSON (STERILIZERS)

1. This test has been preceded by a satisfactory sequence of commissioning/yearly tests. Reference……..
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person: Name …….. Signature …….. Date ……

DECLARATION OF USER AND FOR MEDICAL PRODUCTS QUALIFIED PERSON

The sterilizer is fit for use with the loading condition identified above. The first performance requalification test, due …….

User: Name …… Signature …… Date …….

Qualified Person: Name …… Signature …… Date …….

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Appendix 3
Reference……../SYPage 1 of 1

DRY HEAT STERILIZER – SUMMARY OF YEARLY/REVALIDATION TESTS

Hospital: ……Department: ……Date (s) of tests: ……..

STERILIZER: Manufacturer: ……Model: ……Usable chamber space……..litres

Serial number: ……Plant reference number: …….

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference: ……..

Specified in SHTM 2010	Pass or fail	Cycle number	Start time H min s	Results
Yearly safety checks Automatic control Instrument calibration Chamber overheat cut-out				Sterilization temp (ST) selected °C Max temp attained °C

PERFORMANCE REQUALIFICATION

				Thermometric			Micro (optional)	
PQ report Reference	Loading condition Ref	Operating cycle ref	ST °C	Pass or fail	Cycle Number	Start time H min s	Pass or fail	

Test equipment file references: ……..

DECLARATION OF TEST PERSON (STERILIZERS)

1. All test instruments have current calibration certificates.
2. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The yearly/revalidation checks and tests have been completed and confirm that the sterilizer is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person: Name: …… Signature: …… Date: ……

DECLARATION OF USER AND FOR MEDICINAL PRODUCTS QUALIFIED PERSON

The sterilizer is fit for use. The fist yearly tests are due no later than:

User: Name: …… Signature: …….. Date: ……

Qualified Person: Name: …… Signature: …… Date: ……..

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Appendix 3
Reference……../SC Page 1 of 2

LOW-TEMPERATURE STEAM DISINFECTOR
LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER
SUMMARY OF COMMISSIONING TEST

Hospital: …… Department: …… Date (s) of tests: ……

STERILIZER: Manufacturer: …… Model: …… Usable chamber space……litres

Serial number: …… Plant reference number: ……..

RESULTS OF COMMISSIONING TESTS Data file reference: ……

	Pass or fail	Cycle number	Start time h min s	Results
Steam non-condensable gas				Concentration of NCG (%)
Steam superheat				Superheat (°C)
Steam dryness				Dryness value
Automatic control				Sterilization temp (ST) selected (°C)
Instrument calibration				See below
Vacuum leak monitor				
				Max temp attained (°C)
Chamber overheat cut-out				Chamber cut-out: Max temp (°C)
				Jacket cut-out: Max temp (°C)
Chamber wall temperature				Max temp attained (°C)
Thermometric small load				ST selected (°C) Max temp (°C)
Load dryness*				Average gain in mass (%)
Thermometric full load				ST selected (°C) Max temp (°C)
Load dryness*				Average gain in mass (%)
Basic performance				Holding time min s
Environ formaldehyde				Average gas concentration ppm
Vacuum leak (final)				Leak rate mbar/min
Sound pressure*				Loading area: mean dBA, peak dBA
				Plant room: mean dBA, peak dBA

Test equipment file reference……

STERILIZER INSTRUMENT CALIBRATION

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time.
Sense is measured reading = recorded/indicated error

	Measured	Recorder error	Indicator error
Chamber temperature	°C	°C	°C
Chamber pressure	bar	bar	bar

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Appendix 3
Reference……../SC Page 2 of 2

LOW-TEMPERATURE STEAM DISINFECTOR
LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER
SUMMARY OF COMMISSIONING TEST

SUMMARY OF THERMOMETRIC TESTS

Sterilization temperature (ST) selected ……°C

Automatic controller setting for plateau period: Temperature: ……°C Time ……..mins ……s

			Temperature sensors		
	Elapsed time Min s	Chamber pressure	Drain/vent °C	Test pack °C	Free Space °C
SMALL LOAD TEST			No……..	No……..	No……
Start of plateau period					
Start of holding time					
End of holding time					
Maximum values attained					
Equilibration time					
Total cycle time					
FULL LOAD TEST			No……..	No…….	No…….
Start of plateau period					
Start of holding time					
End of holding time					
Maximum values attained					
Equilibration time					
Holding time					
Total cycle time					

SUMMARY OF MICROBIOLOGICAL TEST FOR BASIC PERFORMANCE*

Automatic controller settings for plateau period: Temperature: …….°C Time …….min ……s
Primary material: ……Batch: …… Expiry date: ……..
Primary material used in the cycle: ……..Settings: ……millilitres. Measured: ……mg/litre

DECLARATION OF TEST PERSON (STERILIZERS)

1. The installation checks and tests have been completed and show that the sterlizer has been provided and installed in accordance with its specifications.
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been checked before and after the thermometric tests.
4. The commissioning tests have been completed and show that the sterilizer functions correctly when operated in accordance with operational instructions.

Test Person: Name: …… Signature: …… Date: ……

DECLARATION OF CONSULTANT MICROBIOLOGIST

The results of the microbiological test for basic safety performance are satisfactory.

Microbiologist: Name: …… Signature: …… Date: ……

DECLARATION OF USER

The sterilizer is fit for use. The first yearly tests are due no later than:

User: Name: …… Signature: …… Date: ……

* not required for LTS

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Appendix 3
References …… /SPQ Page 1 of 2

LOW-TEMPERATURE STEAM DISINFECTOR
LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER
SUMMARY OF PERFORMANCE QUALIFICATION TESTS

Hospital: …… Department: …… Date(s) of tests: ……

STERILIZER
Manufacturer: …… Model: …… Usable chamber space: …….litres

Serial Number: …… Plant reference number: ……..

Chamber shape: …… Width: ……mm Height: ……mm Depth:…….mm

OPERATING CYCLE REFERENCE……..Sterilization Temp: ……°C

LOADING CONDITION REFERENCE……..Batch reference: ……..

Nature of load: ……..…….

LOCATION OF SENSORS FOR THERMOMETRIC PQ TEST

Enter positions of temperature sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor Number	Sensor Type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of Sensor
1	T				Active chamber drain/vent
2	T				
3	T				
4	T				
5	T				
6	T				
7	T				
8	T				
9	T				
10	T				
11	T				
12	T				
13	T				Chamber pressure test port

(T = Temperature P = Pressure)

Test equipment file references:

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References …… /SPQ Page 2 of 2

LOW TEMPERATURE STEAM DISINFECTOR
LOW TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER
SUMMARY OF PERFORMANCE QUALIFICATION TESTS

Summary of Thermometric PQ Test

Sterilisation temperature (ST) selected ……..°C

Automatic controller setting for plateau period: Temperature……°C Time……. min …….s

Identify sensors in the load which are fastest and the slowest to attain the ST.
Enter elapsed times and measured chamber pressures and temperatures.

Sensor Number	Description	Sensor first attains ST		Sensor falls below ST		Time above ST Min s	Max temp °C
		Time min s	Press bar	Time min s	Press bar		
	Drain/Vent Fastest Slowest						

Equilibration time…..min…….s Holding time…..min…..s Total cycle time…..min……s

Cycle number…….. Master Process Record reference…….

*Result of microbiological PQ test: PASS/FAIL Cycle no. ….

*Result of environmental gas test: PASS/FAIL Cycle no. …Average gas concentration...ppm

Declaration of Test Person (Sterilizers)

1. This test has been preceded by a satisfactory sequence of commissioning / yearly tests. Reference…… ……
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person: Name …….. Signature …… Date …….

Declaration of Consultant Microbiologist

The results of the microbiological rest for performance qualification are satisfactory.

Microbiologist: Name ……Signature …….. Date …….

Declaration of User

The sterilizer is fit for use with the loading condition identified above. The first performance requalification test, due …….

User: Name ……Signature …….. Date ……..

* not required for LTS

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Appendix 3
Reference……../SY Page 1of 1

LOW-TEMPERATURE STEAM DISINFECTOR
LOW-TEMPERATURE STEAM AND FORMALDEHYDE STERILIZER
SUMMARY OF YEARLY/REVALIDATION TESTS

Hospital: ……Department: ……..Date (s) of tests: ……..

STERILIZER: Manufacturer: …….. Model: ……Usable chamber space ……litres

Serial number: ……..Plant reference number: ……..

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference: ……..

Test (as specified in SHTM 2010)	Pass or fail	Cycle number	Start time H min s	Results
Yearly safety checks				Max temp attained (°C)
Chamber overheat cut-out				Max temp attained (°C)
Chamber wall temperature				Sterilisation temp (ST) selected (°C)
Automatic control				
Instrument calibration				
Vacuum leak monitor				ST selected (°C) Max temp (°C)
Thermometric small load				ST selected (°C) Max temp (°C)
Thermometric full load				
Basic performance				Average gas concentration ppm
Environment formaldehyde				Leak rate mbar/min
Vacuum leak (final)				

PERFORMANCE REQUALIFICATION (if required)

				Thermometric			Microbio Env. Gas	
PQ report Reference	Loading condition Ref	Operating cycle ref	ST °C	Pass or fail	Cycle Number	Start time H min s	Pass or fail	Pass or fail

Test equipment file references:

DECLARATION OF TEST PERSON (STERILIZERS) AND USER

1. All test instruments have current calibration certificates.
2. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The yearly/revalidation checks and tests have been completed and confirm that the sterilizer is safe to use and the commissioning and performance qualification data collected during validation remain valid.

Test Person: Name: ……Signature: ……..Date: …….

DECLARATION OF MICROBIOLOGIST

The results of the microbiological test are satisfactory.

Microbiologist: Name: ……Signature: ……..Date: …….

DECLARATION OF USER
The sterilizer is fit for use. The fist yearly tests are due no later than:

User: Name: ……Signature:……Date: ……..

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Appendix 3
Page 1 of 1

LOW TEMPERATURE STEAM AND FORMALDEHYDE STERLIZER
REPORT OF MICROBIOLOGICAL AND CHEMICAL INDICATOR TEST FOR BASIC PERFORMANCE

Automatic controller settings for plateau period: Temperature _____°C Time _____ min ____ Secs

Primary materials for generating formaldehyde Batch No _____ Expiry Date _____

Manufacture _____ Reference Certificate No _____

Bath No _____ Expiry Date _____Chemical Indicator Batch No _____ Expiry Date _____

Mass of primary material use in cycle Setting _____ gram Measured _____ gram

Biological Indicators (BI) Organism _____ Strain _____

Manufacturers declared number of recoverable spores on each indicator _____ Expiry Date _____

Batch No _____ Process Cycle No _____ Date _____

TEST PERSON

Name _____ Signature _____ Date _____

LOCATION OF CHEMICAL AND BIOLOGICAL INDICATORS

Location	No	Biological Chemical	No	Biological Chemical	No	Biological Chemical
Rear plane	1	Pass/Fail Pass/Fail	2	Pass/Fail Pass/Fail	3	Pass/Fail Pass/Fail
	4	Pass/Fail Pass/Fail	5	Pass/Fail Pass/Fail	6	Pass/Fail Pass/Fail
	7	Pass/Fail Pass/Fail	8	Pass/Fail Pass/Fail	9	Pass/Fail Pass/Fail
Centre plane	10	Pass/Fail Pass/Fail	11	Pass/Fail Pass/Fail	12	Pass/Fail Pass/Fail
	13	Pass/Fail Pass/Fail	14	Pass/Fail Pass/Fail	15	Pass/Fail Pass/Fail
	16	Pass/Fail Pass/Fail	17	Pass/Fail Pass/Fail	18	Pass/Fail Pass/Fail
Front plane	19	Pass/Fail Pass/Fail	20	Pass/Fail Pass/Fail	21	Pass/Fail Pass/Fail
	22	Pass/Fail Pass/Fail	23	Pass/Fail Pass/Fail	24	Pass/Fail Pass/Fail
	25	Pass/Fail Pass/Fail	26	Pass/Fail Pass/Fail	27	Pass/Fail Pass/Fail

Line Pickerall	Wrapped	No 1	Pass/Fail Pass/Fail	No 2	Pass/Fail Pass/Fail
Helices	Unwrapped	No 3	Pass/Fail Pass/Fail	No 4	Pass/Fail Pass/Fail

Biological Controls

Unexposed BI	No 1	Growth/No Growth	No 2	Growth/No Growth	No 3	Growth/No Growth
No BI	No 4	Growth/No Growth	No 5	Growth/No Growth	No 6	Growth/No Growth

Test performed by:- NAME _____ SIGNATURE _____ DATE _____

NAME _____ SIGNATURE _____DATE _____

NAME _____ SIGNATURE _____DATE _____

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Appendix 3
Reference……../SC Page 1 of 2

ETHYLENE OXIDE STERILIZER – SUMMARY OF COMMISSIONING TESTS

Hospital:…….. Department: ……..Date (s) of tests: …….

STERILIZER: Manufacturer: …… Model: ……. Usable chamber space ….. litres

Serial number: …… Plant reference number: ……..

Composition of gas: …… Gas source: …… Preset gas exposure temp ……..°C

RESULTS OF COMMISSIONING TESTS Data file reference: ……

Test (as specified in SHTM 2010) * = optional	Pass or fail	Cycle number	Start time H min s	Results
Pressure leak*				Leak rate mbar/min
Automatic control				
Instrument calibration				See below
Vacuum leak monitor				
Chamber temp profile				
Chamber overheat cut-out				Chamber cut-out Max temp °C
				Jacket cut-out Max temp °C
Chamber wall temp				Max temp attained °C
Chamber space temp				Max temp attained °C
Gas circulation*				
Gas exposure time				Critical GET h min s
Vacuum leak (final)				Leak rate mbar/min
Sound pressure*				Loading area: mean dBA, peak dBA
				Plant room: mean dBA, peak dBA

Test equipment file references

STERILIZER INSTRUMENT CALIBRATION

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time.

Sensor is measured reading – recorded/indicated error

	Measured	Recorded Error	Indicator Error
Chamber temp	°C	°C	°C
Jacket temp	°C	°C	°C
Chamber pressure	bar	bar	bar
Chamber humidity	%RH	%RH	%RH

* If applicable

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Reference……../SC Page 2 of 2

SUMMARY OF MICROBIOLOGICAL TEST FOR GAS EXPOSURE TIME (GET)

Jacket overheat cut-out setting °C
Chamber overheat cut-out setting °C
Vacuum leak monitor setting mbar
Pressure leak monitor setting mbar

Cycle No	Gas exposure time h……..m…….s…	No Bls surviving

Critical GET (shortest with no survivors)
h……..m…….s……..

Recommended GET for production loads
h……..m…….s……..

SET AND DETERMINE VALUES OF CYCLE VARIABLES FOR CRITICAL GAS EXPOSURE TIME

Cycle Variable	Set Value	Determined	Method of determination
Mass of gas used	g	g	
EO concentration	g/l	g/l	
Minimum chamber temp	°C	°C	
Minimum chamber pressure	bar	bar	
Maximum chamber pressure	bar	bar	
Minimum chamber humidity	%RH	%RH	

DECLARATION OF TEST PERSON (STERILIZERS)

1. The installation tests and checks have been completed and show that the sterilizer has been provided and installed in accordance with its specifications.
2. All test instruments have current calibration certificates.
3. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
4. The commissioning tests have been completed and show that the sterilizer functions correctly when operated in accordance with operational instructions.

Test Person: Name…….. Signature……..Date ……..

DECLARATION OF CONSULTANT MICROBIOLOGIST

The results of the microbiological test for gas exposure time are satisfactory.

Microbiologist: Name…….. Signature……..Date ……..

DECLARATION OF USER

The steriliser is fit for use. The first yearly tests are due no later than

User: Name…….. Signature……..Date ……..

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Appendix 3
Reference……../SPQ Page 1 of 2

ETHYLENE OXIDE STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

Hospital: …….. Department: …….Date(s) of tests: ……..

STERILIZER: Manufacturer: …….Model: ……Usable chamber space: ……..litres

Serial number: …….. Plant reference number: ……

Composition of gas: ……Gas source: ……..Preset gas exposure temperature: ……°C

Chamber shape: ……Width:……..mm Height: ……mm Depth: ……mm

OPERATING CYCLE: Mass of gas ……g Gas exposure time: ……h ……min ……..s

LOADING CONDITION REFERENCE: ……Batch reference:……..

Nature of load: ……

LOCATION OF SENSORS FOR PARAMETRIC PQ TEST

Enter positions of sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor number	Type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of sensor
					On temperature recorder sensor
					Gas entry port*
					Gas preheater*
					Chamber pressure port
					Chamber free space
					Load

(T = Temperature P = Pressure)
Test equipment file reference……

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ETHYLENE OXIDE STERLIZER– SUMMARY OF PERFORMANCE QUALIFICATION TESTS

SUMMARY OF PARAMETRIC PQ TEST

Sterilisation temperature (ST) selected ……..°C

Automatic controller setting for plateau period: Temperature ……°C Time ……..min …….s

Identify sensors in the load which are the fastest and the slowest to attain the ST. Enter elapsed times and measured chamber pressures and temperatures.

Humidity and temperature in chamber at the end of conditioning period: ……%RH……..°C
Humidity and temperature in the load if in hottest part of chamber: ……..%RH……..°C

		Sensor first attains ST		Sensor falls below ST			
Sensor number	Description	Time Min s	Press bar	Time Min s	Press bar	Time above ST Min s	Max Temp °C
1	Recorder sensor						
2*	Gas entry port						
3*	Gas preheater						
	Slowest load item						
	Hottest surface						
	Coolest surface						
	Coolest space						

Equilibration time ……mins ……s Holding time……min …….s Total cycle time ……mins …….s

Cycle number …… Master Process Record reference ……

RESULT OF MICROBIOLOGICAL PQ TEST PASS/FAIL

RESULT OF ENVIRONMENTAL GAS TEST PASS/FAIL Average gas concentration ……ppm

DECLARATION OF TEST PERSON (STERILIZERS)

1. This test has been preceded by a satisfactory sequence of commissioning/yearly tests. Reference: ……
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person: Name: …… Signature: ……Date: ……..

DECLARATION OF CONSULTANT MICROBIOLOGIST

The results of the microbiological test for performance qualification are satisfactory.

Microbiologist: Name: …… Signature: …… Date: ……..

DECLARATION OF USER

The sterilizer is fit for use with the loading condition identified above. The first performance re-qualification test, due

User: Name: …… Signature: …… Date: ……..

* Not required on cartridge systems.

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Reference……../SY Page 1 of 1

ETHYLENE OXIDE STERILIZER – SUMMARY OF YEARLY/REVALIDATION TESTS

Hospital: …….Department: …… Date (s) of tests: ……..

STERILIZER: Manufacturer: ……Model: ……Usable chamber space …….litres

Serial number: ……..Plant reference number: ……

Composition of Gas: ……Gas Source: ……Preset gas exposure temp ……°C

RESULTS OF YEARLY/REVALIDATION TESTS Data file reference: ……

Test (as specified in SHTM 2010)	Pass or fail	Cycle number	Start time h min s	Results
Yearly safety checks				
Pressure leak*				Leak rate mbar/min
Automatic control				
Instrument calibration				See below
Chamber temp profile				
Chamber overheat cut-out				Chamber cut-out Max temp °C
				Jacket cut-out Max temp °C
Chamber wall temp				Max temp attained °C
Chamber space temp				Max temp attained °C
Gas circulation*				
Basic performance				Critical GET ……h…….min ……s
Vacuum leak (final)				Leak rate ……mbar/min
Vacuum leak monitor				

* if applicable

PERFORMANCE REQUALIFICATION

				Thermometric			Microbio Env Gas	
PQ report reference	Loading condition ref	Operating cycle ref	ST °C	Pass or fail	Cycle Number	Start time h min s	Pass or fail	Pass or Fail

Test equipment file references:

DECLARATION OF TEST PERSON (STERILIZERS)

1. All test instruments have current calibration certificates.
2. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The yearly/revalidation checks and tests have been completed and confirm that the sterilizer is safe to use and that commissioning and performance qualification data collected during validation remain valid.

Test Person: Name: ……..Signature: ……..Date: ……

DECLARATION OF MICROBIOLOGIST
The results of the microbiologist test are satisfactory

Microbiologist: Name: ……..Signature: ……Date: ……..

DECLARATIONOF USER
The sterilizer is fit for use. The firstly yearly tests are due no later than:

User: Name: ……Signature: ……Date: ……

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ETHYLENE OXIDE STERILIZER
REPORT OF MICROBIOLOGICAL TEST FOR BASIC PERFORMANCE

Automatic controller settings for plateau period: Temperature _____°C Time _____ min ____ Secs

Pre-set gas exposure temperature _____°C Composition of gas _____ Gas source _____

Manufacture _____ Reference Certificate No _____

Batch No _____ Expiry Date _____ Chemical Indicator Batch No _____ Expiry Date _____

Mass of primary material use in cycle testing _____ gram Measured _____ gram

Biological Indicators (BI) Organism _____ Strain _____

Manufacturers declared number of recoverable spores on each indicator _____Expiry Date _____

Batch No _____Process Cycle No _____ Date _____

TEST PERSON

Name _____ Signature _____ Date _____

LOCATION OF CHEMICAL AND BIOLOGICAL INDICATORS

Location	No	Biological Chemical	No	Biological Chemical	No	Biological Chemical
Rear plane	1	Pass/Fail Pass/Fail	2	Pass/Fail Pass/Fail	3	Pass/Fail Pass/Fail
	4	Pass/Fail Pass/Fail	5	Pass/Fail Pass/Fail	6	Pass/Fail Pass/Fail
	7	Pass/Fail Pass/Fail	8	Pass/Fail Pass/Fail	9	Pass/Fail Pass/Fail
Centre plane	10	Pass/Fail Pass/Fail	11	Pass/Fail Pass/Fail	12	Pass/Fail Pass/Fail
	13	Pass/Fail Pass/Fail	14	Pass/Fail Pass/Fail	15	Pass/Fail Pass/Fail
	16	Pass/Fail Pass/Fail	17	Pass/Fail Pass/Fail	18	Pass/Fail Pass/Fail
Front plane	19	Pass/Fail Pass/Fail	20	Pass/Fail Pass/Fail	21	Pass/Fail Pass/Fail
	22	Pass/Fail Pass/Fail	23	Pass/Fail Pass/Fail	24	Pass/Fail Pass/Fail
	25	Pass/Fail Pass/Fail	26	Pass/Fail Pass/Fail	27	Pass/Fail Pass/Fail

Biological Controls

Unexposed BI	No 1	Growth/No Growth	No 2	Growth/No Growth	No 3	Growth/No Growth
No BI	No 4	Growth/No Growth	No 5	Growth/No Growth	No 6	Growth/No Growth

Test performed by:- NAME _____ SIGNATURE _____ DATE _____

NAME _____ SIGNATURE _____DATE _____

NAME _____ SIGNATURE _____DATE _____

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Appendix 3
Reference……../SC Page 1 of 2

LABORATORY STERILIZER – SUMMARY OF COMMISSIONING TESTS

NAME OF PROCESS CYCLE

Hospital: ……Department: ……Date (s) of tests: ……

STERILIZER: Manufacturer: ……Model: ……Usable chamber space ……litres

Serial number: ……..Plant reference number: ……

RESULTS OF COMMISSIONING TESTS Data file references ……...

Test (as specified in SHTM 2010 * = Optional)	Pass or fail	Cycle number	Start time H min s	Results / notes
Automatic control				Sterilization temp (ST) selected °C
Instrument calibration				See below
Chamber temp profile				Max temp attained °C
Thermometric Small Load				ST selected °C Max temp °C
Thermometric Full Load				ST selected °C Max temp °C
Vacuum leak (final)*				Leak rate mbar/min
Thermal door lock*				
Sound pressure*				Loading area: mean dBA, peak dBA
				Plant area: mean dBA, peak dBA

Test equipment file references

STERILIZER INSTRUMENT CALIBRATION

Errors for instruments fitted to sterilizer as measured by test instruments during the holding time.
Sense is measured reading = recorded/indicated error.

	Measured	Recorded Error	Indicator Error
Chamber temp	°C	°C	°C
Load temp (1)*	°C	°C	°C**
Load temp (2)*	°C	°C	°C**
Chamber pressure	bar	bar	bar

* if applicable

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References …… /SC Page 2 of 2

LABORATORY STERILIZER – SUMMARY OF COMMISSIONING TESTS

Name of Process Cycle

SUMMARY OF THERMOMETRIC TESTS
Sterilization temp (ST) selected ……°C
Automatic controller settings for plateau period: Temp ……°C Time…….. min……..s
Door release temperature setting …°C……. Fo Setting……min*

Event	Time elapsed	Chamber pressure	Temperature Sensors		
	Min s	bar	Drain/ Vent °C	Fast °C	Slow °C
SMALL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Fo value at end* Equilibration time Holding time Total cycle time			No Min	No Min	No Min

Temperature of hottest load item when cycle complete …….°C (sensor no)

FULL LOAD TEST Start of plateau period Start of holding time End of holding time Maximum values attained Fo value at end* Equilibration time Holding time Total cycle time			No Min	No Min	No Min

Temperature of hottest load item when cycle complete ……..°C (sensor no)

Declaration of Test Person (Sterilizers)

1. The installation checks and tests have been completed and show that the sterilizer has been provided and installed in accordance with its specifications.
2. All test instruments have current calibration certificates. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
3. The commissioning tests have been completed and show that the sterilizer functions correctly on this process cycle when operated in accordance with operational instructions.

Test Person: Name ……. Signature …….. Date ……

DECLARATION OF USER

The sterilizer is fit for use. The first yearly tests are due not later than:

User: Name ……. Signature …….. Date ……

* if applicable

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Appendix 3
Reference ……./SPQ

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LABORATORY STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

NAME OF PROCESS CYCLE ……

Site …… Department ……Date(s) of tests ……

STERILIZER: Manufacturer …… Model ……Usable chamber space …….. litres

Serial number …… Plant reference number ……

Chamber shape …… Width …… mm Height ……mm Depth……mm

Sterilization temperature ……°C

OPERATING CYCLE REFERENCE ……

LOADING CONDITION REFERENCE ……

Nature of load ……..

Sample Copy

LOCATION OF SENSORS FOR THERMOMETRIC PQ TEST

Enter positions of temperature sensors within the chamber related to the bottom left-hand corner of a rectangular box viewed from the loading end.

Sensor number	Sensor type	Width (X) mm	Height (Y) mm	Depth (Z) mm	Location of sensor
1	T				Active chamber drain/vent
2	T				
3	T				
4	T				
5	T				
6	T				
7	T				
8	T				
9	T				
10	T				
11	T				
12	T				
13	P				Chamber pressure test port
14	P				Spray pressure test port

(T = Temperature P = Pressure)

Test equipment file references ……

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Appendix 3
Reference ……/SPQ

Page 2 of 2

LABORATORY STERILIZER – SUMMARY OF PERFORMANCE QUALIFICATION TESTS

SUMMARY OF THERMOMETRIC PQ TEST

Sterilization temperature (ST) selected …….. °C

Automatic controller setting for plateau period: Temperature …….. °C Time ….. min …s

Door release temperature setting …….. °C F- setting ……min

Identify sensors in the load, which are the fastest and the slowest to attain the ST. Enter elapsed times and measured chamber pressures and temperatures.

Sensor number	Description	Sensor first attains ST		Sensor falls below ST		Time above ST min s	Max Temp °C	Fo min
		Time min s	Press bar	Time min s	Press bar			
	Drain/vent Fastest Slowest							

Equilibration time …… min…..s Holding time……min …..s Total cycle time …..Min…s

Temp of hottest load item at end …… °C (sensor ……)

Cycle number …… Master Process Record reference ……..

Is a microbiological PQ test required for this loading condition? ……

Result of microbiological test PASS/FAIL PQ report reference …….

DECLARATION OF TEST PERSON (STERILIZERS)

1. This test has been preceded by a satisfactory sequence of commissioning/yearly tests Reference ……..
2. All test instruments have current calibration certificates.
3. Calibration of the thermometric test Instruments has been verified before and after the thermometric tests.
4. The performance qualification tests show that the sterilizer produces acceptable product with the loading condition identified above.

Test Person. Name …… Signature …… Date ……

DECLARATION OF USER

The sterilizer is fit for use with the loading condition identified above. The first performance requalification test, due……

User. Name …… Signature …… Date ……

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Appendix 3
References …… /SY
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LABORATORY STERILIZER -SUMMARY OF YEARLY/REVALIDATION TESTS

Hospital……..……Department…….Date(s) of tests……...

STERLIZER: Manufacturer…….……Model……..…Usable chamber space ……..… litres

Serial Number……..Plant reference number……

RESULTS OF YEARLY / REVALIDATION TESTS Data file ref…….

Test (as specified In SHTM 2010) (as applicable)	Pass or fail	Cycle Number	Start time h min s	Results / Notes
Yearly safety checks				
Automatic Control				
Instrument calibration				
Small discard				Sterlization temp selected °C
Large discard				Sterlization temp selected °C
Culture media (preset)				Sterlization temp selected °C
Culture media (variable)				Sterlization temp selected °C
Fabrics				Sterlization temp selected °C
Empty glassware				Sterlization temp selected °C
Free steaming				Sterlization temp selected °C
Thermometric small load				
Small discard				Sterlization temp selected °C
Large discard				Sterlization temp selected °C
Culture media (preset)				Sterlization temp selected °C
Culture media (variable)				Sterlization temp selected °C
Fabrics				Sterlization temp selected °C
Empty glassware				Sterlization temp selected °C
Free steaming				Sterlization temp selected °C
Thermometric full load				
Small discard				Sterlization temp selected °C
Large discard				Sterlization temp selected °C
Culture media (preset)				Sterlization temp selected °C
Culture media (variable)				Sterlization temp selected °C
Fabrics				Sterlization temp selected °C
Empty glassware				Sterlization temp selected °C
Free steaming				Sterlization temp selected °C
Media preparator				Preset temp °C
Reheat and dispensing				
Vacuum leak test (final)				Leak rate mbar/min
Thermal door lock				Setting °C

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Appendix 3
References …… /SY
Page 2 of 2

LABORATORY STERILIZER -SUMMARY OF YEARLY/REVALIDATION

PERFORMANCE REQUALIFICATION

PO report reference	Loading condition reference	Operating cycle ref	ST °C	Thermometric			Microbio	Notes
				Pass or Fail	Cycle Number	Start time h min s	Pass or Fail	

Test equipment file references

DECLARATION OF TEST PERSON (STERILIZERS)

1. All test instruments have current calibration certificates. Calibration of the temperature test instruments has been checked before and after the thermometric tests.
2. The yearly/revalidation checks and tests have been completed and confirm the sterilizer is safe to use and the commissioning and performance qualification data collected during validation remain valid.

Test Person: Name……..……Signature……..……Date…….

DECLARATION OF USER

The sterilizer is fit for use. The first yearly tests are due no later than:

User: Name……..……..Signature……..……Date…….

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Scottish Health Technical Memorandum 2010

(Part 4 of 6)

Operational management

Sterilization

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NHSScotland, P&EFEx, June 2001

Executive summary

SHTM 2010 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the following types of sterilizer in use in the National Health Service:

a. clinical sterilizers:
   (i) high-temperature steam sterilizers used for processing porous loads (including instruments and utensils wrapped in porous materials);
   (ii) high-temperature steam sterilizers used for processing aqueous fluids in sealed containers;
   (iii) high-temperature steam sterilizers used for processing unwrapped solid instruments and utensils;
   (iv) dry-heat sterilizers (hot-air sterilizers);
   (v) low-temperature steam (LTS) disinfectors and low-temperature steam and formaldehyde (LTSF) sterilizers;
   (vi) ethylene oxide (EO) sterilizers;

NOTE: LTSF sterilizers are considered to be disinfectors.

b. laboratory sterilizers:
   (i) high-temperature steam sterilizers used with one or more specialised operating cycles;
   (ii) culture media preparators.

Users who wish to employ processes not included here bear the responsibility of ensuring that the validation procedures comply with the principles outlined in Part 3 of this SHTM and that the intended operating procedures will ensure an efficacious process for the different types of load.

This SHTM is intended primarily as a guide for technical personnel, whether specialists in sterilizers and sterilization procedures or those responsible for maintenance and testing. It is also intended for those responsible for the day-to-day running of sterilizers, and will also be of interest to microbiologists, infection control officers, supplies officers, architects, estates managers and others in both the public and private sectors.

Detailed information on the planning and design of a sterile services department, including the level of provision of sterilizers, is given in SHPN 13; *Sterile services department*. Guidance for laboratory installations can be found in SHPN 15; *Accommodation for pathology services*.

Although this edition of SHTM 2010 reflects established sterilizer technology, it is recognised that considerable scope exists for the utilisation

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of emerging technology in the management of sterilizers. This will be kept under review with the aim of introducing recommendations for such technology at the earliest opportunity so that the procedures essential for the efficient, safe and effective operation of sterilizers can be optimised.

The sterilizers described in this SHTM may not be suitable, without modification, for safely processing articles infected with Hazard Group 4 pathogens. Design considerations for sterilizers intended to process articles infected with such organisms are discussed in Part 2.

NOTE: Information about Hazard Groups may be found in the HSC document, 'Categorisation of pathogens according to hazard and categories of containment' (4th edition 1995) compiled by the Advisory Committee on Dangerous Pathogens.

The agents associated with transmissible spongiform encephalopathies (TSEs) are unusually resistant to sterilization and cannot be reliably inactivated by the standard procedures described here. Advice on the sterilization of items contaminated with TSE agents can be found in Appendix 2.

NOTE: Information about TSEs may be found in the HSE document, 'Precautions for work with human and animal Transmissible Spongiform Encephalopathies', compiled by the Advisory Committee on Dangerous Pathogens.

This volume substantially revises previous editions of Part 4.

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1. General

Introduction

1.1 This Part of SHTM 2010 covers the maintenance and operation of the various types of sterilizer used in hospitals, laboratories and other healthcare facilities.

1.2 Terminology used in sterilization has long been inconsistent and occasionally ambiguous. This SHTM introduces a set of terms consistent with European Standards (see paragraph 1.18) which, it is hoped, will in time be adopted by sterilization workers in the NHS. The Glossary contains definitions referred to in this Part.

1.3 The Reference section contains full references for all the documents referred to in this Part and for selected documents of which the reader should be aware.

Legal frameworks for sterilization

1.4 There are now two legal frameworks governing the manufacture of sterile products. The long-standing legislation on medicinal products has now joined by new European Union (EU) Directives on medical devices.

1.5 Users should be clear as to whether the load items they intend to process in a sterilizer are classified as medicinal products or medical devices. Definitions for both may be found in the Glossary. While the practical requirements have much in common, their implementation is very different.

1.6 For the guidance given in this SHTM, the various types of sterilizer are presumed to be used primarily as follows (though there are exceptions):

a. for **medicinal products**: fluid sterilizers, dry-heat sterilizers;

b. for **medical devices**: porous load sterilizers, sterilizers for unwrapped instruments and utensils, dry-heat sterilizers, LTS disinfectors, LTSF sterilizers, EO sterilizers.

NOTE: Despite their name, LTSF Sterilizers are disinfectors.

1.7 Where a sterilizer is purchased with the intention of processing both medicinal products and medical devices, users should ensure that the requirements for both types of product are met.

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Medicinal products

1.8 The manufacture and supply of medicinal products are controlled by a large body of legislation stemming from the EU Directives on medicinal products and enacted by the UK Medicines Acts and numerous Regulations. Further details can be found in Part 1 of this SHTM.

1.9 The requirements for the manufacture of medicinal products are set out in the 'Guide to good manufacturing practice for medicinal products' published in volume IV of, 'The rules governing medicinal products in the European Community'. This document is referred to as the "GGMP" in this SHTM.

1.10 The GGMP contains an Annex on the 'Manufacture of sterile medicinal products' which has considerable implications for the operation of sterilizers. Users considering using a sterilizer for the processing of medicinal products should consult the GGMP at an early stage.

1.11 Guidance on the application of medicines legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medicines Control Agency (MCA) whose address may be found in Appendix 1.

Medical devices

1.12 he three EU Directives on the manufacture and supply of medical devices, active implantable medical devices and in-vitro diagnostic medical devices. The directives are implemented in the UK by The Active Medical Devices Regulations 1992, The Medical Devices Regulations 1994 and the In Vitro Diagnostic Medical Devices Regulations 2000. General guidance on these directives and regulations may be found in MDA web site www.medical-devices.gov.uk

1.13 Annex I of the Medical Devices Directive lists a number of "essential requirements", among which the following are relevant to sterilization:

a. Section 7.2 requires that devices are "designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product." This has implications for the quality of steam used in sterilization processes, and for the efficacy of removal of gas residuals in LTSF and EO sterilization.

b. Sections 8.3 and 8.4 require that devices delivered in a sterile state:

   (i) "must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened";

   (ii) "must have been manufactured and sterilized by an appropriate, validated method".

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c. Section 8.7 requires that the "packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition".

d. Section 13.3 sets out the requirements for the labelling of sterile packs.

e. Section 13.6 sets out requirements for the instructions for use which must accompany each device, including instructions in the event of the sterile pack being damaged.

1.14 Requirements for active implantable medical devices are similar, and users should consult the appropriate Directive and Regulations for details.

1.15 It is likely that all or most products for clinical use that are not classified as medicinal products will be classified as medical devices. Whether such medical devices are subject to the Regulations is a complex issue turning on the relationship between the producer and the end-user of the devices and is discussed in MDA Directives Bulletin 18.

1.16 Certain sterilizers used in a "medical environment" are regarded as "accessories" to medical devices, with the consequence that they are to be treated as medical devices in their own right. These machines, which are often (but not necessarily) transportable sterilizers designed for processing unwrapped instruments and utensils, are intended by their manufacturer for use with specific medical devices (such as surgical instruments or endoscopes) in accordance with the manufacturer's instructions for such devices.

1.17 The European Committee for Standardisation (Comité Européen de Normalisation, CEN) has prepared a number of European Standards on the manufacture of medical devices. These are known as "harmonised" standards. Compliance with a harmonised standard is considered to bring with it a legal presumption of compliance with the essential requirements of the Directive it supports. Official notification of European Standards supporting EU Directives is published in the *Official Journal of the European Communities* and in the London, Edinburgh and Belfast Gazettes. European Standards are published in the UK by the British Standards Institution with "BS EN" prefixes.

1.18 Although compliance with a harmonised standard is not the only way of complying with the directives, it is the simplest. Purchasers intending to process sterile medical devices in compliance with the directives should therefore ensure that their processes conform with one of the harmonised standards. The following harmonised standards on the validation and control of sterilization processes are discussed in this Part of this SHTM:

a. EN 556 covering the requirements for a medical device to be labelled "sterile" (BS EN 556);

b. EN 554 covering sterilization by "moist heat" (ie. steam) (BS EN 554);

c. EN 550 covering sterilization by ethylene oxide (BS EN 550).

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1.19 These standards are themselves supported by the following standards for the specification of sterilizers which are discussed in Part 2 of this SHTM:

a. EN 285 covering “large” porous load sterilizers (BS EN 285);

b. EN 1422 covering ethylene oxide sterilizers (BS EN 1422).

1.20 While the guidance given here is designed to be broadly consistent with the standards, SHTM 2010 should not be regarded as a substitute for the standards themselves when ascertaining compliance with EU Directives and the UK Regulations that implement them.

1.21 Guidance on the application of medical devices legislation to particular cases is beyond the scope of this SHTM and advice should be sought from the Medical Devices Agency (MDA) whose address may be found in Appendix 1.

Quality systems

1.22 The European Standards referred to in this SHTM may be used alongside a quality system for the supply of sterile medical devices based upon the EN ISO 9000 series:

a. EN ISO 9001 and 9002 describe the basic requirements for a quality system;

b. EN 46001 and 46002 describe particular requirements for the suppliers of medical devices.

1.23 Written procedures for the procurement, validation and management of sterilizers designed to support a quality system for the production of sterile goods will be found in Part 6, which should be obtained from the Stationery Office. Further guidance may be found in the ‘Guide to good manufacturing practice for National Health Service sterile services departments’ published by the Institute of Sterile Services Management and issued to the NHS as EL89(P)136.

Personnel

1.24 The following personnel are referred to in this Part of SHTM 2010. Further information, including qualifications and areas of responsibility, can be found in Part 1.

1.25 **Management** is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of personnel, for the organisation in which the sterilizer is employed.

1.26 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of

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similar authority. In small, autonomous installations the user may take on this function.

1.27 The **User** is defined as the person designated by Management to be responsible for the management of the sterilizer.

1.28 In a hospital the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the Production Manager (see paragraph 1.37) in charge of the entire manufacturing process.

1.29 The **Competent Person (Pressure Vessels)** is defined as a person or organisation designated by Management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a sterilizer described in the Pressure Systems Safety Regulations 2000 (see Part 1). The shorter term “Competent Person” is used in this SHTM.

1.30 The **Authorised Person (Sterilizers)** is defined as a person designated by Management to provide independent auditing and advice on sterilizers and sterilization and to review and witness documentation on validation. The shorter term “Authorised Person” is used in this SHTM.

1.31 The Institute of Healthcare Engineering and Estate Management (formerly the Institute of Hospital Engineering) is the registration authority for Authorised Persons. The address is given in Appendix 1.

1.32 Guidance on the appointment of an Authorised Person is given in Appendix 4.

1.33 The **Test Person (Sterilizers)** is defined as a person designated by Management to carry out validation and periodic testing of sterilizers. The shorter term “Test Person” is used in this SHTM.

1.34 The **Maintenance Person (Sterilizers)** is defined as a person designated by Management to carry out maintenance duties on sterilizers. The shorter term “Maintenance Person” is used in this SHTM. See paragraphs 4.5 – 4.8 for more information.

1.35 The **Microbiologist (Sterilizers)** is defined as a person designated by Management to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. The shorter term “Microbiologist” is used in this SHTM.

1.36 The **Production Manager** is defined as a person designated by Management to be responsible for the production of medicinal products.

1.37 The **Quality Controller** is defined as a person designated by Management to be responsible for quality control of medicinal products with authority to

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establish, verify and implement all quality control and quality assurance procedures. (A similar role may be defined for the manufacture of medical devices, but this is rarely the practice in hospitals.)

1.38 The **Laboratory Safety Officer** is defined as a person designated by Management to be responsible for all aspects of laboratory safety including equipment, personnel and training relating to safety issues, and ensuring compliance with safety legislation and guidelines.

1.39 An **operator** is defined as any person with the authority to operate a sterilizer, including the noting of sterilizer instrument readings and simple housekeeping duties.

1.40 The **manufacturer** is defined as a person or organisation responsible for the manufacture of a sterilizer.

1.41 The **contractor** is defined as a person or organisation designated by Management to be responsible for the supply and installation of the sterilizer, and for the conduct of the installation checks and tests. The contractor is commonly the manufacturer of the sterilizer.

Safety

1.42 Guidance on the safe operation of the various types of sterilizer is given in Chapters 5 to 12. Guidance on safe practices in the testing of sterilizers is given in Part 3 of this SHTM.

1.43 Low-temperature steam and formaldehyde (LTSF) sterilizers and ethylene oxide (EO) sterilizers both use toxic gases in the sterilization process. Occupational exposure to formaldehyde and EO is controlled by the Control of Substances Hazardous to Health Regulations 1999. Maximum exposure limits are set out in the annual Guidance Note EH40, ‘Occupational exposure limits’, published by the Health and Safety Executive (see Reference section). The limits shown in Table 1 are as at 1999. These limits are statutory maxima but should not be regarded as representing a safe working exposure; employers have a legal obligation to ensure that the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

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Table 1: Maximum exposure limits for atmospheric formaldehyde and ethylene oxide

Gas	Short-term maximum exposure limit		Long-term maximum exposure limit	
	[ppm]	[mg m^{-3}]	[ppm]	[mg m^{-3}]
Formaldehyde	2	2.5	2	2.5
Ethylene oxide	–	–	5	9.2

The short-term maximum exposure limit (STMEL) is the average exposure over any 15-min period.

The long-term maximum exposure limit (LTMEL) is the exposure over any 24-h period expressed as a single uniform exposure over an 8-h period.

COSHH does not specify a STMEL for EO. In the above table the STMEL is deemed to be three times the LTMEL in accordance with the recommendations of the Health and Safety Executive.

Source: COSHH Regulations 1999, HSE Guidance Note EH40 (1999).

1.44 The COSHH Regulations 1999 also introduce new controls on biological agents which are of relevance to users of laboratory sterilizers.

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2. Operational management – an overview

Introduction

2.1 Quality control and safety of a sterilization process are ultimately dependent upon untiring vigilance. The type of process, and the details of the operating cycle, should be selected with due regard to the nature of the product. Items for sterilization should be properly cleaned, packaged and assembled in accordance with procedures established during performance qualification. Every production cycle should be monitored and carefully documented. Products should not be released until predetermined conditions have been met. The sterilizer itself should be subject to preventative maintenance and periodic testing. In these areas vigilance will necessitate skilful personnel, fully trained in the operation of sterilizers.

2.2 For assurance on these points, responsibility rests ultimately with the user, supported by the Authorised Person, the Competent Person, the Test Person, the Maintenance Person and the Microbiologist.

Maintenance

2.3 BS EN 554 (steam sterilization) and BS EN 550 (EO sterilization) make the following requirements for the maintenance of sterilizers:

a. preventative maintenance shall be planned and performed in accordance with documented procedures;

b. the procedure for each planned task and the frequency at which it is carried out shall be specified and documented;

c. the sterilizer shall not be used to process medical devices until all maintenance tasks have been satisfactorily completed and recorded;

d. records of maintenance shall be retained as specified in 4.16 of BS EN ISO 9001 or in 4.15 of BS EN ISO 9002;

e. the maintenance scheme, maintenance procedures and maintenance records shall be reviewed periodically by persons designated by management.

2.4 The guidance in Chapter 4 puts these requirements into practice.

Safety precautions

2.5 Part 1 of this SHTM discusses the principal health and safety legislation applying to sterilization.

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2.6 HSE guidance note PM73: 'Safety at autoclaves', applies to steam sterilizers and emphasises the guidance contained in this memorandum.

2.7 Any equipment issued to operators should comply with the Provision and Use of Work Equipment Regulations 1998. Guidance may be found in the HSE document 'Work equipment' (L22).

2.8 Users should note the requirements of The Manual Handling Operations Regulations 1992 with regard to loading and unloading sterilizers. Guidance may be found in the HSE document 'Manual handling' (L23). Reference should also be made to the 'Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)'.

2.9 Access to sterilizer loading areas, plant rooms and equipment should be restricted to those entitled to be there.

Hazards associated with sterilization

2.10 Attention is drawn to the following hazards which may be encountered in the practice of sterilization:

a. the hazard of scalding from escaping steam;
b. the high temperatures (up to 200°C) at which sterilizers are operated;
c. the stored energy hazards associated with the operation of pressure vessels contained within steam and EO sterilizers;
d. the stored energy hazards associated with the pressurised containers in which EO gas is transported;
e. the explosive hazards associated with the sterilization of fluids in sealed glass containers;
f. the toxic properties of formaldehyde gas used in LTSF sterilizers;
g. the toxic and explosive properties of ethylene oxide gas used in EO sterilizers;
h. the infection hazard associated with pathogens that may be handled by personnel using certain laboratory sterilizers;
i. the hazard of infection to patients and staff by the inadvertent release of an unsterile load due to inadequate quality control;
j. the hazard to patients arising from residual ethylene oxide or formaldehyde present in the product;
k. the hazards associated with the handling of heavy and hot loads while loading and unloading sterilizers.

2.11 More detailed information about each process is given in Chapters 5 to 12.

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Safety of pressure vessels

2.12 The majority of sterilizers discussed in this SHTM contain pressure vessels that are subject to the Pressure Systems Safety Regulations 2000. Users are reminded of the following safety measures:

a. door interlocking safety devices are designed to prevent:
   (i) the pressurisation of the chamber before the door is secured;
   (ii) the uncontrolled release of chamber contents while the chamber is under pressure;
b. any escape of steam should be reported immediately and appropriate action taken;
c. arrangements for regular systematic inspection and maintenance must be adhered to;
d. all operators must be adequately trained and supervised for their allotted tasks;
e. documented operating procedures must be followed at all times.

Unloading

2.13 During the cooling stage the temperature of the load may be much higher than that in the chamber. Containers of liquid could be pressurised and may explode; liquids spilled on unloading may cause scalding. Users should take note of the following safety measures:

a. thermal door-locks are fitted to sterilizers designed to process fluids, to prevent the door mechanism being released while the temperature of the fluid is too high;
b. a cooling timer may be used in addition to a thermal door-lock;
c. adequate training should ensure that the operator is aware of the nature of the load and any hazards associated with it;
d. operators should wear appropriate personal protective equipment in addition to their normal working clothes (see paragraph 2.14);
e. reaching into a hot sterilizer can be hazardous; consideration should be given to the provision of a load transfer system such as sliding shelves or a carriage and trolley.

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Personal protective equipment

2.14 Operators and maintenance personnel should be issued with appropriate personal protective equipment (PPE) complying with the Personal Protective Equipment at Work Regulations 1992 (see Part 1 of this SHTM). The choice of PPE should follow a suitable assessment of risk for each type of sterilizer. Examples of PPE that may be required, in addition to normal working clothes, include:

a. impervious apron to protect against liquid spills;

b. heat-resistant gloves for handling hot loads;

c. protective gloves for handling potentially infected material;

d. safety shoes for use when loading and unloading sterilizers;

e. eye and face protection for use when removing glass containers from a sterilizer;

f. respiratory protective equipment and protective clothing for emergency use with EO sterilizers (see paragraphs A3.35–A3.48).

2.15 PPE should always be regarded as a “last resort” to protect against risks to health and safety; engineering controls and safe systems of work should always be considered first. Guidance on the selection of PPE may be found in ‘Personal protective equipment: guidance on regulations’ (L25) published by HSE.

Compatibility of load and process

2.16 The user should ensure that the load is suitable for the process to which it is to be exposed.

2.17 When selecting a process for a given item, the user should consider the following questions in conjunction with the advice of the manufacturer of the item:

a. *Is sterilization required?* In some cases, where the infection risk is intermediate to low, disinfection or cleaning may be sufficient. The guidance in Table 2 should be followed.

b. *Will the item be damaged by exposure to the process?* Several common items cannot withstand the moisture of steam sterilization or the high temperatures of dry-heat sterilization.

c. *Will the item fail to be sterilized by exposure to the process?* Even if an item can withstand the process it may not be sterilized if, for example, steam cannot penetrate narrow tubing.

d. *Is the process excluded by health and safety considerations?* Some medical devices should not be exposed to formaldehyde or ethylene oxide.

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Table 2: Recommended processes for the decontamination of medical devices according to risk of infection

Infection risk	Application	Recommendation
High	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area.	Sterilization
Intermediate	Items in contact with intact skin, mucous membranes or body fluids, particularly after use on infected patients or prior to use on immuno-compromised patients.	Sterilization or disinfection. Cleaning may be acceptable in some agreed situations.
Low	Items in contact with healthy skin or mucous membranes or not in contact with patient.	Cleaning

Adapted from: *Sterilization, disinfection and cleaning of medical equipment*, MDA 1993.

2.18 The flow-chart in Figure 1 will assist users in selecting an appropriate sterilization process. The Authorised Person should be consulted in cases of doubt.

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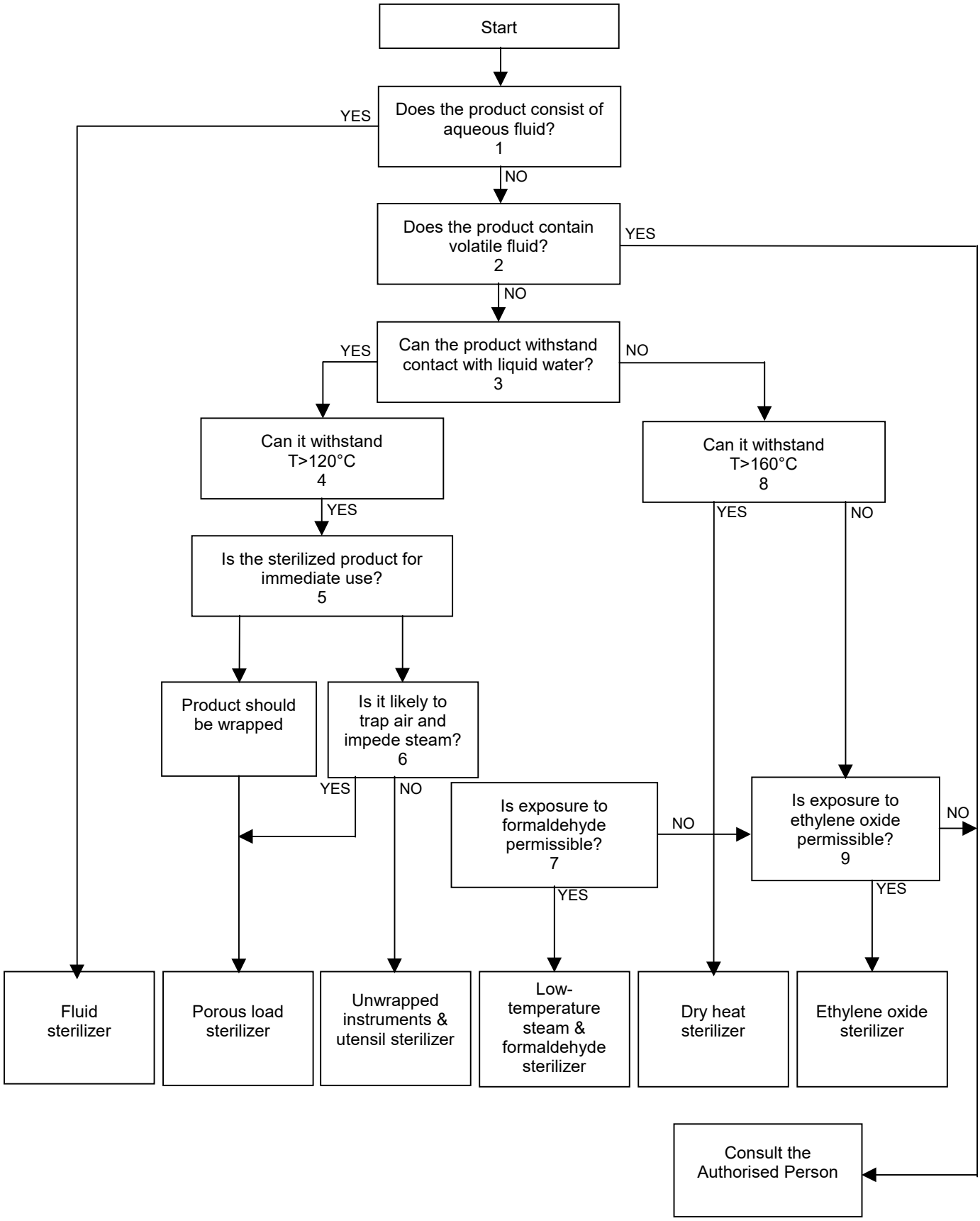
Figure 1: A guide for the selection of a sterilization process



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Notes to Figure 1

Figures refer to boxes on the flow chart.

1 *Does the product consist of aqueous fluid?*

If the product is a water solution, then it must be processed in a fluid sterilizer. Bottles or other containers holding aqueous fluids must not be placed in any other kind of sterilizer.

2 *Does the product contain volatile liquid?*

None of the processes discussed in this SHTM are suitable for volatile liquids other than water.

3 *Can the product withstand contact with liquid water?*

All steam sterilizers produce condensate on any surface which is in contact with steam. Water will therefore condense inside hollow items, within unsealed containers and inside porous packaging. Porous packaging is likely to become saturated. Packaging designed for steam sterilizers will not be damaged by such exposure.

4 *Can it withstand temperatures in excess of 120°C?*

High-temperature steam sterilizers operate at sterilization temperatures of 121°C, 126°C or 134°C, with the highest temperature preferred. Most items of glass or metal will withstand such temperatures, but items with plastic components may not. Some items constructed of two or more different metals may distort at these temperatures and some medicinal products may be damaged. In exceptional cases lower temperatures may be used provided the bioburden and the required sterility assurance level are known.

5 *Is the sterilized product for immediate use?*

If the product is to be used in a controlled medical environment immediately after the chamber door has been opened, then it need not be wrapped and a sterilizer for unwrapped instruments and utensils is acceptable. Otherwise the item should be wrapped and processed in a porous load sterilizer.

6 *Is it likely to trap air and impede steam?*

Items which are for immediate use may nevertheless require a porous-load sterilizer if they are likely to trap air and impede the penetration of steam. See paragraph 7.13 for further guidance.

7 *Is exposure to formaldehyde permissible?*

Certain items should not be processed by LTSF for reasons of health and safety. See paragraph 10.29.

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8 *Can it withstand temperatures in excess of 160°C?*

Products that cannot withstand contact with liquid water may be processed in a dry-heat sterilizer if they can withstand the high temperatures and prolonged holding times.

9 *Is exposure to ethylene oxide permissible?*

Certain items should not be processed by EO for reasons of health and safety. See paragraph 11.18.

2.19 Processes using toxic gases (LTSF and EO) are a last resort and should not be used for items which could be sterilized or disinfected by another method. Many heat-sensitive items are currently processed by LTSF or EO where LTS disinfection would have been adequate and safer.

Process development

2.20 Once a basic process has been selected, users should consider whether the standard operating cycle needs to be modified to cope with specific load items. For example, delicate items may not be able to withstand the rapid pressure changes that take place in the chamber of a porous load sterilizer and the rate of change of pressure may need to be reduced.

2.21 If the cycle variables are modified from the values used during validation, revalidation (and possibly repeat validation) will be necessary (see Part 3 of this SHTM).

“Single-use” medical devices

2.22 Many medical devices are intended by their manufacturers to be used once only and then discarded. However, it is not uncommon for hospitals to clean, sterilize and reuse the more expensive of these devices (such as cardiac catheters) where it is considered safe and economical to do so.

2.23 Users considering reprocessing single-use items should note the following points:

a. the construction of many such devices, often with long and narrow lumens, makes them difficult to clean with any degree of confidence;

b. if the efficacy of cleaning procedures cannot be assured then neither can the sterilization process;

c. where devices have been sterilized by radiation, subsequent sterilization by EO can lead to structural weakening of certain plastic components;

d. the user will have no redress from the manufacturer for any subsequent failure of the device, whatever the cause.

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2.24 The MDA gives the following advice on reprocessing.

An organisation that reprocesses a single-use device for reuse against the instructions of the original manufacturer, and then supplies it to other organisations, will be returning the device to the market and it is likely to be regarded as a manufacturer in its own right, with all of the obligations that entails. This is because the organisation is considered to be placing a new device on the market under its own name and must therefore meet the full obligations of the Medical Devices Directive.

If single-use devices are reprocessed for use solely within the organisation, this would not be seen as placement upon the market. Hence the requirements of the Directive, so far as they relate to manufacture, would not apply.

2.25 Further information may be found in MDA web site www.medical-devices.gov.uk

Cleaning

2.26 Cleaning and drying of reusable load items before packaging and sterilization are essential, since the efficacy of the process will be reduced if soiling protects micro-organisms from exposure to the sterilant. All items should therefore be scrupulously clean. Washer-disinfectors are suitable for preparing many such items for sterilization and guidance may be found in SHTM 2030.

2.27 Discard items and materials should not be cleaned.

Packaging

2.28 BS ENs 550 and 554 require the packaging specification to be part of the definition and documentation of the sterilization process. The user should therefore ensure that each load is packaged and assembled in accordance with documented procedures validated during performance qualification.

2.29 When handled in accordance with instructions the packaging should protect the product from physical damage and maintain the sterility of the product up to the point of use.

2.30 The packaging should not inhibit the efficacy of the process by, for example, hindering the removal of air or the penetration of steam, impeding the conduction of heat to the load, outgassing, altering the humidity in the chamber, or absorbing chemical sterilants.

2.31 The packaging should be able to withstand the sterilization process. It may be necessary to carry out preliminary tests on the product and its packaging in order to determine the levels and rates of change of temperature,

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pressure and other cycle variables which start to cause unacceptable changes in the performance qualities of the product or its packaging.

2.32 Packaging materials should be stored in the conditions recommended by the manufacturer. Packaging material that has become dehydrated, for example, may adversely affect the efficacy of an EO sterilization process.

2.33 Specifications for packaging materials may be found in BS EN 868. Extensive guidance on packaging is given in Part 5 of this SHTM, with a brief summary in Chapters 5 to 12 of this Part.

Performance qualification

2.34 Performance qualification (PQ) is defined as the process of obtaining and documenting evidence that the sterilizer, as commissioned, will produce acceptable goods when operated in accordance with the process specification.

2.35 A loading condition is a specified combination of the nature and number of load items, the items of chamber furniture, and their distribution within the chamber. For example, a load placed on the top shelf of the chamber constitutes a different loading condition from an identical load placed on the bottom shelf. The specification is part of the PQ report for that loading condition. Note that the specification may require load items to be arranged in precise positions or permit them to be placed randomly in the chamber.

2.36 The extent of the PQ required will depend on the type of sterilizer and the nature of the load. All users should adopt the following procedure for every sterilizer.

a. Establish a list of the distinct loading conditions to be processed in the sterilizer. Each production load should correspond to one of the listed loading conditions.

b. Determine whether each loading condition presents a greater or lesser challenge to the process than the small and full loads used in the thermometric tests carried out during commissioning (see Part 3 of this SHTM).

c. Where the loading condition is a lesser challenge than the commissioning loads, the results of the commissioning tests may be used as PQ data.

d. Where the loading condition is a greater challenge than the commissioning loads, PQ tests will be required as specified in Part 3 of this SHTM.

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2.37 The user is responsible for deciding which loading conditions require PQ tests. The user is recommended to seek advice as follows:

a. sterilizers to be used for medicinal products – from the Quality Controller and the Test Person;

b. LTSF and EO sterilizers – from the Microbiologist and the Test Person;

c. all other sterilizers – from the Test Person.

2.38 The flow chart in Figure 2 will assist users in determining whether PQ tests are required or whether data from the commissioning tests will be sufficient. In cases of doubt, advice should be sought from the Authorised Person.

2.39 PQ tests are normally performed as part of the initial validation procedure, as part of any repeat validation procedure, and whenever the user judges that a new loading condition calls for a new PQ test. Detailed instructions for carrying out PQ tests are given in Part 3 of this SHTM.

2.40 In some cases a new load may be adequately represented by one of the existing loading conditions for which a PQ report exists. Further PQ tests will not then be necessary. Where a new load is not covered by an existing PQ report, full PQ tests as specified in Part 3 should be conducted.

2.41 When designing a new loading condition, it is important that the correct packaging is selected and specified along with the load itself. The packaging specification should not then be altered in subsequent production cycles without repeating the PQ procedure unless the loading condition with new packaging can be demonstrated to be equivalent to one covered by an existing PQ report.

Position of PQ sensors

2.42 Temperature sensors should be placed as described in Chapter 8 of Part 3 of this SHTM. In selecting which load items require sensors, the following observations should be noted:

a. small load items will heat up and cool down faster than large items;

b. load items placed near the steam inlet port will heat up faster than those placed further away.

Cycle variables

2.43 For the purposes of this SHTM the following definitions have been adopted.

2.44 The **cycle variables** are the physical properties, such as time, temperature, pressure, humidity and sterilant gas concentration, that influence the efficacy of the sterilization process.

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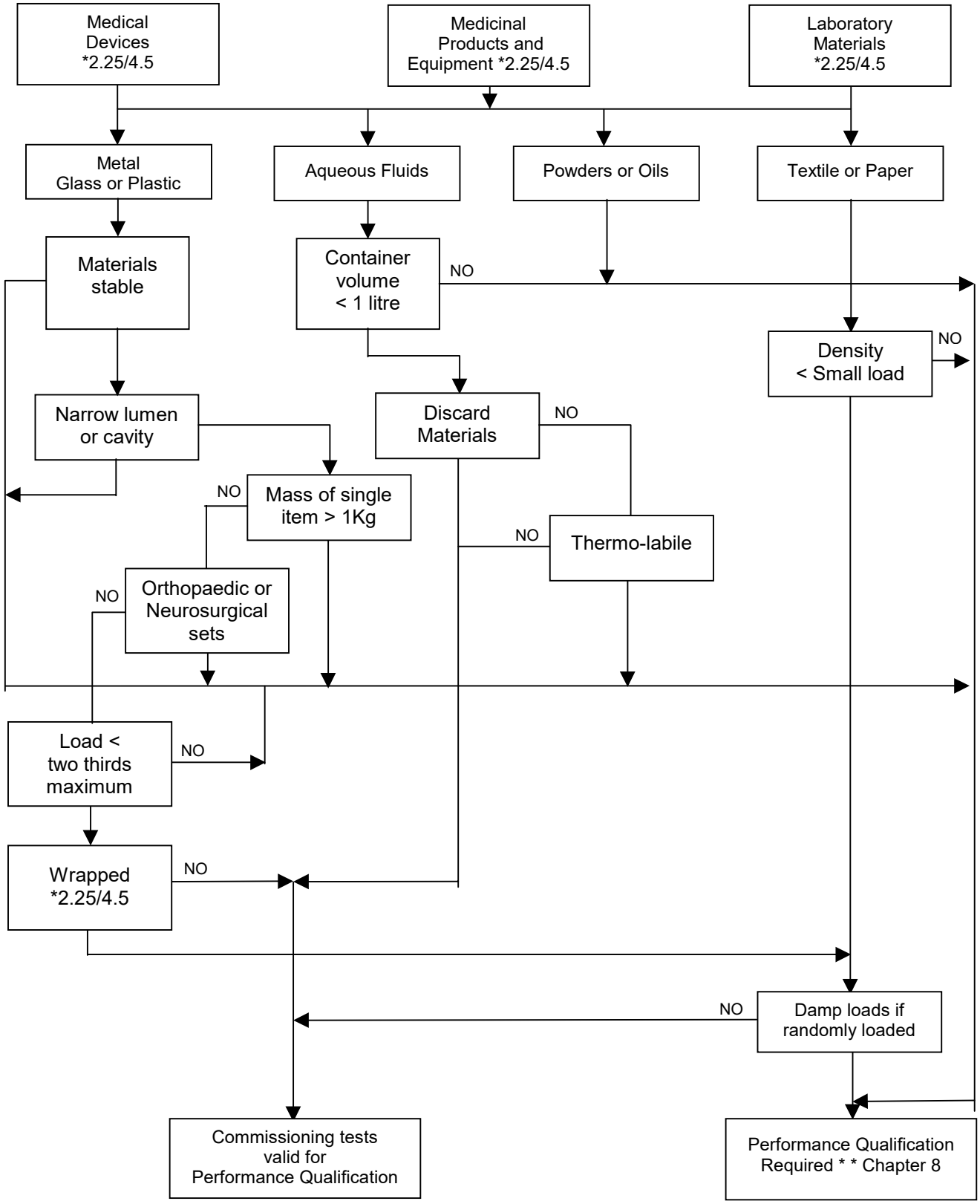
Figure 2: Performance qualification assessment guide

VALIDATION



***Refer to part 3 for clause references**

**** A PQ for a load with a greater challenge to the process may be used providing product efficacy is not affected**

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2.45 Most operating cycles have a stage in which the load is exposed to the sterilization (or disinfection) conditions for a specified length of time. This period is known as the **holding time**.

2.46 The **sterilization conditions** are the ranges of the cycle variables which may prevail throughout the chamber and load during the holding time.

2.47 The holding time is preceded by a period in which the sterilization conditions are present in the chamber but not yet present throughout the load. This is known as the **equilibration time**.

2.48 Together, the equilibration time and the holding time constitute the **plateau period**. While the duration of the plateau period can always be determined from the recorded chamber temperature, the equilibration and holding times cannot be distinguished unless the temperature in the part of the load that is slowest to reach the sterilization temperature is also being recorded or measured.

2.49 Certain LTSF sterilizers may achieve sterilization by exposing the load to a series of pulses of formaldehyde rather than a continuous holding time.

2.50 For EO sterilizers the plateau period is equivalent to the **gas exposure time**. The holding time cannot be determined by thermometry alone.

2.51 For steam and dry-heat sterilizers, the sterilization conditions are specified by a **sterilization temperature band**, defined by a minimum acceptable temperature, known as the **sterilization temperature**, and a maximum allowable temperature. The higher the sterilization temperature the shorter the holding time and the more rapidly the cycle is completed. A sterilization temperature band can also be quoted for LTSF and EO sterilizers, but since these processes depend primarily upon chemical action such a band is only a partial specification of the sterilization conditions. Bands for the different types of process are listed in Table 3. See Table 9 (Chapter 12) for recommendations for laboratory sterilizers.

2.52 Whereas the bands for high-temperature steam are normally 3°C wide, the 134°C band is anomalous in that the maximum allowable temperature may be either 137°C or 138°C. In BS 3970, 138°C is cited both for porous-load sterilizers (Part 3) and transportable sterilizers for unwrapped instruments and utensils (Part 4). At the time of writing these Parts are still current and existing sterilizers are largely designed to operate with a maximum allowable temperature of 138°C.

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Table 3: Recommended sterilization temperature bands

	High-temperature steam			Dry heat			LTS	LTSF	Ethylene oxide
Sterilization temperature [°C][a]	121	126	134	160	170	180	71[b]	71[c]	30-56
Maximum allowable temperature [°C]	124	1029	137[d]	170	180	190	80	80	[e]
Minimum holding time [min]	15	10	3	120	60	30	10	180[f]	[g]

a. The temperature setting on the automatic controller will not generally be the sterilization temperature, but a higher temperature within the sterilization temperature band.

b. Disinfection temperature.

c. This temperature is conventional but others may be used.

d. See paragraph 2.52.

e. For EO, the maximum allowable temperature will normally be 4°C above the sterilization temperature.

f. For LTSF, the sterilization conditions may specify either a continuous holding time or the number of pulses of formaldehyde required to achieve sterilization.

g For EO, the "gas exposure time" is determined for each sterilizer by microbiological methods during commissioning but is typically 2-7 hours depending upon sterilization temperature and gas concentration.

2.53 However, BS EN 285, which replaces BS 3970: Part 3, specifies that for "large" porous-load sterilizers all bands should be 3°C wide, implying a maximum allowable temperature of 137°C. This is the temperature adopted in this SHTM. Unfortunately, the proposed EN on "small" sterilizers (essentially transportables) permits a width of 4°C for all bands where unwrapped instruments and utensils are to be processed. The existing and proposed requirements are summarised in Table 4. The recommendation of this SHTM is that a width of 3°C should be adopted for all sterilization bands.

2.54 The 143°C band listed in Table 4 has been rarely used in the NHS because any time advantage offered by the short holding time is outweighed by the longer heating and cooling times.

2.55 Settings for the automatic controller will be determined during performance qualification. Generally these will consist of a chamber temperature within the sterilization temperature band and a plateau period designed to accommodate the equilibration time and the holding time. Guidance on the setting of the cycle variables will be found in Chapters 5 to 12.

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Table 4: Sterilization temperature bands for high-temperature steam specified by British and European Standards

	Maximum allowable temperature						
	Fluids	Porous loads			Unwrapped		
Sterilization temperature [°C]	BS 3970: Part2	BS 3970: Part3	EN 285 ("large")	Proposed type B* ("small")	BS 3970: Part 4	Proposed type N* ("small")	Holding time [min]
115	-	-	-		118	-	30
121	124	124	124	124	124	125	15
126	-	129	129	129	129	130	10
134	-	138	137	137	138	138	3
143	-	-	-	146	-	147	1

* Proposed European Standard under discussion by CEN

Cycle monitoring and documentation

2.56 It is vital that every production cycle is monitored and documented and that records are kept securely. Guidance on record-keeping is given in Chapter 3.

2.57 Except for the simpler processes (specified in the relevant chapter) documentation noted in the sterilizer process log for each sterilized load should include:

a. sufficient information to identify the sterilizer uniquely (by a unique reference number; by the name of the manufacturer, the model of sterilizer and the serial number; or by any sufficient combination of these);

b. a specification of the loading condition (defined either by the nature and number of load items, items of chamber furniture, and their distribution in the chamber, or by a coded reference to a detailed specification held elsewhere);

c. a specification of the operating cycle (defined either by the settings for the cycle variables or by a coded reference to a detailed specification held elsewhere);

d. a reference to the result of any routine pre-production test, such as a Bowie-Dick test;

e. the batch process record from the recorder fitted to the sterilizer marked with the reference number of the master process record used to validate it;

f. any deviations from the PQ specification in terms of loading condition and settings of cycle variables whether or not these result in an acceptable cycle;

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g. the date and time of the start of the operating cycle;

h. the cycle number as indicated on the cycle counter;

i. the name or other identification of the operator;

j. any other records specified in Chapters 5 to 12.

2.58 The batch process record obtained from the sterilizer recorder should be sufficiently detailed to confirm that the requirements for critical parts of the operating cycle are met. This is best achieved by ensuring that a continuous graph is plotted as the cycle progresses and, for a digital system, that the values of all samples are retained for later inspection.

2.59 Biological indicators are not required for monitoring of steam or dry-heat processes, though they may occasionally be necessary for performance qualification of unusual loads (see Part 3 of this SHTM). See Chapters 10 and 11 about the use of biological indicators in LTSF and EO sterilizers.

2.60 If in doubt as to which records are required, the user should consult the Authorised Person. As a rule, it should be possible to trace any sterilized goods from the point of use back through the supply chain to the specific sterilizer and cycle in which they were processed and establish the precise values of the cycle variables throughout the cycle. A bar code attached to each load item is a practical way of keeping track of sterilized goods.

2.61 Cycles abandoned for any reason should be noted in the sterilizer process log along with any remedial action taken. Operators should be encouraged to note and report any observations which suggest that the sterilizer may not be working as it should be.

2.62 Where a load has been reprocessed following the failure of an earlier cycle, records of the original cycle should be readily traceable from the reprocessing records.

2.63 Further guidance on documentation is given in Chapters 5 to 12.

Process indicators

2.64 A foolproof system to differentiate between processed and unprocessed load items should be used to prevent an unprocessed item being mistaken for one that has been sterilized. A convenient method is to use chemical indicators which change colour on exposure to the sterilization process. Such “process indicators” are available in a variety of forms including adhesive tape, labels and preprinted panels on sterilization packaging. Process indicators should conform to the specifications for Class A indicators given in BS EN 867: Part 2.

2.65 Users should note that process indicators demonstrate only that the load item has been exposed to an operating cycle. *They offer no assurance that the load item is sterile and can play no part in the validation and monitoring of the process.*

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Product release

2.66 The user, in consultation with the Authorised Person, should establish and document procedures to ensure that loads are not released for use until the user is satisfied that the operating cycle has been reproduced within the permitted tolerances established during performance qualification.

2.67 For medicinal products, the Quality Controller will establish the procedures for product release.

2.68 The procedures should confirm the following:

a. that the load has been packaged and assembled in accordance with the PQ specification;

b. that the settings for the operating cycle are in accordance with the PQ specification;

c. that the batch process record for the cycle conforms with the relevant master process record within the permitted tolerances (see paragraph 2.71);

d. that any indicated readings required to be noted during the cycle have been noted and are in accordance with the PQ specification;

e. that the sterilized load shows no obvious anomalies, such as damaged packaging or leaking containers, that may suggest a faulty cycle. (If any degree of deterioration is acceptable this should be part of the PQ specification.)

2.69 Loads processed in LTSF or EO sterilizers should not be released until the results of the routine microbiological tests are known (see Chapters 10 and 11).

2.70 Regardless of the above procedure, whenever an operator has cause to suspect that the load may not have been properly sterilized the load must not be released. The user should be informed immediately.

Master process record

2.71 A master process record (MPR) is a record of the values and permitted tolerances of cycle variables (normally time, temperature and pressure) for a correctly functioning operating cycle against which production cycles can be checked. (The term “master temperature record” was used in earlier editions of HTM 10.) It is derived either from the batch process record (BPR) obtained during a thermometric PQ test or, if no PQ test has been deemed necessary, from the BPR obtained from a full-load thermometric test carried out during commissioning. It may be a one-to-one transparent copy of the BPR, a “template” derived from the BPR, or data stored in a computer control system and compared automatically. See Part 3 of this SHTM for further information on MPRs.

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2.72 Cycle variables recorded on the MPR may include chamber temperature, chamber pressure and the temperature inside one or more load containers as a function of time.

2.73 When a BPR from a production cycle is compared with the appropriate MPR, the value of the cycle variables on the BPR should be contained within the limits shown on the MPR for the entire cycle.

Rejected loads

2.74 Failure to meet any of the product release requirements should lead to the load being placed in quarantine and the cause of the failure investigated. The investigation should be documented and the handling of the product should be in accordance with the procedures for control of non-conforming product required by EN ISO 9001 or 9002.

2.75 Documented procedures for dealing with rejected loads should be agreed between the user and the Authorised Person. There are basically three options:

NOTE: The management of clinical waste and heat treatment processes, published by the Scottish Centre for Infection and Environmental Health, Aug 1994, ISBN 1 873772106, and Scottish Hospital Technical Note 3; *Clinical waste management*, issued by the Property and Environment Forum, should be referred to.

a. the load may be reprocessed; this should only be permitted if the nature of the load and its packaging is such that they will not be unacceptably degraded by a second exposure to the sterilization process;

b. the load may be “reworked”, ie. dismantled, repackaged and then reprocessed;

c. the load may be discarded; in this case, procedures should ensure that load items are permanently marked as rejected, removed from the supply chain and that there is no risk of them being mistaken for correctly processed items.

2.76 Procedures for the disposal of a discarded load should ensure that no hazard is caused either to personnel or to the environment.

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Storage

2.77 After sterilization and before product release, conditions for product storage and handling should not compromise the qualities of the product.

2.78 Detailed guidance on storage and distribution of sterile goods can be found in Part 5 of this SHTM.

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3. Record-keeping

Introduction

3.1 The importance of maintaining careful records cannot be stressed too highly. Complete and accurate records are an essential element in ensuring the safe and efficient functioning of sterilizers and compliance with regulatory requirements.

3.2 The following principles, based upon those issued by the World Health Organisation “The collection, fractionation, quality control and uses of blood and blood products (1981)”, for the processing of blood products, apply equally to quality control of sterilization processes. Records should:

a. be original (not a transcription), indelible, legible and dated;

b. be made concurrently with the performance of each operation and test;

c. identify the person recording the data as well as the person checking the data or authorising continuation of processing;

d. be detailed enough to allow a clear reconstruction and understanding of all relevant procedures performed;

e. allow tracing of all successive steps and identify the inter-relationships of dependent procedures, products and waste materials;

f. be maintained in an orderly fashion permitting the retrieval of data for a period consistent with dating periods (shelf life) and legal requirements;

g. indicate that processing and testing were carried out in accordance with procedures established and approved by management;

h. if necessary, allow a prompt and complete recall of any particular batch;

i. show the lot numbers of materials used for making up specified batches of products.

3.3 The requirements for record-keeping in BS ENs 550 and 554 are the same as BS ENs 46001 and 46002, namely that the supplier should retain the quality records for a period of time at least equivalent to the lifetime of the medical device defined by the supplier, but not less that two years from the date of dispatch from the supplier. The supplier should establish a record for each batch of medical devices that provides traceability and identifies the quantity manufactured and quantity released for distribution. The batch record should be verified and the load authorised for release by the user.

3.4 For medicinal products, the record-keeping principles outlined in the GGMP should be followed.

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3.5 The system recommended in this SHTM requires two sets of records to be kept for each sterilizer:

a. a plant history file;

b. a sterilizer process log.

3.6 Both of these are the responsibility of the user. They should be made available to any other personnel who need to use them. This will include the Authorised Person, Test Person, Maintenance Person, Microbiologist, Competent Person and operators.

3.7 In the case of sterilizers used for processing medicinal products, the form of these records should be approved by both the Production Manager and the Quality Controller.

3.8 Log books for recording data obtained from periodic tests are available from Scottish Healthcare Supplies. An example of a log book for a porous load sterilizer is given in Part 6 of this SHTM. The log book is regarded as part of the plant history file.

Plant history file

3.9 The plant history file contains engineering records of the sterilizer installation. It should be kept throughout the life of the sterilizer (see paragraph 3.3). Examples of the information that should be kept in the plant history file include:

- identification of the sterilizer;
- names, addresses and telephone numbers of the sterilizer manufacturer, owner and key personnel (user, Authorised Person, Test Person, Maintenance Person, Competent Person, Microbiologist);
- dates of installation and commissioning;
- validation procedures;
- validation reports (including PQ reports for each loading condition);
- copies of validation summary sheets;
- copy of any maintenance contract;
- planned maintenance programme including detailed procedures for all maintenance tasks;
- records of maintenance, both scheduled and unscheduled, sufficient to show that all examinations, tests and checks have been carried out;
- manuals supplied by the manufacturer;
- documentation for any software used for control or instrumentation (including the name of an agent where the source codes may be obtained should the manufacturer cease trading);
- the written scheme of examination for any pressure vessel;

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- reports by the Competent Person in respect of pressure vessels;
- data from periodic tests carried out by the Test Person or the Maintenance Person;
- copies of data from the periodic tests carried out by the user (kept in the sterilizer process log);
- records of any defects found on the sterilizer and corrective action taken;
- records of any modification made to the sterilizer;
- references to the plant history files for the test instruments used in the validation and periodic tests;
- specifications for the operating cycles.

Sterilizer process log

3.10 The sterilizer process log contains information required for routine operation of the sterilizer and records relevant to each cycle. It should contain the following information:

- identification of the sterilizer;
- names, addresses and telephone numbers of the sterilizer manufacturer, owner and key personnel (user, Authorised Person, Test Person, Maintenance Person, Competent Person, Microbiologist);
- names of authorised operators;
- written procedures for all duties to be carried out by the operators;
- full operating instructions;
- copies of validation summary sheets (see Part 3 of this SHTM);
- data from the periodic tests carried out by the user;
- records of routine housekeeping carried out by the user (see paragraph 4.21);
- specifications for the operating cycles for which the sterilizer has been validated, defined by the settings for the cycle variables;
- specifications for the loading conditions for which the sterilizer has been validated, defined by the nature and number of load items, items of chamber furniture, and their distribution within the chamber.

3.11 The following information should be noted for each batch processed by the sterilizer:

- the name of the operator;
- the date and time of the start of the cycle;
- the cycle number;

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- a reference to the loading condition;
- a reference to the operating cycle;
- a specification of any preconditioning, conditioning or degassing process (this is essential for EO sterilizers);
- reference number of the master process record;
- values of cycle variables required to be observed and noted by the operator during the cycle;
- a signature confirming whether or not the cycle was satisfactory;
- any notes or observations on the cycle.

3.12 The batch process record for each cycle should be filed in such a way that it can be readily retrieved for inspection. Before filing it should be clearly marked with the following:

- sterilizer identification;
- date;
- cycle number;
- batch number;
- reference number of the master process record;
- a signature confirming whether or not the cycle was satisfactory.

3.13 Other requirements for entries in the sterilizer process log may be found in Chapters 5 to 12.

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4. Maintenance

Introduction

4.1 Sterilization is a process whose efficacy cannot be verified retrospectively by inspection or testing of the product before use. For this reason sterilization processes have to be validated, the performance of the process routinely monitored, and the equipment maintained.

4.2 Means of assuring that a sterilizer is fit for its intended purpose will include the validation and periodic testing programme specified in Part 3 of this SHTM, and also the programme of planned maintenance (PM) as described in this Chapter.

4.3 The philosophy of maintenance and testing embodies three main principles to ensure that required standards of performance and safety are attained and sustained:

a. all sterilizers are subjected to a carefully planned programme of tests to monitor their performance;

b. all sterilizers are subjected to a planned programme of preventative maintenance irrespective of whether or not a preventative maintenance scheme is being operated on the premises generally;

c. expertise on all aspects of the maintenance of sterilizers should be available at two levels; these are represented by the Authorised Person and the Maintenance Person.

4.4 Testing of sterilizers is dealt with in Part 3 of this SHTM.

Maintenance Person

4.5 As discussed in Part 1 of this SHTM, the Maintenance Person is defined as a person designated by management to carry out maintenance duties on sterilizers.

4.6 The Maintenance Person should be a fitter or an electrician with documentary evidence to demonstrate competence in the maintenance of one or more types of sterilizer. He or she should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others. The Maintenance Person is typically an employee of the organisation operating the sterilizer, an employee of the sterilizer manufacturer, or an employee of an independent contractor.

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4.7 The principal responsibilities of the Maintenance Person are:

a. to carry out the maintenance tasks outlined in this chapter;

b. to carry out additional maintenance and repair work at the request of the user.

4.8 A Maintenance Person who has a minimum of two years experience in the maintenance of sterilizers and who has obtained a recognised qualification in the testing of sterilizers may perform the duties of the Test Person for the daily, weekly and quarterly tests described in Part 3 of this SHTM.

Planned maintenance programme

4.9 The planned maintenance programme should be designed according to the following principles:

a. all parts of the sterilizer which are vital to correct functioning or safety should be tested at weekly intervals. This is interpreted as follows:

   (i) there is no need to test components individually in those cases where any malfunction will be revealed by the periodic tests prescribed in Part 3 of this SHTM for weekly or more frequent intervals;

   (ii) where the correct functioning of important components is not necessarily verified by the periodic tests prescribed for the sterilizer, those components should be individually tested each week and reference to testing them should be included in the schedules of maintenance tasks. This applies, for example, to door interlocks which may only be required to perform their safety function when presented with an abnormal condition;

b. the maintenance programme should include, at appropriate intervals, those tasks such as lubrication and occasional dismantling of particular components (such as pumps) the need for which is indicated by normal good practice, manufacturer's advice and experience. Apart from those tasks, the maintenance programme should concentrate on verifying the condition of the sterilizer and its components by means of testing and examination without dismantling. Parts which are working correctly should be left alone and not disturbed unnecessarily;

c. maintenance should be carried out under a quality system such as ENISO 9000. Spares fitted to sterilizers constructed under a quality system should be sourced from a similarly approved quality system.

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Design of a PM programme

4.10 The PM programme supplied by the sterilizer manufacturer should be used where it is available. If no manufacturer's programme can be obtained, a programme should be drawn up in consultation with the Authorised Person and the Maintenance Person.

4.11 Although the sterilizer manufacturer may carry out certain inspection and maintenance procedures under the terms of his guarantee, these may not constitute a full PM programme. The user should therefore ensure that the complete PM programme is carried out by the Maintenance Person (who may be an employee of the manufacturer, see paragraph 4.6) during the guarantee period. The user should also implement any reasonable instructions given by the manufacturer during this period. Failure to carry out maintenance tasks and periodic tests could affect safety. It could also allow a contractor to place some, if not all of his liability on to the management. Where maintenance is carried out under lump sum term contract (see Part 2) such failure is tantamount to breach of contract and can give the contractor cause to terminate the contract if he so wishes.

4.12 A set of procedures should be developed for each sterilizer, containing full instructions for each maintenance task.

4.13 The frequency at which any given task needs to be carried out will depend on how heavily the sterilizer is used. Where there is a two-shift system, for example, it will be necessary to adjust the programme so that work is carried out more frequently than under a single-shift system. Where sterilizers are used infrequently, however, less frequent maintenance is not always acceptable. Infrequent use requires increased maintenance of certain components because of failure of valves, seals, pumps, etc., due to sticking through lack of use. Only when a component is subject to progressive wear in use is the frequency of maintenance related to frequency of use.

4.14 It is important that maintenance is planned so that a sterilizer is out of service for as little time as possible. Maintenance should, where practicable, be scheduled to immediately precede the periodic tests as specified in Part 3 of this SHTM.

Review of the PM programme

4.15 The PM programme, procedures and records should be reviewed at least once a year by the user and the Maintenance Person in association with the Authorised Person. To do this, it is necessary to keep systematic records of all work done, so that judgement can be made in consultation with the manufacturer on what changes, if any, to the PM programme would be desirable.

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4.16 The review should aim to identify:

a. any emerging defects;

b. any changes required to the maintenance scheme;

c. any changes to any maintenance procedure;

d. any additional training required by personnel concerned with maintenance;

e. whether records have been completed satisfactorily, signed and dated.

Inspection of pressure vessels

4.17 Under the Pressure Systems Safety Regulations 2000, all sterilizers containing pressure vessels are subject to a periodic inspection by a Competent Person (see Part 1 of this SHTM). The Regulations apply to all steam sterilizers, to EO sterilizers operating above 0.5 bar, to dedicated steam generators, to cartridges and cylinders used to supply sterilant or purging gas to EO sterilizers, and to the steam and compressed air services. Pressure vessels include doors and their closing systems. The Authorised Person will advise on the application of the Regulations to any particular installation.

4.18 The Competent Person has three principal duties under the Regulations:

a. advising on the scope of the written scheme of examination for each pressure vessel;

b. drawing up the written scheme of examination or certifying the scheme as being suitable;

c. carrying out examinations in accordance with the written scheme, assessing the results and reviewing the written scheme for its suitability.

4.19 The user should cooperate closely with the Competent Person to ensure that the written scheme of examination is accommodated within the maintenance and testing programmes. The written scheme may require certain examinations to be carried out more frequently than recommended by the manufacturer. Each scheme should include detailed procedures and frequency of examination and be regularly reviewed and updated.

Modifications

4.20 Occasionally, modifications to the sterilizer may be recommended by the manufacturer or by the UK Health Departments for reasons of efficacy and safety. The user should arrange for such modifications to be carried out within a reasonable period, normally coinciding with a scheduled maintenance session.

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Routine housekeeping

4.21 Certain simple maintenance tasks may be carried out by the user (or by an operator under the user's supervision) and should be recorded in the sterilizer process log. Examples of such tasks include the following:

a. steam sterilizers: daily, or more often if necessary, clean the strainer fitted in the opening to the chamber discharge line;

b. all sterilizers: daily, wipe the door seal with a clean damp cloth and inspect it for damage. This can normally be done by the operator if the seal is completely exposed when the door is open;

c. all sterilizers: carry out any door safety checks required by the written scheme of examination and which are within the technical competence of the user. (Other door safety checks, normally weekly, will be carried out by the Maintenance Person.)

Maintenance of laboratory sterilizers

4.22 Laboratory sterilizers differ from clinical sterilizers in that they may have cycles expressly designed for the routine making-safe of discard material that is or may be contaminated with pathogenic micro-organisms. Sterilizers without a make-safe cycle may occasionally be used to process infected material if the designated machine is out of service. The user should ensure that a documented procedure is established for the decontamination of a sterilize before it is handed over to maintenance personnel. Such a procedure should comply with the guidelines set out in HSG(93)26, 'Decontamination of equipment prior to inspection, service or repair'.

4.23 Since the contamination status of a sterilizer cannot be established by inspection, all maintenance work should be conducted under a permit-to-work system in which a certificate, signed by the user and the Laboratory Safety Officer, is given to maintenance personnel to indicate that the sterilizer is safe. Where it is not possible to guarantee that a sterilizer is free of contamination (such as where a machine breaks down with a discard load in the chamber), this should be made clear on the permit to work and detailed procedures for safe working should be supplied. This latter option should only be resorted to in exceptional cases and is not an acceptable alternative where decontamination is practicable. A suggested format for the permit to work is given in Figure 3.

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Figure 3 Suggested permit to work for laboratory sterilizers

PERMIT TO WORK

This permit relates only to the hazards caused by the possible microbiological or chemical contamination of the sterilizer. The sterilizer is not guaranteed safe against any other source of risk.

Location of sterilizer_____

Manufacturer _____ Serial no:_____

Model _____ Inv. no:_____

- I confirm that the above sterilizer has been decontaminated and cleaned as required to render it safe for maintenance or repair (or)
- It is not possible to guarantee that the sterilizer is free of contamination. Guidance on safe working practices is attached (delete as appropriate).

User: Name: _____ Signature: _____Date:_____ Time: ___

Safety Officer: Name: _____Signature: _____Date _____ Time: ___

RECEIPT (delete as appropriate)

- I accept responsibility for carrying out the work on the above sterilizer.
- I have received the guidance on safe working practices.

Name: _____ Signature: _____Date: ____ Time: ___

HAND-BACK (delete as appropriate)

- The work on the above sterilizer has been completed / suspended.
- The sterilizer may / may not be returned to service.

Name: _____ Signature: _____Date: ____ Time: ____

CANCELLATION

This permit-to-work is now cancelled.

User: Name: _____ Signature: _____Date ____ Time: ____

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4.24 Maintenance of laboratory sterilizers should conform with the guidance given in BS 2646: Part 4.

Features requiring special attention

4.25 The following sections provide background information to some of the features requiring special attention in any PM programme.

Stainless steel chambers

4.26 Stainless steel, or mild steel clad with stainless steel, is used in the manufacture of many sterilizer chambers. Over a wide variation in specification, stainless steels, and to a much lesser extent stainless-clad mild steel, are susceptible to cracking from crevice corrosion and stress corrosion initiated by chemical attack. These phenomena occur when the material is subjected to a combination of heat, stress and contact with chemicals, notably chlorides or strong alkalis. The damage resulting from the combined effects occurs at levels far below those which would be of significance if acting separately. Heat and stress are present in all steam sterilizers.

4.27 Material in compression is less susceptible to crevice and stress corrosion than material in stress. Some manufacturers use “shot blasting” (also known as “shot peening”), to convert the tension stresses in the skin of the stainless steel to compression stresses.

4.28 Chemical contact may occur in sterilizers under the following circumstances:

a. in sterilizers processing certain fluids, such as saline solution, a spillage will introduce chloride salts into the chamber;

b. if there is excessive carry-over of boiler water with the steam, this is likely to include significant concentrations of both alkalis and chloride salts;

c. in small electrically heated sterilizers, where steam is generated within the chamber by an immersion heater, a build-up of alkalis and chloride salts may occur if tap water is used to generate steam; this can result in severe pitting corrosion leading to the perforation of the chamber.

4.29 Where cleaning with water is required, only water with a low chloride level, such as distilled water or good quality condensate, should be used.

4.30 Vessels which have not been shot-blasted should be lightly polished by hand. This should be done in accordance with the manufacturer’s instructions and at quarterly intervals on sterilizers used to process fluids. Polishing should only be done using iron-free materials. Household or domestic scouring and polishing compounds should not be used since they often contain chlorine or other corrosive agents which might cause, rather than prevent corrosion. After polishing, the chamber should be thoroughly flushed out with water of low chloride content.

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4.31 During cleaning and polishing, precautions should be taken to prevent damage to the door seal and the entry of foreign matter into the chamber drain.

Air-tightness of the chamber

4.32 Air-tightness of the chamber is of fundamental importance to the correct functioning of sterilizers. The door seal is the major potential source of leakage and should receive careful attention as advised by the manufacturer. The working life of door seals varies widely and it is essential that all seals are cleaned regularly. Door seals should be renewed with spares approved by the manufacturer at recommended intervals, or when there is any evidence of damage or deterioration.

4.33 Leaks may also occur in the following places:

a. joints in pipework;
b. connections to gauges;
c. blanked-off connections for test gauges;
d. entry points for temperature sensors (whether in use or blanked off);
e. glands and seats of valves;
f. bellows-operated door safety interlocks;
g. cracks in chamber welds or platework.

Door-locking mechanisms

4.34 There have been a number of incidents in which sterilizer door-locking mechanisms have failed during operation.

4.35 Maintenance and inspection of door safety devices and door-locking and chamber sealing systems must be carried out in accordance with the manufacturer's written instructions. Security and settings of door safety switches and door-locking components must be checked weekly and the settings must comply with those provided by the manufacturer.

4.36 Capstan-operated, hinged door-locking mechanisms should be examined for excessive wear on the internal thread sections. Where these are hard to see, thread profile gauges should be used. If there is evidence of excessive wear, then the sterilizer should be removed from service until the capstan wheel assembly can be replaced.

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Air detector

4.37 Particular care should be taken when installing, removing or adjusting any part of an air detector. It is preferable not to interfere with it except when necessary. The sensitivity of the air detector should be adjusted in accordance with the manufacturer's instructions and the setting determined during validation as detailed in Part 3 of this SHTM.

4.38 Air detectors work by measuring either temperature or pressure. Certain older temperature-operated air detectors may not fail safe if there is a leak from the detector to the outside. It is crucial that air detectors are carefully checked for air-tightness once a week. A leak too small to be detected by the vacuum leak test given in Part 3 of this SHTM could be large enough to permit the expulsion by steam of any air present in the detector and cause it to indicate falsely that all the air had been removed from the chamber.

4.39 If it has been necessary to adjust the air detector, the Test Person should carry out recommissioning tests as described in Part 3 of this SHTM.

Instruments

4.40 Instruments fitted to sterilizers should be maintained and calibrated in accordance with the manufacturer's instructions. Calibration should be verified at the normal sterilization temperature and pressure and at stable ambient temperatures. Any instrument found to read seriously in error or which is inconsistent, i.e. will not repeat satisfactorily, should be discarded, or repaired by the makers if practical and economical to do so. Instruments which do repeat satisfactorily but read slightly in error should be checked for zero and span and then adjusted to read correctly.

4.41 An instrument case should never be left open; broken glass should be replaced promptly.

4.42 The recorder system is an essential monitor of the general functioning and performance of a sterilizer. Temperature measuring systems are subject to both inherent calibration errors and loss of calibration with use. As a consequence temperatures read from a recorder should be regarded with caution and interpreted from knowledge of the characteristics of the particular recording system, the load and previous records.

4.43 Recording systems which are working correctly should not be interfered with more than is absolutely necessary. Adjustments should be done strictly in accordance with the manufacturer's instructions.

4.44 Persons who change charts, print rolls and other consumables on recording instruments should be trained, made fully aware of the delicate nature of the instruments and authorised by the user.

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Ancillary equipment

4.45 Ancillary equipment used in conjunction with the sterilizer should also be subject to planned maintenance in accordance with manufacturers' instructions.

4.46 Where the maintenance of ancillary equipment is not the responsibility of the user, arrangements should be made to give the user reasonable notice of all periods of maintenance (whether scheduled or not) and of impending modifications to any part of the equipment. The user should also have access to maintenance records.

4.47 Examples of ancillary equipment include:

a. all engineering services to the sterilizer, especially steam;
b. dedicated steam generators (see SHTM 2031 for guidance);
c. room ventilation and local exhaust ventilation (see SHTM 2025 and the HSE document 'The maintenance, examination and testing of local exhaust ventilation' (HS(G)54) for guidance); correct functioning is essential to the safe operation of LTSF and EO sterilizers;
d. personal protective equipment;
e. equipment used to monitor, alarm or protect against exposure to formaldehyde or ethylene oxide.

Returning a sterilizer to service

4.48 The user, with the assistance of the Authorised Person, should prepare an operational procedure for the return to service of a sterilizer after maintenance or testing. The procedure should include safety checks and some or all of the recommissioning (yearly) tests specified in Part 3 of this SHTM.

4.49 The Maintenance Person should certify that the work has been completed and that the sterilizer is safe to use.

4.50 The user should ensure that a sterilizer is not used for production until all required maintenance has been successfully completed.

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5. Operation of porous load sterilizers

Introduction

5.1 This chapter gives guidance on the routine operation of clinical high-temperature steam sterilizers designed to process wrapped goods and porous loads.

5.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1.

The process

5.3 Porous load sterilizers heat load items by direct contact with high-temperature steam at a typical sterilization temperature of 134°C (see Table 5).

5.4 The operating cycle of a porous load sterilizer normally has five stages.

a. Air removal – Sufficient air is removed from the chamber and the load to permit attainment of the sterilization conditions.

b. Steam admission – Steam is admitted to the chamber until the specified sterilization temperature is attained throughout the chamber and load.

c. Holding time – The temperature throughout the chamber and load is maintained within the sterilization temperature band for the appropriate holding time.

d. Drying – Steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases.

e. Air admission – Air is admitted to the chamber until the chamber pressure approaches atmospheric pressure.

5.5 The complete cycle time for a sterilization temperature of 134°C is typically 35 minutes for a standard full load, but the drying stage may need to be extended for up to a further 20 minutes for loads of high heat capacity, such as trays of instruments, that take longer to dry.

Product compatibility

5.6 A porous load sterilizer is suitable for processing a very wide range of goods and is the method of choice in most cases.

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5.7 Items to be processed in a porous load sterilizer should have been washed and dried by a validated cleaning process.

5.8 To reduce the possibility of superheating, load items consisting of textiles should be allowed to air for a period of not less than fours hours after laundering (see paragraph 5.50).

Items that should not be processed in a porous load sterilizer

5.9 The following items should not be processed in a porous load sterilizer:

a. items which would be damaged by exposure to moist heat at 121-134°C;
b. items which would be damaged by rapid pressure changes (up to 10 bar min^{-1});
c. aqueous fluids (a fluid sterilizer is required);
d. non-aqueous fluids (a dry-heat sterilizer is required);
e. items in sealed containers (air will not be extracted).

Design of the load

5.10 Items processed in porous load sterilizers will either consist entirely of porous materials (such as dressings) or else comprise wrapped goods, usually of metal (such as surgical instruments).

5.11 The loading condition should be designed with two aims in mind:

a. to permit the rapid removal of air from the load items and the rapid penetration of steam; and
b. to ensure that the condensate formed during the cycle does not result in a wet load.

5.12 With some exceptions, porous load sterilizers may be loaded randomly. It is not necessary to ensure that the loading condition is replicated in detail for each cycle.

Air removal

5.13 The presence of air in the load can impede the penetration of steam and thereby drastically reduce the effectiveness of the sterilization process. Steam will not easily displace air contained in porous materials, such as a paper bag containing an instrument. Any air remaining in the packages before the start of the holding time will occur in random locations and in different volumes. During the holding time it may unpredictably delay or prevent saturated steam from contacting the surfaces over which this air is present. Levels of air will depend on the theoretical dilution rate, the method used for air removal and the air leakage into the chamber.

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5.14 Porous load sterilizers have an active air removal system in which air is replaced with steam by a series of vacuum and pressure changes. Provided it is validated according to the schedule set out in Part 3 of this SHTM, a sterilizer complying with BS EN 285 will be capable of removing sufficient air from packages randomly placed in the chamber and which contain porous material not exceeding the density of the standard test pack.

5.15 Where the density of porous material exceeds that of the standard test pack, or the load consists of components into which steam penetration is not instantaneous, eg. filters and flasks with small orifices, a thermometric performance qualification test is required (see Part 3 of this SHTM).

5.16 As well as air retained in the load, steam penetration may be inhibited if non-condensable gases are liberated from the load as it is heated. This may happen with certain packaging materials, inks, adhesives, labels, etc. Packaging materials should conform to one of standards listed in paragraph 5.27. As a precaution, new non-metallic boxes or trays should be processed in a non-production cycle before being used with production loads.

Handling of condensate

5.17 As in all steam sterilizers, the energy which heats the load is derived almost entirely from the latent heat given up as the steam condenses on the load items. (It is not a simple conduction of heat from hot steam to the cool load.) The more latent heat is given up, the more condensate will be formed. This condensate (hot water) is an essential and unavoidable consequence of steam sterilization.

5.18 The amount of condensate formed will depend on the latent heat required to raise the load to the sterilization temperature. This depends on the heat capacity of the load, which in turn depends on the mass and specific heat capacity of each item. Loads containing metal items have a higher heat capacity than a load of purely porous materials and therefore will produce more condensate. Essentially all of the condensate will be formed before the start of the holding time.

5.19 The process is substantially reversible, however, and by subjecting the chamber to a vacuum during the drying stage, the lowered boiling point of water associated with the reduced pressure enables the heat energy stored in the load item to re-evaporate the condensate and as a consequence the item is both cooled and dried. The re-evaporation process will not occur if the condensate becomes separated from the load items.

5.20 In order to ensure that porous loads are dry at the end of the cycle, it is therefore necessary either to drain the condensate completely clear of the load, or to retain it close to the hot load items where it can be evaporated. With wrapped loads, the latter solution is preferred. No special measures are needed for purely porous loads, but metal items are likely to produce sufficient condensate to saturate their wrapping. The condensate may then spread to other parts of the load from which it may not be evaporated. This

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migration of condensate may be avoided by including absorbent padding (in addition to the wrapping) suitably positioned inside each pack.

5.21 The optimum amount and arrangement of this extra padding can only be determined by experiment. As a rule, metal items should be well spaced and separated by padding. With preset instrument trays, for example, the instruments should be spaced out across the tray. Unusually heavy items, such as orthopaedic hammers, should be placed away from other instruments and well padded. Loads containing large amounts of metal may require performance qualification tests.

5.22 Holloware, such as bowls and tubes, should be arranged in such a way that condensate will not collect inside them. It may not be practical to ensure that wrapped holloware is always processed inverted and in this case the drainage problem may be overcome by placing absorbent materials inside the holloware.

5.23 Drip deflectors between tiers of instrument trays will ensure that condensate does not drain from one tray to another.

5.24 If a mixed load of porous and wrapped metal items is to be processed, the porous items should be placed above the metal items to ensure that condensate does not drip on to them.

Packaging materials

5.25 Items to be sterilized should use packaging materials which are permeable to air and steam but have an effective maximum pore size which is small enough to exclude microbial contamination under the specified storage and transport conditions.

5.26 Goods are normally double-wrapped; at least one of the layers will usually be a sheet of paper, a paper bag or a plastic pouch. The inner lining may be chosen primarily for its absorbency in order to retain condensate as described above.

5.27 Load items should be wrapped in materials complying with one of the following parts of BS EN 868: Packaging materials for sterilization of wrapped goods:

a. Part 1: General requirements and requirements for the validation of packaging of terminally-sterilized devices;
b. Part 2: Sterilization wrap – requirements and tests;
c. Part 3: Paper for use in the manufacture of paper bags and in the manufacture of pouches and reels;
d. Part 4: Paper bags – requirements and tests;
e. Part 5: Heat-sealable pouches and reel material of paper and plastic film construction – requirements and tests;
f. Part 8: Reusable sterilization containers – requirements and tests.

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5.28 Extensive guidance on packaging materials and methods is given in Part 5 of this SHTM.

Performance qualification

5.29 PQ tests are not normally required for the majority of loading conditions processed in a porous load sterilizer since they are less of a challenge to the cycle than the full-load and small-load tests carried out during validation.

5.30 PQ tests are required where:

a. the density of any porous load item exceeds the density of the standard test pack (see Part 3 of this SHTM);

b. the mass of any single metal item exceeds 1 kg;

c. the construction of any load item is such that sufficient air may not be removed to ensure the rapid penetration of steam;

d. any cycle variable has been modified from the setting used in validation.

5.31 Two categories of product require special consideration:

a. minimally invasive surgical instruments (such as laparoscopic biopsy forceps) which present particular problems of air removal and steam penetration;

b. barrier fabrics (such as Gore-tex) which have such low porosity to both air and steam that normal air removal stages may be inadequate.

Selection of cycle variables

5.32 The preferred sterilization temperature is 134°C. However, any of the lower sterilization temperature bands in Table 5 may be used where load items would be damaged at 134°C.

Table 5: Sterilization conditions for porous load sterilizers

Sterilization temperature [°C]	Maximum allowable temperature [°C]	Minimum holding time [min]
134	137	3
126	129	10
121	124	15

See paragraphs 2.52-2.53 for comment on maximum allowable temperatures.

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Cycle monitoring and documentation

5.33 Users are reminded that a Bowie-Dick test should be carried out at the start of each day as described in Part 3 of this SHTM. Production should not begin until the test has been shown to be satisfactory. Some departments may also require a daily vacuum leak test.

5.34 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

5.35 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature (chamber temperature) recorded by a sensor in the active chamber discharge;

b. the pressure (chamber pressure) recorded by a sensor in the chamber.

5.36 It is not necessary to monitor the temperature inside the load.

5.37 In addition to the above information, any cycle aborted due to a fault sensed by the air detector should be noted along with the remedial action taken.

Product release

5.38 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the packaging is undamaged;

c. the load items are visibly dry.

Troubleshooting

Air detector fault

5.39 The air detector is designed to register a fault when the level of air and gas sampled from the chamber is high enough to affect the even and rapid penetration of steam into the load. Possible causes of an air detector fault include:

a. an inefficient air removal stage;

b. an air leak during the air removal stage;

c. non-condensable gases evolved from the packaging;

d. non-condensable gases in the steam supply;

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e. a defective air detector.

5.40 When a cycle has been aborted due to an air detector fault the sterilizer should be taken out of service. If there is no obvious cause for suspicion, such as a change in the loading condition, the sterilizer should be subjected to the weekly tests as described in Part 3 of this SHTM. These will include an air detector function test.

Wet loads

5.41 Any item with wet outer packaging should be rejected since the moisture compromises the protective qualities of the wrapping.

5.42 Wet spots or patches on the packaging show that liquid water has been drawn into the chamber. There are several possible explanations, including:

a. poorly draining steam traps between the sterilizer and boiler (a sudden demand for steam can draw water out of a full trap);

b. severe pressure fluctuations in the main;

c. priming of the boiler leading to carry-over of water in the steam.

5.43 Occasionally, load items with dry outer packaging may be found to be wet inside. While the sterility of the product may be satisfactory, there remains the possibility that the load was wet throughout at some stage and therefore sterility cannot be assured. Since they are invariably discovered by the end-user at the point of need, such wet items do not promote confidence in the sterile supply service.

5.44 Packages that are damp inside are often the result of inadequate packaging and loading (see paragraphs 5.17–5.24), especially when metal objects have been processed. If the precautions outlined above have been followed, however, the cause may be a wet steam supply. This can be confirmed by the steam dryness test described in Part 3 of this SHTM. Users should note that this test will not reliably detect wetness due to sporadic carry-over of water.

5.45 Part 2 of this SHTM describes the engineering requirements for a steam supply of the correct dryness for sterilization. The sudden appearance of wet loads from a loading condition and operating cycle that have been used successfully for a long time may indicate a change in the steam service. For example, there may be a fault somewhere in the system or there may have been engineering modifications to the steam service; new or modified boilers, extensions to the steam main and new equipment installed elsewhere may all affect the dryness of the steam supplied to the sterilizer.

5.46 Another possibility is that operating practice in the boiler room may have changed. For example, it is common in hospitals to shut down all but one boiler for the summer months. When demand increases again in the autumn, the boiler may start to prime (carry over water) before the other boilers are returned to service.

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Superheating

5.47 Superheating, arising from steam that is too dry, can cause a failure to sterilize. It is uncommon and can be difficult to identify. A failed process indicator is one sign; charring of wrapping materials is another.

5.48 One possible cause of superheating is an excessive reduction in pressure through a throttling device, such as a pressure reducing system or a partially closed main steam valve. In this case superheating arises from adiabatic expansion. Engineering solutions to this problem are described in Part 2 of this SHTM.

5.49 Superheat can also arise if the steam is admitted into the chamber with excessive velocity. This problem is usually detected and overcome during commissioning, by fitting a throttling device in or over the steam inlet port with some modifications to the baffle plate assembly.

5.50 Another possibility is superheating from exothermic reaction. This may occur during sterilization as a result of rehydration of exceptionally dry hygroscopic material. In these circumstances the superheating may persist for the entire holding time with consequential risk of a failure to sterilize. This phenomenon is usually associated with certain textiles, particularly those incorporating cellulosic materials (such as cotton), which have become excessively dry before sterilization. It may occur during periods of very cold, dry weather especially where the materials to be sterilized are kept in rooms which are heated and mechanically ventilated without humidification.

Spontaneous combustion

5.51 There have been reports of textile loads bursting into flame within the sterilizer chamber. Invariably this is because the load has been allowed to become excessively dry and hot. There are two circumstances in which this may occur:

a. the load is placed in a heated chamber and left for a considerable time before the cycle is started; ignition is believed to occur when the load becomes rehydrated on the introduction of steam to the chamber;

b. the load is left inside the chamber for a long time after the end of the operating cycle; ignition occurs when the door is opened and the load exposed to air. This is most likely to happen where the operating cycle has aborted due to a fault condition and the load is not removed promptly.

5.52 Users should be mindful of this risk and establish operating procedures to ensure that loads are not left in heated chambers for longer than necessary.

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6. Operation of fluid sterilizers

Introduction

6.1 This chapter gives guidance on the routine operation of clinical high-temperature steam sterilizers designed to process aqueous fluids in sealed containers.

6.2 The guidance given here assumes that the sterilizer is to be used to process medicinal products in compliance with the EU Directives discussed in Chapter 1. Users should be aware, however, that products in which medicinal products are contained within a delivery system, such as certain irrigations and ophthalmic preparations, may be classified as medical devices as well as medicinal products.

The process

6.3 Fluid sterilizers heat load items by direct contact with high-temperature steam at a typical sterilization temperature of 121°C. Although steam does not penetrate to the product inside the sealed containers, sterilization is effected by the water molecules in the product itself. That is why these sterilizers cannot be used to process non-aqueous fluids.

6.4 A fluid sterilizer will normally have the following operating cycle.

a. *Heat-up*. Steam is admitted to the chamber, heating the load.

b. The *plateau period* starts when the chamber temperature, recorded by a sensor located in the active chamber discharge, reaches the sterilization temperature, which is typically 121°C (see Table 6).

   (i) In the first part of this period, the equilibration time, all parts of the load attain the sterilization temperature. This time depends on the nature and amount of the product, and the material, size and shape of the container.

   (ii) The moment when the temperature in all parts of the load finally attains the sterilization temperature marks the end of the equilibration time and the start of the holding time.

c. *Cooling*. The load is cooled, either by spraying with sterile water (usually chamber condensate) or the circulation of cooled air, until the temperature in the hottest part of the load has fallen below 80°C.

6.5 Heat transfer to the contents is predominantly by conduction through the walls of the containers and by internal convection. A small radiant heat transfer component is also present. During the heat-up phase of the operating cycle, the outside temperature of the load containers quickly approaches that of the chamber space, with a corresponding increase in the temperature of condensate in the active chamber discharge.

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Safety precautions

6.6 The main hazard with fluid sterilizers is the high pressure attained inside glass bottles at the sterilization temperature. This pressure may cause weak or damaged containers to burst during sterilization and such explosions may damage other containers in the load.

6.7 A hazard to the operator may result if bottles are removed from the sterilizer before they have cooled to a safe temperature. At a sterilization temperature of 121°C the absolute pressure inside a bottle having a nominal fill of fluid is in the region of 3.6 bar (see Figure 4). If the door were to be opened at this temperature, and the load subject to cold draughts or unintentional impact, the stresses arising in the glass would be sufficient to crack the bottle and cause an explosive breakage. Fluid sterilizers are fitted with a thermal door-lock to ensure that when glass bottles are being processed the door cannot be opened until the temperature inside all the containers has fallen below a safe maximum of 80°C. (Even at this temperature the pressure inside a bottle is approximately 1.8 bar.) Failure to observe this requirement has led to serious accidents resulting from the explosion of glass bottles.

6.8 Operators should be aware that some bottles may break before the end of the cycle and broken glass may need to be removed before the next cycle can begin.

6.9 Operating cycles for plastic containers have the following modifications:

a. pressure ballasting with air is used to prevent pressure differences arising between the inside and the outside of containers sufficient to burst or distort them;

b. the door may be opened when the temperature inside the containers falls below 90°C. This prevents “blooming” of the containers. On no account should these cycles be used with glass containers unless the thermal door lock has been reset to 80°C.

Product compatibility

6.10 Fluid sterilizers may be used to process a wide range of medicinal products in the form of aqueous solutions in sealed containers of either glass or plastic.

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Items that should not be processed in a fluid sterilizer

6.11 The following items should not be processed in a fluid sterilizer:

a. fluids in unsealed bottles (the product may be modified by the evaporation of water and the entry of steam and condensate, and will not remain sterile after removal from the chamber);

b. non-aqueous fluids (they will not be sterilized);

c. contaminated fluids intended for discard (discard material should not be processed in clinical sterilizers).

Design of the load

6.12 Items processed in fluid sterilizers will normally consist of large numbers of identical containers such as bottles, bags, ampoules or vials. While the containers are usually made of glass, plastic containers may also be processed. All containers should be sealed to prevent the escape of the contents and the entry of steam or condensate.

6.13 The loading condition should be designed with the aim of permitting the free circulation of steam and coolant over the surfaces of the containers.

Bottles

6.14 Bottles in a load should preferably all be of the same size. Where mixed sizes are unavoidable, the PQ tests should ensure that the largest bottles are monitored to ensure that they attain the required sterilization conditions.

6.15 It is important that steam is allowed to pass freely around the surfaces of bottles. They should be placed in crates or on trays designed to locate each bottle so that it cannot touch its neighbours. Chamber furniture should also allow the free passage of steam and condensate.

6.16 Plastic bottles, particularly those made of polymers which undergo a reduction in tensile strength at the temperatures used for steam sterilization, are often only suitable for use in sterilizers which include air or gas ballasting to increase the pressure throughout the cycle and thus restrain the bottle from bursting.

Plastic bags

6.17 Plastic bags should not be stacked on top of each other. Steam should be allowed to circulate freely around them. Bags may be hung from racks within the chamber or placed on shallow shelves.

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Vials and ampoules

6.18 Loads consisting of small containers, such as vials and ampoules, have a large surface-area-to-volume ratio and therefore will cause steam to condense rapidly during the heat-up stage. Where steam is admitted to the chamber through a single inlet, it will first condense on the ampoules nearest to the inlet and these will consequently heat up faster than those further from the inlet. This will produce a large difference in temperature across the chamber and an extended equilibration time. This is acceptable provided that the product can withstand the extended heating experienced by the ampoules near the steam inlet and the ampoules slowest to heat up are correctly identified for the thermometric PQ test.

6.19 Where the product cannot withstand this extended heating, the size of the load should be reduced so that it can be placed further from the steam inlet. A sterilizer with multiple inlets is the preferred solution.

Closure systems

6.20 Containers should have gas-tight seals to prevent evaporation of water from the contents and the entry of steam or condensate. Glass bottles for sterile fluids are commonly sealed with compound closures comprising an elastomeric disc or plug which is secured to the neck of the bottle by means of an aluminium screw cap, an aluminium crimped-on (or turned-on) cap, a cap made of plastic material or a retaining closure embodying both plastic and aluminium parts.

6.21 It is essential that the elastomer is held in tight contact with the neck of the bottle in order to prevent the entry of micro-organisms or other materials which might contaminate the product. It is a characteristic of such containers that when they are charged with the specified volume of the product there remains a substantial air space (sometimes referred to as ullage) above the liquid. The proportion of the total internal volume of a bottle filled with liquid may vary with the design of the bottle but is commonly 80-90 percent, so the ullage may be about 10-20 percent of the internal volume. Such a space is necessary for thermal expansion of the liquid during sterilization.

6.22 When a sealed bottle is sterilized, the pressure inside exceeds that in the sterilizer chamber by a substantial margin. The pressure within the bottle is due to the partial pressures of the air and steam at the sterilization temperature plus an additional factor due to the compression of the air and steam mixture in the ullage by thermal expansion of the liquid in the bottle. Thus at any single temperature the pressure within a bottle under sterilizing conditions will be determined largely by the proportion of the total internal volume filled with liquid since, as this increases, the effect of thermal expansion on the air and steam mixture also increases. Figure 4 shows the internal absolute pressure in a rigid container of water at 121°C as a function of filling factor. This diagram is equally applicable to all sizes of container.

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6.23 This high internal pressure imposes a stress on the closures which may be distorted or even ruptured as a result. Distortion of closures, especially of aluminium parts, may allow the elastomeric seal to lift or loosen in the bottle neck and allow the escape of some air from the ullage. Should this occur, the bottle on cooling tends to develop a partial internal vacuum. This itself is no danger to the product but may allow the entry into the bottle of spray cooling fluid which will dilute the product and may carry in chemical or microbial contamination. An attempt is made to reduce the risk of product contamination by using retained condensate in the sterilizer (or in some cases filtered gas) as the cooling agent. But since the failure of the seal may not be apparent by visual inspection, an acceptable product requires that the closure of the bottle remains an effective seal throughout the sterilization process.

6.24 Since the above problems arise as a result of the inevitable excess pressure generated within bottles, the security of bottle closures is the responsibility of the user. Thus the user is required to ensure that the closures and containers are suitably designed to withstand the proposed sterilizing conditions. This is best achieved by ensuring that containers and closures comply with a recognised standard. Where containers are reused, the user has to institute a rigid system of inspection after washing to ensure that all bottles with signs of damage, especially of the neck area, are discarded. It is imperative that a bottle is not charged with a volume of fluid greater than the stated nominal volume of the bottle.

6.25 Users are recommended to establish a quality system to ensure that the probability of failure of a closure is low enough that the sterility of the product is not jeopardised. This will generally require the user to identify the parameters of the container and closure system which could lead to a failure and to set limits of acceptance which have been validated to demonstrate closure integrity. Production cycles may require the introduction of a dye into the chamber to identify failed closures. Electronic monitoring systems are also available. Within the NHS it may not be practicable to determine the probability of failure statistically, and in such cases sufficient assurance of sterility may be achieved by ensuring that the steam supplied to the sterilizer, and any coolant water in contact with the load, complies with the “clean steam” purity specification described in SHTM 2031. See also Part 2 of this SHTM for a discussion on the fail-safe design of heat exchangers.

Performance qualification

6.26 PQ tests are not required for loading conditions presenting less of a challenge to the cycle than the full-load and small-load tests carried out during commissioning. Decisions on which loading conditions require PQ tests should be made by the user, in consultation with the Quality Controller and Test Person.

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6.27 PQ tests are required where:

a. the nominal capacity of any container exceeds 1 litre;

b. the product cannot withstand the equilibration time associated with the commissioning tests (see Part 3 of this SHTM);

c. any cycle variable has been modified from the setting used in validation.

6.28 Users should consider the economic benefits of conducting PQ tests even for stable products, since the heating and cooling times will be generally shorter than that required for the commissioning tests.

Selection of cycle variables

6.29 The sterilizer should be preset to operate in the standard sterilization temperature band shown in Table 6. Other combinations of sterilization temperature and holding time may be used provided that they have been satisfactorily demonstrated to deliver an adequate level of lethality when operated routinely within established tolerances.

Table 6: Sterilization conditions for fluid sterilizers

Sterilization temperature [°C]	Maximum allowable temperature [°C]	Minimum holding time [min]
121	124	15

6.30 The automatic controller should be preset to a plateau period, established during performance qualification, sufficient to include both the minimum holding time and the equilibration time.

Cycle monitoring and documentation

6.31 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

6.32 Where the temperature of the load is to be monitored, the load temperature probe should be inserted into a load item known to be the slowest to attain the sterilization temperature. Where two probes are provided (normally in sterilizers over 600 litres) the second probe should be inserted into the load item known to be the fastest to attain the sterilization temperature. The probe should be located along the geometric axis of the container and inserted to a depth of 85% of the container height.

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6.33 A batch process record should be generated for each production cycle. he batch process record will contain the following:

a. the temperature (“chamber temperature”) recorded by a sensor in the active chamber discharge;

b. the pressure (“chamber pressure”) recorded by a sensor in the chamber;

c. the temperature (“load temperature”) recorded by the load temperature probe.

6.34 In certain applications the operating cycle may be controlled by measuring the lethality (F_0) delivered to the load as the cycle progresses. An extensive discussion on the applications of the F_0 principle may be found in Part 5 of this SHTM.

Product release

6.35 Documented procedures for release of medicinal products should be established by the Quality Controller.

6.36 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. not more than one container (or 1%, whichever is the greater) has burst or broken.

6.37 If the batch process record is unacceptable the load should be rejected. A decision on reprocessing should be based upon a validated procedure which takes account of the chemical and physical stability of the product.

6.38 The load should be examined for damaged containers. The occasional broken bottle or bag may be acceptable provided intact containers have not also been damaged.

6.39 Blooming of plastic containers is a surface effect which normally clears and does not harm the container or the contents. The user and Quality Controller should decide whether blooming is acceptable.

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7. Operation of sterilizers for unwrapped instruments and utensils

Introduction

7.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to process unwrapped solid instruments and utensils by exposure to high-temperature steam.

7.2 The guidance given here assumes that the sterilizer is to be used to process medical devices However, these sterilizers do not meet the essential requirements of the EU Directives discussed in Chapter 1, which do not permit the supply of unpackaged sterile medical devices.

The process

7.3 This type of sterilizer is used to process unwrapped surgical instruments and utensils intended for immediate use in a controlled medical environment. Heating is by the direct contact of the product with saturated steam.

7.4 Air is normally removed from the sterilizer by passive displacement, either downward or upward depending on whether steam is supplied externally or generated internally. Active air removal systems of the type found in a porous load sterilizer are rare.

7.5 A few models have a drying stage in which the load is dried by passing filtered air through the chamber, but it is more usual for the load to be partially dried by evaporation after it has been removed from the machine.

7.6 A sterilizer conforming to BS 3970 will have the following operating cycle:

a. *Heating*. The water is heated and steam generated in order to vent the air from the chamber until the sterilization temperature is attained.

b. The *plateau period* starts when the chamber temperature, recorded by a sensor located in the active chamber discharge, reaches the sterilization temperature.

   (i) In the first part of this period, the equilibration time, all parts of the load attain the sterilization temperature.

   (ii) The moment when the temperature in all parts of the load finally attains the sterilization temperature marks the end of the equilibration time and the start of the holding time.

c. *Cooling*. The load is allowed to cool naturally in the chamber.

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Water supply

7.7 In transportable sterilizers steam is generated by the heating of feedwater within the chamber. The recommendations contained in SHTM 2031 should be followed.

7.8 Users should note that the recommendation for feedwater is designed to facilitate effective sterilization and avoid damage to the machine. Where the steam quality in the chamber is required to meet the specification for pyrogen-free “clean steam” (set out in SHTM 2031), only water complying with Sterilized Water for Injections BP is acceptable.

7.9 A sufficient supply of suitable water should be kept at hand. Operating procedures should ensure that the water level in the sterilizer is checked before every cycle and the reservoir replenished at specified intervals. This is particularly critical for clean steam (see SHTM 2031).

Safety precautions

7.10 As there is no thermal door-lock on the sterilizer, the load may still be very hot (up to 100°C) when it is removed from the chamber. Operators should therefore be issued with heat-resistant gloves.

7.11 Care should be taken not to contaminate load items with the gloves when removing the load from the chamber.

Product compatibility

7.12 These sterilizers are designed to process unwrapped instruments and utensils for immediate use in a controlled medical environment, such as an operating theatre. They should not be used to process items that are wrapped or items intended to be stored or transported before use.

7.13 Because these sterilizers have no active means of extracting air from load items, they should not be used with instruments and utensils whose construction could impede the passive removal of air and the subsequent penetration of steam. In practice, this means that hollow or porous items should not be processed in this type of sterilizer. A sterilizer with an active air removal system, such as a porous load sterilizer, is required in such cases. European standards regard an item as hollow, and therefore unsuitable, if the item possesses a cavity of depth greater than the width of its orifice, or a double-ended hole of length greater than twice its width. This is a conservative criterion, and many borderline items may be safely processed if they are placed correctly in the chamber (see 7.17). However, the risk of incomplete sterilization is a real one, and Users should carefully examine each type of item to be processed to ensure that air removal and steam penetration will be effective. Failure to observe this requirement has led to serious incidents in which patients have become infected by unsterile

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surgical instruments. The Authorised Person should be consulted in cases of doubt.

Items that should not be processed

7.14 The following items should not be processed in a sterilizer for unwrapped instruments and utensils:

a. medical devices intended to be supplied in compliance with the EU Directives discussed in Chapter 1 (unpackaged devices are not acceptable);

b. medicinal products;

c. wrapped items and other items likely to trap air and impede the penetration of steam (see paragraph 7.13);

d. aqueous fluids (a fluid sterilizer is required);

e. items not for immediate use.

Design of the load

7.15 Load items should be arranged on shelves or trays that permit the free circulation of steam and draining of condensate. Items should not be allowed to rest on the bottom of the chamber.

7.16 Trays or baskets should be constructed of open mesh or with sufficient ventilation holes to ensure that they present no barrier to air removal and steam penetration. BS 3970: Part 4 specifies that any such load containers used in these sterilizers should be perforated such that the total area of the perforations is at least 10% of the surface area of the container. The perforations should be uniformly distributed and each of area 20 mm^2 or more. Draft European standards make the same requirement.

7.17 As far as possible, load items should be arranged to ease the removal of air and the penetration of steam and allow condensate to run directly to the drain, away from the individual objects. Items of the load which could retain air and condensate, such as bowls, should be places on their sides so that air will be displaced and condensate will drain out.

Selection of cycle variables

7.18 Sterilizers conforming to the standards discussed in Part 2 of this SHTM will have a single operating cycle, normally with a sterilization temperature of 134°C and a holding time of at least 3 min. If other cycles are provided (see Table 7), the highest sterilization temperature compatible with the load should be chosen.

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7.19 It is recognised that users of transportable sterilizers in primary health care units, such as GP and dental practices, where close supervision of the sterilizer is not practicable may wish to operate their machines with a wider margin of safety than would be the case in a hospital SSD staffed by full-time specialist personnel. In such cases the machine's plateau period may be preset to the extended plateau period given in Table 7.

Table 7: Sterilization conditions for sterilizers for unwrapped instruments and utensils

Sterilization temperature [°C]	Maximum allowable temperature [°C][a]	Minimum holding time [min]	Extended plateau period[b] [min]
134	137	3	4
126	129	10	15
121	124	15	20
115[c]	118	30	-

a. See paragraphs 2.52-2.53 for comment on maximum allowable temperatures.

b. See paragraph 7.19.

c. Permitted by BS 3970: Part 4 but not recommended for NHS use.

7.20 Users should note that the "plateau period" here is regarded as beginning when the chamber temperature attains its preset value as signalled by the indicator light. The conventional plateau period (see paragraph 2.48), which starts when the chamber temperature attains the sterilization temperature, cannot normally be defined on these small sterilizers which have no means of detecting when that temperature has been reached.

7.21 The need for regular testing, as specified in Part 3 of this SHTM, is re-emphasised.

Cycle monitoring and documentation

7.22 Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

7.23 Where a recorder is fitted to the sterilizer (as recommended in Part 2 of this SHTM), a batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature ("chamber temperature") recorded by a sensor in the coolest part of the chamber (normally the active chamber discharge);

b. the pressure ("chamber pressure") recorded by a sensor in the chamber.

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7.24 Where a recorder is not fitted, the following records should be made:

a. once a day, note the duration of the plateau period, and the indicated chamber temperatures and pressures at the beginning, middle and end of the plateau period, for a selected production cycle;

b. where practicable, note the indicated chamber temperature and pressure at the approximate mid-point of the plateau period for each production cycle.

7.25 The load may be released for use provided that:

a. *either*, during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. *or*, during the plateau period:

(i) the values of the plateau period and the indicated chamber temperature and pressures as described in paragraph 7.24a are within the permitted tolerances established during performance qualification;

(ii) the values of the indicated chamber temperature and pressures as described in paragraph 7.24b are also within the permitted tolerances established during performance qualification.

7.26 As load items are not wrapped, they are exposed to the air at the end of the cycle and subject to rapid recontamination. They should therefore be used without delay.

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8. Operation of dry-heat sterilizers

Introduction

8.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to sterilize load items by exposure to hot, dry air. Such sterilizers are correctly known as “dry-heat sterilizers” and sometimes as “hot-air sterilizers” or “sterilizing ovens”.

8.2 The guidance given here assumes that the sterilizer is to be used to process either medicinal products or medical devices in compliance with the EU Directives discussed in Chapter 1.

The process

8.3 Dry heat sterilizers expose the load to hot, dry gas (normally hot air) at a temperature of 160ºC or greater (see Table 8). The load is heated by conduction from the hot air to the load items. The process is slow and cycle times are several hours.

8.4 A dry-heat sterilizer will typically have the following operating cycle.

a. *Heating-up*. Hot air is heated electrically and circulated through the chamber.

b. The *plateau period* starts when the chamber temperature, recorded by a sensor located in the part of the chamber known to be the slowest to heat up, reaches the sterilization temperature.

   (i) In the first part of this period, the equilibration time, all parts of the load attain the sterilization temperature.

   (ii) The moment when the temperature in all parts of the load finally attains the sterilization temperature marks the end of the equilibration time and the start of the holding time.

c. *Cooling*. The load is cooled by circulating cold, filtered air through the chamber or through a jacket.

Safety precautions

8.5 The main hazard associated with dry-heat sterilizers is the high temperatures at which they operate. The highest sterilization temperature permits the temperature of the load to rise to 190°C (see Table 8). In the event of a control failure, the chamber temperature may rise to 200°C before the thermal cut-out shuts off the heaters.

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8.6 In normal operation, a thermal door-lock prevents the door being opened until the temperature in all parts of the load has fallen to 80ºC. Nonetheless, operators should take great care in both unloading hot load items from the chamber and reloading a chamber that remains hot from a previous cycle.

Product compatibility

8.7 Dry heat may be used to process a variety of items and materials which would either be damaged by exposure to high-temperature steam or LTSF or would not be sterilized.

8.8 Suitable items include solids, heat-stable powders, waxes, greases, ointments, non-stainless metals, hollow needles, glass syringes and items in sealed containers. Dry heat may also be used for non-aqueous fluids such as white soft paraffin, paraffin gauze dressings, eye ointment bases, oily injections, silicone lubricant and pure glycerol.

Items that should not be processed by dry heat

8.9 The following items should not be processed by dry heat:

a. items that would be damaged by exposure to hot air at 160°C, such as glycerol/water mixtures, rubber, certain plastic or electrical items;
b. aqueous fluids (a fluid sterilizer is required).

8.10 As cycle times can be several hours, items must be able to withstand not only the holding time, but also the relatively slow heating and cooling stages.

Design of the load

8.11 The loading condition should be designed with two aims in mind:

a. to permit air to circulate freely within the chamber and around each item of the load;
b. to allow heat to be transmitted to and within each item of the load.

8.12 The time required for an individual load item to attain the sterilization temperature will depend upon its size, shape and thermal conductivity, and can vary widely. Powders and oils, in particular, take a long time to heat up. Loads should therefore be designed to contain items of similar size and nature.

8.13 If a mixed load cannot be avoided, then great care must be taken during performance qualification to identify the load items that are the slowest to heat up. The duration of the plateau period should be selected to ensure that these items are exposed to the sterilization temperature for the correct time.

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Load preparation and packaging

8.14 All items must be clean and dry before sterilization.

8.15 Glass or metal syringes should be assembled and hinged instruments should be closed.

8.16 Delicate instruments, such as eye instruments, should be supported to guard against physical damage.

8.17 Good thermal contact between load items and their containers is essential. In the case of a heavy instrument, heat conduction can be improved by supporting the instrument in a metal cradle within its container. Smaller items may be wrapped in heavy or light gauge metal foil or contained in aluminium cans or tubes each of which may be sealed with push-on caps, screw caps, or crimp-on foil caps. Crimp-on foil caps with a pre-printed chemical indicator are also available.

8.18 The packaging does not need to be porous since the heat transfer normally takes place by conduction. However, in sealed packaging the contents of the pack when heated can exert a considerable pressure which may be sufficient to rupture the packaging material or seals. Vented packaging systems that allow pressure equilibration may be suitable for use in sterilizers which operate with a chamber atmosphere which has been filtered through a bacteria-retentive filter. This is particularly important during the cooling stage.

8.19 For items such as laboratory glassware, foil may be used to close the open end of the product to prevent contamination when the load is removed from the sterilizer.

8.20 Kraft paper bags or a simple layer of wrapping material can be used to pack individual items. Plastic bags of the sort sold for roasting meat in domestic ovens may also be suitable.

8.21 An extensive discussion on packaging materials and methods may be found in Part 5 of this SHTM.

Arrangement of load items

8.22 Random loading is not acceptable.

8.23 Load items should be placed in the chamber in such a way that air can circulate freely around them. This requires a space of at least 10 mm between adjacent items. They should therefore not be stacked and should not be allowed to touch each other.

8.24 Shelves and trays should be either perforated or made of wire mesh.

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8.25 Because of the importance of air circulation, even minor variations in the loading pattern may seriously affect heat distribution and prevent complete sterilization of the load. Purpose-made shelving or spacers should be used to ensure accurate and repeatable positioning of load items.

Performance qualification

8.26 Because of the need for careful design of the load, performance qualification is required for each loading condition to be processed. The full-load test used during commissioning is not an acceptable substitute. The number of different loading conditions should be rationalised by careful design to minimise the number of PQ tests required.

8.27 Decisions on which loading conditions require PQ tests should be made by the user in consultation with the Test Person.

Selection of cycle variables

8.28 The cycle variables should be selected to expose the load to one of the three combinations of sterilization temperature and holding time given in Table 8. The highest sterilization temperature compatible with the load should be chosen.

Table 8: Sterilization conditions for dry-heat sterilizers

Sterilization temperature [°C]	Maximum temperature [°C]	Maximum holding time [min]
160	170	120
170	180	60
180	190	30

8.29 A few heat-sensitive products may require lower temperatures and consequently prolonged holding times. The advice of the Authorised Person should be sought in such cases.

Cycle monitoring and documentation

8.30 The integrity of the air filter should be checked daily or, in the case of medicinal products, during each cycle. This will normally be done by measuring the differential pressure across the filter during the cooling stage and ensuring that the measured value is within the limits specified by the manufacturer. Note that this check is not the same as the air filter integrity test described in Part 3 of this SHTM.

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8.31 Where the temperature of the load is to be monitored, the load temperature probe should be inserted into a load item known to be the slowest to attain the sterilization temperature. Where two probes are provided (normally in sterilizers over 600 litres) the second probe should be inserted into the load item known to be the fastest to attain the sterilization temperature. Sensors sealed into load containers should be located along the geometric axis and inserted to an approximate depth of 50% of the container height.

8.32 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

8.33 The batch process record will contain the following:

a. the temperature (“chamber temperature”) recorded by a sensor in the coolest part of the chamber;

b. for medicinal products, the temperature (“load temperature”) recorded by load temperature probes placed:

(i) in the load item known to be the slowest to reach the sterilization temperature;

(ii) for larger sterilizers, also in the load item known to be the fastest to reach the sterilization temperature.

Product release

8.34 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the packaging is undamaged.

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9. Operation of LTS disinfectors

Introduction

9.1 This chapter gives guidance on the routine operation of clinical disinfectors designed to disinfect load items by exposure to low-temperature steam (LTS). See Chapter 10 for guidance on the operation of low-temperature steam and formaldehyde (LTSF) sterilizers.

9.2 The guidance given here assumes that the disinfector is to be used to process medical devices. However, the LTS process does not meet the sterilization requirements of the EU Directives discussed in Chapter 1. LTS should not be used for processing medicinal products.

9.3 LTS disinfectors are occasionally used to decontaminate soiled surgical components to make them safe to handle before they are washed and sterilized (see also paragraph 9.8). In such cases the machine used for initial decontamination should be reserved for that purpose and not be used also for the terminal disinfection of medical devices.

The process

9.4 Disinfection is achieved by direct contact with low-temperature saturated steam at sub-atmospheric pressure at a nominal temperature of 73°C (and not exceeding 80°C) for a minimum holding time of 10 minutes.

9.5 The LTS process kills most vegetative micro-organisms and some heat-sensitive viruses. It disinfects but does not sterilize.

9.6 LTS is free of toxic residues that may occur with chemical disinfection.

9.7 Part 2 of this SHTM specifies that new LTS disinfectors should conform to the requirements of BS 3970. Such a machine will have the following operating cycle.

a. *Preheating*. The walls of the chamber are heated to the preset operating temperature between 71°C and 78°C. This reduces condensation on the walls of the chamber (the door is not normally heated).

b. *Air removal*. Sufficient air is withdrawn from the chamber to permit the attainment of the disinfection conditions. This normally requires an absolute pressure of less than 50 mbar.

c. *Air ingress monitoring*. The chamber is automatically subject to a vacuum leak test before the cycle proceeds any further. If the leak rate is higher than a preset value (normally 5.0 ± 0.2 mbar min^{-1}) the cycle is aborted.

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d. *Steam admission*. Steam is admitted to the chamber until the temperature attained throughout the load is 73 ± 2°C.

e. *Disinfection*. The temperature throughout the chamber and load is maintained at or above the disinfection temperature (71°C) for a holding time of not less than 10 min.

f. *Drying*. Steam is extracted from the chamber and the chamber pressure is reduced sufficiently to permit the evaporation of condensate from the load, either by prolonged evacuation of the chamber or by the injection and subsequent extraction of heated air or other gases within the chamber.

g. *Air admission*. Air is admitted to the chamber through a filter until the chamber pressure is within 100 mbar of atmospheric pressure.

Safety precautions

9.8 Where LTS disinfectors are used to decontaminate soiled items before cleaning, operators should be aware that the steam may not have penetrated below the surface of the soil and that decontamination may therefore not be complete. Care is required in the subsequent handling of the item before it is cleaned.

Product compatibility

9.9 LTS disinfection is suitable for a wide range of heat-sensitive items capable of withstanding a moist process.

9.10 The process is particularly suitable for the disinfection of respiratory and anaesthetic equipment, external pacemakers and for rigid endoscopes not requiring a sterilization process.

Items which should not be processed by LTS

9.11 The following items should not be processed by LTS:

a. items requiring sterilization;

b. items which may be damaged by the conditions of heat, moisture and pressure during the cycle;

c. items in sealed containers (the steam will not reach them);

d. oily or greasy items (oil or grease will impede the penetration of steam);

e. items likely to be contaminated with bacterial spores or other agents of similar resistance to the disinfection process.

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Design of the load

9.12 The loading condition should be designed with two aims in mind:

a. to permit the rapid removal of air from the load items and the rapid penetration of steam; and

b. to ensure that the condensate formed during the cycle does not result in a wet load.

Air removal

9.13 The presence of air in the load can impede the penetration of steam and thereby drastically reduce the effectiveness of the disinfection process.

9.14 The principles of ensuring effective air removal for LTS disinfectors are the same as those for porous load sterilizers (see paragraphs 5.13-5.16).

Handling of condensate

9.15 The principles of ensuring that condensate does not result in wet loads are the same as those for porous load sterilizers (see paragraphs 5.17-5.24).

Packaging materials

9.16 Packaging materials for LTS sterilizers should meet the same requirements as those for porous load sterilizers (see paragraphs 5.25-5.28). Any process indicators in the form of printed panels designed for high-temperature steam processes will not, however, reliably respond to the LTS process. Until specific LTS indicators are available, plain bags should be used.

Selection of cycle variables

9.17 The LTS operating cycle is preset by the manufacturer and usually no adjustment is possible.

Cycle monitoring and documentation

9.18 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

9.19 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature (“chamber temperature”) recorded by a sensor in the active chamber discharge;

b. the pressure (“chamber pressure”) recorded by a sensor in the chamber.

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Product release

9.20 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the packaging is undamaged;

c. the load items are visibly dry.

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10. Operation of LTSF sterilizers

Introduction

10.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to sterilize load items by exposure to low-temperature steam and formaldehyde (LTSF). See Chapter 9 for guidance on the operation of low-temperature steam (LTS) disinfectors.

NOTE: Despite their name, LTSF sterilizers are disinfectors.

10.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1. Due to its toxicity, LTSF should not be used for sterilization of medicinal products.

10.3 LTSF sterilizers are occasionally used to decontaminate soiled surgical components to make them safe to handle before they are washed and sterilized. In such cases the sterilizer used for initial decontamination should be reserved for that purpose and not be used also for the terminal sterilization of medical devices.

10.4 The user should seek advice from the Authorised Person, the Microbiologist or the manufacturer if in any doubt about the operation of LTSF sterilizers.

The process

10.5 Sterilization is achieved by direct contact with a mixture of low-temperature saturated steam and formaldehyde gas at sub-atmospheric pressure at a typical operating temperature of 73°C and not exceeding 80°C.

10.6 LTSF has a broad-spectrum action against vegetative bacteria, bacterial spores, fungi and most viruses.

10.7 Many operating cycles are in use, in which there are variations in the pattern of injection of steam and formaldehyde injection, the depth of vacuum, length of holding stages and the amount of formaldehyde employed. Part 2 of this SHTM specifies that new LTSF sterilizers should conform to the requirements of BS 3970. Such a sterilizer will have the following operating cycle.

a. *Preheating*. The walls of the chamber are heated to the preset operating temperature (typically 73°C, but the standard does not specify this). This reduces condensation on the walls of the chamber (the door is not normally heated).

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b. *Air removal*. Sufficient air is withdrawn from the chamber to permit the attainment of the sterilization conditions. This normally requires an absolute pressure of less than 50 mbar.

c. *Air ingress monitoring*. The chamber is automatically subjected to a vacuum leak test before the cycle proceeds any further. If the leak rate is higher than a preset value (normally 5.0 ± 0.2 mbar min^{-1}) the cycle is aborted.

d. Sterilization.

   (i) Phase 1. The required steam and formaldehyde conditions within the chamber and load are attained.

   (ii) Phase 2. The temperature, humidity and formaldehyde concentration are maintained within specified limits for the holding time.

e. *Gas removal*. Formaldehyde and steam are removed from the chamber and load.

f. *Drying*. Steam is extracted from the chamber and the chamber pressure is reduced sufficiently to permit the evaporation of condensate from the load, either by prolonged evacuation of the chamber or by the injection and subsequent extraction of heated air or other gases within the chamber.

g. Air admission. Air is admitted to the chamber through a filter until the chamber pressure is within 100 mbar of atmospheric pressure.

10.8 Since the sterilization process is ultimately dependent on chemical action, a routine microbiological test is required for each production load to confirm that sterilization conditions have been attained (see paragraph 10.48).

Formaldehyde solution

10.9 Formaldehyde (CH_2O), also known as methanal, is a colourless, toxic gas with a strong, characteristic odour. It is normally produced within the sterilizer by the evaporation of Formaldehyde Solution BP, also known as formalin, containing 34-38% w/w formaldehyde stabilised with methanol.

10.10 Analytical reagent grade formaldehyde solution, also specified in the British Pharmacopoeia, is unstabilised and is not suitable for use in sterilizers.

10.11 BS 3970 permits other “primary materials” to be used for the generation of formaldehyde, though formalin is by far the most common. If other materials are used, the user should ensure that adequate information on safety and usage is supplied by the manufacturer of the product.

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Polymerisation

10.12 When formalin is allowed to stand or evaporate, white flocculent masses of paraformaldehyde are precipitated. Paraformaldehyde is a mixture of polymethylene glycols (of the general form $(CH_2O)_n$, xH_2O, where n is 6-50) formed by the reaction of formaldehyde with water. It is readily converted back to formaldehyde gas by heating.

10.13 Paraformaldehyde may be formed in LTSF sterilizers where the formaldehyde gas is allowed to condense on a cold, wet surface. As the reaction removes formaldehyde from the chamber atmosphere it can lead to a failure of the sterilization process. Paraformaldehyde deposits may also block pipework in the heat exchanger and so reduce the efficiency of vaporisation of the formalin. Polymerisation is controlled mainly by careful handling of condensate (see paragraphs 10.32–10.37). Heated doors, provided on some models, are also helpful.

10.14 Experience has shown that on larger LTSF machines an occasional flushing cycle, in which the formalin supply is replaced with water and a cycle run with an empty chamber, is beneficial in reducing polymerisation problems. Flushing cycles may conveniently be run overnight.

Safety precautions

10.15 Where LTSF sterilizers are used to decontaminate soiled items before cleaning, operators should be aware that the sterilant may not have penetrated below the surface of the soil and that decontamination may therefore not be complete. Care is required in the subsequent handling of the item before it is cleaned.

10.16 Formalin is a toxic liquid which requires careful handling and secure storage.

Effects on health

10.17 Formaldehyde gas has a pungent odour which is very irritating to the eyes and respiratory tract, with a threshold of detection by smell at around 0.8 ppm, though the threshold for irritation may be lower. The threshold for eye irritation may be as low as 0.01 ppm; 4 ppm usually causes the eyes to water. Mild effects on the throat may occur at 0.5 ppm; 10 ppm causes severe irritation to the eyes, nose and throat. Formaldehyde is assigned a maximum exposure limit of 2 ppm (both short-term and long-term limits) under the COSHH Regulations 1999 (see Schedule 1). The presence of formaldehyde in the air can therefore be sensed by personnel at levels below the maximum exposure limit; in this respect, LTSF sterilization is safer than EO sterilization.

NOTE: Refer also to EH40 ‘Occupational Exposure Limits’ Table 1.

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10.18 Workers regularly exposed to formaldehyde may become acclimatised to the effects at low concentrations. There is no evidence to suggest that exposure to formaldehyde leads to chronic impairment of lung function. There have been only a few case reports of occupational asthma associated with formaldehyde exposure, despite its widespread use in industry. However, skin contact has been shown to cause allergic contact dermatitis.

10.19 Although there is no epidemiological evidence that formaldehyde is associated with cancer in humans, HSE advises that it should be regarded as a potential carcinogen.

10.20 Formalin liquid can cause irreparable damage if splashed in the eyes. Eye-washing facilities should be provided. Hazard labels should be displayed prominently in all areas in which formalin is handled and used.

Replenishing the formalin supply

10.21 In normal operation of LTSF sterilizers, the greatest risk of exposure occurs when the formalin supply in the sterilizer is replenished. A written procedure for the filling and the connection of formalin tanks should be devised, based on a risk assessment complying with the COSHH Regulations. Care should be taken that the exposure limits given in Schedule 1 are not exceeded. All staff whose duties include replenishing the formalin supply should receive instruction.

10.22 Formalin should be stored in a closed container in a locked cabinet at a temperature of 15-25ºC. Vessels required for handling the formalin, such as jugs and funnels, should also be kept in the cabinet.

10.23 On certain older sterilizers replenishment of the formalin supply is a matter of removing the empty tank from the sterilizer and installing a full one in its place. On newer sterilizers, formalin is decanted into the tank from a storage container.

10.24 The decanting operation should be done in a well-ventilated room where an accidental spillage will not endanger staff or patients. A safety cabinet or fume cupboard is desirable. The following precautions should be observed when decanting is necessary.

a. Dress in appropriate personal protective equipment (PPE), ie. apron, facemask and gloves (see paragraphs 2.14-2.15).

b. Remove the formalin tank from the sterilizer and take it to a bench or worktop near a sink or hand-basin where plenty of running water is available.

c. Take the formalin bottle from the storage cupboard.

   (i) Check the expiry date. If the date has passed, the solution should not be used.

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(ii) Examine the solution to ensure that polymerisation and separation have not taken place. The solution should be clear, with no sign of white particles or sediment. If there are any signs of polymerisation, the solution is not suitable for sterilization and should not be used.

d. Check the quantity of formalin to be decanted into the tank.

e. Decant the solution slowly into the tank. Do not lift the storage bottle above chest height.

f. When the decanting is complete, wash any jugs or funnels used in the process with ample clean, cold water.

g. Return the tank to the sterilizer and install it in accordance with the manufacturer's instructions.

h. Return the formalin storage bottle and filling vessels to the cabinet and lock the door.

i. Remove the PPE, discard or clean as appropriate, and return it to its storage location.

Product compatibility

10.25 LTSF is a suitable process for a wide variety of items which are unsuitable for sterilization by high-temperature steam or dry heat. This includes many materials and items of equipment with integral plastic parts which could be damaged by heat. Complex items, such as certain electromedical equipment, may be sterilized by this process.

10.26 For example, LTSF can be used for sterilizing ophthalmic and cardiology items such as retinal and cataract detachment probes, cardiac catheters and pacing electrodes. It is also useful for elastic bougies, artificial joints, foetal scalp electrodes, amniotic membrane perforators and similar heat-labile items.

10.27 The reversible adsorption of formaldehyde by some materials must be considered. The high surface area of fabrics can adsorb large quantities of formaldehyde (effectively absorption) and these may remain for long periods unsuitable for patient use.

10.28 Because of the hazards associated with LTSF, it should not be used to sterilize items which could be processed by other means. A survey by the Central Sterilising Club showed that many items processed in hospital LTSF sterilizers carry only an intermediate infection risk (see Table 2 in Chapter 2) and LTS disinfection would have been more appropriate. Examples include face masks, ventilator tubing, nebulisers, airways, mattresses, sheepskins, breast milk expressors and toys.

NOTE: Sterilization and disinfection of heat-labile equipment, by Central Sterilising Club 1986.

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Items which should not be processed by LTSF

10.29 The following items should not be processed by LTSF:

a. items which may be damaged by the conditions of temperature, pressure, moisture and chemical environment prevailing during the cycle;

b. items in sealed containers (the sterilant will not reach them);

c. oily or greasy items (oil or grease will impede the penetration of the sterilant);

d. items contaminated with body fluids (hardened, fixed protein deposits will be produced); eg. “dirty returns” from operating theatres, clinics, etc.;

e. electrical or other items requiring a dry process, e.g. fully assembled air drills, dental hand pieces and infant ventilators;

f. certain flexible fibre-optic endoscopes (differential expansion will crack the sealants and let moisture penetrate the optics);

g. items which may absorb and retain unacceptable quantities of formaldehyde.

Design of the load

10.30 The loading condition should be designed with two aims in mind:

a. to permit the rapid removal of air from the load items and the rapid penetration of steam and formaldehyde; and

b. to ensure that the condensate formed during the cycle is quickly drained clear of the load.

Air removal

10.31 The presence of air in the load can impede the penetration of steam and formaldehyde and thereby drastically reduce the effectiveness of the sterilization process. The principles of ensuring effective air removal for LTSF sterilizers are the same as those for porous load sterilizers (see paragraphs 5.13-5.16).

Handling of condensate

10.32 As in all steam sterilizers, water condenses during the heating stages of the LTSF cycle. This problem is particularly acute when sterilizing metal items.

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10.33 In contrast to porous load sterilizers (see paragraphs 5.17-5.24), where it is preferable to retain condensate close to the load items to permit re-evaporation, condensate formed in LTSF sterilizers should be drained clear of the load as quickly as possible. This is for two reasons:

a. excessive moisture may impede the penetration of formaldehyde gas into the load (especially where items have narrow lumens);

b. condensate allowed to remain on the load will promote the formation of paraformaldehyde (see paragraph 10.13).

10.34 Chamber furniture should therefore be made from materials of high thermal conductivity (such as aluminium) to reduce heat-up time and so avoid cool surfaces. Open mesh supports should be used to allow drainage as well as gas penetration.

10.35 Packs should be arranged in a manner which will permit the free drainage of condensate.

10.36 To retain heat and reduce condensate formation, the door should remain closed whenever the machine is not in use.

10.37 LTSF sterilizers should always be preheated prior to use. This may be either from a previous LTSF cycle, or from an LTS cycle used specifically for preheating.

Packaging materials

10.38 The basic considerations for packaging are similar to those for porous load sterilizers (see paragraphs 5.25-5.28), except for the following:

a. the extent to which packaging materials will retain both moisture and formaldehyde residuals may affect the efficacy of the process;

b. materials which are slow to attain the sterilization temperature may promote polymerisation;

c. materials of high heat capacity promote the formation of excessive amounts of condensate.

10.39 It is therefore recommended that packaging should be kept to a minimum.

10.40 Packaging may consist of paper, used as plain or creped wraps, or in the form of bags or, in combination with plastic film, as pouches. Light cardboard boxes, or corrugated polypropylene boxes, adequately vented and overwrapped with paper or other material as a bacterial barrier, are also suitable. When particularly delicate instruments are to be processed, the use of open-cell foam for support and protection is acceptable.

10.41 To assist in the detection of paraformaldehyde deposits, packaging materials should preferably be of dark colour (such as green) rather than white.

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10.42 If packaging designed for porous-load sterilizers is used, Users should note that any process indicators in the form of printed panels will not reliably respond to the LTSF process. If specific LTSF indicators are not available (they should conform to BS EN 867: Part 2) plain bags should be used.

10.43 Extensive guidance on packaging may be found in Part 5 of this SHTM.

Performance qualification

10.44 Decisions on which loading conditions require PQ tests should be made by the user in consultation with the Microbiologist and Test Person.

Selection of cycle variables

10.45 The concentration of formaldehyde in the chamber during the holding time will have been determined during performance qualification and is typically around 15 g m^{-3} for an operating temperature of 73°C. This is equivalent to the evaporation of 40 ml of formalin per cubic metre of the chamber volume (this is the volume of the pressure vessel, not the usable chamber space).

10.46 Other cycle variables are preset by the manufacturer.

Cycle monitoring and documentation

10.47 Documentation as listed in paragraph 2.57 should be recorded. Each cycle should be noted in the sterilizer process log (see paragraph 3.11).

10.48 A routine microbiological test should be carried out with every production load as described in Part 3 of this SHTM. Note that the full result of the test will not be known until the biological indicator has been cultured for 7 days.

10.49 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature (“chamber temperature”) recorded by a sensor in the active chamber discharge;

b. the pressure (“chamber pressure”) recorded by a sensor in the chamber.

10.50 The operator should note the indicated amount of formalin consumed during the cycle and check that the gas removal stage has been completed satisfactorily before opening the door.

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Product release and storage

10.51 The load may be released for degassing provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. the correct amount of formalin has been taken from the tank;

c. the chemical indicator used in the routine microbiological test shows a uniform colour change;

d. there is no visual evidence of polymerisation (see paragraph 10.59);

e. the packaging is undamaged;

f. the load items are visibly dry.

10.52 The load may subsequently be released as sterile provided that the microbial culture results of the routine microbiological test described in Part 3 of this SHTM are satisfactory.

10.53 It is common practice in some units to release loads on the strength of the batch process record and not wait until the result of the microbiological test is known. The rationale for this is that the BPR confirms that the load has been exposed to a high-grade LTS disinfection process and is therefore safe for use. A subsequent failure of the microbiological test would lead to the sterilizer being withdrawn from service for investigation but would not normally lead to the recall of the released goods.

10.54 While such practices have been justified on the grounds of economy, they would not be acceptable under the EU Directives on medical devices. If the microbiological test shows a failure, the machine is, by definition, not working to the specifications established during validation and the process is therefore not adequately controlled (see paragraph 10.58).

10.55 A degassing time for each load will have been established during performance qualification. This will typically be no more than one hour. An active degassing system is not necessary. Goods processed in an LTSF sterilizer should be stored in such a way that air from the ventilation system cannot carry traces of formaldehyde over goods from other types of sterilizer.

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Troubleshooting

Cycle fault

10.56 The automatic controller may indicate a fault for a number of reasons, including:

a. a vacuum leak greater than a preset value (normally 5.0 ± 0.2 mbar min^{-1});

b. failure to attain the sterilization temperature;

c. insufficient formalin for a complete cycle.

10.57 Should a fault develop, the risk of exposure to formaldehyde is much greater than in normal operation. The Maintenance Person should be notified immediately. The batch process record should be carefully compared with the master process record to establish the precise point the cycle has reached. If it is suspected that formaldehyde has not been withdrawn from the chamber, the door of the sterilizer should not be opened until the loading area has been evacuated. Both the room ventilation and local exhaust ventilation should be operating. Provided the chamber has reached atmospheric pressure, the door can then be cranked partially open by an operator wearing a respirator. The chamber and load should be left overnight with the ventilation systems running during which time the formaldehyde will safely disperse.

Failure of the routine microbiological test

10.58 Failure of the microbiological test shows that the prescribed sterilization conditions have not been attained. If the batch process record shows that the physical cycle variables were satisfactory, then suspicion should fall on the formaldehyde component of the process.

a. The concentration of formaldehyde in the chamber was too low. There are several reasons why this might be.

(i) Insufficient formalin was consumed. This would normally lead to a fault indication and would have been revealed by inspection of the formalin level indicator.

(ii) Some of the formaldehyde was polymerised (see paragraph 10.59);

(iii) Some of the formaldehyde was dissolved in condensate. Check that there are no places in the load or chamber where standing water could collect (this could happen if chamber furniture or loading trolleys become dented).

(iv) Some of the formaldehyde was absorbed into the load. This is improbable if performance qualification tests have been conducted and previous loads have been processed satisfactorily.

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b. The loading condition is too great a challenge to the penetration of formaldehyde. Again, this is unlikely if performance qualification has been satisfactory.

Polymerisation of formaldehyde

10.59 The scientific background to formaldehyde polymerisation is discussed in paragraph 10.12. Evidence that polymerisation has occurred during a cycle is normally in the form of patchy white deposits of paraformaldehyde in the chamber and on the load items. There are three main causes to be considered.

a. Too much water was present in the chamber. Principles for avoiding wetness are discussed in paragraphs 10.32–10.37. If the loading condition has been processed many times before without difficulty, then the problem may lie in the steam supply which should be tested for dryness as described in Part 3 of this SHTM.

b. Too much formalin was used in the cycle. This is unlikely if the formalin indicator is working correctly and has been read correctly.

c. Failure (or partial failure) of the heat exchanger. If white streaks are visible in and around the steam entry port, it is likely that liquid formalin has entered the chamber. This implies that the temperature in the heat exchanger was too low for complete vaporisation.

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11. Operation of ethylene oxide sterilizers

Introduction

11.1 This chapter gives guidance on the routine operation of clinical sterilizers designed to sterilize load items by exposure to ethylene oxide gas (EO).

11.2 The guidance given here assumes that the sterilizer is to be used to process medical devices in compliance with the EU Directives discussed in Chapter 1. Due to its toxicity, EO should not be used for sterilization of medicinal products.

11.3 Sterilization by EO should be regarded as a last resort, only to be used when other forms of sterilization are not possible. The wide variety of items processed in hospital SSDs will increase the difficulty in validating the process to achieve consistently low levels of residual EO. Items sterilized by EO may therefore contain higher levels of residuals than are desirable.

The process

11.4 EO is a highly penetrative, non-corrosive agent which has a broad-spectrum action against viruses, vegetative bacteria, bacterial spores, fungi, and other living cells under optimal conditions of concentration, relative humidity, temperature and exposure time. It may be used at temperatures and pressures which minimise damage to sensitive equipment. Typical operating temperatures are in the range 20-60°C.

11.5 Two types of EO sterilizer are employed in the NHS.

11.6 In low-pressure sterilizers, of chamber volumes around 150 litres, the sterilant is pure EO at sub-atmospheric pressure. The gas is supplied from a single-use, disposable cartridge contained within the chamber. The cartridge limits the amount of EO in use at any one time and so reduces the toxic and explosive hazards. The chamber is designed to contain the effects of an explosion of the contents of a single cartridge. Compared with high-pressure sterilizers (see paragraph 11.7), low-pressure machines are relatively cheap to install and to run, requiring no piped EO service and no gas disposal plant. The low pressure in the chamber allows pressure-sensitive equipment to be processed safely.

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11.7 In high-pressure sterilizers, of chamber volume up to 500 litres, the sterilant is EO diluted with another gas, supplied from cylinders. The mixtures are chosen to expose the load to an EO concentration of around 500-1000 mg litre^{-1} while keeping the potential hazards to a minimum Two gas systems are in common use:

a. EO with chlorofluorocarbons (CFCs) or hydrochlorofluorocarbons (HCFCs) at pressures up to 2 bar: CFCs have traditionally been used as a diluent gas but are no longer acceptable for environmental reasons; HCFCs require even more critical control of humidity than other systems and are themselves due to be phased out;

b. EO with carbon dioxide at pressures up to 6 bar.

11.8 The operating cycle of an EO sterilizer constructed to BS EN 1422 will have the following stages, though the order may be varied slightly.

a. *Chamber preheating*. With the load in place, the chamber is heated to a preset working temperature.

b. *Air removal*. Sufficient air is removed from the chamber and load to permit the subsequent attainment of the sterilization conditions and to ensure that the admission of EO will not result in a flammable or explosive mixture.

c. *Automatic leak test*. A vacuum leak test is carried out to ensure that air does not leak into the chamber. For sterilizers operating at pressures higher than 1.05 bar, a pressure leak test is also carried out to ensure that EO does not leak out of the chamber.

d. *Conditioning*. The load is heated and humidified to a preset sterilization temperature and humidity (at least 40% RH). The length of this stage will depend on the extent of any preconditioning.

e. *Gas injection*. Gas is admitted to the chamber until the operating pressure has been attained.

f. Ga*s exposure.* The temperature and gas pressure (or concentration) are maintained within limits throughout the chamber and load for a preset holding time.

g. *Gas removal*. Gas is removed from the chamber to reduce the concentration below the flammable limit when air is admitted at the end of the stage. Some gas will still be left in the load.

h. *Flushing*. Sufficient gas is removed from the load so that there is no longer a safety hazard to the operator when the sterilizer is unloaded. The flushing agent is normally filtered air or an inert gas.

i. *Air admission*. Air is admitted to the chamber until the pressure approaches atmospheric pressure.

j. *End of cycle*. If the door remains unopened for more than 15 min after the end of the air admission stage, the gas removal and/or flushing stages are automatically repeated to prevent an accumulation of gas in the chamber.

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11.9 Typical process times, including degassing after the cycle is complete, can range from 12 to 24 hours depending on the sterilization temperature, gas concentration and the nature of the load.

11.10 Since the sterilization process is ultimately dependent on chemical action, a routine microbiological test is required for each production load to confirm that sterilization conditions have been attained (see paragraph 11.43).

Safety precautions

11.11 EO presents hazards not found in conventional sterilizers. The gas is toxic, flammable and explosive. Extensive guidance on safety precautions to be followed in handling EO can be found in Appendix 3. See also 'Ethylene oxide sterilization section' (HBN 13 Supplement 1) published by NHS Estates.

NOTE: Management Executive Letter MEL(1995)48 modifies HBN 13 Supplement 1 for use in Scotland.

Product compatibility

11.12 EO sterilizers can be used to process heat-sensitive materials which cannot withstand low-temperature steam. They should not be used to process products which can be sterilized by alternative methods; that is by high-temperature steam, dry heat or LTSF.

11.13 A survey by the Central Sterilising Club showed that many items processed in hospital EO sterilizers carry only an intermediate infection risk (see Table 2 in Chapter 2) and LTS disinfection would have been safer and more appropriate. Examples include face masks, ventilator tubing, airways, breast milk expressors, plastic vaginal speculae, amniotic membrane perforators and eye patches. None of these items requires EO sterilization and some may be designated by the manufacturer as single-use only.

NOTE: Sterilization and disinfection of heat-labile equipment, by Central Sterilising Club 1986.

11.14 It is common practice to use EO to resterilize items such as cardiac catheters that are intended by the manufacturer to be used only once. While this may be justified on economic grounds, attention is drawn in paragraphs 2.22-2.25 to the difficulties in validating cleaning procedures for such items and the possible legal implications of reusing them. Users also should bear in mind that some medical devices designed for single-use may have been originally sterilized by radiation. In certain circumstances these may be weakened by subsequent exposure to EO and should therefore not be resterilized.

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11.15 Low-pressure EO is suitable for items such as certain flexible endoscopes and electronic equipment which would be damaged by exposure to an LTSF process.

11.16 Certain types of EO sterilizer, notably those employing EO diluted with carbon dioxide, operate at pressures up to 6 bar. Users should ensure that load items would not be damaged by exposure to such pressures.

11.17 Care should be taken that materials submitted for sterilization do not undergo undesirable reactions with EO. If doubt exists about this, it is advisable to contact the supplier of the gas.

Items that should not be processed by ethylene oxide

11.18 The following items should not be processed by EO:

a. items that could be sterilized by another process;
b. items which may be damaged by the conditions of temperature, pressure and chemical environment prevailing during the cycle;
c. medicinal products;
d. ventilatory and respiratory equipment;
e. soiled items;
f. plastic items previously sterilized by radiation;
g. items which may absorb and retain unacceptable quantities of EO residuals.

Design of the load

11.19 Packaging materials and methods should be selected which are compatible with the EO sterilization process and which maintain sterility and the quality of the contained product. Packaging should be designed to allow removal of air and penetration of both steam and EO.

11.20 Because a wide variety of EO processes are in use, packaging suitable for one EO sterilizer may not be suitable for another. For example, package seals may be weakened and possibly fail in a cycle with relatively high humidity and several large and rapid changes in pressure, where seals of the same type would have been satisfactory for a cycle employing less extreme conditions.

11.21 The extent to which packaging absorbs or adsorbs EO and its permeability to EO may have a major influence on the efficacy of the cycle and the subsequent aeration process. Cartons (shelf packs, transit cartons) may be convenient but they may increase the humidification time, the gas exposure time and subsequent level of EO residuals.

11.22 Because of the need to control humidity, the extent to which packaging absorbs moisture may have a major influence on the efficacy of the process

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and must be considered before a satisfactory humidification stage can be demonstrated.

11.23 Process control is also a concern since packaging material that has become dehydrated may absorb excessive moisture during the conditioning phase; if this possibility were not recognised during validation the achieved cycle lethality may be adversely affected.

11.24 In practice, many of the packaging materials routinely used for steam sterilization in hospitals are equally suitable for EO. However, Users should be aware that because of the lower temperatures employed in the EO process a wider range of materials is available.

11.25 Paper bags or plastic/paper pouches are usually found to be the most convenient for small items. Polythene bags with gas exchange ports of Tyvek are also suitable.

11.26 Large procedure trays containing endoscopes or other heat-sensitive equipment may be wrapped in sheets of plain or crepe paper, or textiles. Moulded foam inserts may be used to provide mechanical protection.

11.27 Biological indicators should be placed in the load before preconditioning (see 11.43).

Performance qualification

11.28 PQ tests are required for loading conditions representing every production load. Decisions on which loading conditions require PQ tests should be made by the user in consultation with the Microbiologist and Test Person.

11.29 Because of the wide variety of items processed by EO, it is not always practicable to conduct PQ tests for every possible loading condition. Users are advised to categorise load items by the degree to which they can absorb and retain moisture and EO, and then ensure that loads are made up of items in the same category. For example, rubber absorbs EO readily, while electronic devices do not.

11.30 The amount of microbial contamination (the bioburden) after cleaning may need to be determined as part of the performance qualification process, though this is not normally required in hospitals where a wide range of items are to be sterilized and gas exposure times are calculated to be more than sufficient to deal with the maximum anticipated bioburden. Where such determinations are required they should comply with BS EN 1174.

Preconditioning

11.31 If EO sterilization is to be effective, it is essential that the humidity within any part of the load should not be less than 30% RH, and that there should be no free water within the chamber.

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11.32 To ensure that these extremes of humidity are not exceeded when sterilizing different types and sizes of load which have been stored in unknown ambient temperatures and humidity, it may be necessary to subject the load to a preconditioning treatment in a known environment. Preconditioning may be done within the sterilizer chamber before the start of the operating cycle, or in a purpose-built room or cabinet. Specifications for preconditioning rooms or cabinets can be found in Part 2 of this SHTM.

11.33 Preconditioning may not be necessary where workloads are small. In such cases the conditioning stage of the operating cycle may be satisfactory (see paragraph 11.8d). However, Users should note that the humidity instruments attached to the sterilizer may not be as reliable as those provided for a purpose-built preconditioning room or cabinet. For this reason, preconditioning is always recommended.

11.34 Within limits, the humidity within the chamber can be determined from the mass of steam injected, the pressure change within the chamber, the moisture absorbent characteristics of the load and the temperature and humidity of the load before it is placed in the sterilizer chamber. However, whenever preconditioning is to be done in the sterilizer chamber, the humidity should be by direct measurement (but see paragraph 11.46a) and within limits its value should be known for each cycle.

11.35 All packaged product within the preconditioning area should be identified. For each batch processed, the levels of the physical values achieved during preconditioning should be recorded. These should include the following.

a. the ambient temperature of the packaged product entering the preconditioning room;
b. the time when the packaged product enters the preconditioning room;
c. the time when the packaged product leaves the preconditioning room;
d. the temperature record for the period the packaged product is in the preconditioning room;
e. the humidity (RH) record for the period the packaged product is in the preconditioning room.

11.36 The temperature and humidity within the preconditioning area should be set to the same values that will prevail during the gas exposure time. The temperature within the load at the end of the preconditioning period should not deviate by more than ± 5°C from the nominal conditions within the area and the RH should not deviate by more than ± 15% RH from the nominal conditions in the area. The time taken to achieve these conditions during validation should be noted and used as the minimum specified for routine operations.

11.37 The preconditioning area should be subject to performance qualification. PQ should be performed with the preconditioning area in both fully loaded and typical partly loaded states and carried out with the loading patterns and pallet spacings specified in documented procedures.

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11.38 The reference position for monitoring temperature and RH during preconditioning should be that at which it is most difficult to achieve the desired conditions. Data for this routine monitoring should be reviewed before the load is released for sterilization.

11.39 The ambient temperature of items entering the preconditioning area should be at or above the minimum temperature specified during validation. It is not generally necessary to routinely determine the temperature of load items before preconditioning where the conditions of storage are known.

Selection of cycle variables

11.40 The EO concentration prevailing during the gas exposure stage will have been established during performance qualification. A concentration of at least 300 mg litre^{-1} is commonly used. Concentrations greater than 1200 mg litre^{-1} do not result in a substantial increase in the effectiveness of the sterilization process.

11.41 Apart from adjustment of flushing times, other cycle variables are preset and cannot be modified by the user.

Cycle monitoring and documentation

11.42 Each cycle should be noted in the sterilizer process log (see paragraph 3.11). The following information should be recorded for each load processed:

a. for preconditioning (if used), the temperature and humidity monitored and recorded from a position which can be related to that at which it is most difficult to achieve the specified conditions;

b. time of commencement and removal of load from preconditioning (if used) of each load;

c. time of commencement of the operating cycle;

d. chamber temperature and pressure during the operating cycle measured from a representative position within the chamber;

e. evidence that the gaseous sterilant has been admitted to the chamber;

f. a measure of the quantity of EO used or the concentration of EO in the chamber;

g. duration of the gas exposure time;

h. time, temperature, pressure changes (if any) and/or the operation of the air supply (if used) during aeration;

i. the results of the routine microbiological test.

11.43 A routine microbiological test should be carried out with every production load as described in Part 3 of this SHTM. Note that the full result of the test

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will not be known until the biological indicators have been cultured for 7 days.

11.44 A batch process record should be generated for each production cycle. The batch process record will contain the following:

a. the temperature ("chamber temperature") recorded by a sensor in the coolest part of the chamber;

b. the pressure ("chamber pressure") recorded by a sensor in the chamber.

Chamber humidity

11.45 A load which has been preconditioned may lose moisture during the air removal stage of the operating cycle and steam may be injected during the conditioning stage (before gas injection) to maintain the moisture content at the specified level.

11.46 The humidity within the chamber should be monitored in one of two ways:

a. by direct measurement of RH. Many RH sensors are poisoned by absorption of EO and provision should be made either to isolate the sensor from the chamber atmosphere before EO is admitted, or to remove the sensor for degassing after the sterilization cycle is complete. Note that the RH as perceived by a sensor at a low pressure may be different from that measured at a higher pressure;

b. by monitoring the rise in temperature and pressure as steam is admitted; care should be taken to ensure that the measured values truly relate to RH and are reproducible. Details of the calculation are given in Part 3 of this SHTM: Appendix 2.

EO concentration

11.47 The pressure rise at gas injection provides the primary, though indirect, measure of the EO concentration in the chamber. The measuring equipment should have sufficient sensitivity to allow recordings of small quantities of gas which may be admitted throughout both the gas injection and gas exposure stages. Details of the calculation are given in Part 3 of this SHTM: Appendix 2.

11.48 Since the EO concentration is critical to the efficacy of the cycle, a second, independent system is required to confirm that the pressure rise is due to EO. Either of the following may be used:

a. monitoring the change in mass of the gas supply cylinder or cartridge;

b. metering the volume of gas delivered to the chamber.

11.49 Where a sterilizer is supplied from a disposable cartridge, it can be assumed that the entire contents of the cartridge are released into the chamber. However, it should not be assumed that the mass of the contents corresponds precisely to the manufacturer's stated value. As a matter of

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routine, the cartridge should be weighed immediately before it is placed in the sterilizer and after it has been removed to establish the mass of gas consumed, and the results noted in the sterilizer process log.

Product release

11.50 The load may be released for degassing (see paragraph 11.52) provided that:

a. the preconditioning records are satisfactory;

b. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

c. the correct amount of EO has been injected into the chamber;

d. the chemical indicators used in the routine microbiological test show a uniform colour change;

e. the packaging is undamaged;

f. load items are visibly dry.

11.51 The load may subsequently be released as sterile provided that the microbial culture results of the routine microbiological test described in Part 3 of this SHTM are satisfactory and approved by the Microbiologist.

Degassing

11.52 Most, if not all, materials retain varying amounts of EO following sterilization. The residual EO in items for medical use should be reduced to a safe level, both for personnel handling the items and for the patient. Other compounds may also be present as reaction products of EO, such as ethylene chlorohydrin, and the concentration of these may also need to be reduced. Reference in this SHTM to reduction of residual EO should be read as applying equally to any other toxic reaction products which may be present.

11.53 Certain materials, such as polyvinyl chloride, silicone and rubber, are particularly absorbent and require longer degassing times. If not removed, residual EO will give rise to burning sensations and other irritant or toxic effects when the sterilized item is implanted or in contact with body tissue.

11.54 Permitted levels of EO residuals, and methods for their determination, are given in BS EN 30993: Part 7.

11.55 Reduction of residual EO occurs naturally as gas diffuses from the product into the surrounding air down the concentration gradient. Under normal ambient conditions this process may be very slow and significant amounts of EO may be present in the environment. For these reasons degassing by

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storage under ambient conditions is not recommended; mechanical degassing should be used.

11.56 The time required for degassing depends on a number of factors:

a. the composition, form and mass of the items in the load;

b. the concentration of residual EO when the load is removed from the sterilizer (this will in part depend on the EO concentration and gas exposure time, but more importantly on the extent and nature of the flushing stage in the sterilizer);

c. the temperature at which degassing takes place;

d. the concentration of residual EO which is acceptable for the intended use of the product.

11.57 The time required under the prevailing conditions should be determined for each type of product as part of performance qualification. Where this is impracticable, such as where a sterilizer is used for low numbers of a great variety of items, the degassing process should be determined for the item which has the longest degassing time. This is likely to be the largest and most complex item made from polyvinyl chloride.

11.58 A validated and monitored degassing procedure should be followed. Degassing can be performed within the sterilizer or in a separate chamber or area (see Part 2 of this SHTM). The temperature profile and air flow rate during degassing should be monitored and recorded.

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Troubleshooting

Failure of the routine microbiological test

11.59 Failure of the microbiological test shows that the prescribed sterilization conditions have not been attained. If the test itself appears to have been carried out correctly (the biological indicators should be checked to make sure the correct type has been used) and the batch process record is satisfactory, then the following possibilities should be considered.

a. The concentration of EO in the chamber was too low. There are several reasons why this might be.

   (i) Insufficient EO was admitted. This would normally lead to a fault indication and would be revealed by inspection of the chamber pressure record and the secondary method (mass or volume, see paragraph 11.48).

   (ii) Some of the EO was polymerised. Green streaks on the chamber walls near the inlet port suggest that liquid EO entered the chamber. The preheater should be checked.

   (iii) Some of the EO was absorbed into the load. This is improbable if performance qualification tests have been conducted and previous loads have been processed satisfactorily.

b. The humidity in the chamber was either too high or too low. Humidity is critical to the operation of EO sterilizers and even small deviations from the ideal level can have large effects on the efficacy of the cycle. Incorrect humidity is the single most common cause of failure. If the preconditioning records are satisfactory, suspicion should fall on the sterilizer humidifying system.

c. The loading condition is too great a challenge to the penetration of EO. This is unlikely if performance qualification has been satisfactory.

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12. Operation of laboratory sterilizers

Introduction

12.1 This chapter gives guidance on the routine operation of high-temperature steam sterilizers ("laboratory sterilizers") designed to process materials and equipment for use in clinical laboratories.

12.2 These sterilizers are not suitable for processing either medical devices or medicinal products and are therefore not subject to the EU Directives discussed in Chapter 1.

Sterilization conditions

12.3 European Standards for medical devices and medicinal products require that for a product to be labelled "sterile", no more than one micro-organism should survive in 10^6 load items (see BS EN 556). There is no universally accepted probability of survival for laboratory purposes. In laboratory practice for make-safe loads, the high initial concentration of micro-organisms is considered to be balanced by a higher acceptable probability of survival than in items intended to be used on patients. This has allowed the standard sterilization conditions adopted for medicinal products and medical devices (see paragraphs 2.43-2.55) to be used for laboratory make-safe loads.

12.4 The same standards are also used for sterilizing culture media, fabrics and equipment and glassware; for these loads (but not for make-safe loads) times and temperatures may be reduced if necessary to minimise deterioration of the product. Account should also be taken of the contributory effect of high temperatures during the heat-up and cooling stages on the degradation of culture media constituents.

12.5 Examples of recommended sterilization conditions are shown in Table 9.

12.6 The effect of the initial cell population (bioburden) on the number of survivors after heating reinforces the need to reduce numbers by cleaning equipment and glassware before sterilization. In microbiology laboratories it is possible, with good laboratory practice and by using dehydrated culture media from reputable manufacturers, to ensure that there are minimal numbers of contaminating micro-organisms in media prepared for sterilization. However, in discard boxes to be subjected to a make-safe process, the numbers of micro-organisms present are inevitably several orders of magnitude greater and no re-treatment is possible to reduce the concentration of what may be very heat-resistant spores.

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Safety precautions

12.7 Users should ensure that operational procedures are in accord with the safety guidelines set out in the HSC document ‘Safe working and the prevention of infection in clinical laboratories’ and the accompanying ‘Model rules for staff and visitors’.

Table 9: Recommended sterilization conditions for laboratory sterilizers

Name of operating cycle	Sterilization temperature [°C]	Maximum temperature [°C]	Minimum holding time [min]
Make-safe of small plastic discard (a)	134 126 121	138 130 125	3 10 15
Make safe of contained fluid discard (a)	134 126 121	138 130 125	3 10 15
Sterilization of culture media (pre-set cycle)	121 115	124 118	15 30
Sterilization of culture media (variable cycle)	102-134 121 (b)	 124	Up to 60 15
Disinfection of fabrics	134 126 121	138 129 124	3 10 15
Sterilization of glassware and equipment	134 126 121	138 129 124	3 10 15
Free steaming (variable cycle)	102-104 95 (b)	 98	Up to 60 15
Culture media preparator	121 115	124 118	30 15

a. All bands for make-safe are 4 degrees wide to conform with BS 2646: Part 3.

b. Although the cycle is variable, this temperature band should be used for testing purposes.

12.8 The COSHH Regulations 1999 introduce new controls on biological agents which are of relevance to users of laboratory sterilizers.

Hazards

12.9 Due to the wide variety of loads processed in laboratory sterilizers, the range of potential hazards is wider than for a typical clinical sterilizer (see paragraph 2.10). Additional hazards may include:

a. spillage of biohazardous material;

b. spillage of hot material;

c. spillage of corrosive substances;

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d. vapour from volatile chemicals.

12.10 Access to the loading area should be limited to personnel aware of the hazards from potentially infective material. The loading position should not be obstructed.

12.11 All materials awaiting sterilization should be placed so they cannot be overturned, spilled or damaged.

12.12 Loading and unloading procedures should be designed to avoid health hazards and also injuries to personnel by the elimination of awkward lifting positions and excessively heavy load containers (see paragraph 2.8). Heavy loads should not be lifted into or out of vertically mounted chambers by personnel of unsuitable build or strength. Consideration should be given to the provision of mechanical assistance.

Operating procedures

12.13 A written standard operating procedure based on the manufacturer's instructions and local conditions of use should be adopted and should include the following:

a. a statement specifying the safe operating limits of the sterilizer including the maximum pressures and temperatures for safe operation;

b. a statement that operators should be instructed to note and report any defects or unusual or out-of-range conditions to their supervisor;

c. training requirements for the operators of the sterilizer and a statement that those unfamiliar with the equipment are forbidden to operate it unless supervised, or until they are considered competent in its use;

d. maintenance requirements: the scope of user maintenance should be defined and restricted to cleaning, functional checks and any user safety checks recommended in the instruction manual.

12.14 Operating instructions should always be readily accessible and users should ensure that they are followed.

12.15 Certain laboratory sterilizers are provided with a switch to override the thermal door-lock during the cooling stage of the cycle (see Part 2 of this SHTM). The switch is protected by a key, code or tool which is not available to the operator. The responsibility for the operation of the thermal door-lock override should be assigned to the user or other senior member of the laboratory staff. The override should only be used if all the implications of such action are documented and understood.

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Operating cycles

12.16 Operating cycles recommended in this SHTM are as follows:

a. make-safe of small plastic discard;
b. make-safe of contained fluid discard;
c. sterilization of culture media (preset or variable cycle);
d. disinfection of fabrics;
e. sterilization of glassware and equipment;
f. free steaming.

12.17 The specialised sterilizer known as a culture media preparator is also discussed.

12.18 Sterilizer loads should be carefully segregated to ensure that the appropriate cycle is selected for each type of load. Particular care should be taken to ensure that culture media, discard, glass containers with caps fitted, and contained fluid are processed in sterilizers fitted with a thermal door-lock, demonstrated to be effective on these cycles (see Part 2 of this SHTM).

12.19 Materials processed in laboratory sterilizers can be either “clean” or “dirty”. Clean work is material which will be used within the laboratory, such as culture media, tubing and filters. Dirty work is discard material which is to be made safe. In larger laboratories, separate sterilizers are often designated for clean and dirty work.

12.20 The discovery of non-sporing infective agents with an increased resistance to chemical and heat treatment (“slow viruses”, “prions”, “TSE agents”) has led to the need for increased temperatures and holding times for treatment of material from a suspected case of infection by these agents. None of the standard cycles described here is effective in inactivating such agents. Advice can be found in Appendix 2.

Make-safe of small plastic discard

12.21 This cycle corresponds to the “make-safe” cycle specified in BS 2646. It is designed to sterilize infected material held in plastic containers not exceeding 50 ml in volume. Examples of such containers include Petri dishes, specimen bottles and other small plastic items intended for disposal.

12.22 Although the containers would normally be unsealed, the limits on volume ensure that any fluid held in a sealed container does not present an explosion hazard when the door is opened at the end of the cycle. Glass containers and larger plastic containers should be processed with the make-safe cycle for contained fluid discard (see paragraph 12.30). Items of unknown content should likewise be treated as contained fluid discard.

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12.23 Items made from polystyrene, such as plastic Petri dishes, start to soften at around 70°C. Any air remaining in the chamber at that point may become trapped as bubbles within the melting plastic and prevent complete sterilization. The hardened plastic mass removed at the end of the cycle may then contain pockets of viable micro-organisms that may cause a health hazard if the plastic is subsequently broken. Users should therefore ensure that the air-removal stage of the cycle is substantially complete before the load temperature attains 70°C. That is why plastic Petri dishes are specified for the small-load and full-load thermometric tests described in Part 3 of this SHTM.

12.24 Items for making-safe should be placed in a discard box as specified in Part 2 of this SHTM. It is important that the box is of the type used for performance qualification, otherwise the specified sterilization conditions may not be achieved.

12.25 Discard should be stored in the box at the work station for later sterilization. Once in the box, items should not be handled until after they have been made safe. They should not be transferred from one box to another. The box and contents should be sterilized together.

12.26 Discard should be enclosed when the box is moved. Loose-fitting lids are satisfactory for transport within a laboratory. Alternatively, the discard material may be placed in a discard bag (see paragraph 12.27) inside an open box, providing the neck of the bag is closed before the box is moved. Whenever discard material is transported outside the laboratory suite a sealed and locked lid should be fitted. The lid should be opened or removed before the cycle begins and sterilized along with the box.

12.27 Discard bags, if used, should always be contained in a discard box and opened widely before sterilization to permit the removal of air and the penetration of steam. The open mouth of the bag should not be folded back over the rim of the box, since this would impede the removal of air from the space between the bag and the box. Bags with identification markings for discard material are available which are designed to melt at 134°C to assist air removal.

12.28 Discard boxes awaiting sterilization should not be stored in the loading area.

12.29 Load temperature probes should not be inserted into discard loads. Any probes provided in the chamber should be stowed in a safe, fixed position, usually on a bracket provided for this purpose.

Make-safe of contained fluid discard

12.30 This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646. It is designed to make-safe infected material in sealed glass containers of any size or sealed plastic containers of volume greater than 50 ml.

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12.31 While essentially the same as the culture media cycle (paragraph 12.35), higher sterilization temperatures are preferable. Lower sterilization temperatures should only be used if plastic containers are to be processed.

12.32 Fluid containers should be placed in discard boxes to prevent contamination of the chamber if a bottle breaks during the cycle (see paragraph 6.7 about pressure inside bottles).

12.33 A risk assessment should be made before corrosive chemicals or materials and chemicals (including disinfectants) likely to produce harmful vapour are processed. Such materials should be enclosed in a sealed, unbreakable container, preferably of metal.

12.34 Load temperature probes should not be inserted into discard loads. Any probes provided in the chamber should be stowed in a safe, fixed position, usually on a bracket provided for this purpose.

Sterilization of culture media (preset or variable cycle)

12.35 This cycle is a variant of the “liquids sterilization” cycle specified in BS 2646. It is designed to sterilize culture media in open or sealed containers.

12.36 Since culture media are normally damaged by sterilization at 134°C the maximum sterilization temperature is set at 121°C.

12.37 A variable cycle, in which combinations of sterilization temperature and holding time can be set by the operator, is necessary for some heat-labile products. It is normally provided in addition to the preset culture media cycle.

12.38 The culture media cycle is also suitable for disinfecting unwrapped equipment, such as tubing sets, where a glassware and equipment cycle is not available (see paragraph 12.48).

12.39 Culture media are particularly sensitive to heat, the degree of deterioration being related to the time the medium is maintained above the sterilization temperature. The heating and cooling stages also contribute significantly to this deterioration, so heating and cooling times should be as short as possible. Large volumes of fluids will heat up and cool down slowly, therefore volumes of fluid should be kept small; a maximum container volume of 500 ml is recommended.

12.40 Agar-based media take longer to heat up than water-based media; this differential is greater the larger the volume. When media are to be sterilized in volumes of over 100 ml, agar-based and water-based products should be processed separately.

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12.41 Loads should be designed to process containers of similar size. For example:

a. up to 100 ml;

b. 101 ml to 1000 ml;

c. 1001 ml to 3 litre.

12.42 Containers should be loosely capped unless they are specifically designed to be sealed. However, sealing bottles can increase the likelihood of an explosion during sterilization (see paragraph 6.6 about pressure inside bottles) and extends the cooling time.

12.43 A fault may result in contaminated or over-heated culture media. After a fault, a careful assessment should be made before the batch is reprocessed or discarded.

Disinfection of fabrics

12.44 This cycle is a variant of the “glassware and equipment” cycle specified in BS 2646. It is designed to disinfect (but not sterilize) fabric materials such as towels, clothing, wrapped animal bedding, and other porous materials.

12.45 If the fabrics are required to be sterile and dry at the end of the cycle, a machine complying with the performance requirements for a clinical porous load sterilizer should be specified. This will require validation and periodic testing in accordance with the schedule for porous load sterilizers in Part 3 of this SHTM.

12.46 The cycle differs from the glassware and equipment cycle (see paragraph 12.48) in that more pressure pulses will be required to remove air from the load.

12.47 The fabrics cycle is also suitable for sterilizing empty glassware without caps and for disinfecting wrapped tubing and wrapped filters (but see paragraph 12.49).

Sterilization of glassware and equipment

12.48 This cycle corresponds to the “glassware and equipment” cycle specified in BS 2646. It is designed to sterilize clean, empty glassware (without caps) and equipment such as tubing and filters. Loads must not contain any fluids.

12.49 Some microbiological filter membranes may be damaged by the rapid fluctuations in pressure used by an active air removal system, and it may be necessary to provide a separate filter cycle.

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Free steaming

12.50 This cycle is not specified in BS 2646. It is designed to melt solidified agar by exposing it to steam near atmospheric pressure. It is normally a variable cycle. If the workload is heavy, this will not be a cost-effective way of using a sterilizer and a Köch steamer may be more suitable.

Culture media preparator

12.51 Many of the problems which relate to sterilizing culture media can be solved by the use of small sterilizers in which the media constituents are placed directly into the chamber thus avoiding the use of glass containers and their attendant hazards. Since these small machines have a unique function, their design is specialised in comparison with other laboratory sterilizers and BS 2646 is not applicable (see Part 2 of this SHTM).

12.52 The manufacturer's recommendations on operation should be followed.

Performance qualification

12.53 Some loads processed in clinical laboratories may not be represented by the reference loads used in the commissioning tests described in Part 3 of this SHTM. In these cases, thermometric PQ tests should be undertaken to establish master process records for these loads.

Product release

12.54 The load may be released for use provided that:

a. during the whole of the cycle the values of the cycle variables as shown on the batch process record are within the permitted tolerances marked on the master process record established during performance qualification;

b. not more than one container (or 1%, whichever is the greater) has burst or broken.

12.55 The load should be examined for damaged containers. The occasional broken bottle or bag may be acceptable provided intact containers have not also been damaged.

12.56 Discard for disposal outside the laboratory must be safe to handle.

12.57 Other materials processed in the sterilizer will be used in the laboratory. "Fit for use" should be defined by the user.

12.58 Blooming of plastic containers is a surface effect that does not harm the container or the contents. The user should decide whether blooming is acceptable.

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Troubleshooting

Faults on make-safe cycles

12.59 A written procedure based on a risk assessment should be established for dealing with a fault on a make-safe cycle, taking into account the nature of the load. The usual practice is to decontaminate the sterilizer by flushing the chamber with steam. Where this is not possible, the user should proceed on the advice of the Laboratory Safety Officer. The guidelines given in HSG(93)26, 'Decontamination of equipment prior to inspection, service or repair', should be followed.

12.60 When considering the appropriate course of action, users should note the following:

a. the Laboratory Safety Officer should be notified before any attempt is made to open the sterilizer;

b. chamber condensate should be considered to be contaminated with viable micro-organisms;

c. disinfection of the chamber and/or pipework should not involve prolonged contact with disinfectants corrosive to metal;

d. a contaminated sterilizer should never be removed from the laboratory for repair.

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13. Reporting of incidents

Introduction

13.1 The general framework for the reporting of adverse incidents and defective equipment in the NHS in Scotland are set out in MEL(1995)74.

13.2 Management should designate, for each sterilizer, a responsible person to act as liaison officer for the reporting of incidents. For the purposes of this SHTM, the user is assumed to fill this role.

13.3 The user should be familiar with the reporting procedures and with statutory reporting requirements. Training may be required.

13.4 Operators and others concerned with the operation of sterilizers should know what action to take in the event of an incident or failure.

13.5 The user should ensure that a sufficient supply of the correct reporting forms is available at all times.

13.6 The Authorised Person should advise, for each type of sterilizer, which types of defects are to be considered as serious. The list should include all defects which may result in failure to sterilize or danger to personnel or damage to the product.

13.7 If a serious defect occurs, the sterilizer should be withdrawn from service and should not be used until any necessary repairs have been made and a repeat validation has been carried out (see Part 3 of this SHTM). If the defect involves a pressure vessel, an inspection by the Competent Person (Pressure Systems) is required.

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Department of Health reporting procedures Annex A

General guidance

Purpose of the reporting system

1 An adverse incident is an event which adversely affects, or has the potential to effect, the health and safety of patients, users or other persons. Local incidents may often have implications for other healthcare services. IT IS ESENTIAL, THEREFORE, THAT ALL ADVERSE INCIDENTS AND DEFECTIVE EQUIPMENT ARE REPORTED PROMPTLY. Serious deficiencies in the technical performance of equipment should also be reported, as should any observation which gives cause for concern regarding safety, even when an actual incident has not occurred. The central collation of adverse incident reports is essential for the identification of trends which may result in the issue of warnings to users of potentially hazardous equipment or unsafe procedures. The term “equipment” is taken to include any items, device, supplies, service, product, system, or plant as detailed in Annexes B and C.

Health and Safety Executive

2 Under their statutory powers, the Health and Safety Executive (HSE) or Local Authority Inspectors may:

- identify inadequacies in a product’s design;
- issue instructions for use, or manner of use;
- make observations and recommendations.

If any action by the HSE or Local Authority on NHS premises might have implications for other users and/or patients, staff, visitors or contractors, it should be reported to ***Scottish Healthcare Supplies (SHS)***.

Reporting

3 Reports should be submitted in accordance with:

Annex B: reports relating to all *medical equipment*: including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products;

Annex C: Reports relating to *estates equipment*: engineering plant, installed services including piped medical gas and medical scavenging systems, buildings and building fabrics, vehicles.

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All adverse incidents etc. relating to products in Annexes B and C should be reported to Scottish Healthcare Supplies in full at the following address:

Incident Reporting and Investigation Centre (IRIC)
Scottish Healthcare supplies
Trinity Park House
South Trinity Road
EDINBURGH
EH5 3SH

Daytime help and report line: 0131 551 8333
Emergency: 0131 552 6380
Fax: 0131 552 6535

Procedures to be followed and information to be supplied

4 The initial report of an incident should contain as much essential detail as available. However, it should never be delayed on this account and serious cases should be reported by the fastest means possible. **All oral reports should be supported in writing**, preferably using the standard Adverse Incident Report Form (Annex D). Copies of this form are available form Scottish Healthcare Supplies (SHS).

5 All material evidence should be labelled and kept secure, under the charge of a responsible officer. This includes the equipment and, where appropriate, packaging or other means of batch identification. The equipment should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eye witness reports. In serious cases, this record should be witnessed, and the witness should also make a personal written record.

6 Defective items should not be allowed to be repaired or returned to the supplier or discarded before an investigation has been carried out. In addition, items should not be cleaned (but see paras. 11-12 below). The manufacturer or supplier of a defective product should be informed promptly, and may be allowed to inspect the product if accompanied by an officer from the Health Board, NHS Trust or other NHS body, or SHS, with knowledge of the product so as to prevent tampering or false claims. The HSE may also wish to inspect the equipment. In the case of a large batch of consumable items may be possible to pass samples to the manufacturer if this will aid the investigation. However, the manufacturer must not be allowed to exchange, interfere with or remove any part of the product if this would prejudice the investigations of SHS or other official bodies.

7 Where clinical need requires equipment to be kept in use, and the defective part(s) are clearly identifiable and removable, they may be removed, secured and labelled for later inspection, and the equipment repaired for re-use.

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8 Where a manufacturer wishes to investigate a defective, or possible defective, CE marked medical device, this should be reported to SHS who will seek guidance from the medical Devices Agency (the UK Competent Authority). It should be noted that from June 1998 *all* medical devices must be CE marked before they can be placed on the market, in accordance with the medical Device Regulations. Active implantable medical devices however, *must* be CE marked as from 1 January 1995.

9 As far as “estates and associated equipment” incidents are concerned as set out in Annex C, the SHS will oversee any necessary investigations (using private contractors as necessary) and liase with the NHS in Scotland Property and Environment Forum.

Notification system

10 Where the results of investigations have implications for other users a Hazard Notice, Safety Action Notice or other safety warning may be issued. A sample *Hazard Notice* is given in Annex F and a sample *Safety Action Notice* is given in Annex G. General Managers and Chief Executives are responsible for ensuring adequate distribution systems for these publications are in place.

Handling of contaminated products

11 Requirements for the forwarding of contaminated products for investigation are detailed in:

- SHHD letter DGM (1987) 66 dated 6 November 1987 (updated guidance to be issued soon).
- Safety Action Bulletin No 63 SAB (90) 61 issued September 1990.
- Hazard Notification HAZ 1991/007 issued 11 March 1991.

All products, devices and sample which have been or could have been in contact with blood, other bodily fluids of pathological samples must be accompanied by a Contamination Status Certificate when being passed to SHES or the supplier/manufacturer for examination. The Contamination Status Certificate should be presented external to the packaging which contains the potentially contaminated item in order that the certificate may be examined before opening the packaging. The requirement also applies to unused disposable items except where packaging seals are unbroken. A sample of a suitable Contamination Status Certificate is reproduced as Annex E and may be copied or adapted for local use.

12 Advice should be sought from the SHS Incident Reporting and Investigation Centre prior to the sending or transporting of contaminated products for examination by SHS or the supplier/manufacturer. Where possible, products should be decontaminated before being handled. This should be carried out using a method recommended by the manufacturer to avoid destroying vital evidence. It is illegal to send contaminated products through the post.

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Other action/responsibilities

13 This reporting system does not replace the duty of local staff to take other action as required legally, by local procedures or in line with other national requirements eg:

- Preventing further use of equipment which may be defective;
- Reporting to particular local NHS officers (eg. Radiation Protection Advisers);
- Reporting notifiable incidents to the Health and Safety Executive under the Reporting of Injuries, Disease and Dangerous Occurrences Regulations 1995, and the Ionising Radiations Regulations 1999;
- Reporting to the Procurator Fiscal in the case of a fatal accident;
- Informing the manufacturer of a serious adverse incident involving CE marked equipment to assist him in fulfilling his obligations under certain EC directives adopted as UK regulations.

Food

14 Problems with food, other than special dietary products, should be reported to:

- Scottish Executive Health Department
- Scottish Executive Rural Affairs Department
- Scottish Healthcare Supplies, Contracts Branch for Food which is on central contract to the NHS.

Drugs

15 Guidance on reporting problems involving medicinal products (drugs alerts) is contained in NHS Circular 1991 (GEN) 25 issued September 1991 and Circular 1993 (GEN) 16 issued on 14 December 1993.

Notes

16 Official notifications to the HSE which are copied to SHS under the terms of this circular should be clearly stated as such. Notification to SHS does not count as, or substitute for any other report.

17 If a patient dies unexpectedly, the clinician in charge of the case should report the death immediately to the Procurator Fiscal. Pending instructions from the Procurator Fiscal or his officer, any implicated product must not be interfered with in any way unless this is necessary for safety or to prevent the loss of samples or material evidence. Although the manufacturer of suspect equipment should be informed immediately, neither he nor his agent should be allowed to inspect the equipment or remove any part of it without the Procurator Fiscal's prior agreement. SHS may be required to impound implicated equipment on behalf of the Procurator Fiscal.

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18 As a result of regulations implementing EC directives, manufacturers of CE marked devices will be required by law to report to the UK Competent Authority (Medical Devices Agency) any serious incident (ie. death or injury) involving their products. The first directive applies to Active Implantable Medical Devices (for example, implantable cardiac pacemakers), and the UK regulations came into force on 1 January 1993. The second directive covers a much wider range of Medical Devices and the UK regulations came into force for a transitional period commencing on 1 January 1995 and became mandatory in June 1998. The EC directive on In Vitro Diagnostic Devices 98/79/EC is implemented by the In Vitro Diagnostic Medical Devices Regulations 2000 (SI 1315).

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Annex B

Reports relating to all medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products

Reportable cases

1 Adverse incidents involving medical equipment may arise due to short comings in the equipment itself, user practice, service, maintenance, modification or adjustments, management procedures, instructions for use or environmental conditions.

2 A report should be sent if equipment is involved in one of the following:

- death;
- injury;
- deterioration in health;
- unreliable test results leading to inappropriate treatment or medication;
- where there is a potential for any of the above to occur.

NOTE: Single incident, when added to other information or reports, might indicate a national or international problem.

Product categories

- **Imaging and Radiotherapy Equipment**: X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluoroscopy, film processors.
- **Electromedical Equipment**: infusion pumps, fluid warmer, automatic, tourniquets, physiological monitoring and measurements, and equipment used in: dialysis, cardiology, physiotherapy, opthamology, audiology, speech therapy, electrotherapy, endoscopy , obstetrics.
- **Life Support Equipment**: anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and oxygen equipment, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.
- **Operating Department Equipment**: microscopes, operating tables, trolleys, patient transfer apparatus, heating and cooling pads, blood warmers, nerve stimulators.
- **Powered Surgical Equipment**: Diathermy, drills, saws, lasers.

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- **General Ward Equipment**: mobile examination lamps, powered and non-powered beds, ripple mattresses, pressure garments, thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists and lifting apparatus.
- **Dental and Chiropody Equipment**: instruments, chairs, curing lights, drills, water/air/suction.
- **Laboratory Equipment**: analysers, centrifuges, media preparators, safety cabinets, warming cabinets, incubators, refrigerators, test equipment.
- **Cleaning and Sterilisation Equipment**: autoclaves, sterilisers (steam, gas, chemical, dry heat), stills, disinfectors, instrument and equipment washers.
- **Aids for the Disabled**: wheelchairs, walking aids.
- **Implants**: heart valves, pacemakers, defibrillators, infusion pumps, orthopaedic prostheses.
- **Post Mortem Equipment**.
- **Single Use Devices**: syringes, needles, administration sets, catheters, dressings, sutures, etc.
- **Orthotic and Prosthetic Appliances**.
- **Certain Dietary Products**: enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.
- **Electrical Interference Problems**: involving any of the above.
- **Aspects of Control of Substances Hazardous to Health (COSHH)**: involving any of the above.

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Annex C

Reports relating to estates systems and equipment: engineering and plant, installed services including piped medical gas and medical gas scavenging systems, buildings and building fabrics, vehicles

Reportable cases

1 Adverse incidents in estates equipment may arise due to shortcomings in the equipment itself, user practice, service, maintenance, modifications or adjustments, management procedures, instructions for use or environmental conditions.

2 A report should be sent if equipment is involved in one of the following:

- death;
- injury;
- deterioration in health;
- damage;
- where there is a potential for any of the above to occur.

NOTE: Single incident, when added to other information or reports, might indicate a national or international problem.

Product categories

- **Buildings and Grounds**: components, services and plant used in maintenance and construction.
- **Engineering Plant and Services of all Types**: lifts, water systems, boilers and steam systems, electrical generators, heating, ventilation, air-conditioning, water, drainage, electrical systems including high voltage installations and any other fixed plant (but not fixed medical equipment).
- **Fire Protection Installations and Equipment**.
- **Transport**: vehicles and equipment.
- **Equipment**: in laundries, catering departments, work shops and any plant or equipment used for maintenance or cleaning.
- **Piped Medical Gas and Vacuum Installations**: oxygen, medical air etc, vacuum insulated evaporators and anaesthetic scavenging systems.
- **Fixed Luminaries**: including operating and examination lamps.

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- **Communications Equipment**: telephones (including radio telephones), nurse call, paging, alarms, building management systems, radio and television, IT structures cabling/data, VHF/UHF communication equipment.
- **Lighting Protection and Anti-Static Precautions**.
- **Incinerators and Waste Disposal Systems**.
- **Fuel Supply and Storage Systems**.
- **Fume Cupboards and Microbiological Safety Cabinets**: (installation aspects only), ductwork and interaction with ventilation systems.
- **Electrical Interference Problems**: involving any of the above.
- **Legionella Protection Equipment and Systems**.
- **Building Environmental Aspects of Control of Substances Hazardous to Health (COSHH)**: involving any of the above.

Urgent reports

are required in the respect of:

- An explosion or sudden fracture of a pressure vessel, pressurised system or steam/high pressure hot water main.
- A major electrical explosion eg. of power transformers or high voltage switchgear.
- A runaway and crash of a passenger lift.
- Piped medical gas system malfunction.
- Fire alarm system failure.

Annex D
Standard Adverse Incident Report Form

Annex E
Sample Contamination Certificate

Annex F
Sample Hazard Notice

Annex G
Sample Safety Action Notice

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SCOTTISH HEALTHCARE SUPPLIES **Annex D**

By arrangement with the NHSScotland, Property and Environment Forum

ADVERSE INCIDENT REPORT FORM – ADV/REP/1

1. TO: Incident Reporting & Investigation Centre (IRIC)

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
EDINBURGH EH5 3SH

Daytime help & report line: *0131 551 8333*
Emergency: *0131 552 6380*
Fax: *0131 552 6535*

2. FROM:

Hospital/Health unit/NHS Trust:……..
Name:…… Fax:……
Title:…….. Tel No.:……..
Dept:…… Extension:……

3. EQUIPMENT / DEVICE

Description:……
Model:…… Serial/Lot No:……..
Manufacturer:…….. Date of Manufacture:……..
Supplier:…….. marked:……YES/NO*……..
Supplier's Address:……
…… Telephone No:…..……

4. ADVERSE INCIDENT, PROBLEM OR CONCERN (continue on separate sheet if necessary)

Hospital/Unit:……... Injury: None/Patient/Staff/Other*……..
Dept/Ward:……... Injury details and treatment required……..
Observed by:…….. ……
Date(s):…… ……..
Nature of problem:……
……..
Possible Cause:……
……..
Consequence:……
……

5. ACTION TAKEN

Device/Lot Quarantined:…….YES/NO*……Location:……
Additional

6. CONTAMINATED EQUIPMENT/DEVICES

Defective equipment / devices should not be modified or accessories removed before inspection has taken place. All devices with possible contact with blood or other body fluids, or pathological samples, and all disposable devices, whether used or unused, should be accompanied by a Contamination Status Certificate.

CONTAMINATED DEVICES SHOULD NOT BE SENT BY MAIL.

7. DECLARATION

Accompanying this form:
*Detailed report
*Used / unused device (s)
*Contamination Status Certificate

Signature: Date:

…….. ……

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Annex D

ADVERSE INCIDENT REPORTING

PRODUCT CATEGORIES

Reports relating to all medical equipment including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products.

- Imaging and Radiotherapy equipment; *X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluroscopy, film processors.*
- Electromedical equipment; *infusion pumps, fluid warmers, automatic tourniquets, physiological monitoring and measurement, dialysis, cardiology, physiotherapy, ophthalmology, audiology, speech and language therapy, electrotherapy, endoscopy, obstetrics.*
- Life support equipment; *anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and oxygen equipment, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.*
- Operating Department equipment; *microscopes, operating tables, trolleys, patient transfer apparatus, heating and cooling pads, blood warmers, nerve stimulators.*
- Powered surgical equipment; *diathermy, drills, saws, lasers.*
- General ward equipment; *mobile extension lamps, powered and non-powered beds, ripple mattresses, pressure garments, thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists/lifting apparatus.*
- Dental and Chiropody equipment; *instruments, chairs, curing lights, drills, water/air suction.*
- Laboratory equipment; *analysers, centrifuges, media preparators, safety cabinets, incubators, warming cabinet, refrigerators, test equipment.*
- Cleaning and sterilisation equipment; *autoclaves, sterilisers (steam, gas, chemical, dry heat) stills, disinfectors, instrument and equipment washers.*
- Aids for the disabled; *wheelchairs, walking aids.*
- Implants; *pacemakers, defibrillators, infusion pumps, orthopaedic prostheses, heart valves.*
- Post Mortem equipment;
- Single Use Devices; *syringes, needles, administration sets, catheters, dressings, sutures, etc.*

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- Orthotic and Prosthetic Appliances;
- Certain Dietary products; *enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.*
- Electrical interference problems; *involving any of the above.*
- Aspects of Control of Substances Hazardous to Health (COSHH)*; involving any of the above.*

Reports relating to estates systems and equipment:- engineering systems and plant, installed services including piped medical gas and medical gas scavenging systems, building and building fabrics, vehicles

- Buildings and Grounds; *components, services and plant used in maintenance and construction.*
- Engineering Plant and Services of all types; *lifts, water systems, boilers and steam systems, electrical generators, heating, ventilation, air conditioning, water drainage, electrical systems including high voltage installations and any other fixed plant (but not fixed medical equipment).*
- Fire Protection installations and equipment;
- Transport; *vehicles and equipment.*
- Equipment; *in laundries, catering departments, work shops and any plant or equipment used for maintenance or cleaning.*
- Piped medical Gas and Vacuum installations; *oxygen, medical air etc., vacuum insulated evaporators, anaesthetic gas scavenging systems.*
- Fixed Luminaires; *including operating and examination lamps.*
- Communication equipment*; telephones,(including radio telephones) nurse call, paging, alarms, building management systems, radio and television, IT structured cabling/data, VHF/UHF communication equipment.*
- Lightning Protection and Anti-static precautions;
- Incinerators and waste disposal systems;
- Fuel Supply and Storage systems;
- Fume Cupboards and Microbiological Safety Cabinets (installation aspects only) ; *ductwork and interaction with ventilation systems;*
- Legionella Protection Equipment and Systems;
- Electrical interference problems; Involving any of the above.

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- Substances Hazardous to Health (COSHH); Involving any of the above.

13.12 The user is recommended to display a notice on or near each sterilizer setting out the appropriate reporting procedure.

Statutory reporting procedure

13.13 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 place responsibilities on employers to report certain incidents and dangerous occurrences to the local office of the Health and Safety Executive (HSE). The action to be taken following any incident with a sterilizer will need to be detailed in hospital procedures to ensure compliance with this legal requirement.

13.14 The user must notify HSE immediately, normally by telephone, if any of the following should occur:

a. any fatal injuries to employees or other people in an accident connected with the operation of the sterilizer;

b. any major injuries to employees or other people in an accident connected with the operation of the sterilizer;

c. any of the dangerous occurrences listed in the Regulations.

13.15 The user must send a written report to HSE within seven days of any incident including:

a. any of the notifiable incidents listed above;

b. any other injury to an employee which results in their absence from work or being unable to do their normal work for more than three days;

c. any of the cases of ill health listed in the Regulations.

13.16 A record must be kept of any injury, occurrence or case of disease requiring a report. This should include the date, time and place, personal details of those involved and a brief description of the nature of the event.

13.17 Examples of dangerous occurrences applicable to sterilizers include:

a. the explosion, collapse or bursting of any closed vessel;

b. electrical short circuit or overload causing fire or explosion;

c. any explosion or fire resulting in the suspension of normal work for more than 24 hours;

d. an uncontrolled or accidental release or escape of any pathogens or substance from any apparatus or equipment;

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e. any incident where breathing apparatus malfunctions in such a way as to deprive the wearer of oxygen.

13.18 Examples of reportable diseases applicable to sterilizers include:

a. poisoning by ethylene oxide;

b. any illness caused by a pathogen.

13.19 Full details may be found in the guidance which accompanies the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995.

13.20 Incidents and dangerous occurrences which are reported to HSE should also be reported either to the Scottish Healthcare Supplies, as appropriate, by telephone during the first working day after the incident and then followed by a written report.

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Glossary

The following list of definitions has been adopted in SHTM 2010 and used in Part 2. Certain pressure terms have been modified to comply with the requirements of BS EN 764. Paragraph references indicate where further information may be found in Part 2. Cross references to other terms are shown in bold type. References in parentheses at the end of definitions are to this part of SHTM 2010.

absolute pressure	pressure for which the zero value is associated with absolute vacuum.
aeration	a part of the **sterilization process** during which **sterilant gas** and/or its reaction products desorb from the **load** until predetermined levels are reached. See **degassing** and **flushing**.
air detector	a device used to determine that sufficient air or other **non-condensable gases** have been removed from the **chamber**.
allowable pressure	of a pressure vessel, a limit to the **operating pressure** specified for safety reasons. See **design pressure**.
automatic controller	a device that, in response to predetermined **cycle variables**, operates the **sterilizer** sequentially through the required stages of the **operating cycle**.
batch process record (BPR)	a permanent record of one or more **cycle variables recorded** during a complete **operating cycle** by instruments fitted permanently to the **sterilizer**.
Biological indicator	a device, consisting of an inoculated carrier contained within a primary pack, designed to test the efficacy of an **operating cycle**.
Bowie-Dick test	a test, used mainly with porous load sterilizers, to show whether or not steam penetration into a **standard test pack** is even and rapid.
cartridge	in **EO sterilizers**, a portable, single-use, simple vessel containing **sterilant** gas under pressure from which the gas is delivered by puncturing the cartridge.

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chamber	the part of the **sterilizer** in which the **load** is placed.
chamber exhaust ventilation (CEV)	a ventilation system designed to extract gas from the **chamber** of an **EO sterilizer** supplied from a **cartridge**.
chamber furniture	shelves, pallets, loading trolleys and other fixed or movable parts that support the **load** within the **chamber**.
chamber temperature	the lowest temperature prevailing in the **chamber**.
chemical indicator	a device designed to show, usually by change of colour, whether specified values of one or more **cycle variables** have been attained.
clinical sterilizer	a **sterilizer** designed to process **medical devices** or **medicinal products** to be used in the clinical care of patients.
commissioning	the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with the equipment specifications and that it functions within predetermined limits when operated in accordance with the operational instructions.
conditioning	in **EO sterilizers**, the treatment of a **load** within the **operating cycle**, but prior to **sterilization**, to attain a predetermined temperature and humidity throughout the load.
contained fluid discard	discard material held in sealed glass containers or sealed plastic containers of volume greater than 50 ml (see **small plastic discard**).
cooling stage	the period of the **operating cycle**, after the **holding time** has been completed, during which the **load** remains in the **chamber** while the load cools to a safe temperature.
culture media preparator	a specialised **laboratory sterilizer** designed for the **sterilization** and dispensing of culture media.

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cycle complete	recognition by the **automatic controller** that the preset values for the **cycle variables**, necessary for a successful **operating cycle**, have been attained and that the sterilized **load** is ready for removal from the **chamber**.
cycle variables	the physical properties, for example time, temperature, pressure, humidity and gas concentration, that influence the efficacy of the **operating cycle**.
dedicated steam supply	a supply of steam produced by a generator for the exclusive use of a **sterilizer** or group of sterilizers.
degassing	1. in **LTSF** and **EO sterilizers**, an **aeration** procedure in which **sterilant** gas and its reaction products are desorbed from the **load** by defined treatment outside the **sterilizer** after completion of the **operating cycle**. 2. a pre-heating treatment of boiler feed-water to reduce the amount of **non-condensable gases** in the steam supply.
design pressure	of a pressure vessel, the pressure chosen for the design calculations. See **operating pressure**, **allowable pressure**.
discard	laboratory material which is, or may be, infected by micro-organisms and is to be made safe before disposal.
discard bag	a bag, usually of plastic, designed to receive solid **discard** material before being placed in a **discard box** for processing by a **make-safe** cycle.
discard box	a box designed to contain discard material for processing by a make-safe cycle.
disinfection	a process used to reduce the number of viable micro-organisms in a **load** but which may not necessarily inactivate some viruses and bacterial spores.
disinfector	an apparatus designed to achieve **disinfection**.
double-ended sterilizer	a **sterilizer** in which there is a door at each end of the **chamber**.

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dry-heat sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to hot dry air near atmospheric pressure.
dryness value	a dimensionless quantity, approximating to the dryness fraction, derived to determine whether steam is of the correct dryness for **sterilization** purposes. A dryness value of 1.0 represents dry **saturated steam**.
EO sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to **ethylene oxide** gas or EO gas mixtures.
equilibration time	the period which elapses between the attainment of the **sterilization temperature** in the **chamber** and the attainment of the sterilization temperature in all parts of the **load**.
ethylene oxide (EO)	**sterilant** gas used to sterilise items that would be damaged by exposure to heat or moisture. Chemical formula CH_2CH_2O.
F_O	a quantity, measured in minutes, used to determine the efficacy of an **operating cycle** and equivalent to a continuous period at a temperature of 121°C.
fail-safe	an attribute of **sterilizer** design whereby failure of any component or its associated services does not create a safety hazard.
fault	the recognition by the **automatic controller** that the preset **cycle variables** for the **operating cycle** have not been attained and that **sterilization** or **disinfection** has been jeopardised.
flash sterilizer	a device designed to achieve **sterilization** by exposing the **load** to a very high temperature steam for a few seconds.
fluid sterilizer	a **clinical sterilizer** designed to sterilise fluids in sealed containers by exposure to **high-temperature steam** under pressure.
flushing	in **LTSF** and **EO sterilizers,** an **aeration** procedure by which remaining **sterilant** gas is removed from the **load** within the **chamber** by the passage of air or other inert gas.

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formaldehyde	**sterilant** gas used in combination with **low-temperature steam** to sterilise items that would be damaged by exposure to **high-temperature steam.** Chemical formula HCHO. Also known as methanal.
formalin	formaldehyde Solution BP. A 38% aqueous solution of **formaldehyde** stabilised with 10% w/v ethanol, commonly used as the primary material for generating formaldehyde gas.
free steaming	a process, used in **laboratory sterilizers,** in which the **load** is exposed to steam near atmospheric pressure.
free-standing	of a **sterilizer,** installed in a room which is not separated into a **plantroom** and a **loading area**.
full load	a specified **load,** used in thermometric tests, to represent the maximum size and mass of load which the **sterilizer** is designed to process.
gas exposure time	in **EO sterilizers,** the time for which the **chamber** is maintained at the specified temperature, gas concentration, pressure and humidity.
gauge pressure	pressure equal to the difference between the **absolute pressure** and local atmospheric pressure.
high-temperature steam	steam at a temperature above the boiling point of water at local atmospheric pressure.
holding time	the period during which the temperature in all parts of the **chamber, load** and any coolant fluid is held within the **sterilization temperature band.** It follows immediately after the **equilibration time**.
hot-air sterilizer	see **dry-heat sterilizer**.
indicated	an indicated value is that shown by a dial or other visual display fitted permanently to the **sterilizer** (see **recorded** and **measured)**.

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installation checks	a series of checks performed by the contractor to establish that the **sterilizer** has been provided and installed correctly, is safe to operate, does not interfere with nearby equipment and that all connected services are satisfactory and do not restrict the attainment of conditions for **sterilization**.
installation tests	a series of tests performed by the contractor after the **installation checks** to demonstrate that the **sterilizer** is working satisfactorily.
integral steam supply	a supply of steam produced in a sterilizer **chamber** or in a generator directly connected to it. The pressure in the sterilizer chamber is equal to that in the generator.
Köch steamer	a laboratory apparatus designed to expose a **load** to steam near atmospheric pressure and commonly used for melting solidified agar.
laboratory sterilizer	a **sterilizer** designed to sterilise, disinfect or **make-safe** laboratory materials and equipment.
load	collectively, all the goods, equipment and materials that are put into a **sterilizer** or **disinfector** at any one time for the purpose of processing it by an **operating cycle**.
load item	one of several discrete containers, packs or other units that together constitute a **load**.
load-temperature probe	a movable temperature sensor fitted within the **sterilizer chamber** and designed to record the temperature inside selected **load items**.
loading area	the room or area in front of the **sterilizer** in which the operator works and from which the sterilizer is loaded and unloaded. It is commonly separated by a fascia panel from the **plantroom**.
loading condition	a specified combination of the nature and number of **load items,** the items of **chamber furniture,** and their distribution within the **chamber**.
loading factor	the average fraction of the **usable chamber space** occupied by a load during normal operation.

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local exhaust ventilation (LEV)	a ventilation system designed to extract small amounts **EO** or **formaldehyde** vapour released during normal operation of a **sterilizer** and its ancillary equipment.
low-temperature steam (LTS)	steam at a temperature below the boiling point of water at local atmospheric pressure.
LTS disinfector	a clinical **disinfector** designed to disinfect **loads** by exposure to **low-temperature steam** at sub-atmospheric pressure.
LTSF sterilizer	a **clinical sterilizer** designed to sterilise **loads** by exposure to **low-temperature steam** and **formaldehyde** gas at sub-atmospheric pressure.
mains steam supply	the supply of steam produced for distribution to a range of steam-consuming equipment by an independent common boiler.
make-safe	a process, used in **laboratory sterilizers,** to reduce the microbial content of contaminated material so that it can be handled and disposed of without causing an infection hazard or environmental contamination.
master process record (MPR)	a **batch process record** obtained from a thermometric **commissioning** or **performance qualification** test and annotated to show the permitted tolerances for **cycle variables** during subsequent testing and routine production.
measured	a measured value is that shown on a test instrument, such as a thermometric recorder or a test pressure gauge, attached to the **sterilizer** for test purposes (see **indicated** and **recorded**).

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medical device	any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. (Source: EU Council Directive 93/42/EEC.)
medicinal product	any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product. (Source: EU Council Directive 65/65/EEC.)
module	a standard unit of **chamber** size being a rectangular box measuring 300 x 300 x 600 mm of volume 54 litres.
non-condensable gases (NCGs)	gases which cannot be liquefied by compression under the range of conditions of temperature and pressure used during the **operating cycle**.
noted	a noted value is that written down by the operator, usually as the result of observing an **indicated, recorded** or **measured** value.
operating cycle	the set of stages of the **sterilization** or **disinfection** process carried out in sequence and regulated by the **automatic controller.** It is synonymous with the terms “sterilization cycle” for **sterilizers** and “disinfection cycle” for **disinfectors**.
operating pressure	the pressure in the **chamber** during the **plateau period** of an **operating cycle**. See **allowable pressure**, **design pressure**.

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override	a system by which the progress of the **operating cycle** can be interrupted or modified as necessary.
paraformaldehyde	a mixture of polymethylene glycols formed by the reaction of **formaldehyde** with water.
performance class	an integer, from 1 to 20, related to the total cycle time for a **sterilizer** with a **full load**.
performance qualification (PQ)	the process of obtaining and documenting evidence that the equipment, as commissioned, will produce acceptable product when operated in accordance with the process specification.
performance requalification (PRQ)	the process of confirming that the evidence obtained during **performance qualification** remains valid.
periodic tests	a series of tests carried out at daily, weekly, quarterly and yearly intervals.
personal protective equipment (PPE)	equipment, including clothing, which is intended to be worn or held by a person at work, which protects against one or more risks to his or her health and safety.
plant history file	a file containing **validation**, maintenance and other engineering records for each **sterilizer**.
plantroom	the room or area to the rear of the **sterilizer** in which services are connected and which provides access for maintenance. It is commonly separated by a fascia panel from the **loading area**.
plateau period	the **equilibration time** plus the **holding time**.
porous-load sterilizer	a **clinical sterilizer** designed to process, by exposure to **high-temperature steam** under pressure, porous items such as towels, gowns and dressings, and also **medical devices** that are wrapped in porous materials such as paper or fabrics.
preconditioning	treatment of a **load** to attain predetermined conditions, such as temperature and humidity, before the start of an **operating cycle**.

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pressure ballasting	a technique used in **fluid sterilizers** by which the pressure in the **chamber** is maintained at or near to the pressure inside the **load** containers during all or part of the **operating cycle**.
pressure vessel	a collective term describing the sterilizer **chamber,** jacket (if fitted), door(s) and components that are in permanent open connection with the chamber.
priming	of a steam generator, the delivery of steam containing water in suspension due to violent boiling or frothing.
process indicator	a **chemical indicator** used to distinguish between processed and unprocessed load items.
pyrogen	a bacterial toxin that causes a rise in body temperature and which is not destroyed by steam **sterilization**.
recommissioning	a procedure to confirm that operational data established during **commissioning** remain valid.
recorded	a recorded value is that shown on the output of a recording instrument fitted permanently to the **sterilizer** (see **indicated** and measured).
revalidation	a procedure to confirm an established **validation,** consisting of **recommissioning** followed by **performance requalification**.
safety hazard	a potentially detrimental effect on persons or the surroundings arising directly from either the **sterilizer** or its **load**.
saturated steam	steam whose temperature, at any given pressure, corresponds to that of the vaporisation curve of water.
small load	a specified **load,** used in thermometric tests, to represent the minimum size and mass of load which the **sterilizer** is designed to process.
small plastic discard	**discard** material comprising or held in plastic containers not exceeding 50 ml in volume.
sterilant	an agent used to effect **sterilization,** such as steam, hot air or a sterilising gas.

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sterile	condition of a **load item** that is free from viable micro-organisms. See BS EN 556 for the requirements for a **medical device** to be labelled “sterile”.
sterilization	a process undertaken to render a **load sterile**.
sterilization conditions	the ranges of the **cycle variables** which may prevail throughout the **chamber** and **load** during the **holding time**.
sterilization process	the complete set of procedures required for **sterilization** of a **load,** including the **operating cycle** and any treatment of the load before or after the operating cycle.
sterilization temperature	minimum acceptable temperature of the **sterilization temperature band**.
sterilization temperature band	the range of temperatures which may prevail throughout the **load** during the **holding time.** These temperatures are expressed as a minimum acceptable (the **sterilization temperature)** and a maximum allowable and are stated to the nearest degree Celsius.
sterilizer	an apparatus designed to achieve **sterilization**.
sterilizer process log	a log, kept by the User, which contains records for each production cycle.
superheated steam	steam whose temperature, at any given pressure, is higher than that indicated by the vaporisation curve of water.
thermal door lock	an interlock fitted to certain **sterilizers** to prevent the door from being opened until the temperature in the **chamber** and **load** falls below a preset value.
transportable	requiring no permanent connections or installation and capable of being moved manually without mechanical assistance. Synonymous with “bench-top”.
type tests	a series of tests conducted by the manufacturer to establish the working data for a **sterilizer** type.

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usable chamber space	the space inside the **chamber** which is not restricted by **chamber furniture** and which is consequently available to accept the **load**.
utilisation factor	the fraction of the open hours for which a sterilizer is available to process loads.
validation	a documented procedure for obtaining, recording and interpreting data required to show that a **sterilization process** will consistently comply with predetermined specifications.
works tests	a series of tests to establish the efficacy of each **sterilizer** at the manufacturer's works.

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Abbreviations

BP	British Pharmacopoeia
BPR	batch process record
BS	British Standard
°C	degree Celsius
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CEV	chamber exhaust ventilation
CFCs	Chlorofluorocarbons
COSHH	Control of Substances Hazardous to Health (Regulations)
dBA	decibel, A-weighted
EMC	electromagnetic compatibility
EN	European Standard (Europäische Norm)
EO	ethylene oxide
EU	European Union (formerly European Community)
GGMP	EU, *Guide to good manufacturing practice for medicinal products*
h	hour
HBN	Health Building Note
HCFCs	Hydrochlorofluorocarbons
HDN	Hospital Design Note
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HTM	Health Technical Memorandum
ISO	International Organisation for Standardisation
Kg	Kilogram
kW	kilowatt
l	litre
LEV	local exhaust ventilation
LTMEL	long-term maximum exposure limit
LTS	low-temperature steam
LTSF	low-temperature steam and formaldehyde
µm	micrometre (micron, 10^{-6} m)
m	metre
mbar	millibar (10^{-3} bar)
MCA	Medicines Control Agency
MDA	Medical Devices Agency
mg	milligram (10^{-3} g)
min	minute
ml	millilitre (10^{-3} l)
mm	millimetre (10^{-3} m)
mmol	millimole (10^{-3} mole)
MPR	master process record
mS	millisiemens
NCG	non-condensable gas
PES	programmable electronic system
PM	Planned maintenance

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ppm	parts per million
PPE	Personal protective equipment
PQ	performance qualification
PRQ	performance requalification
PVC	Polyvinyl chloride
RH	relative humidity
s	second
SSD	sterile services department
STMEL	short-term maximum exposure limit
TSE	transmissable spongiform enceptalopathy
UK	United Kingdom

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NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

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	Electricity Act	HMSO	1989	
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Publication ID	Title	Publisher	Date	Notes
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
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BS 1781	**Specification for linen and linen union textiles**		1981	
BS 2646	**Autoclaves for sterilization in laboratories**	BSI Standards		
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Publication ID	Title	Publisher	Date	Notes
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BS 4196-0	**Sound power level of noise sources. Guide for the use of basic standards and for the preparation of noise test codes**	BSI Standards	1981	
BS 4275	**Guide to implementing an effective respiratory protective device programme**	BSI Standards	1997	
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BS 5295	**Environmental cleanliness in enclosed spaces** **Part 1:** Specification for clean rooms and clean air devices		1989	
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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
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SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
UK Health Technical Guidance				
HBN 29	Accommodation for pharmaceutical services	HMSO	1988	
HTM 67	Building components: laboratory fitting out system	HMSO	1993	
CONCODE	Contracts and commissions for the NHS estate – contract procedures	HMSO	1994	
MES	Model Engineering Specifications	NHS Estates	1997	As required
MES C14	Sterilizers	NHS Estates	1993	
HBN 13	Supplement 1 – Ethylene oxide sterilization section	HMSO	1994	
MES C02	Thermal insulation	NHS Estates	1993	
Health and Safety Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
HN(76)126	Hospital design note 4 (noise control): amendments to appendices II, IV and VII	DHSS	1976	
STB3A/85/12	Performance and safety specification for media sterilizers. Media devices directorate	DHSS	1985	
	Emmerson, A. M. *Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Committee to the Department of Health Medical Devices Directorate.* Medical devices directorate	Department of Health	1993	
	Biological tests for graded milk. Memo 139/Foods.	Ministry of Health	1937	
	Scottish Infection Manual Guidance on the core standards for the control of infection in hospitals, healthcare premises and at the community interface	The Scottish Office	1998	

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Publication ID	Title	Publisher	Date	Notes
	Programmable electronic systems in safety related applications: General technical guidelines	HSE	1987	
	Programmable electronic systems in safety related applications: an introductory guide	HSE	1987	
L 5	General COSHH ACOP (Control of substances hazardous to health) Carcinogens ACOP (Control of carcinogenic substances) and Biological agents ACOP (Control of biological agents) Control of Substances Hazardous to Health Regulations1999 Approved Code of Practice	HSE	1999	
L 22	Safe use of work equipment: Approved code of practice and guidance	HSE	1998	
L 23	Manual handling operations: guidance on regulations	HSE	1998	
L 24	Workplace health, safety and welfare: Approved code of practice and guidance	HSE	1992	
L25	Personal protective equipment at work at work: guidance on regulations		1992	
L113	Safe use of lifting equipment: Approved code of practice and guidance	HSE	1998	
L122	Safety of pressure systems: Pressure Systems Safety Regulations 2000. Approved Code of Practice	HSE Books	2000	
PM73	Safety at Autoclaves	HSE Books	1998	
	Precautions for work with human and animal. Transmissible Spongiform Encaphalopathies	HSE (ACDP)		
	Categorisation of pathogens according to hazard and categories of containment	HSE (ACDP)	1995	4th Edition
	Safe working and the prevention of infection in clinical laboratories	HSC (HSAC)		
HS(R)23	A guide to the 'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995	HSE	1995	

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Publication ID	Title	Publisher	Date	Notes
Miscellaneous References				
GGMP Volume IV	Guide to good manufacturing practice for medicinal products – The rules governing medicinal products in the European Community			
	Atomic absorption spectrophotometry 1979 version	HMSO	1979	(out of print)
	Cadmium in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Colour and turbidity of waters 1981	HMSO	1981	(out of print)
	Determination of anions and cations, transition metals, and other complex ions and organic acids and bases in water by chromatography 1990	HMSO	1990	
	Lead in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Lead and cadmium in fresh waters by atomic absorption spectrophotometry (second edition) a general introduction to electrothermal atomization atomic absorption spctrophotometry 1986	HMSO	1986	(out of print)
	Measurements of electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters.	HMSO		(out of print)
	Mercury in waters, effluents, soils and sediments etc, additional methods	HMSO	1985	(out of print)
	Phosphorus and silicon in waters, effluents and sludges 1992	HMSO	1993	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
LG 2	Lighting guide: hospitals and healthcare buildings	Chartered Institution of Building Services Engineers	1989	
	Sterilization and disinfection of heat-liable equipment	Central Sterilizing Club	1986	

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Appendix 1: Useful Addresses

Medicines Control Agency,
Market Towers,
1 Nine Elms Lane,
London SW8 5NQ.
Tel. 0171 273 3000.

Medical Devices Agency,
14 Russell Square,
London WC1 B 5EP.
Tel. 0171 972 2000.

Scottish Executive Health Department,
St Andrew's House,
Edinburgh EH1 3DG.
Tel. 0131 556 8400.

NHSScotland, Property and Environment Forum Executive,
4th Floor,
St Andrew House
141 West Nile Street,
Glasgow, G1 2RN.
Tel. 0141 404 3737

Public Health Laboratory Service,
Central Public Health Laboratory,
61 Colindale Avenue,
London NW9 5HT.
Tel. 0181-200 4400.

Health and safety

Health and Safety Executive,
375 West George Street,
Glasgow, G2 4LW.
Tel. 0141 275 3000

Belford House
59 Belford Road,
Edinburgh, EH4 3UE.
Tel. 0131 247 2000

Health and Safety Executive Information Line
Tel. 0870 154 5500

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Standards organisations

British Standards Institution
Head office: 2 Park Street,
London W1A 2BS .

Publications:
Linford Wood,
Milton Keynes MK14 6LE.
Tel. 01908 221 166.

European Committee for Standardization,
Rue de Stassart 36, B-1050 Brussels

Other organisations

Association of Consulting Engineers,
Alliance House, 12 Caxton Street,
London SW1 H 0QL.
Tel. 0171 222 6557.

Institute of Healthcare Engineering and Estate Management ,
2 Abingdon House, Cumberland Business Centre,
Northumberland Road,
Portsmouth PO5 1 DS.
Tel. 02392 823186.

Institution of Electrical Engineers,
Publication Sales Department, PO Box 26,
Hitchin,
Hertsfordshire SG5 1SA.
Tel. 01438 742792.

Institution of Mechanical Engineers, Publication Sales Department,
PO Box 24, Northgate Avenue,
Bury St Edmunds,
Suffolk IP32 6BW.
Tel. 01284 763277.

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Appendix 2: Sterilization of items contaminated with TSE agents

Introduction

A2.1 The following information is extracted from the HSE document 'Precautions for work with human and animal Transmissible Spongiform Encephalopathies', compiled by the Advisory Committee on Dangerous Pathogens and issued to the NHS under Department of Health circular PL(94)CO/5.

A2.2 The term transmissible spongiform encephalopathy (TSE) describes a rare and fatal degenerative condition of the central nervous system occurring in man and in certain animal species. The three TSEs that are recognised in man are:

a. Creutzfeld-Jakob disease (CJD);

b. Gerstmann-Straussler-Scheinker syndrome (GSS);

c. kuru.

A2.3 The two chief TSEs in animals include:

a. scrapie (in sheep);

b. bovine spongiform encephalopathy (BSE).

A2.4 Similar diseases include transmissible mink encephalopathy (TME), chronic wasting disease (CWD) in Rocky Mountain elk and captive mule deer, and TSEs in small numbers of exotic ungulates and cats.

A2.5 Although these diseases appear to be caused by transmissible agents, the nature of these agents remains uncertain.

A2.6 Animal TSEs are classified as Hazard Group 1. Human TSEs are now classified as Hazard Group 3 (formerly Hazard Group 2) as required by the COSHH Regulations 1999, although full Containment Level 3 precautions are not always required.

Sterilization

A2.7 All agents of TSE exhibit an unusual resistance to conventional decontamination methods used in clinical and laboratory practice. They are not significantly affected by a number of standard chemical agents such as formalin and ethylene oxide, and infectivity persists after autoclaving at conventional times and temperatures (such as 121°C for 15 min). In

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addition, only extremely high doses of ionising and UV irradiation have been successful in reducing infectivity.

A2.8 The Advisory Committee on Dangerous Pathogens recommends porous load sterilization as the method of choice in most situations. Two processes are recommended:

a. a single cycle at 134-138°C for a minimum holding time of 18 min;

or

b. six cycles at 134-138°C for a minimum holding time of 3 min.

A2.9 The latter represents the standard operating cycle for a porous load sterilizer (run six times) and may be used if the single, longer cycle is not available.

A2.10 Although no practical problems appear to have arisen with this time and temperature combination, recent preliminary studies of a scrapie agent under rigorous experimental conditions have shown some residual infectivity. This may be due to the use of relatively high-titred and more thermostable strains. Further work is planned to confirm the appropriate lower temperature limit.

A2.11 Users should consult Annex 2 of the HSE document for specialised advice on:

a. the effectiveness of other sterilization processes;
b. treatment of work surfaces and non-heat-stable equipment;
c. decontamination and disposal of liquids;
d. decontamination of microbiological safety cabinets;
e. fixation for histology;
f. disposal of tissue.

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Appendix 3: Safety of EO sterilization

Introduction

A3.1 Ethylene oxide presents hazards not found in conventional sterilizers. The vapour is extremely flammable and irritates both the eyes and the respiratory system. Poisoning by ethylene oxide is a reportable disease listed in Schedule 2 of 'The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995'.

A3.2 Much of the guidance in this appendix is drawn, with permission, from 'Guidelines for the safe operation of ethylene oxide sterilization plant' published by ICI plc but no longer available.

A3.3 The advice is primarily aimed at users of large sterilizers supplied from cylinders. Many of the precautions described here will not be necessary for users of small sterilizers supplied from disposable cartridges. However, all users of EO sterilizers are strongly advised to make a risk assessment of the worst case accident that could occur. The amount of EO that could be involved is of prime consideration; the small amount contained in a cartridge is unlikely, for example, to lead to spillages of liquid.

A3.4 Personnel exposure to ethylene oxide should not exceed the maximum exposure limits given in Table 1.

A3.5 Persons employed on plant handling EO should be adequately trained and provided with detailed operating instructions.

A3.6 A selection of physical and chemical properties of EO is listed in Table A1.

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Table A1: Selected properties of ethylene oxide

Relative molecular mass	44.05
Form	Liquefied gas
Colour	Colourless
Odour	Ethereal
Odour threshold	450-700 ppm
Boiling point	10.5 C
Flash point (open cup)	-17.8 C
Flammable limits in air (v/v)	3-100%
Auto ignition temperature	429 C
Vapour pressure	139kPa (20 C), 349 kPa (50 C)
Density of liquid at 4°C	890 kgm^{-3}
Solubility	Miscible in water
Vapour density (air=1)	1.5

Sources: 'Product safety data', ICI Chemicals & Polymers Ltd, 1995; 'Information relevant to the installation of, and ancillary equipment for, ethylene oxide sterilizers', CEN TC 102 WG6 N67+, CEN (unpublished).

Fire and explosion hazards

A3.7 EO is highly flammable and forms explosive mixtures with air at all concentrations above 3% (v/v). There is no upper explosive limit as normally expected for hydrocarbons; exothermic reaction replaces combustion at higher concentrations up to 100%. The auto-ignition temperature in air at atmospheric pressure is 429°C, and the decomposition temperature in the absence of air is 560°C.

NOTE: Further Guidance is contained in NHS in Scotland Firecode.

A3.8 Because of its flammability and low boiling point, EO is akin to liquefied petroleum gas (LPG). An essential difference is that it is fully miscible with water. At concentrations in water below 1% w/w the vapours are not flammable at air ambient temperature, so a leakage of liquid EO can be rendered non-flammable by diluting it 100-fold with water. In the open air appreciably less dilution (24-fold) can extinguish burning EO.

A3.9 Fire risks in general and electrical classifications are covered by conforming to typical codes related to the storage of LPG or liquefied natural gas (LNG) products and to the selection of electrical installations for use in flammable atmospheres. Additional precautions are called for because of the thermal instability of EO.

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A3.10 Accumulation of electrostatic charge does not take place in EO because of its high electrical conductivity (>3mS m^{-1}). There is thus no reason to limit flow velocities in pipework.

A3.11 The aim should be to handle EO in closed equipment and to deal promptly with any leaks or spillages whenever these occur.

A3.12 For detecting leaks, gas detectors with automatic alarms located at strategic points (eg. near the sterilizer door) are recommended.

A3.13 The prime defence against escaped EO is the use of water in very large quantities to dilute the EO and render it non-flammable. Insufficient amounts of water, on the other hand, may promote the vaporisation of EO from large spillages.

Polymerisation

A3.14 Liquid EO is very susceptible to polymerisation initiated at ambient temperature by acids, bases or catalysts, such as anhydrous chlorides of iron, aluminium, tin and metal oxides. Iron rust is a moderate initiator for this reaction and therefore it should be substantially removed from any equipment containing EO. Purely thermal initiation starts at around 100°C and once started, iron is a promoter. The polymerisation is highly exothermic and if the temperature is not controlled the polymerisation is self-accelerating, leading to vaporisation of unreacted EO and possibly to explosive decomposition of the vapour.

A3.15 Slow polymerisation can occur, producing solid polymer, which is thermally stable. Solid polymer is soluble in the monomer. The polymer may also contain considerable amounts of dissolved monomer which during dispersal, may be released into the atmosphere. Further guidance is contained in NHS in Scotland Firecode.

Toxicity hazards

Vapour toxicity

A3.16 EO boils at 10.5°C and vaporises at normal atmospheric temperature and pressure so that exposure of personnel to vapour, rather than liquid contact, is the more likely hazard. High concentrations of the gas in contact with the skin may produce serious burns if not removed immediately. It has been reported that concentrations of 2000 ppm retained in rubber gloves have caused skin irritation.

A3.17 Exposure to EO vapour causes irritation of the eyes and respiratory system accompanied by headache. The vapour has anaesthetic properties. Signs and symptoms may include nausea, vomiting, coughing, irritation to the nose, loss of smell and, progressively, dizziness, stupor and coma. These effects are noticeable at concentrations greater than 50 ppm. Acute symptoms are normally delayed except in the case of serious exposure.

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Fluid build-up in the lungs (pulmonary oedema) may occur up to 48 hours after exposure and could prove fatal. The effects of low concentrations of EO are not thought to be cumulative, though the evidence is equivocal and the subject of continuing research.

A3.18 The sweetish smell of pure EO is not apparent until the concentration reaches several hundred ppm (figures between 400 and 700ppm have been quoted), far above the level at which harm is caused. Personnel concerned with the operation of EO sterilizers cannot rely on smell to protect themselves against exposure. It is essential that EO environmental tests are carried out at least once a year and that there is an effective system for personal monitoring.

A3.19 Adverse reproductive effects (reduced fertility and embryotoxicity) have been reported in rats exposed to high concentrations for prolonged periods. Epidemiological studies on human reproductive effects have so far been inconclusive although spontaneous abortions and an excess of foetal deaths have been reported among women exposed to EO. The exposure levels are not known.

A3.20 EO is mutagenic in a wide variety of in vitro and in vivo biological test systems. It has been shown to cause cancer in animals and HSE advises that it should be regarded as a potential human carcinogen.

Effects of liquid EO on skin and eyes

A3.21 Liquid EO can persist under open conditions, particularly at low temperatures. Serious freeze burns can result from contact from liquid splashes or spray. Solutions of EO in water cause more rapid burning than the dry material. Delayed inflammation of the skin may also result.

A3.22 The eyes are particularly susceptible to serious permanent damage from splashes, even of dilute solutions. The onset of effects may be delayed for several hours.

Workplace monitoring and recording

A3.23 Atmospheric concentrations of EO should be monitored in the appropriate working area and any abnormalities should be reported, investigated and corrected.

A3.24 While background atmospheric monitoring of the sterilization and quarantine areas is recommended, regular personal monitoring of operators working in these areas is regarded as essential in assessing exposure.

A3.25 All assessment of operator exposure should be based on personal monitoring unless this can be obtained from workplace air sampling by showing the necessary correlation. Monitoring should be based on an 8-hour exposure unless it has been shown that exposure occurs only at specific times; in such cases the shift exposure may be calculated from

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measurements made at these times. Additionally, spot measurements should be made at times of peak exposures with a view to reducing these levels.

A3.26 Plant monitoring may be useful for the early detection of leaks but considerable thought should be given to the siting of sample points and the frequency of sampling.

A3.27 Records should be established of the names and job classification of operators who work in areas where exposure to EO may occur. All personal monitoring results should be recorded. Records should be kept of all cases of acute exposure to EO. All of these records should be kept for at least 30 years.

A3.28 Users setting up monitoring systems are strongly recommended to obtain advice both from gas manufacturers or suppliers and also from properly qualified occupational health consultants.

Personal sampling

A3.29 Personal sampling should be undertaken to evaluate the level of exposure of individuals. It is the only technique recognised by HSE as producing results for judging compliance with the established exposure limits.

A3.30 A number of methods based on collection of atmospheric EO on a solid adsorbent, such as charcoal, are available. There are principally two types;

a. active sampling using a small pump;

b. passive diffusion.

A3.31 Both systems require the subsequent desorption and estimation of EO.

Environmental monitoring

A3.32 Systems which are currently in use for environmental monitoring are based on several analytical techniques including infrared spectroscopy, flame ionisation, photoionisation, mass spectrometry and gas chromatography. It should be borne in mind that each suffers from limitations dependent upon interference from other compounds which may be present concurrently with EO. The system to be established should be considered in relation to the particular installation for which it is intended.

A3.33 Newer and simpler techniques are continuously being developed and the current state-of-the-art should be considered before commitment to any particular system is made.

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A3.34 The principal systems available are as follows:

a. Colour-changes indicator system (1-30ppm). This system is for spot monitoring and cannot give accurate time-weighted average reading of exposure. The MEL for EO is at the low end of the detection range, hence accuracy is poor. The system does not pinpoint the source of emissions.

b. Direct-reading infrared analysers (0.2-1000ppm). This equipment can be portable for single-point monitoring. More elaborate static units are available for continuous cycle and multipoint monitoring. These systems can give accurate time-weighted average figures for specific points and extremely good historical perspective, but give no indication of concentrations in the air breathed by personnel.

c. Gas chromatography. As with infrared there are both portable and static units providing a sensitivity of 0.1ppm, depending upon sample size and analytical system. All gas chromatography applications for time-weighted average readings require charcoal tubes for adsorption and desorption.

Personal protective equipment

A3.35 Personal protective equipment (PPE) guarding against the effects of EO should not need to be used as a matter of routine, since the sterilizer design, ventilation systems and operating procedures should preclude the presence of harmful concentrations of EO.

A3.36 Where work in contact with EO is unavoidable, the following items of PPE should be available:

a. for exposure to EO vapour – respiratory protective equipment and eye protection;

b. for exposure to EO liquid – air breathing hood, protective suit, gloves and rubber boots.

A3.37 There should be training programmes to ensure that the relevant people are able to use PPE correctly and quickly. Training should be carried out by a suitably qualified instructor.

A3.38 Suitable arrangements should be made for periodic maintenance of the equipment.

A3.39 Records should be kept of both training and maintenance.

Respiratory protective equipment

A3.40 Where atmospheric concentrations of EO are, or could reasonably be expected to be, above the Maximum Exposure Limit (see Table 1), suitable respiratory protective equipment should be worn. This may be self-contained breathing apparatus, compressed air line breathing apparatus or a suitable

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canister respirator, the type of equipment being selected according to the levels of EO which may be present.

A3.41 The equipment should comply with all relevant British or European Standards. In selecting suitable equipment, reference should be made to BS 4275: 1997 ‘Guide to implementing an effective respiratory protective device programme’.

A3.42 The system chosen should be adequate for the protection of the wearer under all foreseeable circumstances. Factors to be taken into consideration are:

a. the highest possible exposure level;
b. the longest possible excursion time;
c. the nominal protection factor of the equipment; this will indicate the efficiency of the equipment (the best nominal protection factor is conferred by positive-pressure breathing apparatus);
d. the goodness of fit of face masks.

Breathing apparatus

A3.43 Full, positive-pressure breathing apparatus provides a totally enclosed respiratory environment for the wearer. Because of the design, there is a 30-min usage limit.

A3.44 Two sets of breathing apparatus for rescue work should be kept outside the EO working area.

Chest-mounted canister respirator

A3.45 Canister respirators should only be used when the atmospheric concentrations of EO are known to be within the levels for which the canister is designed and the duration of use should be within the life of the canister. These devices rely on a good seal between the respirator and the face of the wearer; if this seal is lessened by facial hair, spectacles, etc., a very much lower degree of protection will be achieved.

A3.46 The canister filters the air to a full face mask. It should not be used in atmospheres where the exposure level is likely to be in excess of 0.2% by volume. There is a specified time limit for usage. HSE recommends that canisters be discarded after each use unless tests against EO can show that desorption does not occur on re-use. Canisters should be degassed before disposal.

Cartridge respirator

A3.47 The cartridge fits directly into an ori-nasal mask. It should not be used in atmospheres where the EO level is likely to exceed 1000ppm. The useful life of the cartridge is 30 min for exposure to maximum concentration. It is

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essential to adhere closely to the manufacturer's or supplier's instructions. Cartridges should be degassed before disposal.

Protective clothing

A3.48 In emergency situations when handling liquid EO and when atmospheric concentrations are high, full protective clothing should be worn. This should provide complete protection to the skin and eyes. Particular note should be taken of the construction of the clothing, such as the sealing of seams, and of the ability of the material to limit the permeation of EO on to the skin. If any clothing becomes contaminated with liquid EO it should be destroyed.

Emergency procedures

A3.49 Comprehensive written procedures should be prepared covering shut-down, evacuation and rescue. This should involve an assessment of the worst possible consequences of an incident. The procedures thus described should be tested and audited at regular intervals.

A3.50 A fire certificate issued by the Home Office may be required. Guidance from the local fire brigade should be sought. Emergency procedures should be agreed with the fire officers and displayed in a permanent form in a prominent position. Further information is available in NHS in Scotland Firecode.

A3.51 Liaison with the local accident and emergency department is recommended, particularly to ensure that the specific hazards associated with exposure to EO are known and that the remedial treatment is available.

A3.52 First aid procedures relevant to the nature of the sterilization operation should be drawn up and agreed. Sterilizer operators and first-aiders on the site should be trained in these procedures.

Leaking cylinder

A3.53 If the cylinder is in an enclosed area, evacuate the area. Wear suitable protection. Check that the cylinder valve is closed. Move the cylinder to a fume room or open space downwind and away from persons and buildings. Post warning notices and seal off the area. The suppliers should be contacted in the event of difficulty.

Fire fighting advice

A3.54 In the event of a leakage of gas becoming ignited, the fire brigade should be called immediately. The fire should be extinguished only by closing the valve. No attempt should be made to put out the flame in any other way but, provided it is safe to do so, the cylinder should be cooled by copious spraying with water. The person directing the spray should take up a position where he or she will be protected should a cylinder explode. If flame from

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the burning leak impinges on cylinders, the building should be evacuated immediately and no fire-fighting attempted.

A3.55 Cylinders which have not become heated should be moved to a safe place in the open as quickly as possible, making sure any valves are turned off first. If this is not possible, such cylinders should be kept cool by spraying with water from a safe position.

A3.56 On arrival at the premises, the fire brigade should be informed of the position of all cylinders, even those that are not directly threatened by the fire.

Spillage

A3.57 In any area where the spillage of liquid EO can occur a piped water supply should be provided. Escaped EO should be diluted with copious quantities of water sufficient to dilute the EO to less than 4%. At this concentration the vapours are not flammable. Restricted amounts of water may only serve to increase the vaporisation of EO.

A3.58 In the event of spillage, the area should be evacuated immediately. Re-entry should only be by personnel wearing full protective clothing - i.e. procedures should be prepared in accordance with Firecode in Scotland and the appropriate HTMs: rubber boots, non-absorbent overalls, gloves and breathing apparatus. The supply source should be isolated, if possible. Spillages should be cleared by drenching with sufficient water to dilute the EO at least 100-fold and never by mopping up. It should be remembered that EO is heavier than air so higher concentrations will tend to accumulate at ground level.

A3.59 EO is a persistent contaminant, and particular attention should be paid to the cleansing of contaminated clothing and equipment. Where decontamination is not possible (such as on leather items), the article should be destroyed.

First aid advice

A3.60 In the event of an accident personnel should take steps to protect themselves and isolate any sources of escaping EO. If someone is exposed to EO, medical attention should be sought immediately.

A3.61 In all cases of severe or suspected exposure to EO the person should be immediately removed from the contaminated area to a well ventilated area by trained personnel wearing the necessary protective equipment. The following action should be taken.

A3.62 If the skin has been affected:

a. remove all contaminated clothing;

b. if liquid EO is on the skin, allow it to evaporate;

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c. wash skin copiously with water for 15 minutes. Exposed skin should be treated with high-pressure water such as a hose or strong shower – gentle washing is not sufficient.

A3.63 If EO has been inhaled:

a. lay the casualty flat and keep him warm and still;

b. if breathing has stopped, given artificial respiration with a Brooks airway; do not attempt mouth-to-mouth or mouth-to-nose resuscitation. If oxygen is available it should be administered by a suitably qualified person.

A3.64 If the eyes have been affected, flush copiously with water for 15 minutes.

A3.65 If EO has been swallowed, activated charcoal may be used to adsorb unreacted EO. It should be administered as an aqueous slurry of 240 ml of water to 30 g charcoal. The usual dose is 30-100 g in adults. EO is irritating and usually serves as its own cathartic.

A3.66 The possibility of delayed effects following exposure should not be overlooked.

Control and handling of cylinders

A3.67 The gas should be supplied to an agreed specification guaranteed by the supplier. The specification should include:

a. details of the composition and pressure of the gas or gas mixture;

b. a technical description of the construction and fittings of the cylinders;

c. individual cylinder identification to allow the rotation of stock.

A3.68 A procedure should be defined for the acceptance of deliveries of gas cylinders from the supplier. The procedure should include the following details:

a. confirmation of the identity of the gas by reference to the manufacturer's product identification; a copy of the code and procedure should be prominently displayed in the goods received and in the gas storage areas;

b. the leak testing of each cylinder using a suitable leak detection device or soapy water. Leak tests should be carried out:

(i) on the joint between the cylinder neck and the discharge valve;

(ii) around the valve control handle stem;

(iii) around and inside the valve discharge orifice.

A3.69 Any cylinders found to be leaking or otherwise not conforming to the specification should not be accepted and will remain the responsibility of the supplier, who should be informed immediately.

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A3.70 The manufacturer's recommendation regarding the maintenance of residual pressure or weight in nominally empty cylinders for return should be followed.

A3.71 Cylinders should be stored in a cool, well-ventilated, secure area (see Part 5 of this SHTM for guidance). EO should be stored away from fire risk and sources of heat. A suitable cylinder handling trolley should be provided.

Information and training

A3.72 All personnel employed in the operation of EO sterilizers, including maintenance personnel and operators, should receive adequate, documented training. Personnel should not commence their duties until this training has been completed and detailed operating instructions have been provided. Maintenance personnel should be trained and certified by the manufacturer of the sterilizer.

A3.73 As a minimum, training should include:

a. operational policies;
b. safety provisions;
c. connection and disconnection of gas cylinders;
d. first aid;
e. emergency procedures;
f. use of respiratory equipment;
g. duties to be performed;
h. actions in the event of a fire.

A3.74 On completion of training, employees should be assessed to ensure that the training programme has been understood. No person should be permitted to work with EO until he or she has attained an adequate level of proficiency.

A3.75 All personnel coming into contact with EO should be informed of the hazards and provided with a hazard data sheet.

Maintenance

A3.76 Maintenance should only be performed by suitably trained and qualified personnel. Before working on equipment known to contain EO, the equipment should be drained, isolated, washed out with water and demonstrated to be clear of flammable vapour (by gas analysis, for example).

A3.77 Systems which have carried EO but which are thought to be free of any residue should nevertheless be thoroughly purged with nitrogen before work commences.

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A3.78 Planned, regular maintenance of all elements of the gas supply system is essential to safe operation.

A3.79 A list of spares vital for safe operation should be compiled and a stock maintained.

A3.80 Before any work is carried out on equipment known to contain EO, or that has carried EO, or is thought to be free of EO, the local exhaust ventilation should be known to be effective. If work is to be carried out on the supply line from the manifold (cylinder supply) or pipe systems that have carried EO, they should first be purged with a non-flammable gas such as nitrogen before work commences.

A3.81 A procedure should be defined for the maintenance of lines and fittings which have contained EO and for subsequent pressure and vacuum testing. The following details should be included:

a. compulsory wearing of face shields, respiratory protection (where appropriate) and gloves;
b. disconnection and isolation of the source of EO;
c. the source of purging gas, together with any entrained material, shall be vented to a safe location (provision should be made for the handling and disposal of polymerised EO which may contain EO monomer);
d. on completion of the maintenance schedule, pressure testing at an appropriate pressure, with leak testing as required;
e. vacuum testing as appropriate;
f. checking that all valves and other control settings are correct before putting the sterilizer back into service.

A3.82 Where potentially flammable EO mixtures are present, sources of ignition should be prohibited. For example:

a. smoking and the use of naked flames should be strictly prohibited and matches or other means of ignition should not be carried into the work area;
b. tools made from spark-producing metals should also be prohibited; only tools and equipment which do not induce sparks should be issued;
c. garments containing synthetic fibres likely to induce static discharge should not be worn; conductive footwear should be used.

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Appendix 4: Guidance to management on the appointment of an Authorised Person (Sterilizers)

Introduction

A4.1 The Authorised Person (Sterilizers) is defined as a person designated by management to provide independent auditing and advice on sterilisers and sterilization and to review and witness documentation on validation. The shorter term “Authorised Person” is used in this SHTM.

A4.2 The specific requirements for the services of an Authorised Person should be based upon the core responsibilities outlined in Part 1 of this SHTM, namely:

a. to provide general and impartial advice on all matters concerned with sterilization;

b. to advise on programmes of validation;

c. to audit reports on validation, revalidation and yearly tests prepared by the Test Person;

d. to advise on programmes of periodic tests and periodic maintenance;

e. to advise on operational procedures for routine production.

A4.3 The Institute of Healthcare Engineering and Estate Management (formerly the Institute of Hospital Engineering) is the registration authority for Authorised Persons. The address is given in Appendix 1.

A4.4 In appointing an Authorised Person, management should ensure that there is no conflict of interest that would compromise his or her impartiality in carrying out the assigned duties. Candidates should be required to declare any such interest at an early stage. Management should carefully assess whether such declared interests are likely to affect the ability of the candidate to carry out the duties defined above or any proposed extension to them. A candidate employed by a sterilizer manufacturer, for example, may be able to discharge all the core duties satisfactorily but be considered unsuitable to offer advice on procurement of new equipment. See also paragraph A4.7.

A4.5 Management should ensure that the selected candidate has the appropriate qualifications and experience for the sterilizers for which he or she will be responsible. Not all Authorised Persons will be qualified to advise on all types of sterilization process. It may be necessary to appoint one or more Authorised Persons specialised in different processes; namely steam, dry heat, LTSF or EO. In such cases, there should be a clear definition of each appointee’s sphere of responsibility.

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A4.6 In normal circumstances an Authorised Person should have exclusive responsibility for each machine in his or her charge. It is not good practice for more than one Authorised Person to be contracted to share continuing responsibility for a particular machine. This does not prevent Users seeking a second opinion where the need arises, though such action should be the exception rather than the norm.

Contractual arrangements

A4.7 Authorised Persons are required to comply with the 'Code and rules of conduct and disciplinary regulations for registered Authorised Persons (Sterilizers)' issued by the Institute of Healthcare Engineering and Estate Management. Management should ensure that no part of the contract, nor any subsequent instructions, conflict with the code and rules of conduct.

A4.8 A term of contract is suitable for the procurement of the services of an Authorised Person. The minimum term should be one year, although a five-year term has the advantage of greater continuity, enabling the appointee to become familiar with each of the sterilizers for which he or she is responsible. Casual appointments on a one-off basis are unlikely to foster the mutual confidence necessary for a consistent quality of service.

A4.9 The contract should specify the core responsibilities outlined above and further explained below (see paragraph A4.13). Provision should be made for extensions to the contract to include, for example, the duties associated with the validation of a new sterilizer or the introduction of a new product.

A4.10 Management may also require the Authorised Person to undertake additional duties outside the range of the core responsibilities. To enable this assistance to be given when needed, the contract should include the terms of payment for such additional work. Examples of additional services are given in paragraph A4.24.

A4.11 Formal lines of accountability should be made clear in the contract. The Authorised Person should normally report in the first instance to the user, who bears the day-to-day responsibility for the operation of the sterilizer.

A4.12 On appointment, the Authorised Person should be notified in writing of the names, addresses and telephone numbers of key personnel defined in Part 1 of this SHTM; namely, the Executive Manager of the contracting organisation, the user, the Competent Person, the Test Person, the Maintenance Person and the Microbiologist; and for medicinal products, the Production Manager and Quality Controller. The Authorised Person should be notified promptly in writing of any changes to this information.

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Core responsibilities

A4.13 The following are the core responsibilities that should be written into the contract.

General advice

A4.14 The Authorised Person is required to provide general and impartial advice on all matters concerned with sterilization. This will usually be provided in response to enquiries by telephone, post, fax or electronic mail, as appropriate. In some cases site visits may be required.

Validation programmes

A4.15 The Authorised Person is required to advise on programmes of validation for the processes for which he or she is qualified. These programmes should be based on the guidance given in Part 3 of this SHTM and any other regulatory requirements that may be specified.

Auditing of validation and yearly tests

A4.16 The Authorised Person is required to audit reports on validation, revalidation and yearly tests prepared by the Test Person.

A4.17 The Authorised Person should be given reasonable notice of the date of commencement any validation, revalidation or yearly tests which he or she is required to audit.

A4.18 Whether audits require a visit to the sterilizer is a matter of professional judgement dependent on the type of sterilizer, its operational history, the experience of the Test Person and the complexity of the performance qualification procedures. As a rule, site visits are recommended. However, since an Authorised Person cannot effectively audit a machine that he or she has not seen, site visits are essential on at least the following occasions:

a. for each sterilizer, before or during the first audit following appointment;
b. during the initial validation of a newly installed sterilizer.

A4.19 In order to perform this work effectively, the Authorised Person should have access to the sterilizer itself, the plant history file, the sterilizer process log and any other documentation bearing on the functioning of the sterilizer. He or she should also have reasonable access to the user, Test Person and other key personnel, and sterilizer operators. During site visits the Authorised Person should be provided with a quiet room in which to examine documentation.

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A4.20 Within an agreed period following completion of the tests as notified in paragraph A4.17, the Authorised Person should provide a report of the audit. The report should include the following information:

a. names of the user, Executive Manager and the Authorised Person;
b. details of the Test Person who carried out the work, including:
   (i) name;
   (ii) relevant qualifications;
   (iii) name of employer;
c. information for each sterilizer tested including:
   (i) identification of the sterilizer (including manufacturer, model and serial number and any inventory number);
   (ii) type of process;
   (iii) dates of manufacture, installation and validation;
   (iv) date of the audit;
   (v) a list of the tests carried out (validation, revalidation or yearly, as appropriate) and a statement as to whether each was satisfactory;
   (vi) a summary of the evidence that the test equipment used in the tests was properly calibrated;
   (vii) detailed comments on the outcome of the audit, especially if there is any evidence of deterioration in performance, with recommendations;
   (viii) a signed and dated recommendation as to whether the sterilizer should be considered fit for use.

A4.21 Where the Authorised Person has reason to recommend that the sterilizer is not fit for use, this information should be conveyed to the user before leaving the site, both in writing and (if possible) verbally, in advance of the full report.

Test and maintenance programmes

A4.22 The Authorised Person is required to advise on programmes of periodic tests and periodic maintenance. Advice should cover the following:

a. programmes of daily, weekly, quarterly and yearly tests, based on the schedules in Part 3 of this SHTM;
b. maintenance schedules, based on the guidelines in Part 4 of this SHTM;
c. implementation of written schemes of examination for pressure vessels issued by the Competent Person (Pressure Vessels).

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Operational procedures

A4.23 The Authorised Person is required to advise on operational procedures for routine production. Examples where advice may be needed include:

a. load design;
b. packaging;
c. product compatibility;
d. product release;
e. documentation;
f. safety;
g. training requirements;
h. compliance with legislation and standards.

Additional services

A4.24 Examples of services which would not be included in the core responsibilities may include:

a. advice on the planning, operation and quality control of whole departments;
b. delivery of training;
c. auditing of periodic tests at more frequent intervals (quarterly or weekly);
d. technical consultancy for tendering, equipment and services;
e. preparing procurement specifications for sterilizers and washer disinfectors;
f. risk assessments for health and safety purposes.

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Scottish Health Technical Memorandum 2010

(Part 5 of 6)

Good practice guide

Sterilization

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NHSScotland, P&EFEx, June 2001

Preface

SHTM 2010 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the following types of sterilizer in use in the National Health Service:

a. clinical sterilizers:
   (i) high-temperature steam sterilizers used for processing porous loads (including instruments and utensils wrapped in porous materials);
   (ii) high-temperature steam sterilizers used for processing aqueous fluids in sealed containers;
   (iii) high-temperature steam sterilizers used for processing unwrapped solid instruments and utensils;
   (iv) dry-heat sterilizers (hot-air sterilizers);
   (v) low-temperature steam (LTS) disinfectors and low-temperature steam and formaldehyde (LTSF) sterilizers;
   (vi) ethylene oxide (EO) sterilizers;

NOTE: Despite their name, LTSF sterlizers are disinfectors.

b. laboratory sterilizers:
   (i) high-temperature steam sterilizers used with one or more specialised operating cycles;
   (ii) culture media preparators.

No guidance is given on sterilization by irradiation, hydrogen peroxide, gas plasma or filtration. Users who wish to employ these processes bear the responsibility of ensuring that the validation procedures comply with the principles outlined in Part 3 of this SHTM and that the intended operating procedures will ensure an efficacious process for the different types of load.

This SHTM is intended primarily as a guide for technical personnel, whether specialists in sterilizers and sterilization procedures or those responsible for maintenance and testing. It is also intended for those responsible for the day-to- day running of sterilizers, and will also be of interest to supplies officers, architects, estates managers and others in both the public and private sectors.

Detailed information on the planning and design of a sterile services department, including the level of provision of sterilizers, is given in Scottish Hospital Planning Note 13; *Sterile services department*. Guidance for laboratory installations can be found in Scottish Hospital Planning Note 15; *Accommodation for pathology services*.

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Although this edition of SHTM 2010 reflects established sterilizer technology, it is recognised that considerable scope exists for the utilisation of emerging technology in the management of sterilizers. This will be kept under review with the aim of introducing recommendations for such technology at the earliest opportunity so that the procedures essential for the efficient, safe and effective operation of sterilizers can be optimised.

The sterilizers described in this SHTM may not be suitable, without modification, for safely processing articles infected with Hazard Group 4 pathogens nor agents, such as those associated with transmissable spongiform encephalopathies, which are unusually resistant to sterilization. Design considerations for sterilizers intended to process articles infected with such organisms are discussed in Part 2.

This part of SHTM 2010 contains detailed supplementary information that expands upon the guidance given in Parts 1 to 4 and should be read in conjunction with them.

NOTE: Information about Hazard Groups may be found in the HSC document 'Categorisation of pathogens according to hazard and categories of containment' (4th edition 1995) compiled by the Advisory Committee on Dangerous Pathogens.

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Section A

The lethality of heat sterilization processes – the F_0 concept

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A1. Introduction

A1.1 There are several, well established, time temperature relationships for thermal sterilization methods which are regarded as equally acceptable (see Part 3 of this SHTM, Table 8). Clearly temperatures other than those shown, when maintained for an appropriate time, will also be capable of producing a sterile product.

A1.2 For a moist heat sterilization process, we can expect a particular time at a particular temperature to have a predictable lethal effect against a standardised population of organisms. If we choose particularly resistant organisms and assume they are present in numbers in excess of that likely to be encountered in real product we can define standard exposure conditions which will always yield a sterile product in a correctly operated sterilizer. Actual exposures can then be related to these standard exposure conditions.

For example, in the laboratory it is possible to produce conditions where the time to attain a pre-selected sterilization temperature, and the time to cool to ambient temperature after sterilization, is so short that it may be disregarded: a so-called “square wave exposure” system. This will enable very accurate determinations of the thermal resistance of micro-organisms under well defined conditions, and from several such determinations at different temperatures an accurate determination of the change in thermal resistance with temperature to be made.

Operational sterilizer cycles do not produce this rapid heating and cooling but have relatively slow temperature changes. The product is thus exposed to temperatures somewhat below the chosen sterilizing temperatures for considerable periods. It is apparent that there will be some lethal effect on micro-organisms during the heating and cooling phases of any particular sterilization cycle since microbial death occurs over a wide range of temperatures, albeit at different rates.

The F_o concept recognises this and allows us to take account of the lethality obtained during the heating and cooling phases.

A1.3 For heat sensitive products it is desirable to minimise the heat treatment given to the product and reduce the energy input to a level which, while providing adequate assurance of sterility, will minimise the degradation of the product. Because the F_o concept allows us to take account of the inactivation of micro-organisms throughout the cycle, not just during the sterilization hold period, we can thus obtain a cycle with the required lethality but with minimum thermal degradation.

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A1.4 In summary, optimisation of thermal sterilization processes may be achieved by means of the *F* method which uses a knowledge of the lethality of the particular process at different temperatures to assess the overall lethality of the cycle and express this as the equivalent exposure time at a specified temperature.

A1.5 *F* is defined as the equivalent time in minutes at 121.1°C to produce a given sterilization effect.

A1.6 Where the specified temperature is 121.1°C (250°F) and the Z value is 10°C the term F_0 is used.

The F_0 value of a saturated steam sterilization process is the lethality expressed in terms of the equivalent time in minutes at a temperature of 121ºC delivered by that process to the product in its final container with reference to micro-organisms possessing a Z value of 10.

The total F_0 value of a process takes account of the heating up and cooling down phases of the cycle and can be calculated by integration of lethal rates with respect to time at discrete intervals.

A1.7 The F_0 method may be used for assessment, or control, of processes where difference in temperature is the only factor influencing the efficacy of the cycle. For example, it may be applied to the steam sterilization of aqueous fluids in sealed containers but it is not applicable to steam sterilization of porous loads where air removal is also a key factor and failure to achieve direct contact with Dry Saturated Steam can lead to failure, regardless of whether the required temperature was achieved within the load.

A1.8 Similar concepts are also used for dry heat sterilization processes and for depyrogenation by exposure to dry heat.

A1.9 There are a number of pre-requisites which it is necessary to consider before the use of the F_0 method is appropriate. These include:

- the efficacy of the sterilization process under consideration is dependent only on temperature eg. air removal is not critical. Thus in a porous-load steam sterilizer where impaired air removal can allow air to persist in random locations throughout the load, and where it may be present in sufficient quantity to impair sterilization, the use of the F_0 method for cycle control or monitoring is inappropriate;
- the sterilizer to be used has cycle control which is adequate to ensure that production cycles consistently reproduce the conditions established during validation. F_0 monitoring of a process may not be used to justify the use of a sterilizer which demonstrates excessive temperature variation within the load or poor reproducibility from cycle to cycle etc;
- temperature profile studies/validation studies have been conducted to establish the uniformity of conditions throughout load and to identify the location of those parts of the load which are slowest to heat up and fastest to cool down;

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- the loading composition and pattern of production cycles is controlled within the limits established during validation to ensure that the results obtained remain valid;
- production controls and bioburden studies are adequate to maintain a known, low level, of microbial contamination and the thermal resistance and temperature dependence (D and Z values respectively) of the most resistant contaminant(s) are known or the assumed values are in accordance with the Pharmacopoeial recommendations.

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A2. Fundamental concepts

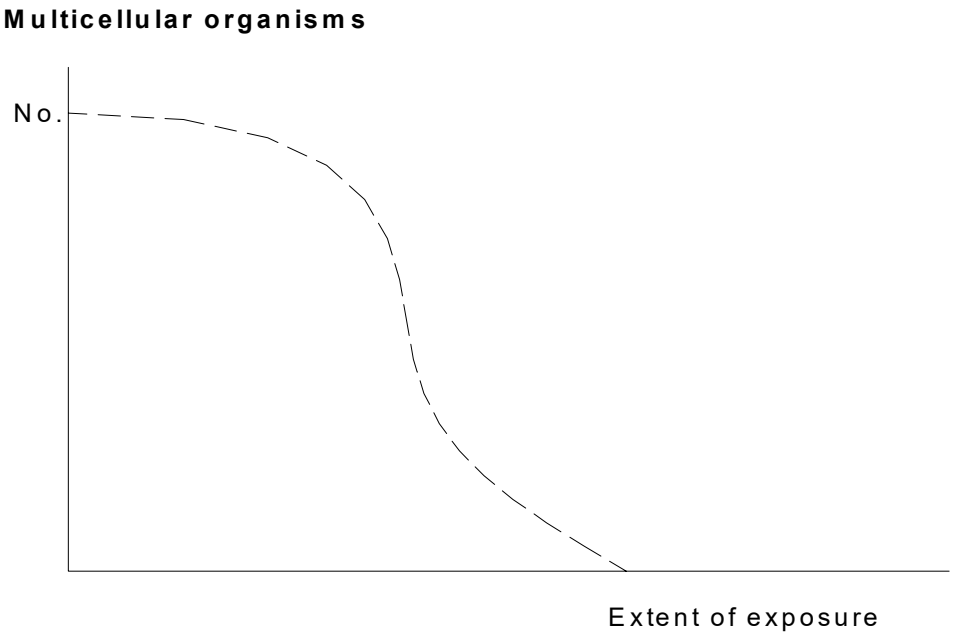
A2.1 In order to use the F_o concept correctly it is important to understand the facts, definitions and assumptions on which the model is based. It has become common place to use certain functions and terms in the analysis and interpretation of data on the effect of physical or chemical stress on microbial survival. These terms are discussed below.

How microbes die: the logarithmic order of death

A2.2 Organisms which die as a result of an imposed stress die in an orderly, and predictable, manner. This can be represented as survivor curve, showing the number of organisms still living at various times after the beginning of exposure to the stress condition.

A2.3 The order of death is, in principle, the same for all multicellular organisms. The survivor curve remains constant for as long as individuals can recover from that length of exposure; then as the first individuals die, the frequency of death rapidly increases until only a few very resistant organisms remain, and they succumb shortly after the majority of the population (see Figure A1). In a unicellular organism the individual is dead when a single cell dies, whereas in multicellular organisms the death of one cell is not likely to kill the individual. The multicellular organism will survive until enough cells have been killed to cause death.

Figure A1: Arithmetic survivor curve for multicellular organisms



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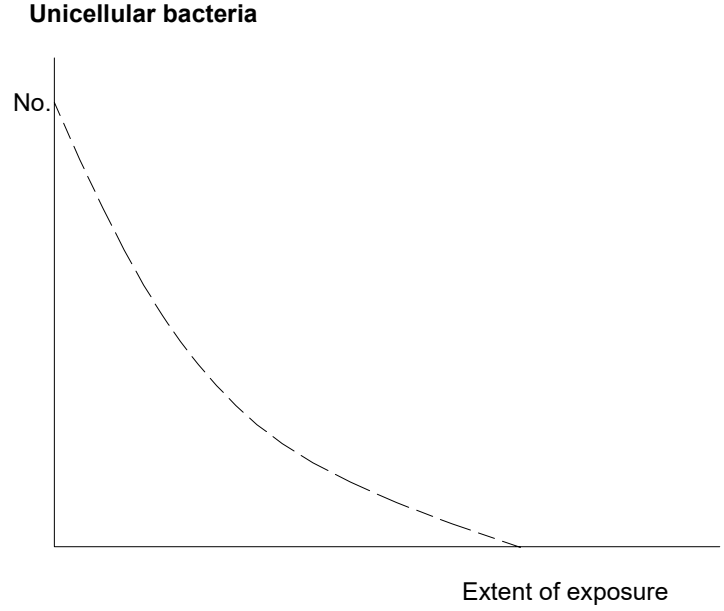
A2.4 Whichever multicellular organisms are tested, for example insects or plants, and whatever the lethal stress, the survivor curve remains essentially the same. This was accepted as universally true for all organisms until the early 1900s when workers such as Harriet Chick [see Chick (1908)] showed that in an homogeneous culture of a single strain of bacteria the cells died at a constant rate when exposed to a particular lethal stress.

A2.5 It was apparent that these bacteria were dying in a manner which was somewhat unexpected. This may be illustrated by taking as an example the survival of microbial spores subjected to heat stress. An experiment may be devised in which all factors other than the heating time are held as constant as possible. If a number of biological indicators, each bearing a known number of bacterial spores, are subjected to a thermal sterilization process, at a predetermined temperature for various increments of exposure time, and then the survivors on each indicator enumerated, the data obtained shows the number of colony forming units remaining viable after each exposure time.

A2.6 A survivor graph can be prepared showing the number of survivors as a function of the length of heating time. Both the number of survivors and the time may be plotted on an arithmetic scale (see Figure A2).

Figure A2: Arithmetic survivor curve for unicellular bacteria



A2.7 Alternatively the number of survivors may be plotted on a logarithmic scale as a function of time on the arithmetic scale, which is referred to as a semi-log survivor curve (see Figures A3 and A4). While both the arithmetic and semi-log survivor curves accurately represent the death of bacteria the latter is more useful in sterilization studies where interest is concentrated on the rate of destruction as the number of survivors approaches zero.

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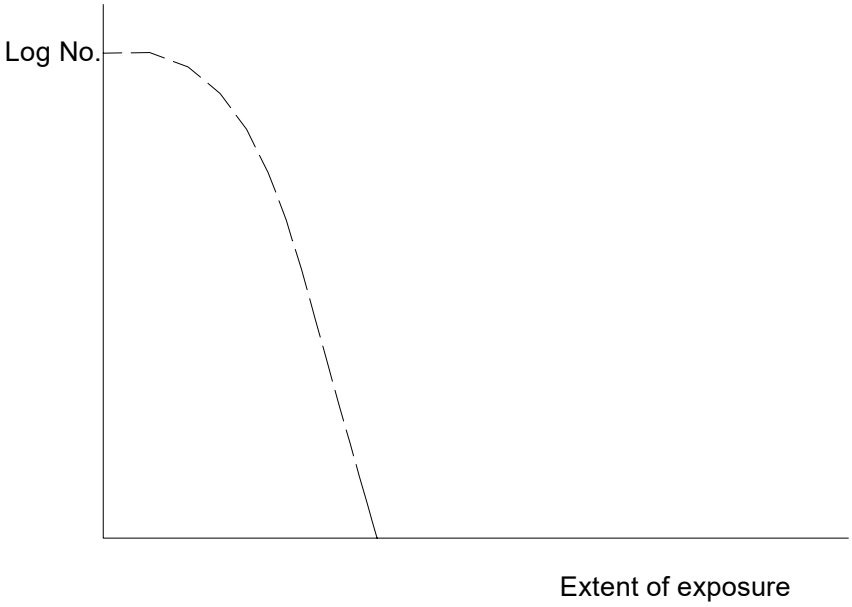
Figure A3: Semi-log survivor curve for multicellular organisms

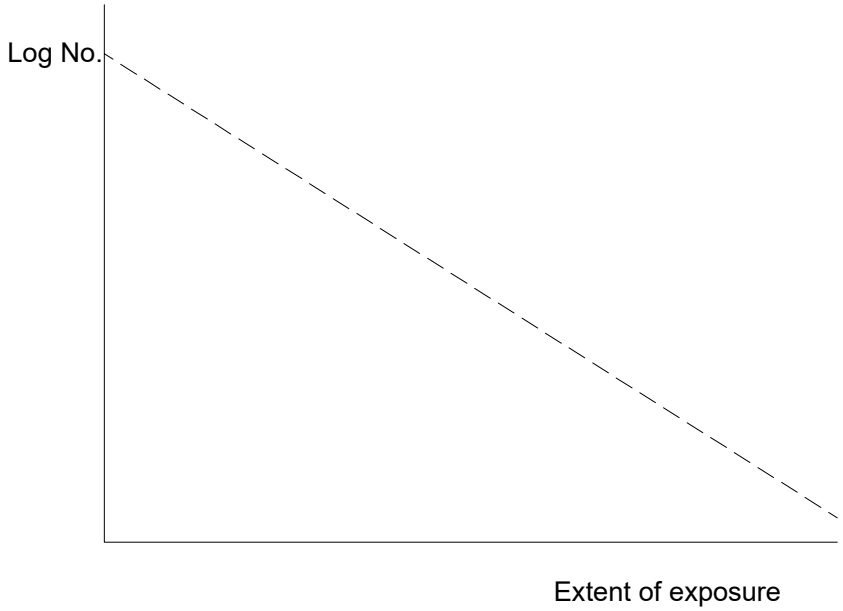
Multicellular organisms



A2.8 It is usual to use the latter approach since in sterilization studies we are interested in the rate of destruction as the number of surviving micro-organisms approaches zero, which is best shown using a logarithmic plot.

Figure A4: Semi-log survivor curve for unicellular bacteria

Unicellular bacteria



A2.9 Experience has shown that the semi-log survivor curve for heat stress often approximates to a straight line for part or all of the survivor curve. However there are many recorded instances where deviations from the “ideal” straight line condition occur (see Figure A5).

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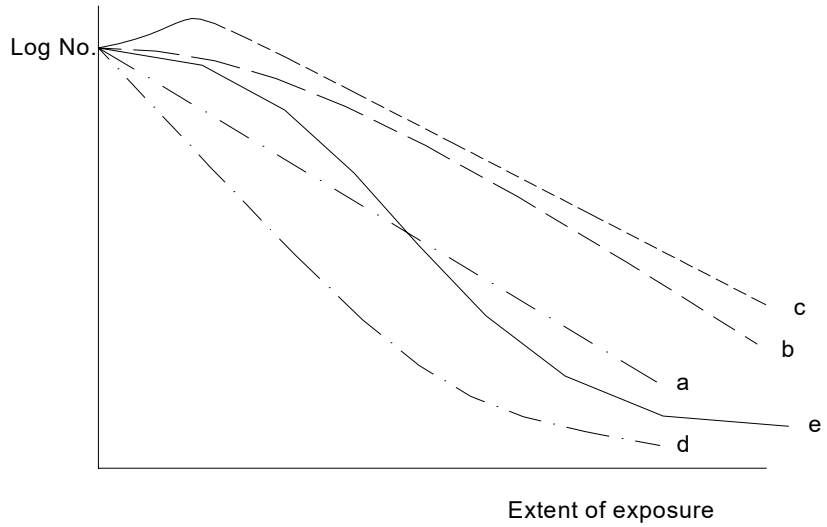
Figure A5



Microbial survivor curves showing typical deviations from the linear model; curve **a** is a theoretical linear survivor curve; curve **b** shows an initial "shoulder" followed by a linear survivor curve; curve **c** shows an initial increase in count, "activation", followed by a linear survivor curve; curve **d** shows an initial linear survivor curve followed by a decreasing rate of kill, "tailing"; curve **e** shows the sigmoidal survivor curve often encountered in experimental determinations.

Conditions resulting in a non-logarithmic order of death

A2.10 Typical survivor curves for bacterial spores exposed to moist heat sterilization processes are shown in Figure A5 in which the logarithm of the number of surviving organisms is plotted against time and various types of response are illustrated:

- *Curve a* – exponential – constant fraction of the population is inactivated per unit time;
- *Curve b* – shows an increasing death rate after an initial period where there was little or no inactivation – a "shoulder";
- *Curve c* – initial activation (increase in population) followed by a constant death rate;
- *Curve d* – decreasing death rate with a low number of highly resistant organisms surviving for a prolonged period – "tailing";
- *Curve e* – a sigmoidal survivor curve of the type frequently encountered in experimental determinations of resistance. This type of survivor curve may be regarded as a composite of elements of the survivor curves described above.

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Factors influencing the nature of the survivor curve

A2.11 There are a number of factors which have a significant effect on the nature of the survivor curve. Workers such as Moats *et al* (1971) have discussed these factors in detail. Some of the key factors can be summarised as follows:

- *Growth index*. During recovery there are many instances when not all viable spores will germinate and outgrow within a short time period. The percentage of those present which do germinate and grow immediately on incubation is referred to as the growth index. The growth index varies both with the species of bacterial spore and the cultural conditions in which it was grown and is to be recovered. It may be as high as 100%,for example for Bacillus subtilis, but may be as low as <1%, for example for Bacillus stearothermophilus. Sublethal heating may increase (activate) or decrease (deactivate) the growth index and give rise to non-linear survivor curves. [see Favero (1967), Finley and Fields (1967)] The interaction of activation and inactivation on the thermal treatment of heat resistant dormant spores of B stearothermophilus can be described mathematically. [see Shull *et al*. (1963)]
- *Cell clusters*. The usual method of counting the number of surviving bacteria is by the plate count method which gives the number of colonies developed from a known volume of suspension inoculated onto the surface of solid growth medium. The number of colonies is equal to the number of bacteria present only when each colony arises from a single cell.

  When the cells are in clusters, for example Staphylococcus spp., or in chains, for example Streptococcus spp., one colony may represent a large number of cells. All the time there are one or more surviving cells within the aggregation a colony will be formed and death therefore becomes evident only when the last cell is dead. Such clusters “die” like multicellular organisms and show convex survivor curves (see Figures A3 and A5, curve b).
- *Cell age*. It has been demonstrated that young cells, that is, the exponential growth phase of a culture, are more susceptible to both chemical and physical stress than old cells from the stationary phase of a culture. Furthermore if old cells are transferred to a new environment they do not all begin to grow at the same time and a culture develops in which both old and young cells coexist leading to heterogeneous resistance and concave survivor curves (see Figure A5, curve d).
- *Mixed populations*. Where more than one strain or species is present, with different resistances to the lethal stress being imposed, a non-linear survivor curve, typically of concave form, will arise (see Figure A5, curve d).

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Factors influencing the heat resistance of spores

A2.12 Any assessment of thermal resistance of micro-organisms must involve consideration of those factors which may affect the thermal resistance.

A2.13 These factors include the species and strain of organisms to be considered; its physiological state, which will in part depend on its immediate cultural history, the manner in which it is presented to the sterilization process, for example the suspending menstruum; and the recovery conditions which are used in an attempt to grow the organism after exposure to the process; as well as the exposure conditions used, for example whether dry heat or moist heat (direct contact with dry saturated steam or being in an aqueous solution) was used, and the exposure temperature. [see Russell (1971).]

A2.14 The nature of the product also affects the thermal resistance of contaminating organisms; the protective effects of various salts and carbohydrates in solution are well documented in the literature.

A2.15 The influence of changes in the manufacturing environment and/or process on the nature and extent of contaminating micro-organisms must also be considered.

Treatment of sterilization-process microbial survival data

A2.16 A mathematical approach to the resistance of bacteria to thermal death is required to allow calculation of equivalent lethality. Two factors need to be considered; the thermal resistance of the micro-organism at a particular temperature and the change in that resistance which occurs with changes in temperature.

These two factors are analogous to the rate constant and temperature coefficient of a chemical reaction, respectively.

A2.17 Spore inactivation in moist heat may be considered as a monomolecular first order reaction, that is where the rate of reaction is governed by the concentration of the reactant, in this case the bacterial spores.

This may be expressed as

$$\frac{dN_a}{dt} = k\,C_a$$

Where t = time,

C_a = spore concentration

k = a reaction rate constant at constant temperature

Then $(\log C_a^0 - \log C_a) = k\,(t - t^0)$

where the superscript 0 indicates initial conditions.

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A2.18 A semi-logarithmic plot of concentration versus time will yield a straight line of slope k. k has dimensions of time^{-1}. The negative reciprocal of the rate constant k is equivalent to the number of minutes required to inactivate 90% of the organisms present, that is a 1 log reduction. This value is referred to as the D value and, as stated, mathematically it is inversely proportional to the inactivation rate constant k.

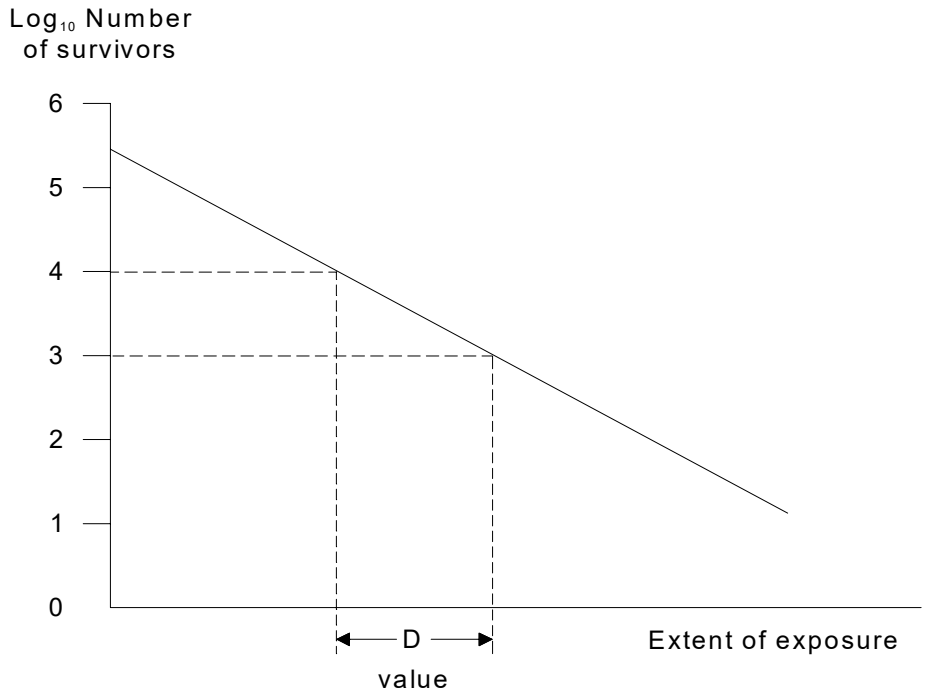
D = 2.303 /*k*.

Decimal reduction value (D value)

A2.19 The D value is used as a measure of the resistance of a defined micro-organism to a defined sterilization process. It is a convenient way to describe the slope of a linear semi-log survivor curve.

A2.20 More particularly it may be defined as the extent of exposure, under stated conditions, necessary to produce a 90%, or 1 log, reduction in the bacterial population (see Figure A6). It is usually stated in minutes, except for sterilization processes using ionising irradiation where it is given in kiloGreys (units of absorbed radiation dose).

Figure A6: Decimal reduction value



A2.21 For moist heat sterilization processes it is often given a subscript to indicate the temperature at which it was determined, for example D_{121}. Although this in itself is insufficient definition of the conditions under which the determination was made to allow valid comparison.

A2.22 The D value is highly specific to the experimental conditions under which it was determined. Even apparently minor changes in experimental procedure,

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for example incubation temperature, recovery medium can have a dramatic effect on the apparent D value.

A2.23 The D value is only relevant to the survivor curve when the survivor curve is truly a straight line over the range of population values of interest, including the “probability” zone.

A2.24 It is not necessary to construct a survivor curve to determine D value The determination may be done by a replicate unit method involving fractional-unit- negative (FN) data. A number of replicates are heated for a certain time and the number viable and the number sterile are determined. [see Pflug and Schmidt (1968).]

Then where r = total number,
p = growth,
q = sterile,
U = time in min,
N_0 = initial population per replicate unit
N_U = population per replicate unit after time U,

then

$N_U = \log_n(r/q) = 2.303 \log (r/q)$

and

$$D = \frac{\textit{duration of treatment}\ (\min)}{\log \textit{initial no} - \log \textit{final no of spores}}$$

$$= \frac{U}{\log N_o - \log N_U}$$

The temperature dependence of resistance

A2.25 A common measure of the temperature dependence of a chemical reaction is the Q_{10} value. This is defined as the change in reaction rate constant k for a 10°C change in temperature:

$$Q = \frac{k^{(T + 10^{\circ} C)}}{k_T}$$

A2.26 For most chemical reactions Q_{10} has a value of about 2, but for spore inactivation in moist heat $Q_{10} \approx 10$ to 18 and for spore inactivation in dry heat $Q_{10} \approx 2.2$ to 4.6.

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A2.27 Other measures of temperature dependence include the Arrhenius equation;

$$k = A \exp(-E_A(RT)^{-1})$$

Where k = the reaction rate constant;
A = the frequency factor;
E_A = the activation energy;
R = the universal gas constant;
T = the absolute temperature.

A2.28 However, the temperature dependence of reaction rates for spores is generally expressed as a Z value,

Where $$Z = \frac{\log Q_{10}}{10}$$

or $$Z = 2.303RT^2E_A^2$$

Z value

A2.29 The *Z* value is a measure of the change of inactivation rate with temperature. It is the slope of a plot of *D* value on a logarithmic scale against temperature on an arithmetic scale (see Figure A7).

A2.30 The *Z* value allows comparison of the lethal effect of heating at different temperatures. [See Bigelow (1921).]

A2.31 As originally defined *Z* is numerically equal to the number of degrees Fahrenheit change in temperature required to reduce the *D* value by 90%, or 1 log. Considerable confusion, and error, can be caused where the temperature scale used is not specified. Although values are now usually given in °C care must be taken when using published data, for example from the official compendia, to note whether the *D* value is quoted in °F or °C.

A2.32 The mathematical relationship with the D value can be expressed as:

$$\log D_2 - \log D_1 = \frac{(T_1 - T_2)}{Z}$$

A2.33 It should be noted that, the greater the *Z* value, the greater the increase in temperature which is required to give a tenfold decrease in *D* value. Hence the assumption of a *Z* value higher than in fact exists will give an additional margin of safety. The *Z* value assumed for most thermophiles, such as Bacillus stearothermophilus, is 10°C.

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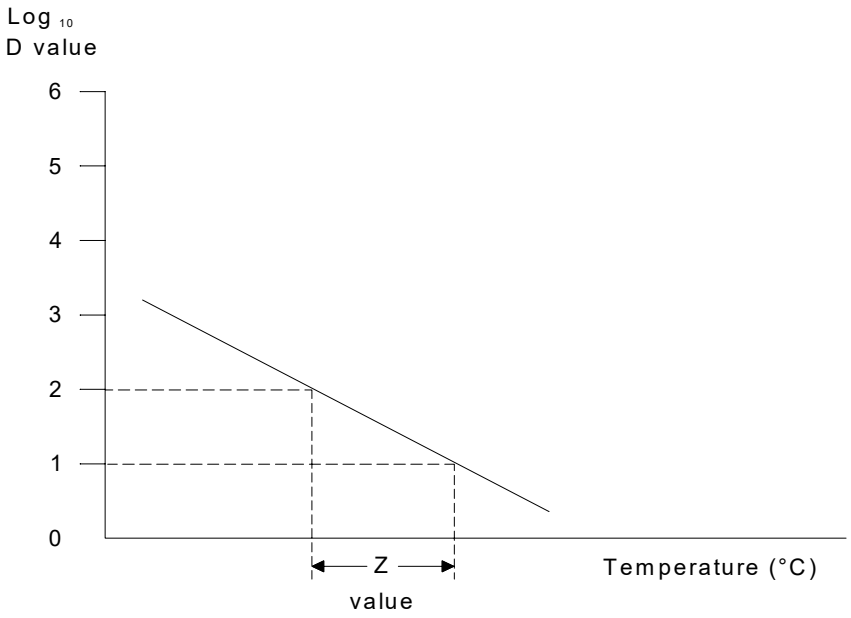
Figure 7: Thermal resistance curve



A2.34 The straight-line relationship holds good only over a limited temperature range for an homogenous culture of a single strain of micro-organisms. Mixed cultures give a non-linear relationship, but in practice one sub-population, either by virtue of its resistance or its prevalence, will be controlling with regard to attainment of sterility.

Lethal rates

A2.35 The usefulness of the temperature dependent model lies in being able to calculate the lethality over a range of temperatures, which will include those experienced during heating-up and cooling-down of a load in a steam sterilizer.

A2.36 The relative lethality at a temperature, T_{exp}, compared to the known lethality at a particular reference temperature, T_{ref}, is dependent on the *Z* value.

Thus, the lethality L is given by the equation

$$L = 10^{(T_{exp} - T_{ref}) Z^{-1}}$$

Lethality factors for any temperature deviation from the reference temperature and for any *Z* value can be calculated using this formula (see Table A1).

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A2.37 A new variable *F*, the thermal death time can be defined. The change in *F* with temperature is analogous to the change in thermal resistance (*D* value) with temperature and both are dependent on the *Z* value. Plots of log *D* versus temperature and log *F* versus temperature both have slope Z:

$$\frac{D_T}{D_{121}} = \frac{F_T}{F_{121}} = 10^{(T-121)/Z}$$

F value

A2.38 The *F* value expresses heat treatment in terms of the equivalent effect of a stated time at some stated temperature for a particular Z value, that is to say that the *F* value is the equivalent time in minutes at 121.1°C (250°F) for an organism of specified *Z* value.

A2.39 F_0 is the *F* value when *Z* is 18°F (10°C):

$$F_0 = \sum 10^{(T-121)/Z} \Delta t$$

where t is the chosen time interval, and T is the temperature in the container.

NOTE: For dry heat *F* values, *F* is equal to the time in minutes at 176°C (350°F).

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Table A1: Lethality factors for a Z value of 10°C

Temperature difference °C	Lethality factor minutes*	Temperature difference °C	Lethality factor minutes*
-20.0	0.0100	+20.0	100.000
-19.0	0.0126	+19.0	83.180
-18.0	0.0159	+18.0	66.070
-17.0	0.0200	+17.0	52.480
-16.0	0.0251	+16.0	41.690
-15.0	0.0316	+15.0	31.620
-14.0	0.0398	+14.0	25.120
-13.0	0.0501	+13.0	19.950
-12.0	0.0631	+12.0	15.850
-11.0	0.0794	+11.0	12.590
-10.0	0.1000	+10.0	10.000
-9.0	0.1259	+9.0	8.318
-8.0	0.1585	+8.0	6.607
-7.0	0.1995	+7.0	5.248
-6.0	0.2512	+6.0	4.169
-5.0	0.3162	+5.0	3.162
-4.5	0.3548		
-4.0	0.3981	+4.0	2.512
-3.5	0.4467		
-3.0	0.5012	+3.0	1.995
		+2.8	1.905
-2.5	0.5623	+2.6	1.820
		+2.4	1.738
		+2.2	1.660
-2.0	0.6310	+2.0	1.585
		+1.8	1.514
-1.5	0.7079	+1.6	1.445
		+1.4	1.380
		+1.2	1.318
-1.0	0.7943	+1.0	1.259
		+0.8	1.202
-0.5	0.8913	+0.6	1.148
		+0.4	1.096
		+0.2	1.047
0.0	1.0000	0.0	1.000

Lethality L is given by $L = 10^{(T_{actual} - T_{reference}). Z\text{-}1}$

* Lethality factor is given in minutes equivalent at the reference temperature.

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A3. Sterility

A3.1 In order to utilise the F_0 method it is first necessary to decide on the extent of treatment which will be necessary to provide the required level of assurance that the product is sterile. Several different definitions are in common use.

Sterility assurance

A3.2 If the survivor curve is extrapolated beyond $\log_{10}0$, that is one surviving organism, we reach a region of "probability" of finding a single surviving organism. For example at $\log_{10}[-1]$ we expect to find, not 0.1 organisms surviving in every sample but, one in every ten samples with a surviving micro-organism.

We can thus determine from the survivor curve a theoretical probability of any one unit of product being non-sterile.

A3.3 The standard, BS EN 556, in common with a definition in the *European Pharmacopoeia*, states that a product may be regarded as sterile when the theoretical level of not more than one micro-organism is present in 1×10^6 sterilized units of the final product.

A3.4 This calculation may be based on data, obtained by investigation, on the extent and resistance of microbial contamination immediately prior to sterilization (the Bioburden) or on a theoretical contamination of 10^6 micro-organisms per unit of product presumed to be of a type having known high resistance to the process, for example bacterial spores. In the latter case the cycle is often referred to as a "12D" or "overkill" cycle and was first proposed by Esty and Meyer (1922) for processing low-acid canned food products.

A3.5 The *British Pharmacopoeia* in Appendix XVIII 'Methods of Sterilization' states: "For aqueous preparations sterilized by heating in an autoclave the preferred combination of temperature and time is a minimum of 121°C maintained throughout the load during a holding period of 15 minutes." However, it goes on to say: "Other combinations of time and temperature may be used provided that the process chosen delivers an adequate level of lethality when operated routinely within the established tolerances."

A3.6 In Annex 2, 'Guidance on application of the F_0 concept to aqueous preparations', the British Pharmacopoeia suggests that "in general for aqueous preparations a microbiologically validated steam sterilization process that delivers, in total, an F_0 value of not less than 8 to every container in the load is considered satisfactory".

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A3.7 In certain circumstances, however, use of a steam sterilization process that delivers, in total, an F_0 of less than 8 may be considered justifiable, for example where the product is especially heat sensitive. The nature of processes delivering an F_0 of less than 8 is such that great care must be taken in order to ensure that adequate assurance of sterility is consistently achieved. It is necessary not only to validate the process microbiologically but also to perform continuous, rigorous microbiological monitoring during routine production to demonstrate that the microbiological parameters are within established tolerances so as to give a theoretical level of not more than one living micro-organism per 10^6 containers in the final product.

A3.8 The *European Pharmacopoeia* also states that the recommended method for parenteral products is moist heat sterilization at a minimum of 121°C maintained throughout the load for a minimum of 15 minutes. Other time temperatures can be used but the crucial requirement is delivery of an adequate level of "lethality" to the product. The use of F_o is recognised with an F_o of 8 being the usually acceptable minimum. It is emphasised that this requires a low pre-sterilization bioburden and the absence of heat resistant spores.

Calculation of F_0 values

A3.9 Reliable F_0 value calculations are simply achieved with modern microprocessor based control and monitoring systems. However F_0 values can be calculated manually, and many of the available computer programs employ essentially similar methods:

a. *Graphical method*. In the graphical method *F* reference paper is used on which the lethal rate per minute, at particular temperature, is represented by length on the vertical axis. The horizontal axis has a corresponding arithmetic scale for time such that the area of a rectangle delineated by the ordinate 121.1°C and a length corresponding to one minute on the abscissa is equal, by definition to an F_o of one. The cumulative area under the curve as the cycle progresses represents the cumulative lethality of the process (see Figure A8). In practice the temperature profile is plotted and the area under the curve determined using a planimeter. The area measured is then converted to an F_o value using the scale of the *F* reference paper.

b. *Summation method*. In the summation method the lethal rate at each specific temperature is calculated or read from a table (see Table A1) and multiplied by the time for which that temperature persisted. The values obtained for each temperature are summed to give the overall F_o value for the cycle.

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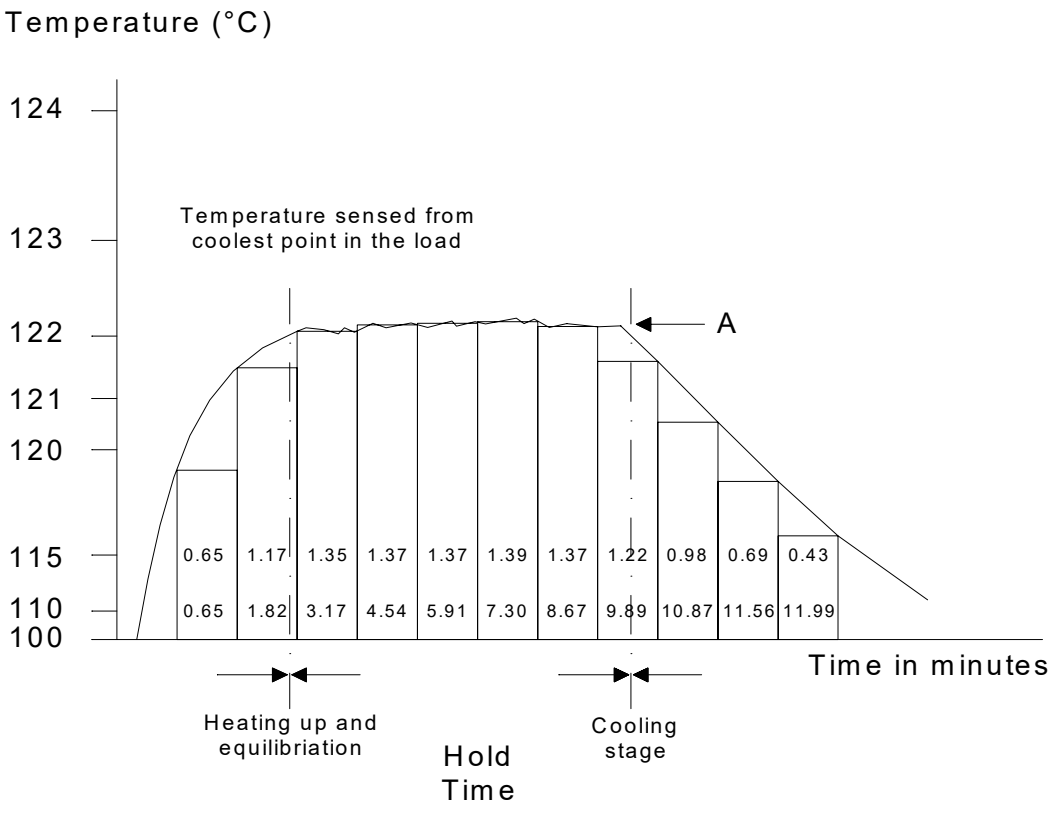
A3.10 The accuracy of the integration is affected by a number of factors.

These include:

- the choice of time interval between successive temperature measurements. BS 3970 Part 2 specifies a maximum interval of two seconds;
- whether the minimum, maximum or average temperature during the chosen time interval is used. (Since the method is an approximation based on summing discrete data to represent continuous data there will always be some error, which may be positive or negative; each may be correct for different purposes);
- the location of the sensor(s) from which the temperature is read and the adequacy of the validation of sensor location;
- should be used only over the temperature range for which *Z* has been determined. The *Z* value for any micro-organism does not remain constant over all possible temperatures. Therefore any particular lower temperature limits for the integration need not be set since, for a Z value of 10, F_0values below 105°C make so little contribution. For example, 40 minutes exposure at 105°C is equivalent to one minute at 121°C.

Figure A8: Graphical determination of F_0 values



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The ordinate scale (temperature) of *F*-reference paper is proportional to the lethal rate so that the area beneath the curve is a measure of the *F* value. The cumulative values during the cooling stage are not used for sterilizer control but may be used in monitoring to provide an accurate assessment of the overall lethality delivered by the sterilization cycle. Within each box the figures in italics indicate the F_0 value calculated for that time-temperature rectangle. The lower figures indicate the cumulative F_0 value through the cycle. The F_0 controller, set to provide an F_0 value of 9, initiates the cooling stage at point A. The total monitored F_0 value of the cycle is 11.99.

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A4. Applications of the F_0 concept

General

A4.1 Part 3 of this SHTM states that if a fluid sterilizer is fitted with an F_0 integrating system, then the recorder should be capable of computing and printing values of F_0 for each channel with integration times no greater than 2 s. This is also a requirement of BS 3970: Part 2.

Control of sterile cooling fluid (in a steam sterilizer for fluids in sealed containers)

A4.2 It is a requirement that if the coolant is derived from a water or steam service and is intended to come into contact with the load containers, the operating cycle must expose the coolant to sufficient heat to ensure that it is free of microbial contamination by the end of the holding time. This is checked by calculating an F_0 value for the heat treatment received by the coolant. If the test recorder is not capable of calculating F_0 both BS 3970 and Part 3 of this SHTM recommend the following procedure:

a. from the measured temperatures, identify the point during the heat-up time at which the coolant temperature first reaches 108°C. Note the temperature (T°C) at subsequent one minute intervals until the end of the holding time;

b. for each measurement, calculate the incremental F_0 (ΔF_0) from the following equation:

$$\Delta F_0 = \log_{10}\left[\frac{T - 121}{10}\right] \text{ minutes}$$

where T is the lowest temperature of the coolant water for each one minute time interval

c. the F_0 value is the sum of all ΔF_0.

The test should be considered satisfactory if the F_0 for the coolant is not less than 8 minutes.

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F_0 controlled sterilizers – Control of operating cycles in steam sterilizers for fluids in sealed containers

A4.3 The operating cycle for steam sterilizers used to process aqueous fluids in sealed containers may be divided into several stages.

1. heat up (and, where necessary, air removal) – the chamber atmosphere attains the required temperature;
2. equilibration time – all parts of the load attain or exceed the minimum temperature of the sterilization temperature band;
3. holding time – all parts of the load are maintained at a temperature within the sterilization temperature band;
4. cooling stage – the load is cooled to a temperature at which it will be safe to handle.

A4.4 Stages 2 and 3 may be controlled by one of the following:

a. adjustable timers of an automatic controller in conjunction with temperature sensors within the active chamber discharge and within containers of the load;
b. a simulator control system;
c. an F_0 system.

A4.5 Provision for adjustment of the equilibration time (stage 2) is necessary and may be achieved by one of the following:

a. an operator adjustable timer on the instrument panel;
b. a simulator control system;
c. an F_0 integrating system.

A4.6 When an F_0 control system is fitted, the control function should be limited to the initiation of the cooling stage (stage 4) once a selected F_0 value has been attained.

A4.7 In addition to the minimum requirement of two temperature sensors (see 13.1.4 of BS 3970 Part 1) two further temperature sensors shall be provided for use in two load containers.

A4.8 The control system shall be designed to integrate from the temperatures sensed within containers of the load at selected locations at time intervals not exceeding 2 seconds.

A4.9 The range of F_0 values selectable shall include 1 to 30.

A4.10 When tested in accordance with Test method 1, the Individual values of F_0 determined using the reference instrument shall be within the ranges stated in Table A2 for each of the F_0 values indicated by the sterilizer under test.

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Table A2: Permitted Ranges For F_0 Values

F_0 value indicated by sterilizer under test	Permitted range for F_0 values determination by the reference instrument*
1	1 to 1.05
15	15 to 15.7
30	30 to 31.5

* The reference instrument is described in Test method 2

Monitoring operating cycles in steam sterilizers for fluids in sealed containers

A4.11 For aqueous products in sealed containers temperatures are measured (with thermocouples or RTDs) throughout the heating and cooling stages as well as during the sterilization hold period. The slowest container to heat and the fastest container to cool may be used to determine the minimum lethality received by the load. these locations are often found in different locations.

A4.12 Determination of the maximum temperatures in the load may also be necessary for thermolabile products where deterioration may be a problem.

A4.13 It is essential that during commissioning and validation it is established that the position of containers which need to be monitored remains consistent from cycle to cycle. A sterilizer where the slowest part of the load to reach temperature is found in different parts of the load on successive cycles is not suitable for control or monitoring by F_0 values and is in urgent need of skilled attention. For air-ballasted sterilizers this may involve additional requirements on monitoring the circulation of the chamber atmosphere to ensure that the location of the cool point remains constant.

A4.14 Calculation of the F_0 value delivered by a process may be estimated from the lowest temperature-time curve registered from the containers in the load. The process is satisfactory if the registered F_0 value is within the minimum and maximum limits established during validation.

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Validation of operating cycles in steam sterilizers for fluids in sealed containers

A4.15 The use of F_0 control or monitoring systems places additional requirements on the validation process.

A4.16 As described in Part 3 of this SHTM, paragraph 8.4 'Sterilizer function using a full load' '... the temperature of all sites monitored within the load ..... shall be within 1°C of each other throughout stage 3'. This requirement applies regardless of whether an F_0 system is used.

Container cool point

A4.17 Container mapping is necessary to determine the container cool point. Container mapping studies should be conducted prior to conducting loaded chamber heat penetration studies in order to determine the position within the liquid-filled container which is slowest to attain temperature.

A4.18 Small volume containers and those of cylindrical form where the length:diameter ratio is large are the least likely to demonstrate a detectable cold spot.

The number of thermocouples within the container should be sufficient to monitor the upper, middle and lower layers of the central region of the container. Using an excessive number of temperature probes may introduce significant errors in the determination.

A4.19 The profile point requiring the longest exposure time to equilibrate with the chamber temperature should then be used in subsequent F_0 studies and monitoring (but see later for degradation/product stability considerations).

A4.20 Suitable container entry systems for the insertion of temperature probes into sealed containers are described in part 3 of this SHTM (Figure 3).

A4.21 Independent measuring equipment should be to the standard described in part 3 of this SHTM, Chapter 6.

A4.22 The test should be carried out as described in part 3 of this SHTM for a thermometric test for a full load (see paragraph 14.10) except that the load should be containers of the type and number to be used in practice and filled with the product to be sterilized or a suitable substitute with similar thermal characteristics, (see paragraph A4.31 below).

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Load cool point

A4.23 It is necessary to determine the coolest point within a specified load type and configuration of load. Cool points arise because of varied rate of heat transfer throughout the load and studies are needed to ensure that the cool points are identified so that they may be exposed to sufficient heat lethality.

A4.24 The study is carried out in the same manner as the performance qualification described in part 3 of this SHTM (see paragraphs 8.13 to 8.28 performance qualification).

A4.25 Similar studies may be used to identify those containers which attain temperature maxima or most prolonged exposure to the equilibrium temperature for product degradation and/or stability studies.

A4.26 The F_0 value for the process may then be determined by integrating the lethal rates throughout the heating process using one of the methods previously described.

Microbial challenge studies

(See also part 3 of this SHTM paragraphs 8.29 to 8.36)

A4.27 Biological challenges may be used during validation studies in order to demonstrate the process lethality provided by the sterilization cycle. Calibrated biological indicators used for this purpose act as bioburden models and can be used in obtaining data to calculate F_0 values delivered by the cycle or to supplement physical temperature measurement, for example from thermocouples.

A4.28 The number of spores to be used in the BI can be calculated from the following formula

$$D_{prod} (\log N_{prod} + 6) = D_{bi} (\log N_{bi} + 1)$$

Where D_{prod} = the resistance of the most resistant organism in the product bioburden;

N_{prod} = the number of organisms in the product to be sterilized;

D_{bi} = the resistance of the BI organism;

N_{bi} = the number of organisms on the BI.

A4.29 Designated liquid-filled containers are inoculated with the indicator organism by injecting an aliquot of a calibrated spore suspension into the suspending menstruum to provide the calculated concentration of spores. The containers chosen should be those previously established by temperature measurement as having the lowest delivered lethality.

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A4.30 The suspending menstruum should be the product to be sterilized unless this contains preservatives, antimicrobials or other substances which inhibit the growth of the indicator micro-organisms.

A4.31 If it is necessary to use a product substitute it should be selected to have similar physical characteristics to the product this should include heat capacity (specific heat), density, viscosity, thermal conductivity.

A4.32 Great care needed when using inoculated product to minimise the possibility of contaminating the production environment.

A4.33 Microbial challenge studies should be conducted concurrently with heat penetration studies.

Product degradation and stability versus cycle lethality

A4.34 When heat-sensitive thermolabile products are to be sterilized it is important that adequate assurance of sterility is not obtained at the expense of product degradation or stability.

A4.35 For sterilization the temperature dependence of the process is described by the Z value, that is the change in temperature required to give a tenfold change in the rate of microbial kill. Increasing or decreasing the temperature of the process requires a corresponding decrease or increase in exposure time to maintain the same cycle lethality or F_0 value.

A4.36 For any given temperature, microbial death and chemical degradation take place at different rates. The relationship between time and temperature which exists for microbial lethality cannot be extrapolated to the product degradation reaction.

A4.37 If the degradation reaction is not altered significantly by the change in temperature the extent of degradation will increase as process (exposure) time is extended. Conversely, if the degradation reaction is highly temperature dependent (high activation energy) a decrease in temperature may more than compensate for the increase in time, resulting in less degradation.

A4.38 The key variable is the activation energy, E_A . If the activation energy for the chemical degradation reaction is lower than that of the microbial death curve, that is it is less temperature dependent, then it can be assumed that a decrease in sterilization temperature will result in greater product degradation.

A4.39 Furthermore it cannot be assumed that sterilization cycles of equivalent lethality, but which differ with regard to time and temperature, will yield product of equal quality.

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A4.40 The assumption that degradation reactions follow first-order reaction kinetics is probably a good approximation in most cases where a single active drug product is contained in the solution.

A4.41 Experience has shown that a decrease in sterilization temperature can have a marked deleterious effect on product and its long term stability.

A4.42 Sterilization of glucose solutions in plastic containers may require a sterilization temperature in the range 115-118°C in order to protect the thermolabile container. The increased time required for sterilization compared with a traditional cycle at 121°C used for similar solutions in glass bottles results in a noticeable increase in caramelization.

A4.43 The activation energy of the lethal reaction for bacterial spores with a *Z* value of 10°C is high (typically around 60 kcal/mole) compared to most first-order liquid-phase decompositions. Thus products that degrade with heat are more affected by an increase in time than an increase in temperature. For example, expressed as a *Z* value the temperature effect of the degradation of glucose would have a *Z* value of about 33°C.

A4.44 The use of *F* values based on the *Z* value of the most resistant contaminating organism found during bioburden studies rather than an assumed *Z* value of 10°C may be necessary for particularly thermolabile products. Great care is needed in the application of this technique because of the inherent variability of microbial contamination and the rigorous process control and monitoring needed to minimise this.

Product stability

A4.45 Product stability may also be related to degradation during sterilization. Chemical reaction kinetic studies on many products indicate that product stability over the desired shelf life can be extrapolated from the extent of degradation measured just after sterilization. In some cases a degradation product formed during sterilization triggers subsequent deterioration and the specific factors affecting the formation of the degradation product would need to be investigated.

A4.46 Both microbial lethality and degradation are cumulative with respect to time and temperature, so variations in the heating and cooling phases of the cycle will affect the extent of degradation, and thus product stability, as well as lethality.

A4.47 Degradation and stability studies should consider the entire cycle and not just the dwell time. These effects are more pronounced for products where the degradation reaction has a lower activation energy.

A4.48 F_0 values are generally calculated from the coolest part of the load. For degradation and stability purposes the hottest part of the load is of more consequence. The entire range of temperature and time experienced throughout the load must be recorded in order to substantiate degradation and stability claims.

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Cycle development studies

A4.49 Determination of F_0 values is often of value in the development of appropriate operating cycles for steam sterilization of both fluids in sealed containers and wrapped goods and porous loads. However, since temperature measurement alone cannot reliably detect failure to obtain direct contact with dry saturated steam, it is not practicable to use F_0 values for monitoring or controlling porous load cycles.

The use of F_0 values for porous load cycles should be limited to determining suitable sublethal cycles for biological challenge studies.

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A5. Test methods

Test for F_0 control compliance

Apparatus

A5.1 Glass bottle, of nominal capacity 1 litre, complying with DIN 58363.

A5.2 Independent F_0 reference instrument, as described in section F.

Procedure

A5.3 Install the reference instrument.

A5.4 Place 1 litre of cold water in the bottle. Insert the two temperature sensors of the F_0 control system and the sensor of the reference instrument so that the sensing points of all three are at about 85% of the bottle depth and over the approximate centre of the bottom of the bottle. Seal the bottle.

A5.5 Select the required F_0 value on the control panel and perform a cycle in which automatic control is terminated manually immediately at the beginning of stage 4. Note the value of F_0 shown by the reference instrument.

A5.6 Repeat the procedure described in paragraph A5.5 twice.

A5.7 This test procedure shall be carried out for F_0 values of 1, 15 and 30.

A5.8 Calculate the mean of the three replicate values for each setting of F_0 control and check for compliance with the values given in Table A2.

Test for performance of reference instrument

Apparatus

A5.9 Temperature regulated heat source capable of being controlled at a given temperature within 0.10°C in the range 115°C to 126°C.

A5.10 Thermometer traceable to national standards to include the range 100°C to 130°C complying with BS 593 and graduated at intervals of 0.1°C.

A5.11 Temperature logging device computing F_0 values of the sensor(s) with integration at least every 2 s and means of print out, together with suitable temperature sensor(s).

A5.12 Stopwatch.

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Procedure

A5.13 Install the sensor(s) into the temperature regulated heat source.

A5.14 Adjust the heat source so that it maintains a temperature of 121±0.1°C.

A5.15 Allow the equipment to integrate F_0 for 15 minutes timed with the stopwatch. Note the indicated F_0 value.

A5.16 Repeat with the temperature source maintained at 115±0.1°C for 30 min.

A5.17 Repeat with the temperature source maintained at 126±0.1°C for 10 min.

A5.18 The replicate F_0 values obtained at 121°C shall lie within the range 14.66 to 15.34.

A5.19 The replicate F_0 values obtained at 115°C shall lie within the range 7.36 to 7.71.

A5.20 The replicate F_0 values obtained at 126°C shall lie within the range 30.90 to 33.36.

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Glossary

D value The *D* value (or Decimal Reduction Value) is a measure of the resistance of a micro-organism to a particular type of sterilization process. It is the value of the appropriate parameter of the process (duration or absorbed dose) required to reduce the number of viable micro-organisms to 10% of the original number.

In connection with sterilization by heating in an autoclave the D value is expressed by the time minutes at a defined temperature (the temperature is often shown as a subscript, for example D_{121}).

Z value In connection with sterilization by heating in an autoclave the Z value relates the heat resistance of a micro-organism to changes in temperature. The Z value is the change in temperature required to alter the D value by a factor of 10.

F_0 A quantity, measured in minutes, used to determine the efficacy of an operating cycle and equivalent to a continuous period at a temperature of 121.1°C for an organism with a Z value of 10°C.

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Section B

Methods for determining the fatigue life of rectangular pressure vessels

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B. Methods for determining the fatigue life of rectangular pressure vessels

This section is not included. Please refer to the printed version of BS 3970.

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Section C

Packaging for terminally sterilized products

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C1. Introduction

C1.1 This section discusses the factors which should be considered in the selection and use of packaging for terminally sterilized products, that is, those materials which are sterilized in their packaging.

Packaging for medical equipment which has been cleaned, decontaminated/disinfected and serviced ready for return to use is not included in this guidance.

C1.2 It does not consider those products which are sterilized and then aseptically packed in sterilized packaging materials nor does it cover packaging of terminally sterilized components to be used in aseptic manufacturing.

Sterilization processes

C1.3 Because the product is sterilized in its packaging it is necessary that the packaging maternal is compatible with the sterilization process to be used.

C1.4 The sterilization processes included are those which are generally available for use either directly or through a sub-contractor. It does not include requirements for new processes which are currently under development or at an early stage of their introduction for practical use. This would include, for example, those systems employing gaseous or plasma phase peracetic acid and/or hydrogen peroxide.

C1.5 Sterilzation processes included are:

a. Steam – for clinical use (see SHTM 2010 Part 1, paragraph 2.1 (a)):
   (i) for wrapped goods and porous loads;
   (ii) for aqueous fluids
      - in rigid containers;
      - in flexible containers;
   (iii) for unwrapped instruments and utensils
      - externally supplied steam;
      - internally generated steam;
b. Steam – for laboratory use (see SHTM 2010 Part 1, paragraph 2.1 (b)):
c. Low-temperature steam and formaldehyde. Note. The packaging materials, systems and procedures described are also suitable for use with disinfection processes intended for use with wrapped goods, for example Low Temperature Steam Disinfectors (LTS);
d. Ethylene oxide;

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e. Dry heat (hot air);

f. Ionising irradiation (gamma and beta).

Product applications

C1.6 The sterile products for which packaging is considered include:

- medical devices and surgical instruments:
  - primarily those products, including re-usable instruments, utensils and textiles, which are processed by Sterile Service Departments, including units directly serving operating theatres (although the same principles apply to other manufacturing systems which have a wide range of product specifications produced singly or in small numbers. Only passing reference is made to high speed automated packaging systems.);
  - re-usable instruments processed in clinics and general practices (dental and medical);
- pharmaceutical manufacturing of sterile products;
- laboratory product manufacturing, for example culture media for microbiology;
- discard (or make-safe) prior to disposal of potentially infective material.

C1.7 Consideration is given to materials and systems for both single-use and re-usable packaging.

C1.8 Single-use packaging includes, for example, ampoules, single-trip bottles, paper bags, paper/plastic pouches & reels, paper wraps, vacuum formed trays, etc.

C1.9 Re-usable packaging includes, for example, multiple-trip bottles, procedure trays, sterilization containers, textile wraps, etc.

C1.10 This guidance section also makes reference to labelling, storage and distribution giving both guidance and particular requirements necessary to ensure compliance with extant regulations.

Responsibility

C1.11 Part 1 of SHTM 2010 (paragraph 1.15 (h)) Identifies the procedures for production, quality control and safety as a major responsibility of management.

C1.12 The provisions of this section should be reviewed by those responsible for the management of sterile production and adapted to local circumstances (for example taking into consideration the nature of the product, the volume of production, the sterilization process(es) available, etc.).

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C1.13 It should be used as the basis for the development of written policies, specifications and procedures to be used in the control of sterile production.

General performance requirements

C1.14 The purposes for which packaging is used are:

- to contain the product;
- to permit sterilization of the packaged product;
- to protect the product from deterioration and damage;
- to maintain the sterility of the product through distribution and storage to the point of use;
- to prevent contamination of the product.

C1.15 In addition the packaging must:

- permit identification of the number and type of product contained, the lot number, the manufacturer and the expiry date (by labelling);
- include specification of storage conditions which the packaging is designed to withstand;
- provide any necessary instructions for the correct use of the product (by labelling and/or instruction sheets);
- present the product in a manner which allows it to be removed aseptically immediately before use.

Packaging operations

C1.16 The procedures and controls implemented for packaging operations must be designed to ensure that:

- each product produced is in the correct type of pack;
- each pack is correctly and effectively sealed;
- each pack is correctly labelled with all the necessary information.

Quality control

C1.17 The nature of packaging for terminally sterilized products is such that:

- it is not possible to test the packaging on finished product in a manner which permits its subsequent distribution for use;
- it is not possible to test any one sample for all necessary characteristics;

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- it is not possible to test each pack immediately before use to ensure that the packaging has performed correctly throughout sterilization, distribution and storage.

C1.18 Adequate control of the quality of packaging can only be obtained through a comprehensive programme including:

- design, and design verification;
- specification of packaging procedures;
- validation of packaging procedures;
- control of purchased material;
- control and monitoring of the packaging process;
- training for all who produce, handle or use sterile packs.

C1.19 Labelling is an essential part of packaging and procedures are required to ensure that particular care is taken to avoid labelling errors.

C1.20 The importance of proper control over all aspects of the packaging process cannot be over-emphasised. When products such as medical devices or medicinal products are presented wrongly labelled, contaminated, or damaged their use can cause serious adverse effect and may, in extreme cases, be lethal.

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C2. Regulatory requirements and standards

C2.1 So far as requirements for packaging, including labelling, are concerned, the chief areas of legislation with which managers should be familiar are those concerned with safety, consumer protection, medicinal products, medical devices, active implantable medical devices and in vitro diagnostics.

The legislation relevant to sterilizers is also discussed in SHTM 2010 Part 1, Chapter 3, to which reference should be made.

Safety

C2.2 Manufacturers have two specific obligations under the Health and Safety at Work etc Act 1974:

1. to take all reasonably practicable steps to ensure that their products have been designed and manufactured so as to be safe when used for the intended purpose;
2. to ensure that persons who use their product in further manufacturing and retailing operations have adequate information and advice about how the products should be used to ensure safety.

C2.3 There is also a more general requirement under common law to protect all persons involved with the use of the product.

Medicinal products

C2.4 Where a packaging material or system is used to contain a medicinal product the licensing provisions of the Medicines Act 1968 apply.

Further information may be found in ‘Guidance to the NHS on the licensing requirements of the Medicines Act 1968’ published by the Medicines Control Agency.

C2.5 The Medicines (Standard Provisions of Licences and Certificates) Amendment Regulations 1992 (SI 1992/2846) give statutory force to the European Commission document ‘The rules governing medicinal products in the European Community Volume IV Guide to Good Manufacturing Practice for medicinal products’.

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Guide to Good Manufacturing Practice for medicinal products

C2.6 The principles and detailed guidelines of good manufacturing practice deal with a number of aspects of packaging including:

- Documentation, which should include:
  - a formal, written specification for packaging materials;
  - formally authorised packaging instructions for each product, pack size and type;
  - a record kept for each batch or part batch processed.
- Purchase, handling and control should be treated in the same manner as starting materials with particular attention paid to printed material;
- Packaging operations should be designed to minimise the risk of mix-ups by the inclusion of a line clearance procedure and special care should be exercised to avoid mislabelling.

The packaging should be verified as being of the correct type, clean and in the correct quantity and there should be suitable on-line control and monitoring to verify the adequacy of the packaging operation.

Consumer protection

C2.7 Part 1 of the Consumer Protection Act 1987 implements Directive 85/374/EEC (the Product Liability Directive) and provides for compensation to be paid to persons suffering injury from a defective product. The implications of this legislation are discussed in SHTM 2010 Part 1 (paragraphs 3.26 to 3.28 inclusive).

Active Implantable Medical Device Regulations 1992

C2.8 The Active Implantable Medical Devices Regulations 1992 (SI/1992/3146) implements Council Directive 90/385/EEC. Schedule 2, paragraph 7 of these regulations requires active implantable medical devices to be designed, manufactured and packed in a non-reusable packaging according to procedures which are sufficient to procedures which are sufficient to ensure that:

a. the device is sterile when placed on the market;

b. if handled in accordance with conditions as to storage laid down by the manufacturer, the device remains sterile until the packaging is removed and the device is implanted.

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Medical Devices Regulations

C2.9 The Medical Devices Regulations 1994 (SI/1994/3017) implements Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices and came into effect on 1 January 1995.

C2.10 Regulation 11 concerns the procedure for systems and procedure packs and requires, inter alia, that any person who puts devices bearing the CE marking together, within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and that the whole activity is subjected to appropriate methods of internal control and inspection.

C2.11 The Essential Requirements described in Annex 1 (of the Directive) include a number of specific requirements for packaging and labelling which are summarised below.

General requirements

C2.12 The devices must be designed, manufactured and packaged in such a way that they are suitable for the functions specified by the manufacturer.

C2.13 The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information supplied by the manufacturer.

Requirements regarding design and construction

C2.14 The devices be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients taking into account the intended purpose of the product.

C2.15 The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties.

C2.16 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

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C2.17 Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization specified by the manufacturer.

C2.18 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

C2.19 Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking into account the training and knowledge of the users.

C2.20 This information comprises the data on the label and the data in the instructions for use.

C2.21 As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging.

C2.22 If individual packaging of each unit is not practicable the information must be set out in the leaflet supplied with one or more devices.

C2.23 Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices classified in Class I or IIa if they can be used safely without any such instructions. The majority of, but not all, products produced in hospital based sterilization units would fall into this category, for example re-usable surgical instruments which are in Class I. Exceptions include implants, and may include devices intended for use on skin wounds that have breached the dermis. In case of doubt reference should be made to the classification criteria given in Annex IX of the directive or advice sought from the competent authority (Medical Devices Agency, DoH).

C2.24 Where appropriate this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.

C2.25 The label must bear the following particulars:

a. the name and trade address of the manufacturer;
b. the details strictly necessary for the user to identify the device and the contents of the packaging;
c. where appropriate, the word STERILE;
d. where appropriate, the batch code, preceded by the word LOT, or the serial number;
e. where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

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f. where appropriate, an indication that the device is for single use;

g. if the device is custom made, the words “custom made device”;

h. if the device is intended for clinical investigations, the words "exclusively for clinical investigations";

i. any special storage and/or handling conditions;

j. any special operating instructions;

k. any warnings and/or precautions to take;

l. year of manufacture for active devices other than those covered by e. This indication may be included in the batch or serial number;

m. where applicable, method of sterilization.

C2.26 If the intended purpose of the device is not obvious to the user the manufacturer must clearly state it on the label and in the instructions for use.

C2.27 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

C2.28 Where appropriate the instructions for use must contain the following particulars:

1. information to avoid certain risks in connection with implantation of the device;
2. the necessary instructions in the event of damage to the sterile packaging and where appropriate details of appropriate methods of re-sterilization;
3. if the device is reusable, information on the appropriate processes to allow re-use, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of re-uses.

C2.29 Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that if correctly followed the device will still comply with the general requirements specified in Section 1, Annex 1 of the directive.

C2.30 The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken.

Glass containers EEC Directive 75/107

C2.31 Capacity tolerances for bottles specified as measuring containers were defined in the Directive and are summarised in Table C1.

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Two methods of capacity verification were specified, the Standard deviation method and the Mean range method.

Table C1: Capacity tolerance for bottles as measuring containers

Nominal capacity C (ml)	Capacity tolerances as %	
	of C	in ml
50 – 100	–	±3
100 – 200	±3	–
200 – 300	–	±6
300 – 500	±2	–
500 – 1000	–	±10
1000 – 5000	±1	–

British and European standards

C2.32 The rapid development in European Standards, which are required to be adopted as national standards by all European members of the European Committee for Standardisation (CEN), is largely due to the role that such standards have in demonstrating compliance with legislation implementing European Directives.

CEN is recognised by the European Union as a competent body for the adoption of harmonised standards.

C2.33 For the purpose of the European Directives on Medical Devices and Active Implantable Medical Devices a harmonised standard is a technical specification (European standard or harmonisation, document) adopted, on a mandate from the European Commission, by CEN.

C2.34 There is a presumption of compliance to the essential requirements of the Directive for devices which are in conformity with the relevant harmonised standards the references of which have been published in the Official Journal of the European Communities.

C2.35 A number of standards are in preparation which are relevant to packaging and labelling of terminally sterilized products.

The following list is not exhaustive. The standards discussed are in various stages of preparation. All EN standards are available in the UK as British Standards; there is now a dual numbering system so that EN *** will be numbered as BS EN ***.

C2.36 EN 1041 *Terminology symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices*

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This standard specifies the information to be supplied by the manufacturer of medical devices necessary to comply with the requirements of the Directive.

C2.37 **BS EN 980** *Terminology symbols and information provided with medical devices - Graphical symbols for the labelling of medical devices*

This standard defines a number of symbols to be used in labelling medical devices. The use of these symbols will both facilitate provision of all the essential information on small packs and minimise the need for multi-lingual labelling.

C2.38 **BS EN 868 series** *Packaging materials for sterilization of wrapped goods*

This standard is presented in a series of separate parts. The first part specifies the general requirements for packaging materials to be used for medical devices which are to be terminally sterilized and provides requirements, guidance and test methods for the validation of packaging materials and systems.

The subsequent parts of the standard specify requirements for a variety of packaging materials and systems. Conformity with the specified requirements in these parts of the standard may be used as one means of demonstrating compliance with some, or all, of the requirements of Part 1.

C2.39 **BS EN 867 series** *Non-biological systems for testing sterilizers*

This series of standards specifies the requirements for chemical indicators used in testing sterilizers. Part 2 of the standard specifically addresses the performance requirements for process indicators, whether used independently of, or printed on, labels or packaging materials. Detailed specifications are given for performance criteria relevant to all the sterilization processes considered in this Section (see paragraph C1.5).

C2.40 **BS EN 724** *Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices*

This standard provides guidance on suitable methods and procedures, including aspects of packaging, for the manufacture of medical devices in conformity with the requirements of the Quality System standards which may be used to demonstrate compliance with the requirements of the Directive.

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C2.41 **BS EN 550** *Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization*

This standard specifies requirements for the development, validation, process control and monitoring of the sterilization of medical devices using ethylene oxide and gives guidance on means by which these requirements may be met. The importance of packaging in the correct functioning of an ethylene oxide sterilization process is recognised.

C2.42 **BS EN 552** *Sterilization of medical devices - Validation and routine control of sterilization by irradiation*

This standard specifies requirements for the development, validation, process control and monitoring of the sterilization of medical devices using ionising radiation and gives guidance on means by which these requirements may be met. The importance of specifying and controlling packaging from validation through to routine batch control is emphasised.

C2.43 **BS EN 554** *Sterilization of medical devices - Validation and routine control of sterilization by moist heat*

This standard specifies requirements for the development, validation, process control and monitoring of the sterilization of medical devices using moist heat.

The methods used are based on monitoring physical factors and control of the packaging is an essential part of the system.

C2.44 **BS EN 1174** series *Sterilization of medical devices - estimation of the population of micro-organisms on product*

This standard describes methods for determining the extent of microbial contamination on products, including packaging, prior to sterilization.

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C3. Design considerations

C3.1 The manufacturer of the sterile product is responsible for adopting a design for the pack which is suitable for its intended purpose.

C3.2 However, in many cases the design of the packaging material and/or system may be controlled by the manufacturer of the packaging material and/or packaging system and sold as suitable for a particular range of applications.

C3.3 The choice of such a pre-designed, commercially available packaging system does not absolve the sterile product manufacturer from the responsibility for ensuring that:

- the design of the packaging system, including the selection of materials, is suitable in all respects for the intended application (see Chapter C6)
- the packaging system as received from the supplier is in conformity with the specification against which the choice was made (see Chapter C5)
- the production facilities, including the skills of production personnel, are compatible with the packaging system chosen and have the demonstrated capability to fill, seal and sterilize the packaging in accordance with the instructions provided by the manufacturer of the packaging system, (see Chapters C7 - C9).

C3.4 The packaging is required to fulfil a number of functions. These may be summarised as: “to minimise the safety hazard to the manufacturer, user or patient arising from interaction of the product with its environment under the conditions of sterilization, transport, storage and use as specified by the producer of the packaging system and/or sterile product”.

C3.5 The design should include consideration of at least the following:

- the compatibility of the packaging with the sterilization process;
- the compatibility of the packaging with the labelling system;
- the compatibility of the packaging with the users’ requirements at the point of use, for example aseptic opening;
- the sensitivity of the pack contents to particular risks, for example irradiation, moisture, mechanical shock, static discharge.
- the compatibility of the packaging with the contents, for example the medical device or medicinal substance, in order that the packaging has no adverse effect on the medical device or vice versa;
- the protection provided by the packaging against adverse environmental influences which may reasonably be anticipated, for example mechanical shock, vibration, chemical or microbial contamination;

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C3.6 The emphasis to be given to each of these considerations will be different for each of the various sterile products manufactured but, compatibility with the sterilization process and the subsequent protection against microbial contamination are paramount in providing the user with a sterile product.

C3.7 In many cases historical data may be used to provide satisfactory evidence that the packaging is suitable for its intended purpose where packaging to the same specification has previously been used satisfactorily for a particular product, or one that is similar in all essential respects.

C3.8 The design documentation should include details of the product to be packaged, the sterilization process to be used, the storage and transport conditions as well as the specification of the packaging materials and processes to be used.

Compatibility with the sterilization process

C3.9 There are two important aspects to sterilization compatibility:

a. the ability of the packaging material to permit the attainment of the required conditions for sterilization in the process with which it is intended to be used;

b. the ability of the packaging material to withstand the sterilization process without deterioration which adversely affects its protective performance.

C3.10 Both attributes should be demonstrated.

Moist-heat/steam sterilization processes

C3.11 For effective sterilization by moist heat all parts of the load should be in contact with water or saturated steam at the required temperature for the required time.

Sterilizers for wrapped goods and porous loads

C3.12 Items to be sterilized, other than aqueous products in sealed containers, should be packaged in a pack which allows removal of air and penetration of steam but which prevents recontamination after sterilization.

C3.13 This is normally achieved by the use of materials which are permeable to air and steam but have an effective maximum pore size which is small enough to exclude microbial contamination under the specified storage and transport conditions.

C3.14 This includes wrapping in porous materials, the use of rigid containers which are fitted with filters or valves, or a combination of these methods.

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C3.15 Effective sterilization requires complete permeation of the porous materials with the moisture and heat of the steam. This may occur rapidly or slowly and depends, inter alia, on the size and density of the pack, the method of air removal, the nature of the porous material etc.

C3.16 With packaged solid, hollow or fibrous products air may become trapped, randomly, in the sterilizer chamber and load. The microbial lethality of elevated temperatures under dry and moist conditions are vastly different. The presence of air can cause an unacceptable impairment of the sterilization process.

C3.17 Unpredictable air retention is of particular concern with porous wrapping materials. Hence for effective sterilization of wrapped goods and porous loads it is important to employ a sterilization process which incorporates forced air removal prior to the sterilization stage.

C3.18 Preliminary tests on the product and its packaging in order to determine the levels and rates of change of pressure, temperature and vacuum which start to cause unacceptable changes in the performance qualities of the medical device and/or its packaging may be necessary.

C3.19 Performance qualification should be performed on the introduction of new or modified packaging unless equivalence either to a validated reference load or to previously validated packaging has been demonstrated.

C3.20 Materials used for packaging should be compatible with the sterilization process not only in permitting passage of steam and air as required by the process but also in not contributing any other inhibitory factors. For example they should not generate gases which could mimic the presence of retained air and restrict the penetration of steam.

Sterilizers for unwrapped instruments and utensils

C3.21 Sterilizers not intended for use with wrapped goods, for example bowl and instrument sterilizers, and small transportable electrically heated sterilizers rely on steam flow to remove air. Although the air may eventually be displaced from wrapped loads the process is slower and less predictable than when forced air removal is used.

C3.22 The only packaging suitable for unwrapped instrument and utensils sterilizers are “instrument orientation” trays which are constructed of open mesh or with sufficient ventilation holes to ensure that they present no barrier to air removal and steam penetration.

C3.23 BS 3970 Part 4 requires that load containers for transportable sterilizers should be designed to permit free draining of condensate and penetration of steam by perforation of appropriate surfaces. The perforated surfaces should have not less than 10% of their area as uniformly distributed perforations, each perforation being at least 20 mm^2.

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Aqueous products in sealed containers

C3.24 Sealed glass or plastics containers containing aqueous solutions permit moist heat sterilization of the contents by virtue of the moisture present in the product.

C3.25 The container must have a gas-tight seal if the composition of the contents is not to be modified by evaporation of water from the contents or the ingress and condensation of steam from the sterilizer chamber.

C3.26 The container must be able to withstand the considerable internal pressures which will be generated during the sterilization process. This increase in pressure arises from the volumetric expansion of the container being insufficient to compensate for the volumetric expansion of the liquid, the increased vapour pressure of the liquid and the increased pressure of the heated air in the vacuity.

C3.27 The pressure generated in a correctly filled 1 litre bottle when it is heated to 121°C may exceed 8 bar.

C3.28 Plastic containers, particularly those made of polymers which undergo a reduction in tensile strength at the temperatures used for steam sterilization, are often only suitable for use in sterilizers which include air or gas ballasting to increase the pressure throughout the cycle and thus restrain the container from bursting. A similar approach may be used to sterilized devices used as packaging for example pre-filled syringes.

C3.29 The safety of operators will be at serious risk from the violent failure of containers and dispersal of their contents if the containers are removed from the sterilizer at too high a temperature (see SHTM 2010 Part 3 paragraph 14.20 d).

C3.30 The use of unsealed containers to avoid this problem is unacceptable. Not only is the composition of the contents subject to unpredictable changes, but liquids such as molten agar might still be boiling violently. Splashes from hot liquids of high thermal capacity can cause serious burns.

C3.31 Containers which are “unsealed” but plugged with porous material, or have the cap in place but left loose, that is not screwed tightly closed, may also become unsafe at elevated temperature. The evaporation of water from residues of the contents which boiled over during the early stages of the cooling process can effectively seal the container. It is important to emphasise that these are not theoretical considerations but represent a real hazard which has, in the past, caused injury to a number of personnel.

Low-temperature steam and formaldehyde

C3.32 The basic considerations for packaging for this process are similar to those for steam sterilizers for porous loads and wrapped goods.

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C3.33 However, the thermal characteristics (both the thermal capacity and thermal conductivity) of the packaging can be of importance:

a. Materials which are slow to attain the required temperature may promote the polymerisation of the formaldehyde gas.

b. Materials of high thermal capacity promote the formation of excessive quantities of condensate which also may adversely affect the sterilization process.

C3.34 In addition, the extent to which the packaging material will absorb and adsorb both moisture and formaldehyde gas may affect the efficacy of the process.

C3.35 In general packaging should be kept to the minimum compatible with adequate protection for the product and the maintenance of sterility.

Ethylene oxide

C3.36 The packaging should be designed to allow removal of air and penetration of both steam and ethylene oxide and it should be demonstrated that the specified sterilization process does not affect adversely the functioning of the packaging.

C3.37 Impervious packaging materials are unsuitable for ethylene oxide sterilization.

C3.38 There are a considerable number of different ethylene oxide sterilization processes ranging from those employing pure ethylene oxide at sub-atmospheric pressures to those which use a mixture of ethylene oxide and carbon dioxide at pressures of several bar.

C3.39 The nature of the process, including the rate of air removal and the nature of the humidification stages used, will influence the suitability of packaging to be used in the process.

C3.40 A sterilization process that employs a high moisture content and several large and rapid changes in pressure may affect the strength of package seals, with a consequent loss of integrity, whereas. package seals of the same type would have been perfectly satisfactory for a process employing less extreme conditions.

C3.41 The extent to which the packaging absorbs moisture may have a major influence on the efficacy of the process and must be considered before a satisfactory humidification stage can be demonstrated.

C3.42 The extent to which the packaging absorbs or adsorbs ethylene oxide, and its permeability to ethylene oxide may have a major influence on the efficacy of the process and the subsequent aeration process used to remove the potentially toxic residuals.

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C3.43 Process control is also a concern since packaging material that has become dehydrated may absorb excessive moisture during the conditioning phase; if this possibility was not recognised during validation the achieved cycle lethality may be adversely affected.

C3.44 The use of cartons (shelf packs, transit cartons) may be convenient for handling product but increase the post-sterilization level of ethylene oxide residuals, the necessary humidification time and the length of the gas exposure stage of the cycle (by inhibiting gas penetration). All the packaging which is intended to go into the sterilizer must be compatible with the process.

C3.45 The standard on validation of ethylene oxide sterilization processes (see BS EN 550) includes the requirement that the packaging specification be part of the definition and documentation of the sterilization process. The validation report should include or reference details of product sterilized, including packaging specification and load patterns in the sterilizer.

C3.46 It is therefore necessary that product used for physical and microbiological performance qualification studies should be packaged in an identical manner to that to be used routinely when they are presented for sterilization.

C3.47 The introduction of a new, or altered, packaging material or system requires validation. Physical and microbiological performance qualification studies should be performed on the introduction of new or modified packaging, although demonstration of equivalence to a previously validated package would satisfy this requirement.

C3.48 Many of the packaging materials for hospital use are the same as those for use in steam sterilizers because of similar permeability requirements; however, the lower temperatures involved in the process permit a wider range of materials to be used.

Hot-air sterilizers

C3.49 The thermal conductivity, specific heat and ability to withstand temperatures of 165°C, 175°C or 185°C (depending on the process used) for extended periods, without deterioration which impairs the utility of the packaging, are obvious considerations.

C3.50 The packaging does not need to be porous since the heat transfer normally takes place by conduction.

C3.51 However, in sealed packaging the contents of the pack when heated can exert a considerable pressure and may be sufficient to rupture the packaging material or its seals.

C3.52 Vented packaging systems that allow pressure equilibration may be suitable for use in hot air sterilizers which operate with a chamber atmosphere which has been filtered through a bacteria retentive filter. This is particularly important the during the post-sterilization cooling stage.

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Irradiation

C3.53 The standard for validation of radiation sterilization processes (BS EN 552) requires that the process specification should include descriptions of the dimensions, density and orientation of the product within the packaging, as well as the pattern for the loading of product within the container to be used to transport the packs through the irradiator. This should be established and documented before commencing performance qualification studies.

C3.54 The orientation of the product during irradiation is one of the factors ensuring uniformity of dose and the ability of the packaging to maintain consistent orientation of the product must be considered.

C3.55 The density of the packaging, and hence its “transparency” to the radiation to be used may be an important consideration, particularly in the case of electron beam irradiation.

C3.56 Although radiation sterilization is a low-temperature process there is nevertheless some increase in temperature above normal ambient temperatures and this should be considered.

C3.57 There is no requirement for the packaging to be gas permeable. If the packaging is gas tight it may reasonably be assumed to be a satisfactory barrier to microbial contamination.

C3.58 Many materials are structurally altered by the radiation process; they may become hardened and embrittled, or discoloured, for example.

C3.59 These radiation induced changes may be beneficial or disadvantageous to the subsequent performance of the packaging or they may simply be aesthetically unacceptable, for example the yellowing which occurs with some PVC materials.

C3.60 Many polymers are now available specifically formulated with stabilisers which make them suitable for use in irradiation processes. The adhesives used to seal packages must also be considered for potentially adverse effects of the radiation.

C3.61 For most hospital users, with only small numbers of items to be irradiated, the advice of the sub-contractor providing the irradiation sterilization service should be sought. Based on their experience of radiation sterilization of similar products they will often be able to suggest appropriate packaging which can be validated by comparison with previously validated products.

Compatibility with the labelling system

C3.62 The importance as labelling as an integral element of the product packaging has been stressed (see paragraphs C1.15 and C2.19 to C2.30).

C3.63 Labelling may take a number of forms, including:

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- labelling printed directly on the packaging;
- printed labels attached to the surface of the packaging by adhesive, etc.

C3.64 Whether labels are printed directly on the packaging or onto discrete labels which are subsequently attached to the pack, the labelling system should:

a. not adversely affect the compatibility of the packaging with the sterilization process to be used, for example by excessively restricting the porous area available for gas exchange;

b. not be rendered illegible by the sterilization process to be used;

c. not employ ink of a type which may

(i) transfer to the pack contents;

(ii) react with the packaging to impair its utility;

(iii) change colour and render the label illegible;

(iv) interfere with the sterilization process by, for example, evolution of volatile components.

C3.65 Labels fixed to the surface of the packaging must be able to withstand exposure to the sterilization process and the defined storage and transport conditions without becoming detached.

C3.66 Given the low cost of computerised label printing systems there can be little justification for using hand-written labels with the inevitable variation in legibility that this causes.

C3.67 Writing on the packaging also presents an unacceptably high risk of causing damage to, for example, paper packaging, which may not be readily visible but is sufficient to breach the microbial barrier properties of the material.

Furthermore, some pens, such as ‘felt-tip’ pens and ‘marker’ pens, have inks which may release volatile components in sufficient quantities to interfere with the correct functioning of a steam sterilizer.

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Compatibility with requirements for aseptic opening

C3.68 Failure to consider adequately how a pack is to be opened and the contents removed may significantly increase the chance of contamination occurring. With inadequate provision for aseptic opening a 10^{-3} probability of contamination is easily possible which compares unfavourably with a 10^{-6} probability of sterility required as a minimum standard before labelling a product as sterile (BS EN 556).

C3.69 The means of sealing or closing the pack should be tamper evident in order that the user may rely upon the integrity of the contents.

C3.70 For sterile products the other major consideration at the point of use must be the ability to remove the product from the packaging without it becoming contaminated with micro-organisms, in other words the aseptic removal of the product.

C3.71 The provision of aseptic removal may be influenced by a number of elements in the design of the packaged product including:

- the type of product;
- the packaging system chosen;
- the method of closure or sealing;
- the number of layers of packaging material;
- the arrangement of the contents of the pack;
- the use of special equipment to remove the contents.

C3.72 Sterile medicinal products include both parenteral and topical preparations. The former are predominantly aqueous solutions whereas the latter may be aqueous solutions, oils, emulsions (ointments or creams), or dry powders.

C3.73 The packaging system employed for sterile medicinal products will normally consist of a closed rigid or flexible container as the primary pack. This may be closed by being hermetically sealed or by being sealed with a penetrable (or removable) elastomeric closure (such as a bung, stopper or disk) held in place with a screwed cap or crimped overseal.

C3.74 Sterile medicinal products are usually best presented in single-use form. Where a multi-use presentation is employed there will be a requirement for a suitable preservative to be included in the product formulation.

C3.75 The primary pack may need to be overwrapped if it is necessary to provide for aseptic handling of the primary pack.

C3.76 Sterile medical devices may be presented as single items such as individual instruments, dressings, etc. or, as a single pack containing multiple items;

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the composition of which is designed so that contents comprise the items required for one (or more) particular procedure(s).

C3.77 These are commonly described in a variety of terms such as:

- Basic packs (dressing packs which may or may not contain instruments);
- Composite packs (instruments, dressings and other equipment/utensils);
- Supplementary packs (which include instruments, utensils, dressings for use with basic packs and composite packs);
- Procedure packs (which contain all the instruments, drapes, dressings and utensils required for a particular procedure);
- Linen packs (which contain all the drapes required for a particular procedure);
- Gown packs, dressing packs, etc.

C3.78 The packaging system employed for sterile medical devices may consist of flexible or rigid packaging, or the two types used in combination; and may be intended for single use, or be re-usable or be a combination of single use and re-usable.

C3.79 These may be closed by heat-seal, adhesive, compression gaskets, or tortuous path closures. A common format used in hospital SSDs is a pack formed from a rigid tray wrapped in a flexible packaging material. The tray may be re-usable metal or plastic, such as polypropylene, or single use, such as metal foil, moulded pulp, folded cardboard.

C3.80 For medical devices the arrangement of the pack contents will be of importance. The contents generally are arranged so that when the pack is opened they are available in an order convenient to the user for the intended purpose and suitable for aseptic removal.

C3.81 The method of opening the sealed or closed pack and/or removing the contents affects the aseptic removal capability. The various sealing and closing methods may involve particular risks with regard to transfer of contamination from the outside surface of the pack, or to transfer of fragments of the packaging.

C3.82 Tortuous path seals formed by the folding of flexible packaging material may be constructed so that they may be opened without touching the inner surfaces.

C3.83 Pealable seals are used on heat sealed, and some adhesive-sealed, flexible packs and on many commercially produced packs, for example lidded blister packs. The construction of the seal should allow the opposing surfaces to be grasped easily and the seal on separating should not cause fibre shedding by, say, the splitting or tearing of either surface.

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C3.84 Both flexible and rigid packaging systems are used which are intended to be broken, cut or torn open, for example ampoules, paper bags and pouches. It is important that this can be done without introducing contamination into the pack contents either from fragments of the packaging (for example glass particles from an ampoule), or from instruments used in the opening procedure, such as scissors for cutting open paper bags.

C3.85 Rigid re-usable containers for dry goods should have a tamper evident seal which must be broken before the container can be unlatched and the lid opened.

C3.86 Both single-use and re-usable containers for liquids, particularly those intended for topical administration or laboratory use, may have a seal which is formed from a compressible gasket (for example a rubber wad or stopper) held in place by, or as an integral part of, a screw capped lid. Aseptic removal of the contents will depend not only on the ease with which the cap and gasket can be removed but also on the method used subsequently to dispense the contents, for example pipetting, pouring.

C3.87 Both single-use and re-usable containers for liquids, particularly those intended for parenteral administration, may have a seal which must be punctured and penetrated by a suitable device to remove the contents, for example using a hypodermic needle and syringe to remove the contents of a vial.

C3.88 The potential risk of introduction of contamination from surface of seal should be considered. The external surface of the seal may need protection (overseal) which can be removed immediately before use, or the instructions for use may require pre-treatment of the seal surface, for example by swapping with a 70% m/v aqueous solution of spore-free isopropanol.

C3.89 For re-usable systems the ability of the closure to re-seal after each penetration will be an important consideration in the maintenance of sterility.

C3.90 The seal for either single-use or re-usable systems must be of a material which will not be damaged by the penetrating needle to the extent that fragments of the closure will contaminate the contents of the container.

C3.91 Sealed packs should always be carefully inspected for seal integrity, or adventitious contamination, before being opened and this requirement should be drawn to the users' attention both in the labelling of the pack and on any instructions for use or training programme which may be given.

Compatibility with the contents

Medical devices

C3.92 The suitability of the packaging for use with the particular medical device should be established. This should include limiting values for physical

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characteristics of both the medical device as well as the stresses which will be imposed during sterilization and subsequent transport and storage.

C3.93 Factors to be considered include, but are not limited to:

- the mass and configuration of the medical device to be packed;
- the presence of sharp edges or protrusions;
- the need for mechanical and other protection;
- interactions with the packaging materials.

C3.94 Consideration of product interaction should also include physical contamination with the packaging material. Small particles introduced into the body during, for example, surgical procedures are widely reported to cause clinical problems including inducing adhesions, granulomata and foreign body reactions in tissues.

Medicinal products

C3.95 Factors to be considered include:

- interactions with the packaging materials, including adsorption, absorption and chemical reactions with components of the packaging materials, for a period not less than the specified storage life under the specified storage conditions;
- adverse effects on the contents due to gas or water vapour permeability, such as permitting loss of water from a formulation, or permitting the ingress of oxygen and subsequent oxidation of one or more components of the formulation.

C3.96 Materials used for packaging should be compatible with the contained product. For example packaging intended for use with parenteral fluids should not shed particulate material to an extent which could compromise the quality of the parenteral being administered.

Laboratory products

C3.97 Factors to be considered include all those noted in the two previous sections for medical devices and medicinal products.

Toxicity

C3.98 Packaging materials and/or systems should not release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the specified conditions of use.

C3.99 Evidence that the packaging material and/or system does not either contain material known to be toxic, or contain material which may react during the sterilization process to form a substance known to be toxic, in sufficient

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quantity to cause a health hazard is normally sufficient to meet this requirement.

C3.100 Manufacturers of packaging are aware of this requirement and should be able to provide evidence that the formulation of the packaging has been reviewed by a competent toxicologist and found to meet this requirement.

Biocompatibility

C3.101 The biocompatibility of the packaging should be assessed with regard to the intended use of the pack contents. If particular requirements for the product to be sterilized, for example freedom from particulate matter, cannot be established from the material specification for the packaging under consideration expert advice should be sought. In the first instance this advice should come from the manufacturer of the device, who has a legal obligation to specify any particular requirements for the safe sterilization of the product.

C3.102 Test methods for bio-compatibility are described in BS EN 30993; they require the services of a specialist laboratory.

Preservation of sterility

C3.103 The packaging materials and/or systems assembled in the form in which it will be presented to the sterilizers, when assembled, stored, transported and used in accordance with the producer's instruction, should preserve the sterility of the contents from the time at which they are rendered sterile to the expiry date specified by the manufacturer and/or the point of use.

C3.104 Preservation of sterility is achieved by preventing the ingress of micro-organisms. Many factors affect the probability of such ingress occurring. These include, but are not limited to:

- the concentration of micro-organism in the environment;
- the size of particle on which the micro-organisms occur;
- environmental conditions of temperature, humidity and pressure;
- the rate of change of these environmental conditions;
- flow rates through the layers of packaging material;
- pore size and other filtration parameters of the packaging material.

C3.105 There is no universally applicable, single test method which can be used to establish the microbial barrier properties of a pack.

For particular types or sizes of pack there are tests which may be of value as an overall monitor of microbial barrier properties.

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C3.106 For most practical purposes it is necessary to infer satisfactory microbial barrier performance from a combination of tests designed to test attributes of the packaging which are related to microbial barrier properties, for example to test the gas tightness of seals.

C3.107 The time for which any packaging system will maintain the sterility of the pack contents is event related not time related. It is therefore necessary to define, and control, the conditions for both storage and transport, within which the pack will maintain the sterility of the contents.

Storage and transport of sterile packs

C3.108 It is necessary to ensure that the packaging is able to provide the protection necessary to maintain the performance characteristics of:

- the packaging during storage and transport under the specified conditions;
- the contents during storage and transport under the specified conditions.

C3.109 When handled according to instructions, the packaging should protect the product from physical damage and maintain the sterility of the medical device up to the point of use.

Number of layers of packaging material

C3.110 Products may be packaged in a single layer of packaging material, or in multiple layers. Multiple layers of packaging may be used to reduce the likelihood of contamination during storage and when the pack is opened.

C3.111 When two layers of packaging are used to facilitate aseptic removal of the contents:

- the outer wrap is sealed and acts as a barrier to microbial penetration to the product from the environment,
- the inner wrap may, or may not, be sealed and may, or may not, be intended to be a barrier to environmental microbial contamination. It acts as a protective cover during removal of the product.

C3.112 When the inner wrap is a microbial barrier it may serve to provide additional assurance of the maintenance of sterility.

C3.113 This inner wrap, having been maintained in a sterile state by the presence of the outer wrap, may be handled by persons, wearing sterile gloves and about to undertake an aseptic procedure.

C3.114 Moulded plastic shields covering hypodermic needles, plastic end-caps on intravenous administration sets are two examples of inner wraps found on commercially sterilized products. They may also serve additional functions

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unrelated to the sterile nature of the product, such as mechanical protection, protection of operators from hazards associated with the product etc.

C3.115 Double wrapping is essential for equipment that will be used in an aseptic environment such as an operating room or a protective isolation unit.

C3.116 In particular instances, triple-wrapped product may be necessary to permit the adoption of procedures with a high level of assurance that there will be no contamination, for example transfer of laboratory products into a sterility test containment facility or transfer of equipment and components into an aseptic manufacturing environment.

C3.117 Single wrapping may be more economical and appropriate when the product, although sterile, will not be used in an aseptic environment and will not be used parenterally or to penetrate tissue, for example Ryles tubes, oesophageal and suction tubes, urine bags, rectal examination sets etc.

C3.118 The various layers of packaging may be used to provide for different functional requirements, for example many surgical instrument and dressings packs are wrapped with an inner layer of paper or cloth which is used to provide a sterile field when opened onto a table, trolley or tray at the point of use.

C3.119 Two or more layers of packaging may be used together to provide a functional requirement which neither alone could meet, for example a single layer of textile may not be an adequate barrier to microbial penetration but two layers in combination may provide satisfactory performance.

Primary and secondary packaging

C3.120 If two layers used together are needed to meet a basic performance requirement then layers both together constitute the primary pack.

Secondary packaging

C3.121 Several individual units, each wrapped in its own primary packaging, may be packed together in a “shelf pack” which may consist of a carton, plastic film wrap, film-wrapped carton or similar.

C3.122 For distribution, multiples of individual units or shelf packs may be packed in transit containers.

C3.123 These may be intended as single-use, for example fibreboard cartons or re-usable, for example plastic or aluminium boxes. Their primary function is to withstand the predictable risks arising during transport and distribution.

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C3.124 Some or all of the secondary packaging may be applied before sterilization, especially in commercial sterilization. When this is the case the packaging, in its entirety as presented to the sterilization process, must meet the requirements for sterilization compatibility.

C3.125 When re-usable transport containers are employed, a documented and monitored procedure for maintaining them in a clean, hygienic condition and a good state of repair is necessary.

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C4. Packaging materials and systems

C4.1 The following section summarises various packaging systems and materials that are available, including methods of effecting suitable seals or closures, their suitability for use with sterilization processes which may be employed by hospital users, and equipment necessary for their effective use.

C4.2 The summary is wide ranging and comprehensive, but not exhaustive. The absence of a particular system or material should not be taken as implying that it is unsatisfactory for use, nor should the inclusion of a particular system or material been seen as an endorsement of its use.

C4.3 The choice of suitable packaging systems and materials will be based on a number of factors. These include, but are not limited to:

- compatibility with available sterilization processes and other factors (see paragraph C3.5);
- particular requirements of the user;
- availability and cost of suitable automatic equipment for filling, sealing, labelling;
- availability and cost of suitable re-processing facilities for re-usable packaging;
- availability and cost of suitable disposal methods for used single-use packaging;
- standardisation of packaging systems within a single production unit.

C4.4 There is no one packaging system that is “correct” for all applications; and for any particular application there may be several systems available none of which is perfect. It may then be necessary to prioritise the requirements to be met by the packaging and select the system which most nearly meets these requirements (Table C2). The two characteristics which are afforded the highest priority most often are compatibility with the sterilization process and maintenance of sterility in storage and distribution.

Sterilization compatibility

Steam sterilization

Wrapped goods and porous loads

C4.5 Goods are normally double wrapped; at least one of the layers will usually be a sheet of paper, paper bag or paper/plastic pouch.

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C4.6 The inner lining may be chosen primarily for its absorbency in order to retain condensate in a position from which it will be successfully evaporated during the drying stage of the sterilization cycle.

Table C2: Selection of packaging materials by sterilization process

Sterilization process	Re-useable packing	Single-use packing
Steam sterilization		
for wrapped goods and porous loads*	Containers(valves or filter) Textiles (cotton and/or synthetics)	Papers Plastic/paper pouches Cellulose/synthetic wraps Spun-bonded polyolefins up to 121°C
for instruments and utensils	Free-draining “instrument orientation” trays	
for aqueous fluids	Glass bottles Glass vials Plastic bottles	Glass bottles Glass vials/ampoules Plastic bottles Plastic pouches
Ethylene oxide	Containers (valve or filter)	Papers Plastic/paper pouches Spun-bonded polyolefins (eg.. Tyvek)
LTSF	Polypropylene boxes Open cell foam (for instrument protection)	Plastic/paper pouches Papers
Dry heat	Metal (eg.. Aluminium) canisters Glass containers	Metal foils Plastic films
Radiation		Treated paper Polyethlene Polypropylene Metal foils Various laminates Cardboard (PVC)

* the same packing materials are also suitable for use with LTS disinfectors

Fluids in sealed containers

C4.7 Glass or plastic bottles, vials or ampoules are used for rigid containers and plastic pouches, usually a laminated construction to optimise the performance characteristics, are suitable for flexible containers.

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Dry heat

C4.8 Aluminium cans or tubes, glass tubes or jars, each of which may be sealed with push on caps, screw caps or crimp-on foil caps, are suitable for dry heat sterilization. Crimp-on foil caps with a pre-printed colour change indicator are also available.

C4.9 Items may be wrapped in heavy or light gauge metal foil or, for items such as laboratory glassware the foil may be used simply to seal the open end of the product.

C4.10 Plastic bags of the sort sold for roasting meat in domestic ovens may also be suitable.

LTSF

C4.11 Packaging may consist of paper, used as plain or creped wraps, or in the form of bags or, in combination with plastic film as pouches.

C4.12 Light cardboard boxes, or corrugated polypropylene boxes, adequately vented and overwrapped with paper or other material as a bacterial barrier are also suitable. When particularly delicate instruments are to be processed the use of an open cell foam for support and protection is acceptable.

C4.13 The quantity of packaging should be kept to the minimum possible.

Irradiation

C4.14 Polythene/polyester/nylon or metal foil may be used. The material may be non-porous and gas impermeable which gives good microbial barrier properties. Paper, spun-bonded polymers and non-wovens can also be used but lose the advantage of a process that can deal with impermeable packaging.

Ethylene oxide

C4.15 For ethylene oxide sterilization a high permeability to air, steam and ethylene oxide is essential.

C4.16 Paper bags or plastic/paper pouches are usually found to be most convenient for small articles. Wrapping in sheets of plain or crepe paper, or textiles, may be required for large procedure trays containing endoscopes or other thermolabile equipment.

C4.17 Moulded foam inserts may also be used to provide protection for sensitive equipment such as endoscopes.

C4.18 Polythene bags with gas exchange ports of Tyvek are also suitable.

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Bacterial barrier properties

C4.19 The basic requirement is for a material which will not allow the product within the pack to be contaminated by the ingress of microbes in the environment from the time that it is removed from the sterilizer, during transport and storage up to the point of use.

C4.20 With a non-porous material, where gas flow through the material can only occur through diffusion, the material itself will be an absolute barrier to microbial contamination. The microbial barrier properties of the pack will then depend on the adequacy of the seal or closure. For example, an ampoule, if correctly sealed by fusion, and having no cracks or other flaws, will be an absolute barrier to microbial contamination.

C4.21 When a porous material is used the barrier to microbial penetration will not be absolute; there will be always a finite possibility of a micro-organism penetrating the barrier and potentially contaminating the pack.

C4.22 The probability of a micro-organism penetrating the barrier will depend on many factors, including, but not limited to:

- the rate of air flow through the web, which may be influenced by the rate and extent of environmental changes in pressure and temperature;
- the relative humidity, which can affect both the pore size and surface charge of natural fibrous materials (paper, linen etc.);
- the type and number of micro-organisms in the environment;
- the form in which they are presented, for example as single organisms or, as they are more usually found, on relatively large particles such as skin squames;
- the nature of the product, which may influence whether contaminating organisms can survive or multiply.

C4.23 The effect of these various factors is not the same for all materials. For example some porous materials are better at excluding particles of a given size at very low flow rates while other materials perform best at higher flow rates.

C4.24 It is apparent that the storage conditions will also be a controlling factor in the maintenance of sterility. Dirty, damp conditions can give rise to high microbial counts in the environment; large and rapid changes of temperature, and changes of pressure (including the slamming shut, or violent opening, of doors) will lead to an exchange of air between the contaminated air of the environment and the interior of the pack.

C4.25 The ability to maintain sterility is primarily “event related” rather than “time related”, although even under controlled conditions there is a greater probability of an adverse event having occurred after prolonged storage.

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C4.26 The most sensitive time for contamination through porous wrapping material is when steam sterilized product has been removed from the sterilizer and is cooling down. During this process air will be taken into the warm and humid environment in the pack.

Materials used in packaging

C4.27 The materials of which the packaging is made will necessarily limit the sterilization processes with which it is compatible as well as affecting its ability to meet other performance requirements.

C4.28 Performance requirements for packaging materials include:

- permeability to air, steam and gaseous sterilants, (although this does not apply to materials intended for use with aqueous fluids in sealed containers, dry-heat sterilization by hot air or sterilization by ionising irradiation);
- resistance to penetration by micro-organisms from the surrounding environment;
- resistance to punctures, tears and other mechanical damage which would breach the barrier to microbial penetration;
- freedom from loose fibres and particles;
- freedom from toxic ingredients and non-fast dyes;
- compatibility with the contents under the proposed sterilizing conditions;
- compatibility degraded by with the sterilization process to be used, that is, not degraded by it.

Textiles

C4.29 Textile fabrics are used for packaging; traditionally these are woven cotton materials but may also be cotton/polyester blends.

C4.30 Specialist fabrics are also available which may are intended to be water repellent while at the same time being gas permeable. This may be achieved by several means, for example a particularly tight weave of polyester fibres, or a laminated construction with a middle lamella of a suitable polymer film. Care needs to be exercised in using these fabrics that the flow rate of both air and steam through the fabric is adequate for the sterilization process.

C4.31 Textiles are often used as a wrapping material for heavy packs, especially of theatre instruments, which are to be sterilized in a porous-load steam sterilizer.

C4.32 Textiles are stronger than paper, and stronger than many non-wovens, and will resist tearing and rupture.

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C4.33 However, textiles are generally a less efficient bacterial barrier than sterilization grade wrapping paper and should always be used in two or more layers. The second layer may be a textile wrap also or a suitable sterilization grade wrapping paper. Alternatively, a sterilization grade paper bag may be used to enclose the textile-wrapped pack.

C4.34 Textile wraps are re-usable.

Papers and non-wovens

C4.35 Both papers, which are made from cellulose fibres, and non-wovens, made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilization and most gas processes because they are permeable to air, steam and other gases.

C4.36 The original papers used for steam sterilization wrappers were kraft papers produced for general purposes. Purpose made papers with better controlled porosity and microbial barrier properties, and with enhanced wet strength and water repellency are now used. These are available as plain sheets, creped sheets which give better drape characteristics, as bags and in combination with a plastic film as pouches (or reel material from which pouches can be made).

C4.37 Good drape and handle characteristics are also provided by crepe paper (BS EN 868-2: 1999).

C4.38 Plain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gussetted to accommodate bulky items.

C4.39 Wet strength and water repellency are specifically improved over “normal” papers by the impregnation of the paper with high wet-strength resins.

C4.40 The water content of the paper may be maintained at a relatively high level, thus improving the feel and drape of the paper and minimising superheating due to exothermal rehydration, by the addition of humectants such as sorbitol.

C4.41 Over many years experience the various forms of paper packaging have been demonstrated to provide an effective microbial barrier.

C4.42 Non-wovens are generally less effective as a microbial barrier and may need to be used in, or as one of, two layers; they are however generally softer with better handling and drape characteristics.

C4.43 British Standards exist for all the paper packaging materials and should be used as the basis for purchasing specifications. (These standards will be replaced in due course with European Standards currently in preparation; the draft standards cover the same range of requirements as the existing standards.)

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C4.44 Non-woven materials, made from a combination of natural and synthetic fibres are also widely used. These are often used where otherwise re-usable textiles would be used. They are generally of greater porosity than paper wraps and for this reason may not be as effective as a microbial barrier. They have higher tear and puncture resistance and are softer with better drape qualities. They may also show extremely good water repellency.

Synthetic materials and laminates

C4.45 Polymeric materials, or plastics, may be used in the manufacture of rigid, semi-rigid, or flexible packaging systems.

C4.46 They may be in the form of sheet or film, which is non-porous, or be produced as a spun-bonded or non-woven sheet which is porous.

C4.47 Plastic materials are also used in the manufacture of moulded containers, for dry products or for liquids.

C4.48 Film or sheet material may be an absolute barrier to microbes if it is free from pinholes. Although it may be non-porous that does not necessarily mean that it will be impermeable. Most polymers have some permeability to gas, air, and water vapour. The extent of the permeability varies with temperature, concentration gradient of the diffusing substance etc. and although generally low may be important, for example in the long term storage and stability of a pharmaceutical product.

C4.49 Plastic materials are generally robust and resistant to tearing. The extent to which they show puncture resistance depends much more on the polymer and film thickness used. There have been in the past major problems with thin-film moulded polyethylene commercially produced packs being breached by the sharp edges of the product within.

C4.50 Plastic materials can usually be heat-sealed to give a high-integrity barrier.

Polyethylene (polythene)

C4.51 Polyethylene is effectively impermeable to air and water and is not suitable therefore for general use in ethylene oxide sterilization processes without special precautions. However very thin films (up to 0.076 mm) thick allow the passage of ethylene oxide (by dissolving in the thin film and then evaporating from the inner surface). Paper laminated with a thin polythene film may thus be used to provide a heat sealable paper for use in ethylene oxide sterilization.

C4.52 High-density polyethylene is produced as a spun-bonded, non-woven (known commercially as Tyvek) paper-like material. It is very tough, and although it is porous like paper it is water repellent.

C4.53 In commercial use it has been found to provide a satisfactory bacterial barrier. It is frequently used in packs which are to be ethylene oxide sterilized and may be used with a clear film in the form of a pouch, as

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venting panels in impermeable bags made of, for example polythene, or as a sealing lid on blister packs.

C4.54 It has also been found suitable for use in steam sterilizers operating at sterilization temperatures up to 121°C.

C4.55 It has some disadvantages in that it may attract dust and fibres owing to its electrostatic character, it can be difficult to print on and also it may be difficult to seal, although these latter difficulties largely can be overcome by using non-oil based inks and lacquering with a suitable heat-seal lacquer, respectively. It is also expensive compared with paper.

C4.56 At temperatures above 125°C even high-density polythene has softened too much to be used on its own as an effective packaging material and it is therefore unsuitable for steam sterilization at 126°C or 134°C or for hot-air sterilization.

C4.57 Polythene can be sterilized by ionising radiation.

Polyester

C4.58 Polyester, in the form known as oriented or crystallised polyester, is used as a laminate with polythene in the construction of paper/plastic pouches and reel material.

C4.59 The polythene forms the inner surface which is heat sealed to the paper. The outer layer of the plastic laminate is polyester which gives the required mechanical strength at elevated temperature as well as a good printing surface.

Polyvinyl chloride (PVC)

C4.60 PVC generally has a very low stability to both heat and ionising radiation.

C4.61 PVC will absorb ethylene oxide in large amounts. This is exacerbated by the ethylene oxide combining with the phthalate plasticiser, from which it is aerated only very slowly under ambient conditions.

C4.62 Some grades of PVC are used for the moulded bases of commercially available blister packs.

Polypropylene and polycarbonate

C4.63 Both polypropylene and polycarbonate are relatively heat stable materials.

C4.64 Polypropylene has a very low permeability to air, moisture and ethylene oxide. It has been used extensively, either separately or in combination with other polymer laminates, as flexible, semi-rigid or rigid containers for heat sterilization of water and aqueous fluids.

C4.65 Polypropylene has been laminated with aluminium foil for use as packaging for wet or oily materials such as skin swabs, alcohol wipes.

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C4.66 Polycarbonate has been used extensively for the manufacture of autoclavable laboratory bottles (at 121°C).

C4.67 Certain grades of polypropylene, specifically formulated for the purpose, can be radiation sterilized.

Nylon

C4.68 Nylon is heat stable, and is also steam permeable but it is impermeable to air. Packaging constructed entirely from nylon film is unsuitable for steam sterilization because the air retained in the package may interfere with effective sterilization. It may however be used effectively in combination with a porous material, such as paper, to form a steam-sterilizable pouch.

Glass containers

C4.69 Glass containers, are usually in the form of ampoules, vials, jars or bottles and come in a variety of capacities and shapes, with several different closure systems.

C4.70 Three different grades of glass are available.

a. Soda glass is normally the cheapest (also referred to as Grade I). It is subject to hydrolytic attack particularly when autoclaved containing aqueous solutions. Solutions sterilized in bottles made of soda glass may become contaminated with reactive silicates and show an increased pH. Such bottles are rarely intended for more than a single use.

b. Sulphated soda glass, also referred to as Grade II, is soda glass which is protected against hydrolytic attack by a surface coating of sulphate. The coating is normally applied by sublimation of ammonium sulphate onto the surface of the hot glass concurrently with annealing during the manufacturing process. Bottles made of sulphated soda glass are rarely intended for more than a single use and, if re-used, the sulphate coating is eventually lost and the glass is once again subject to hydrolytic attack.

c. Borosilicate glass, also referred to as Grade III, is much more resistant to hydrolytic attack than Grade I or II glass and is generally the preferred material for containers which are to be used for autoclaving aqueous solutions. Providing there is a suitable cleaning process compatible with the intended end-use, bottles made of borosilicate glass may be re-used a number of times.

C4.71 Borosilicate glass also has better thermal shock resistance characteristics than soda glass when used in a similar container.

C4.72 Glass containers may also be used for dry heat sterilization, and can withstand radiation sterilization. However, irradiation causes a darkening of the glass which may be aesthetically unacceptable.

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Metals

C4.73 Metals are used in the fabrication of sterilization containers for use in both steam and hot-air sterilization processes, and to a lesser extent in gas processes such as LTSF or ethylene oxide. Since the material is neither porous nor permeable it must be constructed with a suitable venting system for use in sterilization processes other than dry heat or radiation.

C4.74 The choice of metal should be based on consideration of both its corrosion resistance to the sterilization process, for example in a steam atmosphere, and on its thermal characteristics. The ideal material would have a high thermal conductivity and a low heat capacity and would attain the required temperature quickly, uniformly and without the formation of excessive amounts of condensate.

C4.75 In practice, the choice is usually between aluminium, anodised or otherwise surface treated to give it suitable corrosion resistance, and a suitable grade of stainless steel.

Single-use packaging

C4.76 Both flexible and rigid packaging systems are available which are intended for single use.

C4.77 The recently enacted medical device regulations (see Chapter C2) include a requirement that sterile medical devices be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market. There is thus a clearly stated preference for single-use packaging as the primary packaging for sterile medical devices.

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Paper or textile wraps

C4.78 For wrapping materials two different folding methods have been adopted, both of which, when correctly executed, provide a suitable tortuous path to prevent the ingress of contamination.

C4.79 For large packs the parcel fold is the preferred method (see Figure C1).

C4.80 The pack contents are placed on the wrap, approximately in the centre of the wrap. The long edge of the contents should be aligned parallel to the long edge of the wrap.

C4.81 One of the long edges of the wrap is folded over the pack contents to overlap the centre line, and the edge of the wrap is turned back on itself. The fold made by the turning back of the wrap should overlap the centre line of the contents.

C4.82 The opposite side of the wrap is then folded over pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself.

C4.83 The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.

C4.84 The same procedure may then be repeated for an outer wrap(s).

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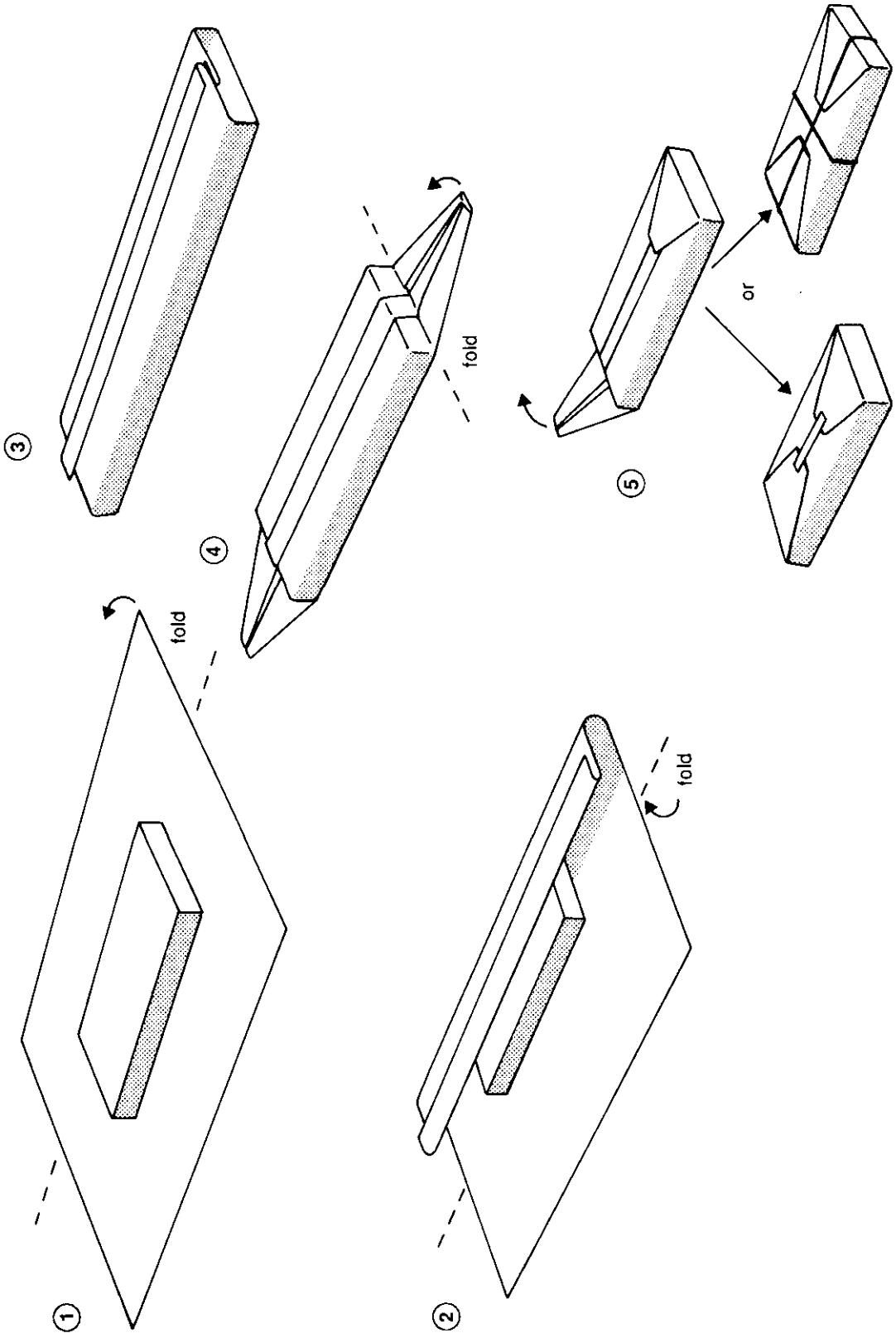
Figure C1: Diagrammatic representation of method for closing paper, non-woven or textile wrap using the parcel fold



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C4.85 The wrap is secured in position using pressure-sensitive adhesive tape (high-temperature masking tape or autoclave indicator tape) or by tying with tape or cords.

C4.86 For smaller packs the envelope fold is preferred (see Figure C2).

C4.87 In the envelope fold method the contents are placed on the wrap diagonally and slightly off the centre line.

C4.88 The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.

C4.89 This is repeated with the corners to the right and left of the first folded corner.

C4.90 In each case the corner is turned back to provide a flap for opening.

C4.91 Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.

C4.92 The envelope fold if properly executed is quite secure without further attention but if preferred may be secured also with tape or by tying.

Paper bags, paper/plastic pouches

Folding

C4.93 Folding is the simplest method to obtain a satisfactory closure for both pouches and bags, although it may not be convenient for high volume production (see Figure C3).

C4.94 The corners at the open end of the bag or pouch are folded diagonally to give mitred corners.

C4.95 The top of the bag or pouch is then folded over three times in succession and secured in place with a piece of high-temperature masking tape, or autoclave indicator tape.

C4.96 The folded top should always be secured with tape; staples should never be used because of the holes that are then made in the package.

C4.97 The folded top may be opened by cutting through the bag or pouch with a pair of sterile scissors. For non-critical applications it may be torn open; it should not be opened by removing the tape and unfolding the closure.

Self-seal

C4.98 Self-seal bags and pouches are closed by folding as described for plain top bags and pouches, above. However the bag or pouch is manufactured with an impact adhesive coating in a small area of the paper, which is protected before use by a piece of “release paper”.

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C4.99 When the bag has been filled the top is folded over as previously described, the release paper is removed and the adhesive patch is pressed onto the surface of the bag to secure the folded top in place.

Heat seal

C4.100 Paper bags and paper/plastic pouches and reel material are available in forms suitable for heat sealing.

C4.101 The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above those specified by the packaging manufacturer.

C4.102 Heat sealing is performed by compressing the opposing sides of packaging, coated on one or both inner surfaces with a lacquer, adhesive or polymer film, between heated plates.

C4.103 Packaging intended for heat sealing may be film coated, grid lacquered, or have an adhesive band.

C4.104 Film-coated heat-seal packaging has a thin film of a suitable polymer, such as polythene, laminated to the inner surface. When heated this melts sufficiently to fuse with the opposing surface and form a seal. The heat-seal polymer may be laminated to another plastic or to paper. The polymer film, if applied to the paper element, may limit the porosity of the pack.

C4.105 Grid-lacquered heat-seal packaging has one side, usually the paper, printed with a heat-seal adhesive in a repeating diamond pattern all over the inner surface. Care needs to be taken that the width of the heat-seal is sufficient to ensure that there is a continuous seal across the width of the packaging.

C4.106 Adhesive-coated heat-seal packaging has a band of heat-seal adhesive printed on the inner surface of the packaging in the area where the heat-seal is to be made. The adhesive is coloured, usually blue, to aid identification of the heat-seal area.

C4.107 The seals need to be peelable. They should peel without splitting, tearing or shedding paper fibres since fibres can cause adverse reactions if introduced into open wounds.

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Figure C2: Diagrammatic representation of method for closing paper, non-woven or textile wrap using the envelope fold

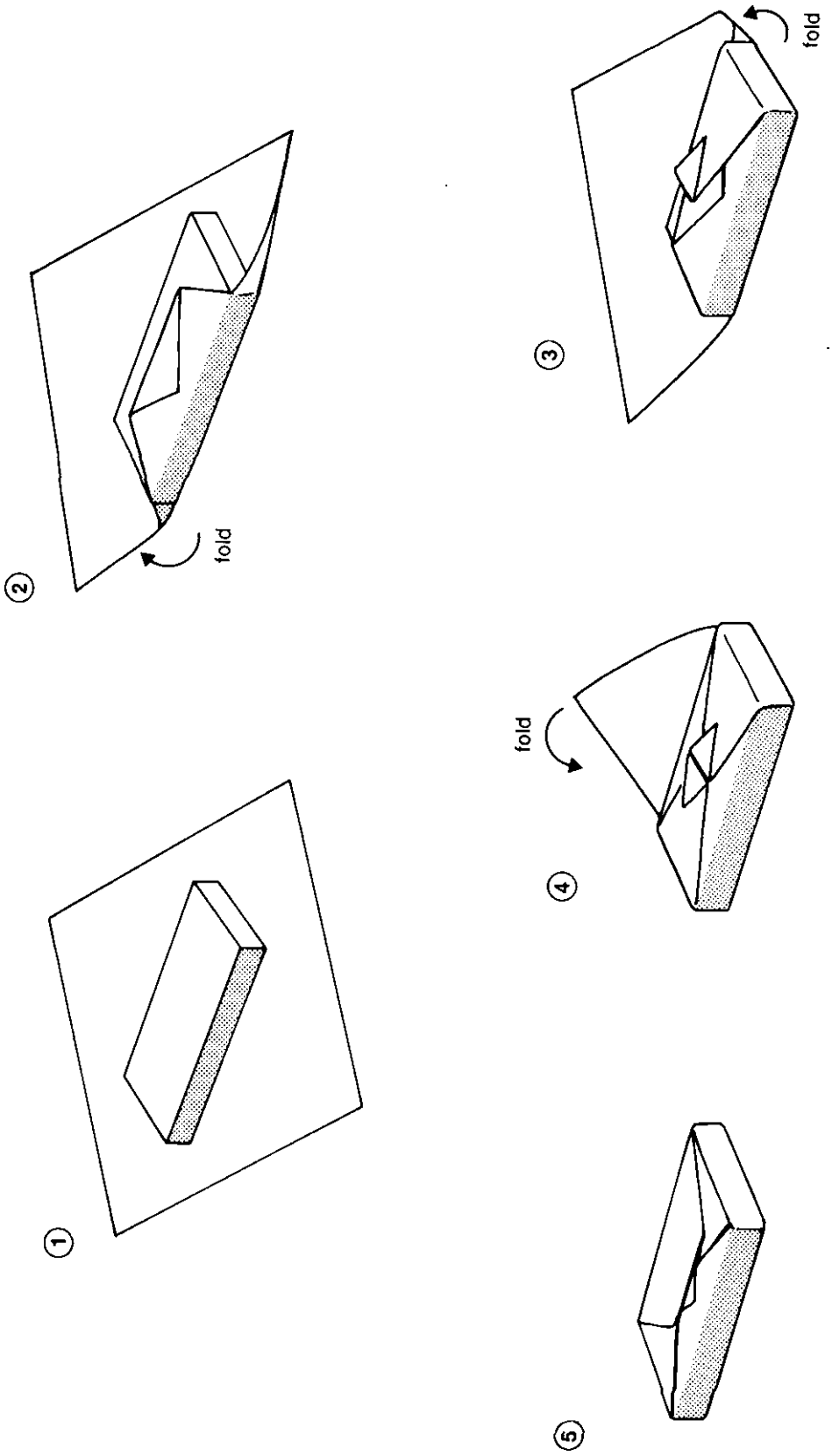

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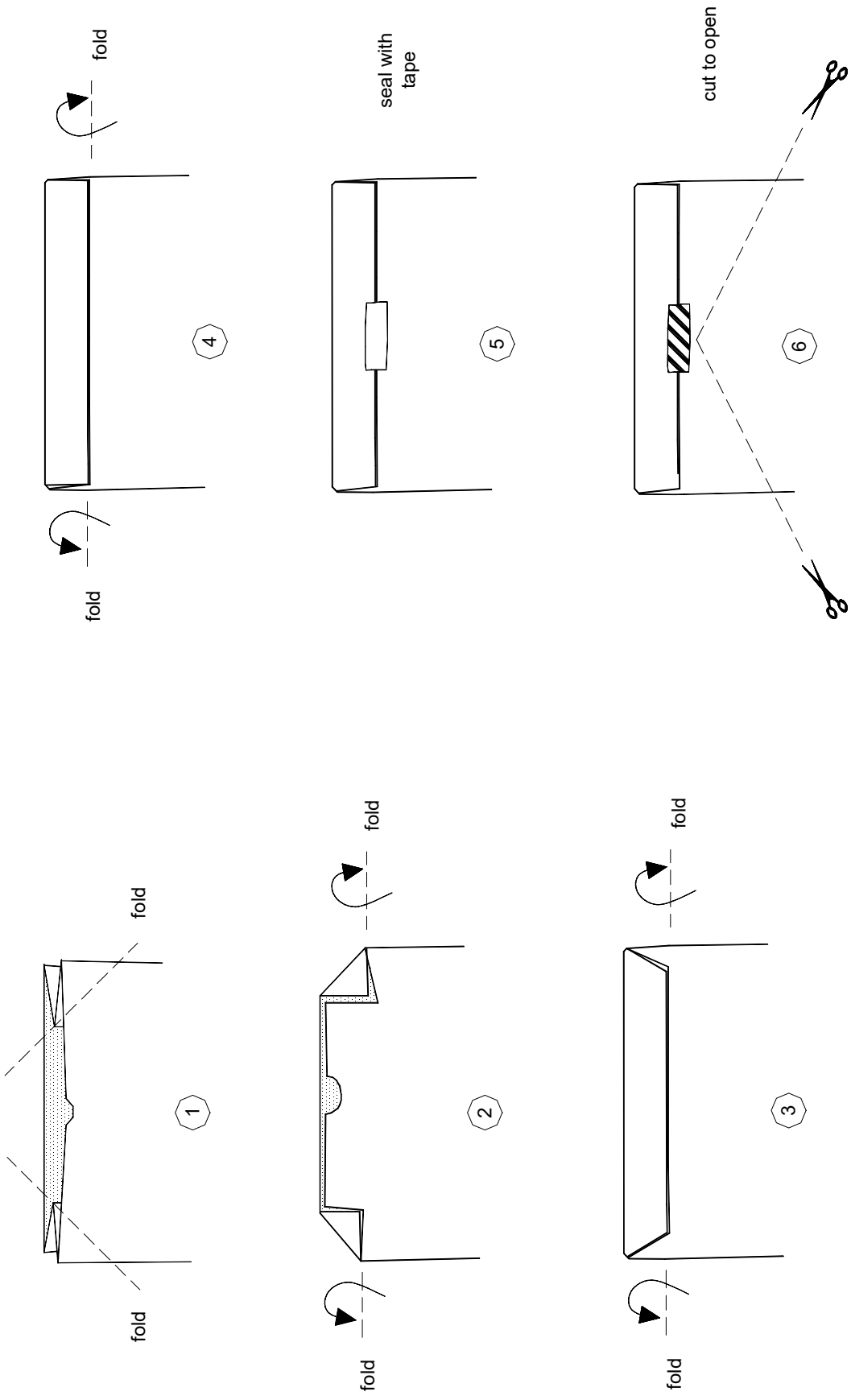
Figure C3: Closure method for plain top sterilizer bags



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C4.108 Peelability is a compromise between seal strength and the peel characteristics required which can only be achieved by use of the correct heat-sealing conditions.

C4.109 The heat-seal may be a single line, in which case it should be not less than 5 mm deep and extend across the width of the pack, or a series of lines each about 1 mm wide and 1 mm apart to give a seal width of about 9 mm, with each line extending across the full width of the pack.

C4.110 The heat-sealing process must be undertaken with care. Creases in the packaging material can result in inadequate or uneven seals.

C4.111 A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.

C4.112 The effect of the sterilization process on heat seals must be considered. The elevated temperatures involved in steam sterilization can weaken the seals. Ethylene oxide gas leaves many seals unaffected but can cause embrittlement of others.

C4.113 Heat sealing is not only used for flexible packaging. It may be used also on rigid packaging when lids are sealed onto moulded plastic bases. The base tray may be moulded in-line just before filling or may be pre-formed. The lid may be of paper, Tyvek or other porous material for use in steam or gas sterilization processes or of impermeable film for use with radiation sterilization.

Glass containers

C4.114 Bottles and vials are extensively used for aqueous solutions for use as topical and parenteral medicines, microbiology media, laboratory reagents, in vitro diagnostics, disinfectants, etc. which are to be sterilized by moist heat.

C4.115 Glass containers may also be used for hot air sterilization of non-aqueous liquids, such as oils.

C4.116 Containers should never be filled with a volume greater than the manufacturer’s recommended maximum.

Ampoules – fusion seal

C4.117 Two forms of glass ampoule are available; one form intended only for automatic (or semi-automatic) filling and sealing and one which is suitable for manual sealing.

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C4.118 Ampoules intended for automatic filling and sealing may be supplied, internally clean, sterile and apyrogenic, with the neck closed by a “bubble” of glass. During the automatic filling process this “bubble” is melted by a flame directed vertically downwards to open the ampoule immediately prior to filling. This normally takes place in an environment controlled to be free from contamination. This type of ampoule is not suitable for manual filling and sealing operations.

C4.119 The relevant DIN standards may be used as suitable specifications.

C4.120 Ampoules are sealed by fusion. After filling, the neck of the ampoule is heated, almost invariably in a gas flame, until the glass softens and the walls of the neck coalesce, surplus unmelted glass in the neck above the point of melting is drawn away and the fused end of the neck is allowed to cool.

C4.121 For any given design of ampoule, the temperature of the flame, the duration of heating and the time and speed at which the surplus neck material is drawn off all affect the quality of the seal. When correctly performed the seal is as strong, or stronger than other parts of the ampoule.

C4.122 Ampoules for use in freeze driers are similarly sealed by fusion.

C4.123 Ampoules are opened by breaking off the neck. This may be facilitated by the inclusion of a deliberate weak point, in the form of a break ring, at the base of the neck during manufacture. Other methods which are available include notching the neck of the ampoule with a glass file, creating a fracture line by the application of a hot wire or rod and several commercially available devices.

C4.124 Whichever method is to be employed, users should be given appropriate instructions and training and should always take precautions to protect their hands from injury due to broken glass.

C4.125 Ampoules are produced to a high level of consistency and faults in sealing are likely to be due to poor setting up or control of the sealing method and rarely, if ever, due to variations in the ampoules.

C4.126 After the ampoules have cooled, careful visual examination, preferably using a magnifier and a polarised light source, should be used to inspect the seal and any showing cracks, thinning or “blowing” of the seal and sharp protrusions or “tails” of glass, should be rejected.

C4.127 A vertical drop of 10-15 cm, for example inside a tube of suitable diameter so that the sealed end impacts onto a solid surface, such as a plastic laminate, may also be used to test the ampoule seal. A satisfactory seal will survive, whereas a weak seal will break.

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Vials and bottles

C4.128 As manufactured, glass bottles are generally clean, sterile and apyrogenic. Nevertheless they should be washed before use since they may have become contaminated during packaging and distribution, unless special precautions were taken to avoid this happening.

Screw caps

C4.129 Screw caps may be made of metal or plastic. They may be used to used to retain in place a separate elastomeric seal, such as a stopper or a wad, or they may incorporate a seal within the cap. In either case the seal is formed by compression of a deformable sealing material between the cap and the glass container. The compressive force applied is a key factor in creating a leak-tight seal.

C4.130 Metal caps may “back-off” during autoclaving. The differential thermal expansion of the metal of the cap and the glass of the bottle combine to make the cap unscrew slightly during processing. This rarely happens with plastic screwcaps.

C4.131 The problem can be minimised for metal caps by careful control over the extent to which the cap is tightened before sterilization.

C4.132 Devices to control the force used to tighten the cap (torque) should be used both to ensure reliable sealing and to minimise the risk of overtightening which can damage the cap or make it difficult to remove.

Crimp caps

C4.133 Crimp caps are metal, or sometimes plastic, capsules used to retain an elastomeric seal, usually in the form of a stopper, in position in the neck of the container.

C4.134 During the application of the crimp seal, pressure is applied to compress the stopper slightly against the top surface of the neck finish of the bottle. The skirt of the overseal is bent under the base of the retaining rim on the bottle neck by the crimping device. This retains the stopper in place and maintains it under slight compression to provide a good seal.

C4.135 During steam sterilization of the sealed container the pressure applied by the crimp may be released to some extent by the thermal expansion of the metal capsule. This, and the high internal pressure generated within the container, may cause the seal to leak. It should not be assumed that a seal which is demonstrably leak tight at room temperature will remain so throughout the various stages of steam sterilization.

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Re-usable packaging

Textiles

C4.136 Textiles are used in combination with aluminium trays for packs of theatre instruments.

C4.137 The textile wraps should be laundered before each re-use.

C4.138 Control should be exercised over the laundry process to ensure that fabric softeners and fresheners are not used since many of these contain volatile components which will evolve gas during steam sterilization and compromise the efficacy of the sterilization process.

C4.139 The importance of thorough inspection before re-use cannot be over-emphasised. A light table should be used, and wraps with pinholes, clearly visible as points of light, should not be used.

C4.140 The location of the defect should be clearly marked and the item sent for repair by means of a heat-seal patch. Sewn patches are not acceptable because of the needle holes created around the patch.

C4.141 Worn textile wraps are readily discernible since the light will shine through the more open weave that occurs as the fabric wears. These should no longer be used as a sterile packaging wrap.

Containers for solid goods

Impermeable or unvented containers

C4.142 Aluminium tubes with crimped foil caps and larger canisters (made from aluminium, copper or stainless steel) with slide or screw-fit caps may be used satisfactorily for hot-air sterilization. Containers of this sort are used frequently for pipettes or glassware in the laboratory.

Open-topped trays and perforated containers

C4.143 Trays for containing sets of theatre instruments, or similar, are often constructed in aluminium. Plastics such as polypropylene may also be used. The trays may have solid bases and sides or be equipped with drainage ports to allow condensate formed during steam sterilization to run off.

C4.144 When condensate drainage is provided it is necessary to ensure that the condensate is not discharged onto other parts of the sterilizer load, which will then emerge from the sterilizer wet.

C4.145 Trays may be overwrapped in textiles, single-use wraps or bags, or a combination of these materials to achieve the required protection, absorbency and microbial barrier properties.

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Instrument orientation trays

C4.146 These trays, usually constructed in metal, are fitted with retaining clips designed to hold a particular set of instruments in position. They are often found in dental practice and also for use with sets of orthopaedic instruments and rigid endoscopic instruments.

C4.147 They are almost invariably fully vented, or unlided, and in this condition may be suitable for use in a steam sterilizer intended for unwrapped instruments and utensils (see paragraph C3.23).

Dressings drums

C4.148 Perforated metal containers, fitted with a filter material and closable louvres were specified in BS 3281, 1960 (now withdrawn), for use as “dressings drums”. These were intended to contain dressings and porous goods sufficient for a number of clinical procedures. The product has been regarded as obsolete except for its use, until recently, as a convenient container for towels for the Bowie and Dick test. Even this use has now been discontinued.

C4.149 There is, however, a new generation of re-usable rigid containers intended for use as a packaging system in steam (and in some cases, gas) sterilization processes. These are intended to contain instruments and/or porous goods which will be used in a single clinical procedure. They are thus more akin to the trays described in paragraphs C4.143 to C4.145 than to the obsolete dressings drums.

Re-usable rigid containers

C4.150 BS EN 868-8 specifies performance requirements for rigid re-usable containers.

C4.151 Container systems are constructed in a variety of materials and those from various manufacturers differ greatly in design, construction and mode of operation.

C4.152 The containers are constructed from impermeable materials. The joint between the lid and the base is sealed by means of a suitable gasket, which should be accessible for inspection and cleaning between uses.

C4.153 In order to permit the flow of gases (air and steam and, where applicable, sterilant gas) in and out of the container that is required by the sterilization process the containers are fitted with one or more sterilant ports.

C4.154 Two different operating principles are used for the sterilant ports, although both may be used in combination. The exchange of gases may be through a porous filter material or through a valve system.

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C4.155 The filter system is little different in principle from the porous packaging systems considered previously. Its compatibility with the sterilization process depends on its porosity and on being able to provide the necessary flow rate through the filter to permit attainment of the sterilizing conditions within the container.

C4.156 The ability to maintain sterility depends on the filter efficacy and whether it is able to exclude particles of a size which may contain viable organisms. The small area of surface available compared with the volume of the pack produces relatively high flow rates across the filter material and this influences the materials which can be used effectively.

C4.157 If a re-usable filter is used then great care is needed to ensure that:

- it has not become partially blocked, thus impairing the flow of gases and compromising the sterilization process;
- it has not been damaged, thus allowing the passage of unfiltered gases which would compromise the maintenance of sterility.

C4.158 Both re-usable and single-use filters need to be installed correctly so that the filter is effectively sealed in the holder and there is no passage of unfiltered gases around the filter.

C4.159 The alternative system for sterilant ports is the valve system.

C4.160 Outside the sterilizer the valve is normally closed and, if the seals on the valves are effective, presents an impermeable barrier to external contamination.

C4.161 The valve system has to be arranged to open automatically in the sterilizer to permit the exchange of gases between the container and the environment.

C4.162 A number of systems are used by the various manufacturers but most depend on valves which open in response to a pressure difference between the container and its surroundings. A diagram of the operation of such a system is shown in Figure C4.

C4.163 It is apparent that a finite pressure difference must exist across the valve before it will open. The magnitude of the pressure difference will depend on the force exerted by the springs keeping the valve closed.

C4.164 If the pressure difference required to open the valve is too great, the contents of the container will not be exposed to the sterilizing conditions in the sterilizer chamber. The correct functioning of the container is closely related to the pressure change characteristics of the sterilization cycle.

C4.165 If the required pressure difference is too small the valve will open outside the sterilizer due to changes in ambient pressure and temperature, thus allowing the inflow of unfiltered air from the environment.

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C4.166 Some container systems are also fitted with a valve in the base of the container which is used to allow condensate to drain away, to assist in drying the contents of the container.

C4.167 The condensate drain valve may be fitted with a thermostatic device to open the valve when it is above a specified temperature, say 80°C, or it may operate on pressure differential as previously described for valved sterilant ports.

C4.168 After repeated use, the springs controlling a valved system will age and the force exerted by them will change. It is essential that the manufacturer's instructions for maintenance, testing and replacement of key components such as seals, sterilant ports and drainage valves are followed rigorously.

C4.169 The performance of either type of container may be seriously affected both by the nature of the sterilization cycle (particularly the characteristics of the air removal phase and the drying stage) and by variations in the quality of services supplied to the sterilizer (for example the dryness fraction of the steam). These variables are sterilizer and site specific respectively.

C4.170 It is necessary, therefore, to establish, by appropriate on-site testing, that any particular design which it is intended to use functions correctly in the specific sterilization cycle with which it is to be processed, in the sterilizers which will be used in practice.

C4.171 Re-usable containers have a number of apparent advantages. They offer excellent mechanical protection to the contents and a convenient, modular system for storage and distribution.

C4.172 The use of a solid-walled container gives the impression of providing good protection against microbial and other environmental contamination. In practice the barrier properties are dependent on the adequacy of gaskets and seals and the sterilant ports described above.

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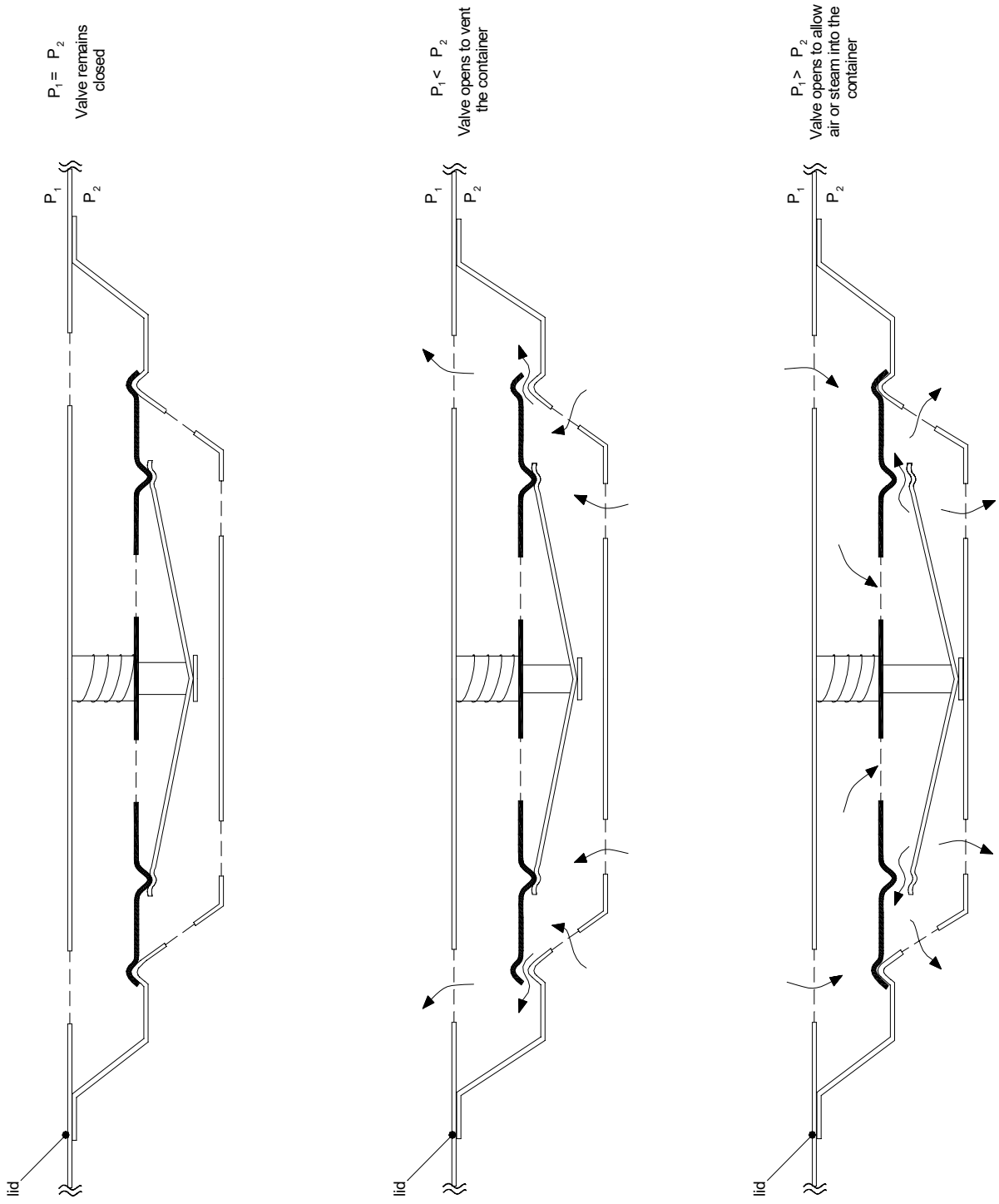
Figure C4: Diagram to show the principle of operation of value-type re-usable container systems



NOTE: The above diagrams are intended to be an idealised example of the operation of a valved system. They do not represent any commercially available system.

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C4.173 The condition and function of filters, valves, sealing gaskets and locking systems needs to be verified on each container before each use.

C4.174 Between uses containers should be disassembled and cleaned following the manufacturer's recommendations. These usually suggest cleaning by washing with a mild detergent, either manually or in a washer/disinfector.

C4.175 The choice of detergent should accord strictly with the manufacturers recommendations since a number of cleaning agents in common use can cause corrosion or surface cracking on the metal or plastic surface of containers.

C4.176 These containers are often used to return used and soiled instruments, which are potentially contaminated. Whenever practicable they should be decontaminated and cleaned in a washer/disinfector.

C4.177 Most containers are fitted with interior baskets or mesh trays used to hold the instruments. These may be suitable to contain returned instruments as they are processed through a washer disinfector.

C4.178 In use the containers need to be properly loaded if they are to be used successfully. The manufacturers recommendations concerning the maximum weight, the proportion or density of metal ware or rubber goods and the presence and location of absorptive materials in the load should be followed.

C4.179 Some containers are intended to be used in conjunction with porous packaging materials, either as an inner or outer layer of packaging, whereas others are intended to be used, and will only function correctly, without any other packaging being present during sterilization. It is important that the manufacturer's instructions are followed.

C4.180 Containers which are not intended for use with a second layer of packaging, that is those which can only function as a single packaging layer, are not suitable for use in an aseptic environment (see paragraph C3.111).

C4.181 Containers manufactured to the proposed European Standard will be sized in relation to the standard loading module for large steam sterilizers (see EN 285). High packing densities within the sterilizer chamber can be achieved and it is important to ensure that the maximum permitted load for the sterilizer is not exceeded.

C4.182 To avoid problems with moisture retention within the container it may be necessary to increase the time allowed for the drying stage of the sterilization cycle.

C4.183 Each container should be fitted with a tamper evident closure system which should provide a clear indication when the integrity of the closure has been compromised.

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C4.184 The containers are designed to stack for storage purposes. Containers from any one manufacturer should stack securely but containers of different provenance may not.

C4.185 When purchasing this type of packaging system all the containers should be from the same manufacturer to ensure compatibility.

C4.186 Re-usable containers are often promoted on the basis that they are more cost effective than single-use packaging. A decision based on cost grounds requires careful evaluation of the initial capital cost, cleaning and maintenance costs (including all equipment, components, consumables and labour required), the working life (the number of re-uses) which the manufacturer is prepared to guarantee, the likelihood of damage or loss and the cost of eventual disposal.

Glass containers

C4.187 Bottles intended for single use should not be re-used. Bottles intended for multiple use are available for most applications.

C4.188 Re-usable containers should not be used for solutions intended for parenteral administration.

C4.189 The information given for single-use screw cap and crimp-on closures is equally applicable to re-usable containers, with the following additional requirements.

Vials and bottles

Cleaning

C4.190 Before bottles can be satisfactorily re-used a cleaning procedure is required which has a demonstrated capability to remove any dirt or contamination, as well as any residues from the previous use. It is also important that the cleaning process is well controlled and ensures that there are no residues of cleaning agents.

C4.191 Cross-contamination can be most easily controlled by ensuring that whenever possible re-usable containers are only refilled with the same product, for example by reserving a set of bottles only for sterile water and another set only for sterile isotonic saline and so on.

Inspection

C4.192 Inspection of the bottles after cleaning and prior to re-use should include a careful visual examination of the neck finish. A chipped or cracked neck finish could prevent an adequate seal or lead to the failure of the seal during transport or storage. Bottles that have been damaged in this way should be scrapped.

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C4.193 Inspection of the outer surface of the bottle should also be made. Bottles being sterilized are subjected to considerable stress both from the high internal pressures generated and from thermal shock. Scratches or other mechanical damage on the outer surface of the bottle weaken it and significantly reduce the pressure and the thermal shock which can be tolerated without breakage.

C4.194 One bottle breaking in a sterilizer load may provide sufficient force to cause others to break also. Re-usable bottles with surface damage should be rejected and either used for applications which do not require steam sterilization or be scrapped.

C4.195 The inspection of the neck finish should also consider any damage to the screw threads or the retaining shoulder on the outside of the neck of bottles which are closed with screw caps or crimped seals respectively.

Screw caps

C4.196 Screw caps, and the elastomer wads, stoppers or bungs used in conjunction with them, are often regarded as re-usable, and many of them may be satisfactorily re-used a number of times.

C4.197 The screw cap should be separated from any sealing wad and both should be thoroughly cleaned and inspected for damage before re-use.

C4.198 Metal caps that have been dented, or are showing visible signs of wear on the threads, should be scrapped.

C4.199 Rubber wads and rubber stoppers should also be carefully inspected for surface damage and any showing cuts, abrasions, staining or permanent deformation should be scrapped.

C4.200 Plastic screw caps with a built-in seal are also commonly used. These should be inspected very carefully for damage to the thin sealing gasket which is moulded into the inner surface of the cap. Any damage to this area will almost certainly cause the cap to leak.

Crimp caps

C4.201 Crimp caps are not themselves re-usable but the bottles on which they may be used can be. A special tool and some care is needed to remove crimped seals without risk of injury.

C4.202 The old seal should be discarded. The seals are usually fabricated from aluminium and the metal can therefore be reclaimed.

C4.203 The elastomer seal should also be scrapped.

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C5. Purchase, quality control and storage

C5.1 The purchase, handling and control of packaging materials should be given similar attention to that given to components and other materials incorporated directly into the product.

Purchase

C5.2 All packaging materials should be purchased, whenever possible, to a British Standard or other suitable specification from approved suppliers.

C5.3 Packaging material should be purchased only to an agreed, written specification. When it is intended to purchase a catalogue item, the specification for that item should be obtained from the supplier and used as the basis of that purchase, and all subsequent purchases of the material. This should ensure that the user is informed of any changes in specification subsequently made by the supplier.

C5.4 The purchase order should be based on not more than the quantity which can reasonably, be expected to be used within the manufacturer's stated shelf life for the product.

C5.5 Although paper products, and other packaging materials, have a prolonged shelf life the manufacturer's expiry date may relate to other properties of the product such as a process indicator or a heat-seal adhesive whose performance may deteriorate on storage.

C5.6 The specification and purchase order should require that the material be delivered in unopened containers, using covered vehicles, suitably protected from water damage or soiling and that it is handled with care to prevent mechanical damage.

C5.7 The packaging materials should be supplied suitably wrapped to provide the required protection when it is stored under the specified conditions.

Specification

C5.8 For medical devices and medicinal products, and generally for laboratory products also, the specification should include:

- a description of the materials including:
  - the designated name and any code or reference;
  - the size;
  - the quantity in each unit pack delivered;

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- the reference, if any, to a pharmacopoeial monograph, British Standard or other published specification;
- the approved suppliers, and if possible, the original producer of the material;
- a specimen of printed materials;

- directions for sampling and testing, or reference to written procedures;
- qualitative and quantitative requirements with acceptance limits;
- storage conditions and precautions including the maximum period of storage.

Quality control

C5.9 In many cases users of packaging materials will lack the facilities necessary to carry out a comprehensive independent assessment of delivered materials for conformity to their purchase specification.

C5.10 Nevertheless every reasonable step should be taken to establish conformity. This requires that each delivery should be examined to ensure that:

- there is no visible damage to the shipment;
- the delivery note, the label description and the purchase order are in agreement concerning the quality, size and number of the material;
- that each consignment has clearly identifiable lot numbers;
- that each lot delivered is accompanied by a Certificate of Analysis or Certificate of Conformity, or if the delivery is a further supply from a lot previously received that the appropriate certificate is on record.

C5.11 When, due to the nature of the packaging or the product, it is necessary to carry out tests, other than a careful visual appraisal, on incoming packaging materials a random sample should be taken and submitted for analysis.

C5.12 There should be a formal sampling plan which should take account of:

- the quantity received;
- the quality required;
- the nature of the material, and the risk involved if the material is not to specification, for example if the product makes contact with the packaging material;
- the established reliability of the packaging manufacturer.

C5.13 The number of samples taken should be specified statistically, in accordance with a recognised standard, such as BS 6000 or BS 6001.

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C5.14 In confirming that the material supplied is identical in every respect with the material ordered particular attention should be paid to printed labels and packaging materials.

C5.15 A system for segregating delivery of packaging materials which have not been examined from those which have been found suitable for use should be implemented.

C5.16 Provision should be made for the temporary secure storage, prior to disposal or return to the supplier, of material which was delivered but, on examination was found not to conform to the specified requirements.

Storage

C5.17 Packaging materials should be stored under conditions which are maintained within those specified by the manufacturer of the packaging. This is best achieved by environmental control of the storage area.

C5.18 The temperature, and where necessary the humidity, of the storage environment should be monitored with a maximum-minimum thermometer and hygrometer, even if the store is not environmentally controlled.

C5.19 Paper and other moisture sensitive packaging materials should not be stored adjacent to:

- external walls or other surfaces which may be at a lower temperature than the ambient temperature of the store;
- sources of heat which could cause dehydration of the packaging material.

C5.20 Sheet materials should be stored flat, not on edge.

C5.21 Packaging materials should be stored on shelves, clear of the floor.

C5.22 Pre-printed labels and other printed packaging materials should be stored in secure conditions which exclude unauthorised access and should be transported in separate containers in order to avoid mix-ups.

C5.23 Packaging materials should be issued for use only by authorised personnel following an approved and documented procedure.

C5.24 Outdated or obsolete packaging material, especially printed material, should be destroyed and this disposal recorded.

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C6. Validation of packaging systems

C6.1 All materials and procedures for packaging should be specified in documented form.

C6.2 Before a particular packaging system is adopted for a product, or group of similar products, it should be evaluated to establish its suitability.

C6.3 This evaluation should be documented.

C6.4 Specific testing may not be necessary when appropriate data are available, historically from similar use (whether by the same or different sterile product manufacturers), from the manufacturers of the packaging system or from an independent third party.

C6.5 The factors that need to be considered for evaluation include, as a minimum, those listed in paragraph C3.5.

C6.6 The compatibility of the packaging with the sterilization process can be established for many packaging systems by demonstrating conformity of the packaging and the sterilization process with published standards, for example sterilization-grade paper bags manufactured in conformity to BS EN 868-4 for use in a sterilizer conforming to BS EN 285 and operated in accordance with the guidance given in this SHTM may be presumed to be compatible.

C6.7 Re-usable containers should be subjected to thermometric performance tests before they are adopted as a packaging system. This may be accomplished using a container modified to provide a gas-tight thermocouple entry port and carrying out tests essentially similar to the small load and full load tests described in SHTM 2010 Part 3 paragraphs 13.7 to 13.14 and 13.15 to 13.24 respectively.

C6.8 The tests should be carried out with a container fully loaded with items of the type which it is intended to process. If both instruments and textiles are to be processed the container should be tested under both fully loaded conditions. The full load test should be carried out with the sterilizer fully loaded with fully loaded containers.

C6.9 The temperature profile obtained should not show any delay in the contents of the container equilibrating with the sterilization temperature in the chamber, when compared to the results obtained using a small-load test pack.

C6.10 Load dryness should be verified using either the hospital load test described in SHTM 2010 Part 3 paragraph 13.37 or, when quantitative results are necessary, by a modification of the method described in SHTM 2010 Part 3 paragraphs 13.25 to 13.36.

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C6.11 The compatibility of the packaging with the labelling system will usually be established by using the labelled pack for such tests as may be necessary.

C6.12 The compatibility of the packaging with the user's requirements at the point of use, for example aseptic opening, should be verified by consultation with the user. Testing is rarely required.

C6.13 The sensitivity of the pack contents to particular risks, such as irradiation, moisture, mechanical shock, static discharge and the compatibility of the packaging with the contents, for example the medical device or medicinal substance, in other words, that the packaging has no adverse effect on the medical device or vice versa, will usually be apparent from historical data. When new products are to be packaged and sterilized, the instructions which the device manufacturer is required to provide should be followed.

C6.14 The protection provided by the packaging against adverse environmental influences which may reasonably be anticipated, such as mechanical shock, vibration, chemical or microbial contamination, may be considered in two stages:

a. First, the extent to which the environment to be encountered during transport and storage may be controlled. Secondly, the protection provided by the packaging.

b. Adequate performance of the packaging should be demonstrated under the anticipated conditions of use by simulating the abuses a pack may encounter during routine methods of transit and storage.

C6.15 Guidance on the methods to be adopted is given in BS EN 22872: 1993.

C6.16 The protection provided by the packaging against microbial contamination should also be evaluated.

C6.17 Tests for bacterial penetration of packaging are beyond the experience and competence of most hospital users and could only be carried out by specialist subcontractors. There is no agreement on suitable test methods, or performance standards, for the microbial barrier properties of sterile packs.

C6.18 The microbial barrier properties of a sterile pack are dependent on both the materials of which the packaging is made and the construction of the package.

C6.19 Materials that are impermeable to gases may reasonably be assumed to present an absolute barrier to microbial contamination. When such materials are used in the construction of a pack which is hermetically sealed (for example glass ampoules) the barrier may also be assumed to be absolute.

C6.20 Package testing may be avoided by the compilation of evidence that the materials of construction are themselves an adequate barrier together with evidence that all seals and closures are adequate barriers.

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C6.21 Two different approaches have been adopted to testing porous materials for their ability to exclude microbial contamination; tests based on physical particulate retention (for example the methylene blue test specified in British Standards for sterilization packaging) and tests based on the use of micro-organisms (for example the tests specified in German standards for sterilization packaging).

C6.22 For many materials a standard specification has been adopted which specifies the physical and/or chemical characteristics of the material which have been shown to provide satisfactory performance against a standard penetration test. Whenever possible materials in compliance with one of these standards should be adopted so that purchases are to an agreed specification which will give the required level of assurance.

C6.23 The methods available for verification of the adequacy of the seal or closure depend on the method chosen. Seals formed in impermeable packaging materials can be tested by one of several leak test methods but these are not generally applicable to seals formed in porous materials, nor to closures which rely upon a tortuous path to exclude microbial contamination.

C6.24 Heat seals are also dependent for their success on the performance of the heat sealer used. Several methods for testing heat seals are available but visual examination of the quality and uniformity of the seal from samples of packaging taken before and after sterilization and before and after storage and journey trials may be sufficient.

C6.25 Closures which rely on a tortuous path formed by folding are very dependent for their success on the skill of the operator forming the closure. There is good published evidence, from a number of studies carried out over many years, that the closures described in paragraphs C4.78 to C4.97 are satisfactory.

C6.26 For packaging materials to be used in gas or irradiation sterilization processes it may be necessary to determine the extent and nature of microbial contamination on the packaging before sterilization. This should not be necessary for steam sterilization processes operating at 134°C for not less than three minutes.

C6.27 When knowledge of the packaging bioburden is required this information should be sought from the packaging manufacturer or it should be determined in accordance with BS EN 1174 by an appropriately experienced laboratory.

C6.28 When re-usable packaging systems are being evaluated it is important that the cleaning, inspection and maintenance procedures and methods are also evaluated for their ability to consistently restore the packaging system to the required condition for re-use.

C6.29 Before any performance testing is undertaken a test protocol should be prepared. This should document:

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- the tests to be performed, including full details of the equipment and methods to be used, personnel etc;
- the purpose of the tests;
- the sequence in which the tests are to be carried out;
- the format in which the results are to be documented;
- the pass fail criteria for each attribute being evaluated.

C6.30 The test protocol and the written report of the results should form part of the validation documentation.

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C7. Facilities and environmental control for packaging operations

Packaging operations

C7.1 In SSDs the assembly of components, placing them in primary packaging and sealing or closing the packaging usually is referred to as a “packaging operation”. Thus is in contrast to pharmaceutical and laboratory practice where the same operation is described usually as a “filling operation” and the term “packaging operation” is reserved for the subsequent, often post-sterilization, application of secondary packaging. In the following section “packaging operation” refers to the application of primary packaging and any secondary packaging which is included in the sterilization process.

C7.2 Detailed guidance on suitable facilities is given in Scottish Hospital Planning Note13; *Sterile services department* and Scottish Hospital Planning Note 29; *Accommodation for pharmaceutical services*.

General requirements

C7.3 All areas used for the reception, inspection, storage, filling, and sealing of packaging require a high standard of finish and cleanliness.

C7.4 Areas where clean, unpacked product is to be handled for, say, assembly and packaging, need a controlled environment to minimise the potential for recontamination of product by, for example mechanical ventilation or gowning procedures.

C7.5 All exposed surfaces should be smooth, water resistant and sufficiently durable to withstand frequent cleaning. The construction and any fitments should be designed to be free from crevices and sharp internal corners, which can trap dirt.

C7.6 Areas where product, ready for incorporation into primary packaging, and primary packaging materials are exposed to the environment for significant periods should be controlled to defined standards of environmental cleanliness.

C7.7 For SSDs there should be a dedicated room where the production of packs, trays etc. takes place. This should be a controlled environment. SHPN 13 recommends that packaging facilities for SSDs should be controlled to BS 5295 Class L and a detailed summary of the environmental needs of the various areas is provided in SHPN 13, Appendix 5.

C7.8 The GMP Guide for Pharmaceuticals recommends that parenteral solutions should be filled under a laminar flow work station (Grade A) within a cleanroom controlled to Grade C.

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C7.9 The provision of controlled, clean environments has additional implications for staff hygiene, gowning and entry procedures and the behaviour of personnel within the facility. These requirements are fully described in the relevant GMP guides.

C7.10 Doorways throughout the facility should be wide enough, and free from damaged or rough edges, to eliminate the danger of packs of product on trolleys being damaged as they are wheeled through.

Facilities for packaging operations

Cleaning

C7.11 All operational areas of a sterile-product manufacturing facility need to be maintained to a high standard of cleanliness.

C7.12 Detailed cleaning procedures and schedules should be documented and their implementation monitored.

C7.13 For guidance on suitable procedures and schedules see ISSM Guide to Good Manufacturing Practice for NHS Sterile Services Departments and The DoH MRS Guide to Water and Environmental Cleaning.

C7.14 Surface finishes and cleaning methods must be compatible. Appendix 6 of SHPN 13 suggests appropriate finishes.

C7.15 Cleaning equipment and facilities for the storage and preparation of cleaning materials and equipment should be provided separately for areas between which cross-contamination could be problematic.

Cleaners' room

C7.16 SHPN 13 recommends the provision of a dedicated cleaning facility for the packing room, and a separate, dedicated, cleaning facility for the linen preparation area (if one is used).

C7.17 The cleaning facility provides storage for cleaning equipment and materials, a sink or sluice with hot and cold water of the appropriate quality and other facilities needed for the cleaning and preparation of the cleaning equipment. In addition, it usually accommodates consumable items for operational areas which are normally replaced by the cleaner. This would include plastic waste bags, liquid or leaf soap refills for dispensers in changing rooms etc.

C7.18 Hand washing and drying facilities should also be available in the cleaning facility.

C7.19 Whether or not separate facilities are provided, it is necessary to ensure that separate cleaning equipment is used for the assembly/packing area and other areas within the unit.

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Sterile services departments - SSD

C7.20 The packing room receives single-use materials from materials' store and reusable goods after the completion of appropriate decontamination procedures.

C7.21 The decontaminated re-usable goods will include components to be incorporated into packs and may include re-usable packaging, such as textiles, instrument trays, re-usable containers.

C7.22 Within each of the areas supplying the packing room, or at the interface between these areas and the packing room there is usually provision of inspection/verification facilities to ensure that all product transferred into the packing room is the correct item and in a suitable condition for use.

C7.23 In the packing room these goods are then assembled into the combinations specified to form the pre-set trays and procedure packs which are required. These are then packed in preparation for sterilization (see SHPN 13).

Linen room

C7.24 Cleaning facility - dedicated required same as packing room. Textiles for incorporation into packs may be product items, such as surgical drapes, towels or gowns, or they may be wrapping materials.

C7.25 Textiles for wrapping purposes may be received in the SSD as laundered linen which has already been checked and folded to an agreed pattern or in bulk form, unchecked and unfolded.

C7.26 The SSD has an obligation to ensure that the laundry process is defined and controlled and the quality checks on the textiles to be used are rigorously applied to ensure that the pre-determined standard is maintained, even if the laundry has the devolved responsibility for inspecting the packaging textiles (see paragraphs C4.136 to C4.141).

C7.27 When unchecked linen is provided from the laundry, the SSD will require suitable inspection facilities within a linen preparation room.

C7.28 When textiles are to be used as the primary wrap for sterile packs they have to be inspected to a defined standard, which should include freedom from all tears, cuts and visible holes. A light table is essential for inspection to this standard.

C7.29 When the textiles are used only as an inner wrap and it is intended that the necessary bacterial barrier properties will be provided by an outer wrap of another material, such as a sterilization grade paper wrap or bag, a less rigorous inspection standard may be accepted for the textiles. A large flat surface where the wrap can be fully unfolded and a good standard of ambient lighting are still necessary.

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C7.30 The linting of fabrics can be a major problem. Lint is a respiratory hazard and a fire or explosion hazard and together with other dust may contribute to an insanitary environment by providing a vehicle for the transfer of micro-organisms.

Packing room

C7.31 The activities undertaken in the packing area may be summarised as to:

- receive QC released single use, re-usable and consumable items. Note that in some units the QC inspection on cleaned and decontaminated items is carried out within the packing area. When this system is used, and particularly when inspection is done at the same time as assembly, great care is needed to ensure proper segregation of rejected items;
- assemble items into pre-set trays and procedure packs;
- verify that the contents match the specification;
- pack;
- close and/or seal the packaging system;
- label;
- verify the accuracy of the label;
- transfer to sterilizer.

C7.32 The packing room should be mechanically ventilated to ensure that the particulate count and pressure differentials meet the requirements of BS 5295 Class L in the “unmanned condition”.

C7.33 Although it may be possible to demonstrate that areas lacking mechanical ventilation can meet the required particulate standard when tested, this is not a satisfactory substitute. Mechanical ventilation is required to ensure that the particulate standard can be met consistently and also to ensure that there is a positive pressure relative to surrounding areas to minimise the ingress of contamination.

C7.34 SHPN 13 recommends that the air supply filters should have a minimum resistance of 85% when tested in accordance with BS EN 779: 1992.

C7.35 Humidification may also be required to avoid dehydration and subsequent problems.

C7.36 When plastic materials are being used for packaging excessively dry atmospheres can promote a build up of static electricity which causes problems, such as attraction of particulate material.

C7.37 Dry atmospheres may lead also to excessively dry absorbent materials, such as paper or cotton textiles. When steam sterilized the exothermal rehydration of these materials can lead to local superheating and impairment of the sterilization process.

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C7.38 Ethylene oxide sterilization requires goods to be sterilized which have been humidified to provide an optimum moisture content. This can be greatly facilitated by the maintenance of appropriate ambient humidity during assembly and packaging.

C7.39 The layout of the packing room should allow an orderly flow of work and should provide sufficient separation between activities to preclude the possibility of mix-ups, mis-labelling etc.

C7.40 Work surfaces should be of sufficient size to allow the largest wrapping materials which will be used to be fully opened without draping over the edges of the work surface.

C7.41 In-line labelling and label printing may be used to advantage, but printers are often noisy. Their location should be considered carefully to minimise the adverse effect of this noise. In addition, when it is necessary for staff to read information displayed on VDU screens it is essential that the ambient lighting is suitable.

Sterilizer loading area

C7.42 When single-ended sterilizers are used it is important to ensure adequate segregation of unprocessed goods from processed goods. Chemical process indicators in conformity to BS EN 867-2 may be of value.

C7.43 Adequate space must be available for the number and type of trolleys to be used.

Post-sterilization area

C7.44 This area provides the interface between the sterilizers and the processed goods store and should provide adequate space and facilities to allow product removed from the sterilizer to be inspected and to be quarantined until verification that the cycle was satisfactory.

C7.45 The area should provide space where packs may be allowed to cool to room temperature before they are handled.

C7.46 Each pack should then be inspected to verify that the packaging is not wet or damaged and that the seal or closure is intact.

C7.47 For gas sterilization processes an additional facility to provide the controlled removal of residual sterilant gas may be required. After verification that the sterilization cycle was satisfactory and inspection of the sterilized packs they may be transferred to the processed goods store or sent directly to despatch for immediate distribution.

Processed goods store

C7.48 The area should provide facilities where sterile packs may be stored away from excessively humid, hot or cold locations, strong light sources and

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electrical power supplies. Adverse conditions can cause deterioration of plastics, rubber and cellulosic materials found in the packaging or the contents, giving rise to embrittlement, loss of tensile strength, and so on (see SIB(7)3 'Storage of sterile medical devices and surgical products', DHSS 1982).

C7.49 The storage area needs to be clean, dry and well ventilated but free from draughts. Ideally the environment in the store should be maintained at 18-22°C with RH 35-75%.

C7.50 Storage may be on open shelves or in closed cupboards. When shelves are used they may be solid or of wire mesh construction. The lowest shelf should be solid and should be 25-30 cm above floor level. The top of shelving stack should be a solid shelf 25-30 cm below ceiling level to allow room for cleaning, but should not be used for storage.

C7.51 Shelves should be located away from outside walls which can suffer from condensation problems, and from other sources of water such as sinks, and sprinklers.

C7.52 There should be no unlagged cold water pipes or other similar services which may cause condensation to form and drip onto packs.

C7.53 A high standard of cleanliness is required in this area. When facilities are less than ideal the inadequate conditions may be ameliorated by wrapping the sterile packs in a protective dust cover such as a polythene bag during storage. This may then be removed immediately prior to despatch. Note that, if packs are to be wrapped in dust covers, they must be allowed to cool to room temperature first.

Materials storage

C7.54 SHPN 13 Appendix 4 provides guidance on determining the space required.

C7.55 A materials store is required for the storage of incoming supplies, including single use items, consumables, and new re-usable items as well as packaging materials.

C7.56 The same store may also be used for incoming supplies of commercially produced supplies items (for example commercially produced sterile packs).

C7.57 The passageway between shelves or racking should be wide enough to permit proper use of handling equipment without causing damage to stored materials.

C7.58 Secure separate storage needs to be provided for the segregation of defective or non-conforming materials products.

C7.59 Facilities are required for the reception of purchased goods and subsequent inspection and confirmation that they are supplied in accordance with the purchase specification.

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Packaging equipment

Heat sealers

C7.60 Several patterns of heat sealer are in common use:

a. Hand-operated heat sealers with scissor action jaws; many of these were designed for sealing light gauge polythene bags for food use and are rarely satisfactory for sterilization packaging.

b. Parallel-jaw sealers, which may be hand or foot operated, have one of the jaws heated and this presses against the opposing unheated jaw. Heat-seal packaging placed between the jaws is heated and compressed.

c. Heat-seal conveyors work in a similar manner, items to be sealed are but moved between heated elements of the conveyor.

C7.61 The seal integrity and strength is affected by the temperature, pressure and dwell time of the heat-sealing equipment.

C7.62 In order to ensure reproducible satisfactory sealing all three variables should be validated, controlled and monitored.

C7.63 Many of these heat sealers are available without a built-in timer, with no reproducible control over sealing pressure and with no indication of the operating temperature. The design of many heat sealers makes effective monitoring, calibration and adjustment of the operating conditions difficult.

C7.64 Any heat sealer which is to be used for sealing packs for sterilization should be monitored regularly for the controlling variable of temperature, pressure and dwell time. Machines which cannot be independently tested should not be used.

Overseal crimpers

C7.65 Crimping devices for the application of crimp-on overseals may be manual or automatic.

C7.66 The manual crimpers are available as hand-held devices or as bench-mounted, lever-operated machines.

C7.67 Most, if not all, of the manually operated crimping equipment available is pre-set for overseals of a particular size, or has sets of change parts to accommodate other sizes. The compressive force applied is not adjustable.

C7.68 It is essential that the crimper is only used with overseals, stoppers and containers of the pattern for which it is intended.

C7.69 Crimpers for applying foil caps to aluminium tubes for use in hot air sterilizers are also available. These are usually hydraulically operated.

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Screw cappers – controlled torque

C7.70 Capping machines with a built-in, adjustable, torque limiter are available. The torque setting to be used varies with the size and type of cap and the stopper or other seal being used. The settings recommended by the manufacturer of the closure should be used.

C7.71 The calibration of the torque limiting device should be verified at regular intervals.

Ampoule sealers

Manual sealing

C7.72 Although it is possible to effectively seal an ampoule without a purpose-built ampoule sealer, it is difficult to get the correct temperature, sufficiently localised and in the required time.

C7.73 Commercially available ampoule sealers use a natural gas/compressed air (low pressure of the order of 2-3 psig) or gas/oxygen flame, in burners set either side of the ampoule.

C7.74 The ampoule stands on a support platform which is vertically adjustable to position the flames at the required position on the ampoule.

C7.75 The flames are positioned and adjusted so that the glass wall of ampoule neck is just by the points of the blue cones within the flames.

C7.76 The filled ampoule is rotated in the flame.

C7.77 When the glass in the heated region of the neck melts and starts to fuse the top of the ampoule is grasped with pliers or forceps and pulled upwards in a smooth but fairly rapid movement.

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C7.78 This detaches the unwanted portion of the neck leaving a fused end which should be smooth and round without any sharp pointed protrusion or a long tail of glass.

C7.79 To produce consistently successful seals requires some skill, which is only achieved through practice and experience.

C7.80 Semi-automatic and automatic ampoule sealers reproduce the same sequence of events but the whole process is automatic.

C7.81 The flame temperature, the position of the flame, the dwell time, and the timing and rate of detachment of the neck extremity all affect the quality of the seal.

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C8. Packaging operations

Routine operation, control and monitoring

C8.1 The materials, systems, equipment and procedures used should have been evaluated for their suitability before implementation for routine use (see Chapter C6).

C8.2 The following guidance is based on the assumption that high-speed packaging machinery capable of handling large batches will not be used. When large batches are to be processed on such equipment the guidance and requirements in the Regulations and Standards applicable to commercial manufacturers should be adopted.

Documentation

C8.3 There should be written specifications for all packs giving details of both the contents and the packaging requirements.

C8.4 The order in which the contents of composite packs should be placed, to facilitate their aseptic removal from the pack, should be documented in the pack specification and the associated packing procedure.

Packaging instructions

C8.5 There should be formally authorised packaging instructions for each product, pack size and type. These should normally include or make reference to the following:

a. the name of the product;

b. either a description of its pharmaceutical form and strength, where applicable, or a list of the contents of the pack;

c. the pack size expressed as the weight or volume of the product in the final container, where applicable;

d. complete list of all the packaging materials required including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;

e. where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply any batch number, references and shelf life of the product;

f. any special precautions to be observed, including the order in which components should be assembled to facilitate aseptic removal;

g. a description of the packaging operation, including any significant subsidiary operations, and equipment, to be used;

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h. details of in-process controls with instructions for sampling and acceptance limits, where applicable.

Batch packaging records

C8.6 When products are prepared in batches a batch packaging record should be kept for each batch or part batch processed.

C8.7 The record should carry the batch number and the quantity of bulk product to be packed as well as the batch number and the planned quantity of finished product that will be obtained.

C8.8 Before any batch packaging operation begins, there should be recorded checks that the equipment and work station are clear of previous products documents or materials not required for the planned packaging operations and that the equipment is clean and suitable for use.

C8.9 The information should be entered at the time each action is taken and, after completion, the record should be dated and signed.

Packaging records for single packs

C8.10 The records kept should have a sequential batch code enabling finished pack to the manufacturing's lot number for any single, including packaging, used in the composition of the pack.

Batch numbering

C8.11 All packs produced should have a sequential batch code enabling traceability and, when necessary, the recall of defective product.

C8.12 The batch code used should indicate the date of sterilization, the machine used and the process log/cycle number.

C8.13 Batch numbering with sterilizer and cycle may conveniently be done after sterilization when inspecting each pack to ensure that it has not become wet or sustained any damage.

Labelling

C8.14 Each sterile pack should be clearly labelled with a description of the pack contents and the description “sterile”.

C8.15 Normally filling and sealing should be followed as quickly as possible by labelling to ensure that no mix-ups or mislabelling can occur.

C8.16 The correct performance of any printing operation (for example, code numbers, expiry dates), whether done separately or in the course of the packaging operation, should be checked and recorded.

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C8.17 The accuracy of labelling should be checked. Special care should be taken when using individual pre-printed labels and when over-printing is carried out off-line. Roll feed labels are normally preferable to cut labels, in helping to avoid mix-ups.

C8.18 When large batches of single product are being processed the correct number of bags may be labelled for each batch. On completion of the packaging operation for each batch the number of labelled bags should be reconciled with the number of products packed and any surplus bags destroyed before commencement of a different product. Any pre-stamping or labelling of bags should be controlled by documented procedures.

C8.19 Checks should be made to ensure that any electronic code readers, label counters or similar devices are operating correctly.

Control of the packaging operation

C8.20 When setting up a programme for the packaging operations particular attention should be given to minimising the risk of cross-contamination, mix-ups, substitutions, or mis-labelling.

C8.21 Before packaging operations begin, steps should be taken to ensure that the work area and packaging equipment are clean and free from any products, materials or documents previously used, if these are not required for the current operation.

C8.22 All products and packaging materials to be used should be checked on delivery to the packaging department for quantity, identity and conformity with the packaging instructions.

C8.23 Containers and packaging for filling should be clean before filling; particular attention should be given to avoiding and removing any contaminants such as glass fragments and metal particles.

C8.24 Control of the product during packaging should include at least checking the following:

- general appearance of the packages;
- whether the packages are complete;
- whether the correct products and packaging materials are used;
- whether the labelling, including any over-printing, is correct;
- the correct functioning of packaging equipment, for example the temperature gauge reading on heat sealing equipment.

C8.25 All wrapping material used should be inspected for flaws, holes, tears, dirt, stains and other defects at the time of packaging by the operator using it.

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C8.26 Any of these defects should be cause for rejection of the material, which should be scrapped.

Heat-sealing equipment

C8.27 Closing and sealing machines must be in good condition, properly set and maintained to the manufacturer's specification, and closing and sealing operations should be under constant supervision.

C8.28 For heat-sealing operations the critical variables of temperature, temperature uniformity, pressure, pressure uniformity, dwell time, and the characteristics of the packaging materials, for example the type, thickness and uniformity of the heat-seal adhesive, should, ideally, be verified at frequent regular intervals.

C8.29 If the available equipment does not provide the facility for routine monitoring of the physical operating variables then routine monitoring of process efficacy by checking the quality of the output should be adopted.

C8.30 The efficacy of the seals should be tested and proved on a regular basis, not less than daily for each heat sealer.

C8.31 As a minimum daily heat-sealing records should be kept and these should be reviewed quarterly; there should also be a quarterly check on the temperature control of each heat sealer.

Glass containers

C8.32 Because of the hazards associated with glass contamination it is essential that, if packing in glass takes place, suitable precautions are described in formal documented procedures to deal with any glass breakages which may occur.

C8.33 Equipment for handling and processing glass containers should be adequately screened to ensure that any broken glass is contained. In particular, cleaning and filling equipment must be suitably screened and it is good practice to fully enclose all conveyors between cleaning and closing.

C8.34 Conveyors for glass should not pass over areas where exposed product or components may be held.

C8.35 Suitable lidded containers to be used only for the disposal of broken glass should be provided.

QC tests

C8.36 Quantitative testing of the adequacy of packaging seals and closures requires the use of laboratory facilities and equipment not available in most hospitals.

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C8.37 However, there are qualitative procedures that can be carried out which are sufficient to demonstrate a satisfactory seal, although they may be of less value in any investigation as to the cause of an unsatisfactory seal.

C8.38 These procedures are based on visual examination which can be carried out either by the operator during the various stages of the packing operation or by a QC inspector given that specific task.

Pinholes

C8.39 The performance of both porous and impermeable materials as a bacterial barrier depends on them being free from pinholes and other similar defects.

C8.40 Laboratory tests for pinholes are based on detecting the passage of a dye solution.

C8.41 However, visual examination of opaque or translucent material against a bright light is a sensitive method of detection, which may be applied in the packing room.

C8.42 The method is unsatisfactory for transparent film. However the plastic film used in pouch and reel material is typically a laminate of two films. There is a very low probability of a pinhole occurring in the same spot in both films.

Inspection of seals

C8.43 A subjective assessment may be carried out by examining and opening a number of sample packs taken from production.

C8.44 Where one of the webs being sealed is transparent the uniformity of the seal can be examined without opening the pack. In other cases it will be necessary to peel open the seal.

C8.45 In carrying out the examination the following factors should be considered:

- the appearance of the seal; it should be uniform across the entire sealed surface and should be free from creases, striations or unsealed areas;
- the seal strength; the seal should be peeled apart and attention paid to whether the force required remains constant or whether there are apparent weak spots; with practice and experience it is also possible to recognise overall increased or decreased seal strength;
- the seal characteristics; when the seal is peeled apart there should be visible evidence of the seal on both of the webs, but there should be no spitting, tearing, delamination or fibre shedding;
- the condition of the packaging, particularly in the area of the seal; excessive pressure during heat sealing may cause damage or distortion; high temperatures or prolonged dwell times may cause scorching of the paper web.

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Packaging for sterile medicinal products

C8.46 Filled containers of parenteral products should be inspected individually. When inspection is done visually this should be done under suitable and controlled conditions of illumination and background.

C8.47 Operators doing the inspection should pass regular eye-sight checks, with spectacles if worn, and be allowed frequent breaks from inspection.

C8.48 When other methods of inspection are used the process should be validated and the performance of the equipment checked at intervals.

Process indicators

C8.49 A system to differentiate between processed and unprocessed items should be used.

C8.50 Single-use packaging materials may be obtained pre-printed process indicators suitable for one or more sterilization processes.

C8.51 For other packaging materials suitable process indicators may be purchased printed onto adhesive packaging tape, adhesive patches or onto labels.

C8.52 Whichever system is chosen the process indicator should conform to the requirements of the relevant European standards (BS EN 867-I and BS EN 867-2).

Sterile product release

C8.53 Post-sterilization it is necessary to verify that the sterilization cycle was satisfactory and check that each pack is either:

- labelled with a reference to the number of the sterilizer cycle through which it was processed, or
- reconciled with the load manifest for the cycle, for packs which were labelled before sterilization with a reference intended to be traceable to the cycle number.

C8.54 Packaged sterile product should be inspected after sterilization and before release to ensure that the seal or closure remains intact, and that the pack is undamaged.

C8.55 The nature of the inspection will depend upon the nature of the packaging system used.

C8.56 For example, glass ampoules may be inspected for cracks and flaws visually, by means of a dye penetration test or by means of a corona discharge crack detector.

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C8.57 Whenever the integrity of the packaging is in doubt the sterilized product, or in extreme cases the sterilizer load, should be regarded as non-sterile and not released for distribution.

Operator training

C8.58 All operators should receive training in the documented procedures that they will be expected to carry out.

C8.59 Particular emphasis should be placed on operator dependent techniques such as the correct folding and closure of wraps.

C8.60 Training should include instruction on the correct use of equipment, inspection techniques and test methods and on the intended use of the product.

C8.61 Training should be documented and recorded and should be reviewed periodically.

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C9. Storage and distribution

Shelf life

C9.1 Time-related expiry dates for the maintenance of sterility are widely recognised as being of little value since under artificially created worst-case storage conditions packs such as textile wrapped packs could be shown to have become contaminated within 18-30 days.

C9.2 When the products were overwrapped with a dust sheet this was extended to at least nine months, and in paper/plastic pouches was found to be at least a year.

C9.3 Maintenance of sterility depends to a great extent on the storage conditions including such factors as:

- the microbial contamination of the storage environment;
- movements of air;
- movements and behavioural standard of personnel;
- environmental temperature, relative humidity;
- moisture, such as condensation;
- location in the store, etc.

C9.4 The barrier properties of the packaging material are also a contributory factor. The general concept is that the combination of the packaging and the control exerted over storage and distribution conditions should guarantee that the contents remain sterile until opened for use.

C9.5 Some form of date coding may still form a convenient inventory control system, means of assessing the frequency of usage and for deciding whether unused packs are of a type which no longer need to be produced.

C9.6 The use of arbitrary expiry dating on packs should be replaced with batch numbering and/or manufacturing date codes which can be used to facilitate good stock rotation, based on a first-in-first-out system.

C9.7 Maintenance of sterility cannot be guaranteed once the packaging has been breached and the labelling should warn the user to verify the condition of the packaging before opening the pack for use. A warning such as “sterile unless packaging opened or damaged” is usually sufficient.

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Distribution of sterilized supplies

C9.8 Trolleys used for distribution within the hospital should be covered or closed with a solid bottom shelf.

C9.9 Each article to be loaded onto a trolley or into a transit container should be inspected and handled with care; packs should not be crushed together. Cramming additional packs into too small a space will invariably result in damage.

Storage of sterile supplies

C9.10 The function of this storage area may be limited to the storage of packs produced in the SSD or may also accommodate commercially produced packs and sterile devices purchased from commercial suppliers.

C9.11 Medical equipment that has been decontaminated, disinfected, cleaned, serviced, repaired and ready for re-issue may also be stored here.

C9.12 Sufficient space is required for loading trolleys and containers distribution on site and for loading containers for delivery off site.

C9.13 Entry to the area should be restricted to authorised and trained personnel.

C9.14 Staff should wash their hands before entering; where no convenient washing facility is available, it may be acceptable to substitute treating clean hands with an alcohol-based hand rub for washing.

C9.15 Movement of personnel within the area should be kept to the minimum necessary.

C9.16 The floor should be cleaned regularly by damp mopping and/or vacuuming; sweeping, brushing or the use of rotary scrubbing and polishing machines should be avoided since these may disperse contamination from the floor as an aerosol.

C9.17 Shelves, trolleys, delivery carts and transit containers should be subject to regular cleaning in accordance with a documented procedure and schedule.

C9.18 Packs should be spaced on shelves with sufficient room to avoid friction or the jarring of adjacent products when one is removed.

C9.19 Rigid re-usable transit containers may be used with advantage to contain smaller packs; these containers should also be on the cleaning schedule.

C9.20 Packs dropped on the floor should be discarded or sent for re-processing, as applicable, unless they were protected by an outer dust cover, such as a polythene bag, show no visible damage to the packaging and do not contain items which could be damaged by impact.

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C9.21 Storage arrangements should be orderly to facilitate efficient rotation of stocks, batch differentiation and ease of cleaning.

C9.22 Sterilized packs should be issued in rotation based on the First-In–First-Out (FIFO) principle in accordance with a documented procedure.

C9.23 Sterilized packs should be handled as little as possible.

C9.24 After sterilization it is important that packs are stored safely in a manner which will assist in preserving the sterility of the contents.

Handling sterile packs

C9.25 It is important that all personnel who will be required to handle sterile packs (porters, drivers, SSD assistants, phlebotomists, nurses, clinicians, etc.) receive appropriate training in the correct handling procedures and why they are necessary.

C9.26 Many sterile packs will contain expensive and delicate instruments and require careful handling. All sterile packs need to be handled in a manner which will not compromise their sterile condition.

C9.27 As a minimum the following rules should apply:

a. The hands of personnel who will handle sterile packs need to be clean and dry;

b. The sterile packs need to be kept dry and must not be torn, punctured or otherwise damaged;

c. Any packs that are visibly damaged, stained or wet should be returned to the SSD for disposal or re-processing, as appropriate;

d. It should be possible to verify that the pack has been processed; this may be by means of a process indicator, or by appropriate labelling such as a sterilizer cycle number. Note that process indicators do not indicate the sterility of the pack contents, only that the pack was processed through a sterilizer;

e. Containers, distribution trolleys and any surfaces on which the packs will be placed must be clean and dry.

Transport and distribution

C9.28 There should be documented procedures for delivery and for the packaging, collection and return of used goods.

C9.29 Containers and trolleys should be easy to clean, properly maintained and should adequately isolate the goods in transit from environmental hazards.

C9.30 The cleaning procedure for bulk containers and trolleys should be documented and records should be kept of cleaning carried out.

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C9.31 In transit the contents of containers should be adequately identified by means, such as labels, which will not be erased in transit.

C9.32 Used goods being returned must be segregated from clean and sterile goods being delivered.

C9.33 Vehicles reserved for the delivery of clean and sterile goods should be used whenever possible. If dedicated vehicles are not used then each vehicle used must be cleaned after use for the return of used goods and before use for the transport of sterile goods.

C9.34 The cleaning procedure for the vehicle interior should be documented and records should be kept of cleaning carried out.

C9.35 As an alternative the use of sealed leakproof containers may be used for transport in either or both directions.

Storage in clinical areas

C9.36 The same principles apply as were discussed for the processed goods store.

C9.37 The storage facility should be secure, easy to clean and organised to aid stock rotation (for example a double-sided cupboard filled from the back but where goods are removed from the front).

C9.38 The quantity of goods stored should be limited to those actually needed within a reasonable time period.

C9.39 The place and method of storage varies, but it should be separate accommodation, not a general store with bedpans, urinals etc.

C9.40 Storage should be segregated or, if it has to be shared, it should be with other clean and/or sterile equipment.

C9.41 A high standard of cleanliness is required and packs must be kept well away from sinks and other sites of possible contamination.

Packaging for return of used items for re-processing

C9.42 A local policy for the handling of potentially contaminated and hazardous items, and practices for safe containment during transport back to the SSD need to be established.

C9.43 All returned items should be regarded as potentially contaminated and thus infective.

C9.44 Containers for returning goods should be leak proof, securely closeable and safe to handle. The container design should include the facility for clear labelling to indicate the nature of the contents.

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Glossary of terms

Bioburden	Population of viable micro-organisms on an item.
Capacity (for glass containers)	The internal volume at 20°C.
Closure	Means used to close a package where no seal is formed, for example by repeated folding to construct a tortuous path.
Closure integrity	The quality of the closure which ensures that it presents a microbial barrier.
Final pack	The pack in which a medical device is sterilized. In addition to the primary pack a secondary and/or transport pack may be included.
Internal pressure resistance	The internal hydraulic pressure which a glass container at 20°C can withstand without breaking.
Microbial barrier	The ability to prevent the ingress of micro-organisms.
Multi-trip container	A glass container which has strength characteristics sufficient for it to withstand a number of filling/use operations.
Packaging compatibility	The ability of the packaging material and/or system to achieve the required performance without detrimental effect on the medical device.
Packaging material	Any material used in the fabrication or sealing of a packaging system or primary pack.
Packaging system	One or more packaging materials assembled into a single unit intended as part or all of a primary pack.

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Primary pack	The sealed or closed packaging system forming a microbial barrier enclosing the medical device, and (usually) in contact with the medical device.
Seal	The result of joining of layers, for example by use of adhesives or thermal fusion.
Seal integrity	The quality of the seal which ensures that it presents a microbial barrier.
Secondary pack	The pack containing one or more medical devices, each in its primary pack.
Shelf pack	see Secondary pack.
Shipper pack	see Transport pack.
Single-trip container	A glass container designed and manufactured to be sufficiently strong to withstand only one filling/use operation.
Terminally sterilized	Descriptor for medical devices which are sterilized after being completely sealed or enclosed in at least the primary pack.
Thermal shock resistance	The ability of a glass container to withstand a sudden temperature change without breaking.
Transport pack	The pack containing one or more primary and/or secondary packs intended to provide the necessary protection during transport and storage.
Ullage	That part of the contents of a container which wants for filling. Expressed in units of volume or as a percentage of the total container volume.
Unit pack	see Primary pack.
Vacuity	The free space left above the contents in a sealed container expressed as a percentage of the nominal volume of the contents.

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Validation	Documented procedure for obtaining, recording and interpreting the data required to show that a process will comply with predetermined specifications.

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SECTION D

A Contract for the Annual Testing of Sterilizers

GC/Works/4 (1998)

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INVITATION TO TENDER

Works: **Annual Testing of Sterilizers**

Site: _____

1. You are invited on behalf of _____NHS Trust to tender, upon the basis of GC/Works/4 General Conditions (1998), for the Works described in the following enclosed documents:

   a. Abstract of Particulars;

   b. Supplementary Conditions and Annexes referred to in the Abstract of Particulars;

   c. Specification for the Annual Testing of Sterilizers.

2. Your tender with the completed Abstract of Particulars and Supplementary Clauses should be submitted on the Form of Tender and Tender Price Form also enclosed. Any obvious errors in pricing or errors in arithmetic will be dealt with as stated in the Form of Tender.

3. You are required to keep your tender confidential and not divulge to anyone, even approximately, what your tender price is or will be. The sole exception to this is information you may have to give to your insurance company, or broker, in order to compile your tender, but you must stress to them that this information is given in strict confidence.

4. You must not make any arrangements with anyone else about whether or not they should tender, or about their or your tender prices or terms and conditions. You may however, obtain any necessary subcontract quotations.

5. No tendering expenses will be reimbursed by the Employer.

6. Tenders received late will not be considered unless due to genuine postal delays. If the tender is qualified it may be set aside, or you may be required to withdraw the qualification without amending your offer. Any proposals for alternatives to the specified requirements should be submitted by way of a separate, unqualified, bid, after checking with the Employer on the procedure to follow.

7. The Employer does not bind himself to accept the lowest, or any tender.

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8. Your form of tender should be submitted in a sealed envelope prominently marked:

   FORM OF TENDER FOR ANNUAL TESTING OF STERILIZERS

   The envelopes should bear no external indication of the identity of the tenderer.

9. Tenders must be completed and returned by 12 noon on _____

   To: _____

   SIGNED by

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INSTRUCTIONS FOR TENDERERS

Tenders for the work included in the following Tender Document shall be written on the attached Form of Tender. The Price Schedule must be fully priced, extended and totalled throughout in black ink and returned under sealed cover to the _____

to arrive not later than Noon on _____ endorsed on the outside “Tender for the Annual Testing of Sterilizers.”

Tenders to remain open for acceptance for a period of 60 days from the above date.

_____NHS Trust reserves the right to decline the lowest or any Tender and no expense in submitting a tender will be reimbursed.

Tendering procedures will be in accordance with the principles of the “Code of Procedure for Single Stage Selective Tendering 1996”, the examination and correction of priced Bills of Quantities being in accordance with Alternative 2 of paragraph 6.4 of that Code.

In the event of a Contractor not tendering, the documents are to be returned immediately to the Project Manager.

The Contractor shall comply with the requirements of all regulations, codes and statutes applicable to the execution of the works.

Where in the opinion of the Project Manager any of the finished works or materials or workmanship in any part of the works, do not comply with all the relevant requirements of this specification and drawings, that part of the works shall be classified as defective work.

All work classified as defective work shall be made good to the satisfaction of the Project Manager.

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TENDER AND TENDER PRICE FORM

THE ANNUAL TESTING OF STERILIZERS

_____NHS Trust

To be returned by 12 Noon on _____ to _____

1 We have examined GC/Works/4 General Conditions (1998), and the following documents:

a. Abstract of Particulars;

b. Supplementary Conditions and Annexes referred to in the Abstract of Particulars;

c. Specification for the Annual Testing of Sterilizers.

2 We have obeyed the rules about confidentiality of tenders and will continue to do so as long as they apply.

3 We submitted to the Employer a Price Schedule and Summary of prices with an alternative. We undertake to satisfy the Employer that the prices in the summary are fair.

4 We agree that, should errors in pricing or errors in arithmetic be discovered in the summary submitted by us during consideration of this offer, we will, in addition to the chance to confirm the offer as tendered despite the errors, be afforded the opportunity of withdrawing it.

5 Subject to and in accordance with paragraphs 3 to 5 above and the terms and conditions contained or referred to in the documents listed in paragraphs 1 and 2, we offer to execute the Works referred to in the said documents in consideration of payment by the Employer of the sum shown in our accompanying Tender Price Form, which shall be deemed to form part of our tender, plus reimbursement by the Employer of Value Added Tax in accordance with Condition 19 (*VAT*).

6 We agree that differences or questions arising out of or relating to the Contract shall be resolved in accordance with Condition 28 (*Adjudication*) of the General Conditions.

SIGNED by
for and on behalf of
Tel:
Fax:
Telex:
Date:

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TENDER PRICE FORM

THE ANNUAL TESTING OF STERILIZERS

_____NHS Trust

To be returned by 12 Noon on _____ to _____

The sum referred to in our accompanying form of Tender is;

£_____for Year One

and/or

Alternative No. 1

£_____for Five Years.

Alternative No. 2

£_____for Five Years.

£_____% materials on cost

SIGNED by

for and on behalf of

Tel:
Fax:
Telex:
Date:

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ABSTRACT OF PARTICULARS

Works : THE ANNUAL TESTING OF STERILIZERS

Site:_____NHS Trust

Condition 1(1) (*Definitions, etc.*) Employer

The Employer shall be the _____NHS Trust,

Conditions 1(1) (*Definitions, etc.*): Project Manager, and 3 (*Delegations and representatives*)

The Project Manager shall be Mr_____

_____NHS Trust

who shall act generally on behalf of the Employer in carrying out those duties described in the Contract, subject to the following excluded matters:

In relation to such excluded matters, the person authorised to act for the Employer is:

Mr _____

Only Regulations 7 and 13 of the CDM Regulations apply.

Condition 7 (*Defects in Maintenance Periods*)

Condition 7 shall apply.

The Maintenance Period for the Works shall be six months for any work done and 12 months for parts supplied and fitted and shall apply from the day after that on which the Works are completed as certified by the Project Manager.

Condition 8 (*Occupier's rules and regulations*)
The rules and regulations for _____ NHS Trust are appended.

Condition 12 (*Passes*)
Passes are required for admission to the Site.

Condition 15 (*Commencement and completion*)
Period within which Order to Proceed: within Ten Days of the acceptance of the tender.

The Date for Completion of the Works shall be _____

Condition 20 (*Advances on account*)
Condition 20 shall not apply.

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Condition 26 (Damages for delay)
Damages for delay shall be at large.

Condition 28 (Adjudication)
The adjudicator shall be as agreed by the Employer and the Contractor.

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Item	Preamble	£	P
	FORM TYPE AND CONDITIONS OF CONTRACT The works shall be carried out and completed in accordance with the rights and duties of GC/Works /4. The expression “the Contract Documents” shall mean, the Specification, the Price Schedule, the Tender and the letter of acceptance. The Contract shall be deemed to be a Scottish Contract and shall be construed and the rights of the parties and all matters arising hereunder determined in all respects according to the Laws of Scotland.		
	Amount to Collection Page		

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Item	Preamble	£	P
	SCHEDULE OF CLAUSES 1 Definitions 1A Fair dealing 2 Contract documents 3 Delegations and representatives 4 CDM Regulations 5 Protection of Works 6 Loss or damage 7 Defects in Maintenance Period 8 Occupier's rules and regulations 9 Discrimination 10 Corruption 11 Site admittance 12 Passes 13 Photographs 14 Official Secrets and confidentiality 15 Commencement and completion 16 Extensions of time 17 Project Managers Instructions 18 Valuation of Instructions 19 VAT 20 Advances on account 21 Final Account 22 Certification 23 Withholding payment 24 Recovery of sums 25 Suspension for non-payment 26 Damages for delay 27 Determination by Employer 28 Adjudication 29 Choice of Law 30 Assignment and subletting 31 Other Works		
	Amount to Collection Page		

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Item	Preamble	£	P
	SUPPLEMENTARY CLAUSES **Asbestos** If during the execution of the work, the Contractor discovers any material suspected of being asbestos, the following procedures will apply: 1. Immediately cease work in the suspected areas. 2. Immediately notify the Project Manager by telephone, then confirm same in writing. 3. Do not commence work in the area(s) involved until instructed by the Project Manager. **Noise Control** The Contractor shall comply with statutory requirements relating to control of noise levels on site, include for complying with DOE Advisory Leaflet No.72 Noise Control on Building Sites and for fitting all compressors and percussion tools with effective silencers of a type recommended by the manufacturers of the compressors or tools. The Contractor shall not use pneumatic drills or other noisy appliances outwith normal working hours without consent of the Project Manager . The Contractor shall not use or permit employees to use radios or other audio equipment. **Inspection of Work before Covering** In cases where the Project Manager has given notice to the Contractor that the work must be inspected and/or tested previous to same being covered up or hidden, the Contractor shall give adequate notice in writing to the Project Manager before any such work shall be so covered up or hidden. Should the Contractor fail to give such notice he may be required to uncover same and make good at his own expense. **Programme** The Contractor shall prepare and submit to the Project Manager within two weeks of agreement of access and site occupation with the Employer, a programme in a form as required by the Project Manager, which shall clearly set forth the sequence of all operations and the time limits within which the Contractor proposed that each operation shall be commenced and completed. The Contractor, in the preparation of this programme, shall be held to have co-ordinated the while works embraced in this Contract.		
	Amount to Collection Page		

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Item	Preamble	£	P
	On agreement or negotiated amendment of the programme by the Project Manager, the Contractor shall be responsible for the execution of the works in conformity therewith. He shall submit copies of same, record progress and update or redraft as required to take account of any circumstances which arise affecting the progress of the works. **Limitations of Working Space** The Contractor shall not be allowed to use existing roadways or footpaths for parking or depositing material or plant unless he is given prior approval by the Project Manager . The Contractor shall at all times confine his workpeople to those parts of the site and building on which he is engaged and shall on no account allow them to trespass into any other parts of the site and buildings without the prior consent of the Project Manager . The contractor shall not be allowed to erect temporary buildings, deposit plant, store materials or rubbish on any part of the property or grounds outside that assigned to him for this contract. The Contractor shall allow in his tender for all necessary preparatory work and later, at the completion of the contract, for removing debris and reinstating the storage etc. areas to their original condition, all to the satisfaction of the Project Manager . The original condition shall be established with the Project Manager prior to the commencement of work. The Contractor shall take all necessary precautions to minimise nuisance or discomfort to the occupiers of adjacent premises arising from his operations. Any damage, structural or otherwise caused to the existing buildings by the construction process shall be made good at the Contractor's expense.		
	Amount to Collection Page		

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Item	Preamble	£	P
	The Employer reserves the right to send their own or other workmen to the site to execute work not included in this contract and the Contractor shall be required to afford such workmen all reasonable facilities for the execution of their work but the Contractor shall not be entitled to any profit on the cost of such work. The Contractor will liaise and co-operate with the Project Manager and will take all reasonable steps to ensure that the works are carried out in such a fashion as will in no manner, or at any time, impair the security of the existing buildings. All scaffolding or temporary access will be erected in such a fashion as, without in any way impairing the stability of the scaffold, will prevent ease of access to the scaffold by any unauthorised person. The Contractor shall maintain permanent supervision and attendance at mechanical or other dangerous plant, when in use, to ensure the safety of the staff, patients and others using the hospital. Alternatively all such plant and equipment shall be kept in a secure compound to prevent unauthorised access. On no account shall any ladders or tools be left unattended and at the end of each day's work all plant shall be removed and placed in the Contractor's site hut or other secure place. No windows, doors or hatches have to be left open after workmen have left site. The Employer will not be responsible for any such acts of vandalism by any person, to the Contractor's materials or plant. All materials will be disposed of in a proper manner off site. Any skips brought to site shall have lids which shall be securely closed when not attended. The Contractor shall not use existing sanitary fittings, gullies or drains to dispose of any materials including paint, turpentine, oils, etc. The area immediately around the site must be kept clear of rubbish, protective casings and coverings and general debris at all times. No scattered or accumulated debris will be allowed to gather and the Project Manager may require daily cleaning or clearings of any such debris to ensure compliance with this requirement. **Working Hours & Access to Site** Access will normally be outside normal hours (0800-1700 Monday to Friday). No additional costs due to overtime working will be paid for by the Employer unless that overtime has been instructed in writing by the Project Manager and he will clearly state in writing that the additional cost will be borne by the Employer. Any overtime thus authorised will be based on the standard time rates and paid net.		
	Amount to Collection Page		

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Item	Preamble	£	P
	Any overtime working by the Contractor must be agreed beforehand with the Project Manager and it should be noted that any additional costs of supervision on behalf of the Employer will be paid by the Contractor. **Fire Precautions** The Contractor is to take all necessary precautions to prevent loss or damage from fire. The Contractor is to familiarise himself and staff with all fire escape routes and procedures in use within the property involved. All escape routes to be kept operational during occupation by the Employer. **Existing Services** The Contractor shall not interfere with the operation of the existing services, such as gas, water, electricity, telephones, buried cables sewers and the like without permission of the Project Manager . **Smoking/Alcohol Policy** Smoking or the consumption of alcohol will not be permitted within any Employer property. **Employer Facilities and Equipment** All equipment necessary to carry out the works shall be provided by the Contractor. Employer equipment shall not be used. **Health, Safety and Welfare** The Contractor shall identify a Safety Officer responsible for all aspects of Health, Safety and Welfare on site including the control and actions of all Sub-Contractors in this respect. The Contractor shall permit access to the site by the Employers designated Safety Advisers who shall have the right to enter onto the Site at any time without prior notice to the Contractor. The Contractor shall implement any recommendations with regard to Health, Safety and Welfare measures which may be made by the Employer's designated Safety Advisers. Such recommendations shall not be deemed variations to the Contract if they are necessary, in the opinion of the Employer's designated Safety Adviser, to comply with the terms and conditions of any relevant Health, Safety and Welfare Acts or Regulations. The Contractor shall be deemed to be familiar with the Employer's document "Health and Safety Guide for Contractor's" and shall comply with its requirements as necessary. A copy of this document may be obtained from the Project Manager.		
	Amount to Collection Page		

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Item	Preamble	£	P
	Joint Code of Practice on the Protection from Fire of Construction Sites and Buildings Undergoing Renovations, Fourth Edition, June 1997. The Contractor's attention is drawn to the above Joint Code published by the Building Employers Confederation. The Contractor shall allow for compliance with the recommended standards in this Code of Practice. This contract is not deemed a "Large Project". **Method Statement** The Contractor shall present Method Statements which will describe fully his operations on site and discuss and agree with the Project Manager and Planning Supervisor prior to the commencement of the Works. The method Statements shall in particular include details about:- 1. General Site Safety 2. General Site Security 3. Protection of the General Public 4. Protection of Patients, Visitors and Staff using the Premises, etc. 5. Access and Exit Arrangements **General Facilities and Obligations** Maintaining, altering, adapting and clearing away any temporary works and making good after same shall be deemed to be included with the items. Notices, rates, fees and charges to Local Authorities and public undertakings related to the following items shall be included in the appropriate items. The Contractor shall obtain all necessary Planning and other permission for all temporary accommodation. **Pricing** Plant, tools and vehicles. Scaffolding and temporary access. Site administration and security, including safeguarding the work, materials and plant against damage and theft, include for providing all watching, accommodation and lighting if necessary. Transport of work people. Protecting the works from inclement weather.		
	Amount to Collection Page		

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Item	Preamble	£	P
	Lighting and Power for the Works Electrical power at 240 volts 50 cycles/single phase/AC required for the works will be provided free of charge by the Employer. *(Note: This should be suitably transformed to 110V for the use of power tools).* Temporary connections will be located and carried out in strict conformity with the Employer Authority's requirements and shall be approved by the Project Manager before work commences. The Contractor shall not use power provided for the Works, by the Employer for cooking facilities or heating. Building (Safety, Health and Welfare) Regulations and Health and Safety at Work Act in respect of all work people will apply. Removing rubbish, debris, protective casings and coverings from the site and cleaning the works internally and externally. These to be removed regularly and the site to be kept clean. On completion, the works shall be cleaned, which shall be deemed to include where necessary scrubbing floors, cleaning glass both sides, removing all stains from facework, cleaning sanitary fittings and leaving the whole premises clean and ready for occupation. The Contractor may make reasonable use of existing facilities as he so wishes subject to the approval of the Project Manager with the Employer's consent. **Insurance** Allow for the costs in complying with insurance provisions. **Materials and Workmanship** The Contractor will supply all materials that may be necessary for the due and proper completion of the work (except those materials specified to be supplied by the Employer under direct purchase arrangements or as part of sterilizer testing agreement). The materials shall be new unless otherwise described and shall be the best procurable of their respective kinds and so far as practicable. All goods and materials unless otherwise described, shall be in accordance with the latest revised BS current at the date of tendering. The contractor shall be responsible for providing all tools, equipment and instruments for the execution of the work. This is to include provision of 3 sets of Huckaback towels or cotton sheets to the requirements of SHTM 2010 Part 3. The Contractor shall provide all labour and pay all expenses in connection therewith and do everything necessary for the due and proper completion of the work. Workmanship shall be in accordance with the latest revised BS Code of Practice. **Samples** Samples of proposed materials and workmanship shall, if required by the Project Manager be submitted for approval and those samples kept by the Project Manager who shall have the power to reject all such materials and condemn such workmanship as do not correspond with the approved samples.		
	Amount to Collection Page		

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Item	Preamble	£	P
	Nuisance The Contractor shall take the necessary precautions to prevent nuisance from water, smoke, dust, rubbish and other cause. **Existing Furniture, Fittings and Equipment** Prevent damage to any furniture, fittings and equipment left in the existing property. Move as necessary to enable the work to be executed, cover and protect as necessary and replace as required. Including but not limited to: Fire fighting equipment, carpets, shelving, building fabric etc. **Making Good Defects** Allow for arrangements with the Employer and giving reasonable notice of the precise dates for access to the various parts of the Works for the purpose of making good defects. **Maintenance Instructions** Where applicable allow for obtaining and handing over to the Project Manager at practicable completion any maintenance instructions provided by manufacturers, suppliers or sub-contractors. **Control of Noise, Pollution and all other Statutory Obligations** The attention of the Contractor is drawn to the provisions of Section 60 of the Control of Pollution Act 1974 with reference to the control of noise in relation to any demolition or construction works and the need, particularly where such works are adjacent to occupied property where a high sensitivity to noise may be anticipated to ascertain what requirements, if any, shall apply to the works in this respect. The restrictions may relate to the type of plant to be used, the methods of working to be adopted, the hours of working permissible and may in addition impose a maximum noise level at the site boundary which may not be exceeded. The Contractor is to be held responsible for complying with such requirements, restrictions or consents, together with any other stipulations to which his attention may be drawn from time to time by the competent Authorities and is to allow in his tender for any costs or expenses arising from such compliance. No instructions issued to the Contractor by the Project Manager or his authorised representative shall relieve the Contractor from compliance with the Control of Pollution. The Contractor will at all times ensure that his operatives create the minimum of noise consistent with the work being undertaken. All necessary noise, including the playing of transistor radios and like will be prohibited. No discomfort or annoyance from the noise will be occasioned to patients or staff where such noise is reasonably avoided.		
	Amount to Collection Page		

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Item	Preamble	£	P
	Fire Precautions Before any works are carried out, the Contractor is to discuss his proposals with the Project Manager and Fire Prevention officer, to ensure that he is fully aware of any fire hazard that may be involved. He is to draw the attention of all his workmen to the special vulnerability of Employer property and patients in the event of fire, and the dangers involved in the careless disposal of matches, cigarettes and tobacco ash must be fully impressed on them. The Contractor's workmen are to be required strictly to conform with all "NO SMOKING" rules applicable in specific areas of the property. Fire escape routes are to be kept unobstructed and, if necessary illuminated at all times and the Contractor will post such notices as are necessary to ensure compliance with this requirement. **Year 2000 Compliance** Prior to the start of the project certificates of Year 2000 compliance must be made available to the Project Manager demonstrating that any parts or equipment to be installed is compliant with: BSi DISC PD 2000-1 A Definition of Year 2000 Conformity Requirements. NHS Estates Guidance, The Year 2000 problem, Testing of estates embedded systems and devices. Details of year 2000 compliance tests and test procedures must be submitted to the Project Manager for all the equipment being installed. On completion of the project, or stages of the project, Year 2000 compliance must be demonstrated and certificates issued to the Project Manager before the systems become operational.		
	Amount to Collection Page		

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Item	Preamble	£	P
	COLLECTION PAGE Amount of total from Page No. 134 Amount of total from Page No. 135 Amount of total from Page No. 136 Amount of total from Page No. 137 Amount of total from Page No. 138 Amount of total from Page No. 139 Amount of total from Page No. 140 Amount of total from Page No. 141 Amount of total from Page No. 142 Amount of total from Page No. 143		
	Amount to Price Schedule Summary		

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APPENDIX 1

SCHEDULE OF INFORMATION TO BE SUPPLIED BY THE TENDERER

SITE .....

SERIAL NO.	ITEM	TO BE COMPLETED BY THE TENDERER
1.	Names of Technicians allocated to the above site.	
2.	The precise details of the qualifications and experience of the above technicians.	
3.	The average number of technicians available off site for unplanned or emergency work.	

Signed ..... in capacity of .....

For and on behalf of (IN BLOCK CAPITAL)

.....

Date .....

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APPENDIX 2

LIST OF SUB-CONTRACTORS

The contractor shall list hereunder the names of the Sub-Contractors he proposes to employ on the Works.

Work Section or Trade	Name/Address/Tel. and Fax No. of Sub-Contractor

Signed by…… Date……

In Capacity of……...

For and on behalf of……..

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APPENDIX 3

SCHEDULE OF CONTRACTOR'S PARTICULARS

Contract:

The Annual Testing of Sterilizers

Contractor's Title:

Address:

Day Telephone Number:

Emergency Telephone Number:

Facsimile Number:

Contractor's Representative for this Contract:

Daytime Telephone Number:

Emergency Telephone Number:

Facsimile Number:

VAT Registration Number:

Date of Expiry of Insurance Policy:

Signed by……..…... Date……

In Capacity of……..

For and on behalf of…..……..

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EMERGENCY REPAIRS

The Contractor must state below the emergency telephone numbers at which his emergency repair staff can be contacted and called out immediately at any time to deal with emergencies occurring at the Contract Works.

Contractor to state here his emergency repair telephone numbers:

THIS SECTION MUST BE COMPLETED AT TIME OF TENDER

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CERTIFICATE OF NON-COLLUSION

_____NHS Trust

to be returned by _____

The essence of selective tendering is that the client shall receive bona fide competitive tenders from all those tendering. In recognition of this principle we certify that this is a bona fide tender, intended to be competitive and that we have not fixed or adjusted the amount of the tender by or in accordance of any agreement or arrangement with any other person. We also certify that we have not done and we undertake that we will not do at any time before the hour and date specified for the return of this tender any of the following acts:-

a. communicating to a person other than the person calling for those tenders the amount or approximate amount of the proposed tender, except where the disclosure in confidence of the approximate amount of the tender was necessary to obtain insurance premium quotation required for the preparation of the tender.
b. entering into any agreement or arrangement with any other person that he shall refrain from tendering or as to the amount of any tender submitted.
c. offering or paying or giving or agreeing to pay or give any sum of money or valuable consideration directly or indirectly to any person for doing or having done or causing or having caused to be done in relation to any other tender or proposed tender for the said work any act or thing of the sort described above.

In this certificate the word “person” includes any person and any body or association, corporate or unincorporate and “any agreement or arrangement” includes any such transaction, formal or informal, and whether legally binding or not.

Signed……

on behalf of…….

……..

Date……

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PRICE SCHEDULE

SUMMARY

YEAR ONE

a. The price in this Schedule covers the cost of working within the hours as listed in the Preamble, Appendix A: Sterilizer inventory and Unit Costs.

b. Sterilizer testing shall be carried out in accordance with the advice contained in the appropriate Appendix at the frequencies stated.

c. Value Added Tax shall be reimbursed as stated in the Tender.

d. The price inserted in this Schedule shall include:

	A.	**Preamble: Collection page**	**£**
	B.	**Testing the cost of all visits as detailed in Appendix A of the particular specification**	**£**
	C	**Compiling reports, copying and determining tests**	**£**_____
Total Cost (excluding VAT)	**To Tender Price Form**		**£**_____
Alternative No. 1.	Year No. 1 from Above		£
	Year No. 2	+……..%	£
	Year No. 3	+……..%	£
	Year No. 4	+……..%	£
	Year No. 5	+……..%	£_____
Total Cost (excluding VAT)	To Tender Price Form		£_____
Alternative No. 2:	Years 1-5 Fixed Price		£_____
Alternative No. 2	To Tender Price Form		£_____

Note:

Tenderers may price for one or both of the above options.

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Materials

All material costs to include administration, ordering, delivery and handling charges.

Material invoices will accompany all claims for payment.

Material shall be charged at cost plus… _____%

Signed _____ in the capacity of _____

(IN BLOCK CAPITALS) _____

on behalf of _____

_____

Telephone No_____Date_____19_____

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Summary 3

Summary of staff rates

The rates below will apply to work not covered in this contract requested for the sterilizers listed in Appendix A

The rates below are to be valid for a period of _____ years

Rates per hour			**Overtime Rates**			
Grade of staff	**Trade**	**Standard rate**	**Mon - Fri**	**Sat & Sun**	**Public Hols**	**Callout Rate**
Technician						
Supervisor						
Any other staff as appropriate						

Signed_____ in the capacity of _____

(IN BLOCK CAPITALS)_____

On behalf of _____

Telephone No _____ Date _____ 20_____

TERM CONTRACT FOR ANNUAL TESTING OF STERILIZER

INVITATION TO TENDER – SHEET 1

……..NHS TRUST / EMPLOYER
……..
……
……

Contract No ……

FOR TRUST/ USE

You are invited by the above NHS Trust/Employer to submit on this form , which together with all documents when completed is to be delivered to the above NHS Trust Employer…… on…… 20…….. the enclosed label being

The NHS Trust Employer do not bind themselves to accept the lower or any

IF NO TENDER IS BEING SUBMITTED ALL OF THE DOCUMENTS SHOULD BE RETURNED WITHOUT DELAY USING THE ADDRESSED LABEL WHICH SHOULD BE MARKED 'NO TENDER'.

FORM OF TENDER

TO THE ……..NHS TRUST/EMPLOYER

FOR THE ANNUAL TESTING OF
(hereinafter referred to as the Employer)

1. I/We have examined the following parts of the Contract

    1. Invitation to
    2. Price
    3. VAT Form
    4. Schedule of Information to be supplied beTendere
    5. Abstract of
    6. General Conditions of
    7. Particular

and subject and in accordance with the terms and conditions in the Contract. I/We offer to execute all the work described in the said documents during the contract period defined in the Conditions of Contract commencing……20…….. at such times as may be set forth therin or as the Employer may otherwise order, in consideration of:

A. Payment by Employer at the rates or prices I/We have inserted in the said Schedule, as detailed in Annexe A.

B. Reimbursement by the Employer of Value Added Tax to be declared to HM Custom and Excise.

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INVITATION TO TENDER – SHEET 2

2. The essence of selective tendering is that the NHS Trust/Employer receive bona fide competition tenders from all persons tendering. In recognition of this principle:

I/We certify that this is a bona fide tender, and that I/We have not fixed or adjusted the amount of the tender by or under or in accordance with any agreement or arrangement with any other person. I/We certify that I/We have not done and I/We undertake that I/We will not do at any time before the hour and date specified for the return of this tender any of the following acts:

A. communicate to a person other than the person calling for those tenders the amount or the approximate amount of the proposed tender, except where the disclosure, in confidence, of the premium quotations required for the preparation of the tender;

B. enter into any agreement or arrangement with any other person that shall refrain from tendering or as to the amount of any tender to be submitted;

C. offer or pay or give to pay or give any sum of money or valuable consideration directly or indirectly to any person for doing or having done or causing or having caused to be done in relation to any other tender or proposed tender for the said work any act or thing of the sort described.

In this invitation the work 'person' includes any person and any body or association, corporate or unincorporate; and 'any agreement or arrangement' includes any transaction, formal or informal, and whether legally binding or not.

3. I/We agree that other terms or conditions of contract or any general reservations which may be printed on any corresponding emanating from me/us in connection with this tender or any other agreement resulting from this tender, shall not be applicable to this tender or to the Agreement.

Signed……..in the capacity of……
duly authorised to sign tenders for and on behalf of

(IN BLOCK CAPITALS)……..

Telex No…….. Fax No…….

Postal Address…….

……

Telephone No…… Date……..20……

Contractor's nominal liaison officer:……

……..

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PRICE SCHEDULE

…….NHS TRUST/EMPLOYER Contact No……..

THE WORK

1. The price in this Schedule covers the cost of working within the outside normal hours as indicated in Appendix A: Sterilizer Inventory and Unit Costs.

2. Sterilizer testing shall be carried out in accordance with the advice contained in the appropriate Appendix at the frequencies stated.

3. Value Added Tax shall be reimbursed as stated in the Tender.

4. The price inserted in this Schedule shall include:

A. the cost of all visits;

B. the cost of compiling reports, copying and determining tests.

Total Cost (excluding VAT) £……

Signed……in the capacity of……..

(IN BLOCK CAPITALS)…….

Telex No…… Fax No…….

Postal Address…….

……..

Telephone No…….. Date……..20……..

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A48235836

VALUE ADDED TAX FORM

…… NHS TRUST/EMPLOYER

……

……

……

……

……

Job Title – Annual Testing of Sterilizers Contract No…….

To: The Chairman and Members of the ……NHS Trust/Employer

I/We the undersigned, hereby give our Provisional Assessment of Value Added Tax payable on positively – rated Taxable Supplies of goods and/or Services chargeable to the ……

Description of Goods and/or Services	Value (Tax Exclusive) £	Positively Rated at: %	Tax £

Total £……

Signed…… Date……

On behalf of……..

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Contract No…….

.

SCHEDULE OF INFORMATION TO BE SUPPLIED BY THE TENDERER

SITE……..

SERIAL NO.	ITEM	TO BE COMPLETED BY THE TENDERER
1.	Names of Technicians allocated to the above site.	
2.	The precise details of the qualifications and experience of the above technicians.	
3.	The number of technicians available off site for unplanned or emergency work.	
4.	The location of off site technicians who will respond to unplanned or emergency requirement.	OFFICE LOCATION 1. …… 2. …… 3. ……
5.	The location from which out of-hour call outs will be arranged.	OFFICE ADDRESS 1. …….. 2. …….. 3. …….. TELE ……..…

Signed……in capacity of……

On behalf of (IN BLOCK CAPITAL)

……

Date…….

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ABSTRACT OF PARTICULARS

The following shall be read in conjunction with the General Conditions of Contract.

1. DEFINITIONS

Refer to;

1.04 The Schedule(s) shall be the Price Schedule(s) for the Annual Testing of Sterilizers listed in Appendix A.

1.05 The Employer shall be the ……

……..NHS Trust /Health Employer

1.07 The Project Manager shall be

……

4. CONTRACT RATES AND PRICES

Refer to:

4.01/4.02 Applies/Does not apply*

The following shall be read in conjunction with the Particular Specification of Contract.

7. SECURITY AND PUBLIC HEALTH PRECAUTIONS

Refer to:

7.01 areas subject to special security precautions:

……

……

7.02 Areas subject to special Public Health precautions:

……

……

10. REQUISITIONING OF WORKS

Refer to:

10.1 Local liaison Personnel

……

……

* Delete whichever is not to apply.

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PARTICULAR SPECIFICATION FOR THE ANNUAL

TESTING OF STERILIZERS

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NHSScotland Property and Environmental Forum

PARTICULAR SPECIFICATION

1. REGULATIONS

All work shall be carried out in accordance with.

1.01 All relevant Acts or Parliament, statutory instruments and regulations.

1.02 Any public health, security and conduct requirements as from time to time be issued to the Contractor by the Employer.

1.03 Any relevant Safety Regulations published by the Employer copies of which are available from the Project Manager.

2. COMPLIANCE WITH BRITISH STANDARDS

2.01 All work and material shall company with relevant European and British Standards and Codes of Practice.

3. RESPONSIBILITIES OF THE EMPLOYER

The Employer shall be responsible for:

3.01 The keeping of each item of Mechanical and Electrical Plant in such a condition that its functions in accordance with the requirements of SHTM 2010, BS 3970, BS 2646 and BS 3421.

3.02 Arranging for statutory inspections to be carried out (under a separate contract).

3.03 Maintenance of a record for each item of Mechanical and Electrical Plant in accordance with the requirements of SHTM 2010.

This shall contain details of all maintenance and remedial works carried out on each item of equipment to the following standards:

A.	Failures	Date Symptoms of failure
B.	Visits by other Contractors	Date Details of Work carried out including details of tests and replacements. Date and time of completion
C.	Statutory Inspections	Date Details of any remedial work required. Signature of competent person carrying out inspection.

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4. INSTRUCTIONS

4.01 The Person from whom the Contractor will be required to accept instructions and attend any urgent or necessary recommissioning is listed in the Abstract of Particulars.

4.02 All requisitions for emergency action will be made by telephone to the Contractor's office or central control point and will be confirmed in writing within 7 days by the Project Manager.

5. DOCUMENTATION

5.01 The Contractor must ensure that on each occasion his staff enter the details of any work carried out on the plant in the Plant History Record before leaving the site.

5.02 The Contractor, within 14 days of the completion of the tests, shall supply the Project Manager with a Test Report carried out under this contract as detailed in Appendix D, together with 3 copies.

6. DESCRIPTION OF THE WORK

6.0l The Contractor shall undertake annual tests as described in Appendix B – Testing Philosophy & Procedures and Appendix C - Annual Performance Tests on those Sterilizers listed in Appendix A - Sterilizer Inventory.

6.02 The Contractor shall employ persons, experienced, qualified and preferably certified to a minimum City and Guilds standard, who would be competent to perform all the required tests, documentary evidence of this shall be provided. The Employer may require the said persons to demonstrate his/her competence by performing a test laid down by the Project Manager, to be witnessed by Project Manager or his/her nominated representative, prior to the letting of the Contract or during the period of the Contract.

6.03 The Contractor shall demonstrate that he has all the necessary equipment which is detailed in Part 3, Paragraph 6.1 – 6.63 of the current edition of Scottish Health Technical Memorandum 2010 (SHTM) and either evidence of its calibration or the means of verifying its calibration.

Current certification of accuracy traceable to the National Physical Laboratory and where appropriate to NAMAS Standards will be required.

6.04 The Contractor shall prepare a schedule of the order and time in which he would perform the tests on the Sterilizers listed in Appendix A, to be agreed by the Project Manager prior to the awarding of the Contract.

6.05 The Contractor will confirm his intention to perform the scheduled test with the Project Manager or his/her nominated representative 14 days in advance.

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6.06 The Project Manager or his nominated representative will arrange for the Local Maintenance Engineer to be available to rectify any faults which the Contractor identifies during the test.

6.07 The Contractor shall on completion of an annual test, make a signed and dated entry in the Plant History Record that the Sterilizer complies or does not comply, with the performance requirements. In the event of non-compliance the Contractor shall notify the Project Manager or his local nominated representative (normally a departmental manager) within 24 hours.

6.08 The Contractor shall issue to the Project Manager, or his/her nominated representative, within 21 days of any test being carried out, the results of the tests in a test report as demonstrated in Appendix D together with 3 copies.

6.09 The Contractor shall satisfy himself from the Plant History Records of each Sterilizer give the service maintenance records, and where appropriate, the microbiological records for all routine tests and ascertain they have been performed on each Sterilizer throughout the previous year and is in a condition in which tests can be undertaken safely. Comments shall be included in the Test report.

6.10 The Contractor shall nominate on Appendix 2: Schedule of Contractor's Particulars a representative who will act for the Contractor to liaise with the Project Manager on all matters relating to the Contract.

6.11 The Project Manager will take up any problems of the Contract with the Project Manager or his/her nominated representative.

6.12 The Project Manager or his/her nominated representative may visit any site at any time to inspect the Contractor's test procedures and results.

6.13 The Contractor when requested, on the appropriate form (See Appendix E) will be required to retest any sterilizer that has not satisfactorily passed the annual test criteria.

Repeat tests will be paid for at not more than the cost of the test original of the said Sterilizer as listed in Appendix A, unless investigative testing has been previously agreed.

6.14 The Contractor shall confirm a date for retesting of sterilizers within two days of receiving the request and should carry out the retesting of Sterilizers where applicable within 10 working days of receiving the request.

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Appendix A

STERILIZER INVENTORY AND UNIT COSTS

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STERILIZER INVENTORY AND UNIT COSTS

.....NHS TRUST OR EMPLOYER

No.	Location	Department	Make	Col. Model	Serial No.	Type	Periodical/ Yearly	Date to be undertaken	Normal hours	Out of hours	Unit cost £
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20										TOTAL	

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Appendix B

TESTING PHILOSOPHY AND PROCEDURES

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TESTING PHILOSOPHY & PROCEDURES

The Testing of Sterilizers required under the contract are those called for in the Scottish Health Technical Memorandum No. 2010, Part 3 (SHTM 2010).

The relevant clauses required for the execution of this contract in fulfilling the procedures for annual testing are presented in full in Appendix C.

Calibration of Instruments

It is the Contractors responsibility to ensure that all instruments used in executing the work are suitably calibrated and hold current certificate of calibration clearly traceable to National Physical Laboratory, British Accreditation Service and that the test system calibration is checked immediately before and immediately after each annual test and ‘is recorded and included in each Test Report. Copies of current certificates are to be forwarded to the Project Manager.

Test Equipment

The relevant clauses required for compliance of equipment used for sterilizer testing are those called for in the Scottish Health Technical Memorandum No. 2010 Part 3 (SHTM 2010) Chapter 6.

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Appendix C

ANNUAL PERFORMANCE TESTS

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YEARLY AND REVALIDATION TESTS

The tests are listed in the Scottish Health Technical Memorandum 2010, Part 3, Chapters 7 – 19.

The results of tests done should be recorded in the Plant History Record for each sterilizer in the form of a report as described in Appendix D.

This contract requires the yearly tests to be carried out only on those Sterilizers which are listed in SHTM 2010, Part 3, Chapters 4-5 (Check the relevant detail in Schedule of periodic tests to establish those tests only required for yearly testing in the tables).

The Contractor shall include in his report to the Project Manager if he becomes aware that the daily, weekly or quarterly tests have not been satisfactorily carried out. The contractor should be satisfied that the sterilizers are in a condition in which the tests can be undertaken safely.

Schedule of Periodic Tests. Reference SHTM 2010 Part 3.

REFERENCE SHTM 2010 PART 3 SCHEDULE OF TESTS		
STERILIZER PROCESS TYPE	**CHAPTER**	
	4	**5**
	VALIDATION TABLE	**PERIODIC TEST TABLE**
Porous load	2a	4a
Fluids	2b	4b
Unwrapped Instrument and Utensil	2c	4c
Dry Heat	2d	4d
Low Temperature Steam	2e	4e
Low Temperature Steam and Formaldehyde	2e	4e
Ethylene Oxide	2f	4f
Laboratory	3a	5a
Laboratory Culture Media Preparators	3b	5b

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Appendix D

REPORTS

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REPORTS

Each annual test carried out must be fully reported in the format shown.

Each report will consist of:

1. Title page with details of NHS Trust or Hospital, Department, Manufacturer, Sterilizer type, References and date of test and person(s) carrying out the test.
2. Sequence Test Sheet listing each test carried out, a brief statement on test result and any adjustments or actions taken.
3. Test Report Sheet giving detailed analysis of the test carried out with a conclusion and recommendations.
4. Test Sheets showing details of test carried out (See specimen test sheets).

NOTE: Test sheets may be replaced by suitable computer printouts providing they are authorised by Project Manager.

5. Associated test recorder thermocouple charts, including calibration checks, sterilizer recorder charts, and/or print-outs, Bowie/Dick sheet where applicable. All annotated and suitably identified.
6. Each reports must be suitably bound and forwarded to the Contract Administration together with 2 copies – charts need only be incorporated into the original report.

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1. Title page

STERILIZER ANNUAL TEST REPORT

NHS TRUST/EMPLOYER .....

HOSPITAL .....

DEPARTMENT .....

MANUFACTURER .....

MACHINE TYPE .....

REFERENCE .....

FILE REF .....

TEST DUE NO LATER THAN .....20……..

DATE OF TEST .....

TEST CARRIED OUT .....

SIGNATURE .....…….

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2. TEST SEQUENCE SHEET

. . . . . NHS TRUST/EMPLOYER

Hospital:	**Department:**	**Date Tested:**
Manufacturer:	**Ref No:**	**Our Ref or File No:**

SEQUENCE OF TEST

No.	Test Undertaken	Pass/Fail	Comments Brief Statement
1.			
2.			
3.			
4.			
5.			
ETC.			

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3. TEST REPORT SHEET

. . . . . .NHS TRUST/EMPLOYER

Hospital:	**Department:**	**Date Tested:**
Manufacturer:	**Ref No:**	**Our Ref or File No:**

1. DETAIL REPORT

Detailed report of findings as to conforming to standards, faults found, action taken, and recommendations.

2. RECORDS

SHTM 2010 APPENDIX 3. Thermometric Charts/Data Logged/Summary Sheets for process type
Statement on findings of Plant History Record regarding Maintenance and Periodic Testing status.

3. CONCLUSIONS

Brief statement from above detailed report.

4. TESTER'S NAME

.....

5. TESTER'S SIGNATURE

.....

6. DATE

.....

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4. SPECIMEN TEST SHEETS	REFERENCES
Unwrapped Instrument & Utensil Sterilizer	REF 46/130V
Porous Load Sterilizer	REF 46/129V
Fluids Sterilizer	REF 46/132V
Dry Heat Sterilizer	
Laboratory	REF 46/133

LOW TEMPERATURE STEAM WITH AND WITHOUT FORMALDEHYDE

Full logbooks including inspection, test and maintenance recording facilities for porous load, unwrapped instruments and utensils, laboratory, fluid and dry heat sterilizers are available from:

Printing Services,
Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
EDINBURGH
EH5 3SH
Tel. 0131 552 6255
Fax 0131 552 6536

LABORATORY – MEDIA

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Appendix E

RETEST REQUEST FORM

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STERILIZER PERIODIC TESTING

REQUEST FOR RETEST

CONTRACT NO……..

Request for Retest Form No……

FROM:……NHS TRUST

TO:……..CONTRACTS

Request for retesting following rectification of faults:

Trust / Employer	…….
Hospital	…….
Clinic	…….
Sterilizer	…….
Plant No.	…….
Department	…….
Room Number	…….

Signature of Contracts Manager or Contractor's Representative:……

Date of request:……

Note: The retesting following any remedial works shall be carried out within ten working days of receiving notice, unless requested later.

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Section E

Procedures for determining the sound power generated by a sterilizer

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Contents

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E. Procedures for determining the sound power generated by a sterilizer

Introduction

E.1 This test, to be carried out by the manufacturer of a sterilizer, is based on the test in Appendix D of BS 3970: Part 1: 1990 and BS EN 285.

E.2 Except where otherwise stated here, the sound power levels of sterilizers are determined by the method described in BS EN ISO 3746. The information given here is by itself not sufficient to permit the test to be carried out by personnel unfamiliar with the requirements of BS 4196 and BS EN ISO 3746.

E.3 Measurements made by this method have a standard deviation of up to 5 dB for discrete tone sources and up to 4 dB for wide-band noise sources. The uncertainties can be minimised by careful consideration of the conditions in which the test is carried out.

a. The environmental correction factor, K, depends on the relative sizes of the sterilizer and the test room and the sound absorbing qualities of the room. For a given sterilizer, the larger the room the smaller the value of K. Although BS EN 285 specifies that K should be less than 7 dB, this is a relatively high value and the manufacturer should aim to achieve K = 2 dB or less. This figure can normally be achieved by carrying out the test in a sufficiently large room. The assembly hall in which the sterilizer is constructed should be suitable;

b. Another source of error is the ambient background noise. Table 4 of BS 4196: Part 6 gives correction factors for different levels of background noise, but the lower the correction factor the more reliable the result will be. The correction is essentially zero if the background noise level is 10 dB or more below the level measured when the sterilizer is operating. It should be possible to achieve this on the manufacturer's premises if the test is carried out when the factory is closed and all other plant is shut down. Steam and compressed air plant not part of the sterilizer should be run on storage during the test, with boiler feed pumps and compressors switched off.

Apparatus

E.4 Sound-level meter, complying with type 1 of BS EN 60651: 1994, or an integrating-averaging sound level meter complying with type 1 of BS EN 60804: 1994. The sound power level is determined from at least six microphone positions (Figure E1). If the sound meter has insufficient input channels, additional instruments and/or repeated operating cycles are required.

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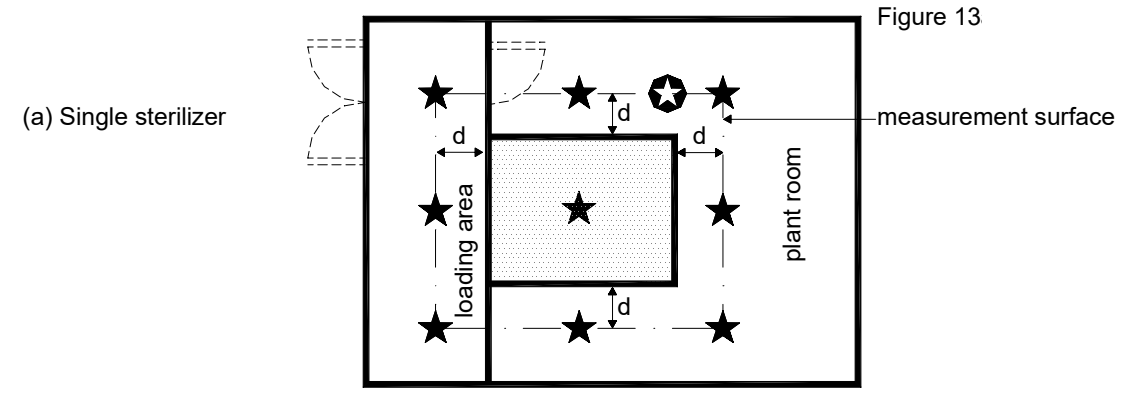
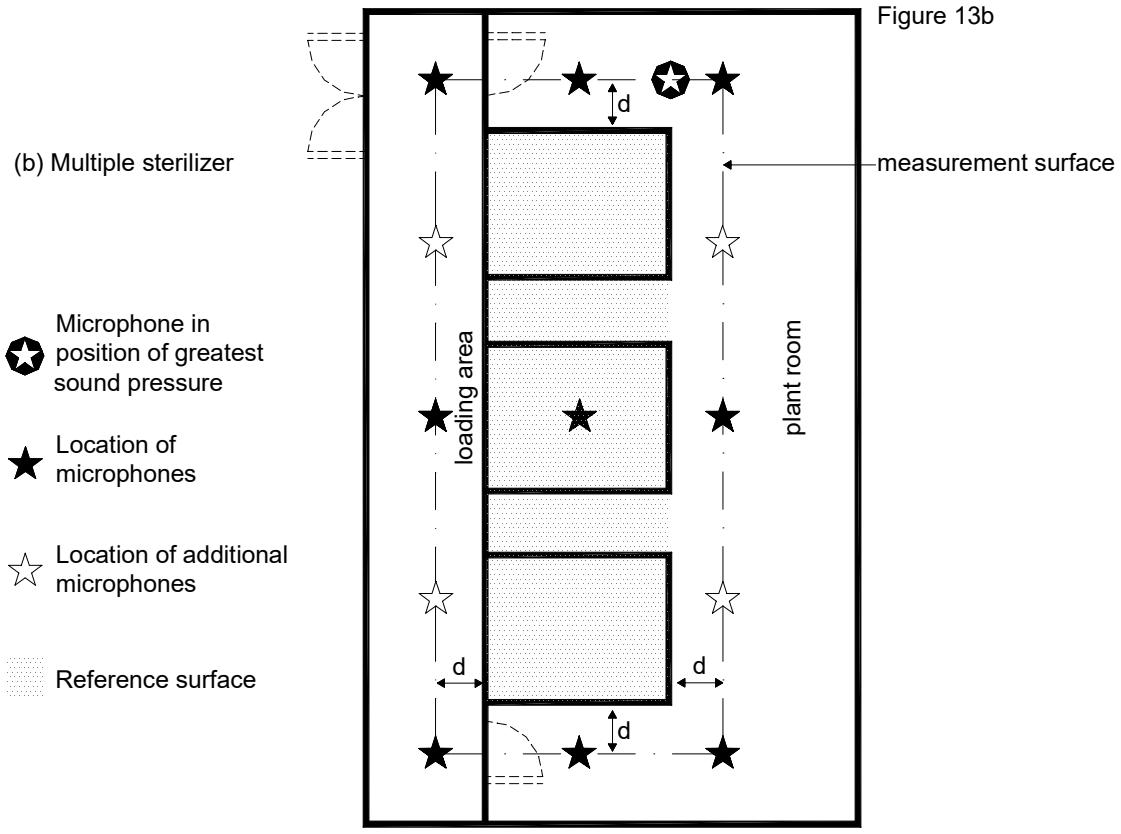
E.5 Test room, configured so that the distance between any wall or other object in the room is not less than 3 m from any reference surface (see paragraph E.6) on the sterilizer to be tested. The room in which the sterilizer is assembled may be suitable providing the conditions discussed in paragraph E3 are met.

Figure E1: Location of microphones for sound pressure test





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Test procedure

E.6 The test determines the A-weighted sound power using a rectangular measurement surface. The “reference surface” defined in BS EN ISO 3746 is the smallest rectangular box that just encloses the sterilizer, with a width and depth measured from the outside of the vessel lagging and a height measured from the floor to the top of the vessel lagging. The box does not include pipes and valves used to connect the sterilizer to its services.

E.7 Determine the sound absorption area, A, of the test room using the experimental method described in BS EN ISO 3746. The method of estimation described in A.3.1.1 may be used as a check.

E.8 Determine the environmental correction factor, K, as described in BS EN ISO 3746. Although BS EN 285 allows K to be as high as 7 dB, a figure of around 2 dB should be achievable as described in paragraph E.3a.

E.9 Sterilizers should be regarded as “large sound sources” as defined BS EN ISO 3746. The measurement distance, d, should be 1.0 ± 0.1 m. Microphones should be placed on the measurement surface as described in BS EN ISO 3746. At least six microphones will be required.

E.10 The test is to be carried out with all integral equipment (for example, water pumps, vacuum pumps, compressors) operating normally.

E.11 Load the sterilizer with a full load as described in Part 3 of this SHTM. If there is a choice of operation cycle, select the cycle with the highest sterilization temperature. Ensure that the pressure and flow from the steam and water services are set to levels which cause the maximum noise and are within the ranges specified for normal operation. Start the operating cycle.

E.12 Using the procedure for measuring the rectangular measurement surface described in BS EN ISO 3746, determine the A-weighted sound power level and the peak sound power level of the sterilizer either for one complete operating cycle or for a 30 min period that contains the most prominent sounds.

Test result

E.13 Record the calculated mean and peak A-weighted sound power levels in decibels to the nearest integer. Other information should be recorded in accordance with BS EN ISO 3746.

E.14 The test should be considered satisfactory if the peak A-weight sound power level at no time exceeds the mean A-weighted sound power level by more than 15 dB.

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Section F

Accommodation for ethylene oxide gas cylinders, manifolds and canisters

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F. Accommodation for ethylene oxide gas cylinders, manifolds and canisters

General

F.1 For use in large sterilizers operating at above atmospheric pressure, ethylene oxide is mixed with carbon dioxide or chlorofluorocarbon. Given recent concerns about environmental issues however, the use of the latter is deprecated and is no longer in widespread use. The cylinders therefore are less hazardous than those of pure ethylene oxide.

F.2 Single-shot cartridges of pure ethylene oxide for use in sub-atmospheric pressure machines require care but in view of the modest volumes involved do not pose a major safety problem.

Ethylene oxide cylinders

F.3 Cylinders are categorised in accordance with Table F1 and, although ethylene oxide is supplied in mixture with inert gas, they should be stored under the toxic and/or corrosive and flammable category.

F.4 Cylinders may be stored with other industrial and medical gas cylinders in accommodation designed in accordance with SHTM 2022.

General principles

F.5 Accommodation should be well ventilated and labelled clearly to describe the gases contained. The labelling should include details of emergency action procedures and the location of keys should be identified. Cylinder storage should be designated as a “no smoking” area and appropriate labels should be posted.

F.6 Clear and secure and access is required to permit safe cylinder loading/unloading and handling with vehicular access.

F.7 The maximum temperature in the cylinder store should be that recommended by the gas supplier/manufacturer. Normally this should not exceed 38°C.

F.8 Accommodation should be free from naked flames and sources of ignition and appropriate fire extinguishing equipment should be available. Lighting protection may be necessary for isolated buildings.

F.9 For electrical equipment in the vicinity of the gas cylinders the recommendations of BS EN 60079-14, Zone 2 classification will usually be appropriate for the open-air type of installation.

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F.10 Safety equipment in the form of protection goggles, gloves and a respirator should be available inside this space and also at the point of entry.

Ethylene oxide cartridges

F.11 Sufficient secure storage within the loading area in the form of a locked cabinet is satisfactory for cartridges for use in a single day.

F.12 Additional cartridges will be required for an operational unit and external storage, for example one week's supply, should be held externally. Small special-purpose cabins typically used for the storage of LPG containers fully protected from the elements will be appropriate.

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Table F1: Clarification of gas cylinders typically found on hospital sites

Group classification of gas cylinder contents		Medical gas	Non-medical gas
1	Flammable	Cyclopropane – this is no longer manufactured	Acetylene LPG(eg.. Propane, butane) STG (synthetic town gas) Methane, natural gas, hydrogen
2	Oxidising and/or supports combustion	Medical compressed air Oxygen Nitrous oxide Oxygen/nitrous dioxide Oxygen/carbon dioxide Oxygen/ helium mixtures	Compressed air oxygen Nitrous oxide Oxygen/nitrous oxide mixtures
3	Toxic and corrosive		
3.1	Toxic and/or corrosive and flammable		Ammonia Ethylene oxide (C_2H_4O) Carbon monoxide C_2H_4O/CO_2 mixtures > 6% C_2H_4O
3.2	Toxic and/or corrosive and oxidising		Nitric oxide mixtures Sulphur dioxide Chlorine
3.3	Toxic and/or corrosive only		Ethylene oxide/halo-carbon mixture < 15% C_2H_4O Certain conditions only – ethylene oxide/carbon dioxide mixtures < 6% C_2H_4O
4	Others including inert, but excluding toxic or corrosive	Carbon dioxide Helium	Carbon dioxide Nitrogen Argon Helium Halo-carbon Refrigerants

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
	Health and Medicines Act	HMSO	1988	
	Registered Establishments (Scotland) Act	HMSO	1998	
	Water (Scotland) Act	HMSO	1980	
SI 3146	Active Implantable Medical Devices Regulations	HMSO	1992	
SI 1995	Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995	HMSO	1995	
SI 2179 & 187	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
SI 2092	Carriage of Dangerous Goods (Classification, Packaging & Labelling) and Use of Transportable Pressure Receptacles Regulations	HMSO	1996	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988	

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Publication ID	Title	Publisher	Date	Notes
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 1315	In Vitro Diagnostic Medical Devices Regulations 2000	HMSO	2000	
SI 3232	Ionising Radiations Regulations 1999	HMSO	1999	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 2051	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulation	HMSO	1992	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
British Standards				
BS 593	**Specification for laboratory thermometers**		1989	
BS 1781	**Specification for linen and linen union textiles**		1981	
BS 2646	**Autoclaves for sterilization in laboratories**	BSI Standards		
	Part 1: Specification for design, construction, safety and performance		1993	
	Part 2: Guide to planning and installation		1990	
	Part 3: Guide to safe use and operation		1993	
	Part 4: Guide to maintenance		1991	
	Part 5: Methods of testing for function and performance		1993	
BS 2648	**Performance requirements for electrically heated laboratory drying ovens (PD2517,6/56)**	BSI Standards	1955	
BS 2775	**Specification for rubber stoppers and tubing for general laboratory use**		1987	
BS 3693	**Recommendations for design of scales and indexes on analogue indicating instruments**		1992	
BS 3928	**Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors)**	BSI Standards	1969	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 3970	**Sterilizing and disinfecting equipment for medical products** **Part 1:** Specification for general requirements **Part 2:** Specification for steam sterilizers for aqueous fluids in sealed rigid containers **Part 3:** Specification for steam sterilizers for wrapped goods and porous loads **Part 4:** Specification for transportable steam sterilizers for unwrapped instruments and utensils **Part 5:** Specification for low temperature steam disinfectors **Part 6:** Specification for sterilizers using low temperature steam with formaldehyde	BSI Standards	1990 1991 1990 1990 1993	
BS 4196-0	**Sound power level of noise sources. Guide for the use of basic standards and for the preparation of noise test codes**	BSI Standards	1981	
BS 4275	**Guide to implementing an effective respiratory protective device programme**	BSI Standards	1997	
BS 5164	**Specification for indirect acting electrical indicating and recording instruments and their accessories**		1975	
BS 5295	**Environmental cleanliness in enclosed spaces** **Part 1:** Specification for clean rooms and clean air devices		1989	
BS 5304	**British standard code of practice for safety of machinery**	BSI Standards	1988	
BS 5815	**Sheets, sheeting, pillowslips, towels, napkins and continental quilts secondary covers** **Parts 1:** Specification for sheeting etc **Part 2**: specification for towels etc. **Part 3:** Specification for counterpanes etc.	BSI Standards	1989 1988 1991	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 6000	**Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots**	BSI Standards	1996	
BS 6001	**Sampling procedures for inspection by attributes**	BSI Standards	1991	
BS 6068	**Water quality** **Sect.1.2** Glossary	BSI Standards	1997	
	Sect 6.5 Guidance on sampling of drinking water and water used for food processing		1991	
	Sect. 6.7 Guidance on sampling of water and steam in boiler plants.		1994	
BS 6257	**Specification for paper bags for steam sterilization for medical use**		1989	
BS 6447	**Specification for absolute and gauge pressure transmitters with electrical outputs**		1984	
BS 7671	**Requirements for electrical installations. IEE wiring regulations**	BSI Standards	1992	16th edition
BS 7720	**Specification for non-biological sterilization indicators equivalent to the Bowie and Dick Test**		1995	
BS EN 134	**Respiratory protective devices. Nomenclature of components. Names of components in three CEN languages and diagrams for respiratory protective equipment**	BSI Standards	1998	
BS EN 285	**Sterilization, steam sterilizers, large sterilizers**	BSI Standards	1997	
BS EN 550	**Sterilization of medical devices. Validation and routine control of sterilization by ethylene oxide**	BSI Standards	1994	
BS EN 552	**Sterilization of medical devices. Validation and routine control of sterilization by irradiation**	BSI Standards	1994	
BS EN 554	**Sterilization of medical devices. Validation and routine control of sterilization by moist heat**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 556	**Sterilization of medical devices. Requirements for terminally sterilized medical devices to be labelled 'STERILE'**	BSI Standards	1995	
BS EN 724	**Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices**	BSI Standards	1995	
BS EN 764	**Pressure equipment. Terminology and symbols: pressure, temperature, volume**	BSI Standards	1995	
BS EN 837-1	**Bourdon tube pressure gauges: dimensions, metrology, requirements and testing**	BSI Standards	1998	
BS EN 866	**Biological systems for testing sterilizers and sterilization processes** **Part 1:** General requirements **Part 2:** Particular systems for use in ethylene oxide sterilizers **Part 3:** Particular systems for use in moist heat sterilizers	BSI Standards	 1997 1998 1997	
BS EN 867	**Non-biological systems for use in sterilizers** **Part 1:** General requirements **Part 2:** Process indicators **Part 3:** Specification for Class B indicators for use in the Bowie and Dick test	BSI Standards	 1997	
BS EN 868	**Packaging materials and systems for medical devices which are to be sterilized. General requirements**	BSI Standards	1997	
BS EN 980	**Graphical symbols for the use in the labelling of medical devices**	BSI Standards	1997	
BS EN 1174	**Sterilization of medical devices. Estimation of population of micro-organisms on product**	BSI Standards	1996	
BS EN 1422	**Sterilizers for medical purposes – ethylene oxide sterilizers – specification**	BSI Standards	1998	
BS EN 22872	**Complete, filled transport packages. Method for determination of resistance to compression**	BSI Standards	1993	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 25667-1	**Water quality. Guidance on design of sampling programmes**	BSI Standards	1994	
BS EN 25667-2	**Water sampling . Guidance on sampling techniques**	BSI Standards	1993	
BS EN 30993	**Biological evaluation of medical devices**	BSI Standards		
	Part 3: Tests for genotoxicity, carcinotoxicity, and reproductive toxicity		1994	
	Part 4: Selection of tests for interaction with blood		1994	
	Part 5: Tests for cytotoxicity, in vitro methods		1994	
	Part 6: Tests for local effects after implantation		1995	
BS EN ISO 3746	**Acoustics. Determination of sound power levels of noise sources using sound pressure. Survey method using an enveloping measurement surface over a reflecting plane**	BSI Standards	1996	
BS EN 45003	**Calibration and testing laboratory accreditation systems, general requirements for operation and recognition**	BSI Standards	1995	
BS EN 45011	**General requirements for bodies operating product certification systems**	BSI Standards	1998	
BS EN 45012	**General requirements for bodies operating assessment and certification/registration of quality system**	BSI Standards	1998	
BS EN 45014	**General criteria for supplier's declaration of conformity**	BSI Standards	1993	
BS EN 45020	**Standardization and related activities**	BSI Standards	1998	
BS EN 46001	**Specification for the application of EN ISO9001 to the manufacture of medical devices**	BSI Standards	1997	
BS EN 46002	**Specification for the application of EN ISO9002 to the manufacture of medical devices**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 50081	**Electromagnetic compatibility. Generic emission standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1992 1994	
BS EN 50082	**Electromagnetic compatibility. Generic immunity standard** **Part 1:** Residential, commercial and light industry **Part 2:** Industrial environment	BSI Standards	 1998 1995	
BS EN 60079-14	**Electrical apparatus for explosive gas atmospheres. Electrical installations in hazardous areas (other than mines)**	BSI Standards	1997	
BS EN 60581-2	**Thermocouples. Manufacturing tolerances**	BSI Standards	1996	
BS EN 60584-1	**Thermocouples reference table**	BSI Standards	1996	
BS EN 60651	**Specification for sound level meters**	BSI Standards	1994	
BS EN 60751	**Industrial platinum resistance thermometer sensors**		1996	
BS EN 60804	**Specification for integrating averaging sound level meters**		1994	
BS EN 61010	**Safety requirements for electrical equipment for measurement, control and laboratory use** **-1:** General requirements **-2-041:** Particular requirements for autoclaves and sterilizers using steam for the treatment of medical materials and for laboratory processes **-2-042:** Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes **-2-043:** Particular requirements for autoclaves and sterilizers using either hot air or hot inert gas for the treatment of medical materials and for laboratory processes		 1993 1997 1997 1998	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN ISO 9001	**Quality systems. Model for quality assurance in design, development, production, installation and servicing**	BSI Standards	1994	
BS EN ISO 9002	**Quality systems. Model for quality assurance in production, installation and servicing**	BSI Standards	1994	
European Union Directives				
65/65/EEC	Approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.	Official Journal of the European Communities (OJEC), no 22, 9/2/65, p 369		
75/107/EEC	Approximation of the laws of member states relating to bottles used as measuring containers.	Official Journal of the European Communities (OJEC), L42, 15/2/75		
90/385/EEC	Approximation of the laws of the Member States relating to active implantable medical devices.	Official Journal of the European Communities (OJEC), L189 20/7/90, p 17		
91/356/EEC	Laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.	Official Journal of the European Communities (OJEC). L193 17/7/91, p 30		
80/778/EEC	Quality of water intended for human consumption	Official Journal of the European Communities, 1980		
93/42/EEC	Medical Devices Directive	Official Journal of the European Communities (OJEC), L169 12/7/93, p 1		
98/79/EC	In Vitro Diagnostic Medical Devices Directive	Official Journal of the European Communities, (OJEC), L331 7/12/98		
Scottish Health Technical Guidance				
SHTM 2007	Electrical services supply and distribution	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2014	Abatement of electrical interference	P&EFEx	2001	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2022	Medical gas pipeline systems	P&EFEx	2001	CD-ROM
SHTM 2023	Access and accommodation for engineering services	P&EFEx	2001	CD-ROM
SHTM 2025	Ventilation in healthcare premises	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHTM 2031	Clean steam for sterilizers	P&EFEx	2001	CD-ROM
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHTM 2045	Acoustics	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHPN 13	Sterile services department	HMSO	1994	
SHPN 15	Accommodation for pathology services	HMSO	1994	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	EEF	1999	CD-ROM
SHTN 4	General Purposes Estates and Facilities Model Safety Permit-to-Work system	EEF	1998	CD-ROM
SHGN	'Safe' hot water and surface temperatures	EEF	1999	CD-ROM
	NHS in Scotland – PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
UK Health Technical Guidance				
HBN 29	Accommodation for pharmaceutical services	HMSO	1988	
HTM 67	Building components: laboratory fitting out system	HMSO	1993	
CONCODE	Contracts and commissions for the NHS estate – contract procedures	HMSO	1994	
MES	Model Engineering Specifications	NHS Estates	1997	As required
MES C14	Sterilizers	NHS Estates	1993	
HBN 13	Supplement 1 – Ethylene oxide sterilization section	HMSO	1994	
MES C02	Thermal insulation	NHS Estates	1993	
Health and Safety Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
HN(76)126	Hospital design note 4 (noise control): amendments to appendices II, IV and VII	DHSS	1976	
STB3A/85/12	Performance and safety specification for media sterilizers. Media devices directorate	DHSS	1985	
	Emmerson, A. M. *Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Committee to the Department of Health Medical Devices Directorate.* Medical devices directorate	Department of Health	1993	
	Biological tests for graded milk. Memo 139/Foods.	Ministry of Health	1937	
	Scottish Infection Manual Guidance on the core standards for the control of infection in hospitals, healthcare premises and at the community interface	The Scottish Office	1998	

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Publication ID	Title	Publisher	Date	Notes
	Programmable electronic systems in safety related applications: General technical guidelines	HSE	1987	
	Programmable electronic systems in safety related applications: an introductory guide	HSE	1987	
L 5	General COSHH ACOP (Control of substances hazardous to health) Carcinogens ACOP (Control of carcinogenic substances) and Biological agents ACOP (Control of biological agents) Control of Substances Hazardous to Health Regulations1999 Approved Code of Practice	HSE	1999	
L 22	Safe use of work equipment: Approved code of practice and guidance	HSE	1998	
L 23	Manual handling operations: guidance on regulations	HSE	1998	
L 24	Workplace health, safety and welfare: Approved code of practice and guidance	HSE	1992	
L25	Personal protective equipment at work at work: guidance on regulations		1992	
L113	Safe use of lifting equipment: Approved code of practice and guidance	HSE	1998	
L122	Safety of pressure systems: Pressure Systems Safety Regulations 2000. Approved Code of Practice	HSE Books	2000	
PM73	Safety at Autoclaves	HSE Books	1998	
	Precautions for work with human and animal. Transmissible Spongiform Encaphalopathies	HSE (ACDP)		
	Categorisation of pathogens according to hazard and categories of containment	HSE (ACDP)	1995	4th Edition
	Safe working and the prevention of infection in clinical laboratories	HSC (HSAC)		
HS(R)23	A guide to the 'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995	HSE	1995	

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Publication ID	Title	Publisher	Date	Notes
Miscellaneous References				
GGMP Volume IV	Guide to good manufacturing practice for medicinal products – The rules governing medicinal products in the European Community			
	Atomic absorption spectrophotometry 1979 version	HMSO	1979	(out of print)
	Cadmium in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Colour and turbidity of waters 1981	HMSO	1981	(out of print)
	Determination of anions and cations, transition metals, and other complex ions and organic acids and bases in water by chromatography 1990	HMSO	1990	
	Lead in potable waters by atomic absorption spectrophotometry 1976	HMSO	1976	(out of print)
	Lead and cadmium in fresh waters by atomic absorption spectrophotometry (second edition) a general introduction to electrothermal atomization atomic absorption spctrophotometry 1986	HMSO	1986	(out of print)
	Measurements of electrical conductivity and the laboratory determination of the pH value of natural, treated and waste waters.	HMSO		(out of print)
	Mercury in waters, effluents, soils and sediments etc, additional methods	HMSO	1985	(out of print)
	Phosphorus and silicon in waters, effluents and sludges 1992	HMSO	1993	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
LG 2	Lighting guide: hospitals and healthcare buildings	Chartered Institution of Building Services Engineers	1989	
	Sterilization and disinfection of heat-liable equipment	Central Sterilizing Club	1986	

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Scottish Health Technical Memorandum 2010

(Part 6 of 6)

Testing and validation protocols

Sterilization

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NHSScotland, P&EFEx, June 2001

Contents

NOTE: We acknowledge the support of Scottish Healthcare Supplies in providing the Test Forms. Complete Test Log books containing the Forms are available from Scottish Healthcare Supplies, Trinity Park House, South Trinity Road, Edinburgh, EH5 3SH. Telephone 0131 552 6255. The Forms marked Sample Copy are copyright of Scottish Healthcare Supplies.

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1. Sample log-book for porous load sterilizers.

Schedule of periodic tests

Log book report(s) periodic tests for porous load

			SHTM 2010 Ref. Part 3
User / operator		**Daily Test**	
	1.	Warm Up Cycle	
	2.	Bowie-Dick test for steam penetration	13.39
Test Person		**Weekly tests**	
	1.	Weekly safety checks	5.7
	2.	Vacuum leak test	11.2
	3.	Air detector function test	11.60
	4.	Automatic control test	12.1
	5.	Bowie-Dick test steam penetration*	13.39
Test Person		**Quarterly tests**	
	1.	Weekly safety checks	5.7
	2.	Vacuum leak test	11.2
	3.	Vacuum leak test (temperature and pressure sensor connected)	11.2
	4.	Automatic control test	12.1
	5.	Verification of calibration of sterilizer instruments*	12.2
	6.	Thermometric test for a small load*	13.7
	7.	Vacuum leak test (sensors removed)	11.2
	8.	Air detector function test	11.60
	9.	Bowie-Dick test for stream penetration	13.39
Test Person		**Yearly and revalidation tests**	
	1.	Yearly safety checks	5.8
	2.	Steam, non-condensable gas test**	9.4
	3.	Steam superheat rest**	9.20
	4.	Steam dryness test**	9.30
	5.	Vacuum leak test	11.2
	6.	Vacuum leak test (temperature and pressure sensors connected)	11.2
	7.	Automatic control test	12.1
	8.	Verification of calibration of sterilizer intsruments*	12.2
	9.	Air detector performance test for a small load	11.45
	10.	Air detector performance test for a full load	11.53
	11.	Thermometric test for a small load	13.7
	12.	Tests for performance requalification as required by the user	8.64
	13.	Vacuum leak test (sensors removed)	11.2
	14.	Air detector function test	11.60
	15.	Bowie-Dick test for steam penetration	13.39
Test Person		**Performance requalification test**	
	1.	Performance Requalification	8.64

Sample Copy

* *May be done at the same time as the preceding test*

** *Subject to agreement between the User and Authorised person these test may be omitted providing there is no evidence of a steam quality problem.*

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POROUS LOAD STERILIZERS

INSTALLATION RECORD Date completed

Client	Department	Date of Tests
Sterilizer manufacturer	Serial number	Plant reference number
Type test file reference	Date	

Task	Schedule Reference	Result	Initial
Preliminary checks completed (3.14)			
Electrical checks (3.15)			
Functional checks (3.16)			

Installation checks (3.6)	Results						
	Steam	Water	Compressed air	Drainage	Ventilation	Electrical	
Pressure							
Pressure drop all services operating							
Flow rates are adequate							
Drains effectively remove effluent when all sterilizers are operating							

Task	Cycle No	Start time	Results	
Vacuum leak test (11.2)			leakage per/min	Pass / Fail
Automatic control test (12.1)				Pass / Fail

Automatic control test (12.1) Insert data from each automatic control test

Air Removal		Negative pulsing				Positive pulsing			
	Cycle		Pulses				Pulses		
	Start time	**Duration**	**Number**	**Pressure**		**Duration**	**Number**	**Pressure**	
				Minimum	**Maximum**			**Minimum**	**Maximum**
Works tests				**kPa**	**kPa**			**kPa**	**kPa**
Installation				**kPa**	**kPa**			**kPa**	**kPa**

Sterilizing		Holding Time							
		Duration	Recorder				Indicators		
			Temperature		Pressure		Temperature	Pressure	
			Minimum	Maximum	Minimum	Maximum	Maximum	Maximum	
Works Tests			°C	°C	kPa	kPa	°C	kPa	
Installation			°C	°C	kPa	kPa	°C	kPa	

Drying & Vacuum break	Cycle	Drying			Vacuum break	
	Finish Time	Duration	Pressure	Temperature	Duration	
Works tests			kPa	°C		
Installation			kPa	°C		

Verification of calibration sterilizer instruments (12.2)			
	Measured	Recorder Error	Indicator Error
Chamber temperature	°C	°C	°C
Chamber pressure	kPa	kPa	kPa
Jacket pressure	kPa	kPa	kPa
Holding timer setting	Set……..Mins……Secs……..	Error……..	

Contractor

The sterilizer and its installation have been checked for safety and for compliance with the specification (schedule reference……) and they have been found to be satisfactory

Contractor signature …….. Print name …… Date …….

Note:- The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature

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POROUS LOAD STERILIZERS										**Sheet 1 of 3**	
COMMISSIONING RECORD										**Week No……**	
Plant reference number……								Validation file reference……			
Date of tests……								Sterilizer serial number……			
Task		Schedule **Reference**						Result			Initial
Preliminary checks completed (3.14)											
Electrical checks (3.15)											
Functional checks (3.16)											
Installation checks (3.6)		**Results (3.6)**									
		Steam		Water		Compressed air		Drainage		Ventilation	
Pressure											
Pressure drop all services operating											
Flow rates are adequate											
Drains effectively remove effluent when all sterilizers are operating											
Steam tests		Schedule **Reference**						Result			Initial
NCG (9.4)											
Superheat (9.20)											
Dryness (9.30)											
		Cycle number									
Vacuum leak test * (11.2)								Leakage per minute			
Vacuum leak test * (11.2) (with sensors)								Leakage per minute			
Automatic control test (12.1)											
Air detector test (small load) * (11.45)								Leakage per minute			
Air detector test (full load) (11.53)								Leakage per minute			
Small load test (13.7)											
Load dryness test (13.25)								% gain in mass			
Full load test (13.15)											
Load dryness test (13.25)								% gain in mass			
Sound power test (10.1)											
Vacuum leak test * (11.2) (with sensors removed)								Leakage per minute			
Air detector function test * (11.60)								Setting: ….°C / Leakage per minute			
Bowie & Dick test * (13.39)								Type of test pack……			
Automatic control test (12.1)							**Insert data from each automatic control test**				
Air Removal			Negative pulsing					Positive pulsing			
	Cycle			Pulses					Pulses		
	Start time	Duration	Number	Pressure			Duration	Number	Pressure		
				Minimum	Maximum				Minimum	Maximum	
Commissioning				kPa	kPa				kPa	kPa	
Works				kPa	kPa				kPa	kPa	
Sterilizing		**Holding Time**									
		Duration	Recorder					Indicators			
			Temperature		Pressure			Temperature	Pressure		
			Minimum	Maximum	Minimum	Maximum		Maximum	Maximum		
Commissioning			°C	°C	kPa	kPa		°C	kPa		
Works			°C	°C	kPa	kPa		°C	kPa		
Drying & Vacuum break	Cycle	Drying						Vacuum break			
	Finish Time	Duration	Pressure		Temperature			Duration			
Validation			kPa		°C						
Quarterly			kPa		°C						

Note*:- *The holding time is deemed to start when the chamber temperature attains the pre-set sterilizing temperature

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POROUS LOAD STERILIZERS	**Sheet 2 of 3**
COMMISSIONING RECORD	**Week No……**
Plant reference	Serial number

Calibration

	File reference……..
Test instruments	Calibration date due ……..

Verification of the calibration of the sterilizer instruments

	Measured	Recorder error		Indicator error	
		Works	Commissioning	Works	Commissioning
Jacket pressure	kPa	kPa	kPa	kPa	kPa
Chamber pressure	kPa	kPa	kPa	kPa	kPa
Chamber temperature °C	°C	°C	°C	°C	°C
Time min,sec					

Small load test

Insert data from each small load test

Readings to be noted when:-

a. drain/vent temperature attains the sterilizing temperature

b. the centre of the standard test pack attains the sterilizing temperature

c. when the vent/drain temperature falls below the sterilizing temperature

Small load test	**a**		**b**		**c**	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature above the STP	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Commissioning	Works				
Total cycle time						
Holding time						
Cycle start time						
Cycle finish time						

Full load test	**a**		**b**		**c**	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature above the STP	°C	°C	°C	°C	°C	°C
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa	kPa	kPa
	Commissioning	Works				
Total cycle time						
Holding time						
Cycle start time						
Cycle finish time						

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POROUS LOAD STERILIZERS — Sheet 3 of 3

COMMISSIONING RECORD — Week No……

Plant reference	Serial number

Air detector tests :-

insert data from each air detector tests

Measurements (a) (b) are as for the automatic control test and are the values which causes the air detector to reject the process

Small load test	**a**		**b**		**c**	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa		
Temperature difference	°C	°C	°C	°C		

Full load test	**a**		**b**		**c**	
	Commissioning	Works	Commissioning	Works	Commissioning	Works
Temperature in the drain/vent	°C	°C	°C	°C	°C	°C
Temperature in the centre of the STP	°C	°C	°C	°C	°C	°C
Chamber pressure	kPa	kPa	kPa	kPa		
Temperature difference	°C	°C	°C	°C		

controller setting……

sensor location……

Comments

……
……
……
……
……
……
……
……
……
……

Data from the tests confirm conformity with the requirements detailed in SHTM 2010

Test Person signature…… print name …… date……..

Audited by:-

Authorised Person signature…….. print name…… date……..

I have reviewed the date from the tests with the Test Person and Authorised Person and I am satisfied that the sterilizer is fit for use

User signature…….. print name…… date……

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POROUS LOAD STERILIZERS	**Sheet 1 of 2**
PERFORMANCE QUALIFICATION RECORD (PQ)	**Week No…….**

Plant reference number…….	Validation file reference……..
Date of tests……	Sterilizer serial number……...
Performance qualification reference……	Loading condition reference……..

Task	**Schedule reference**	**Result**	**Valid until**	**Initial**
Commissioning				
Yearly test				
Performance qualification				
microbiological *				
thermometric				

* Performance qualification using microbiological methods if a sterilizing environment cannot be demonstrated by thermometric tests. Data from the microbiological test are attached to this log sheet

Test instruments

File reference……	Calibration certificate number……..	Calibration due……

Error at the sterilizing temperature:-

Sensor number	1	2	3	4	5	6	7	8	9	10	11	12
before PQ test												
after PQ test												

Data from the tests have been compared with the requirements for sterilization detailed in specification reference……..for loading condition reference……. It is confirmed that compliance with the requirements are obtained using operating cycle reference……

Test Person signature…… print name……..date……..

Audited by:-

Authorised Person signature…… print name……..date……..

I have compared this data with the requirements given in the specification and I am satisfied that this loading condition can be processed in sterilizer serial number…….

User signature…… print name……..date……

.

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POROUS LOAD STERILIZERS									**Sheet 2 of 2**
PERFORMANCE QUALIFICATION RECORD (PQ)									**Week No…….**
Plant reference number…….				Validation file reference……..					
Date of tests……				Sterilizer serial number……...					
Performance qualification reference……				Loading condition reference……..					
Summary of thermometric tests									
			Test 1		Test 2		Test 3		
Cycle number									
Air removal	Negative pulsing	duration							
		number							
		pressure minimum							
		pressure maximum							
	Positive pulsing	duration							
		number							
		pressure minimum							
		pressure maximum							
Sterilizing temperature (ST) (Set)									
Holding time (Set)									
		Location of each sensor	Test and sensor number						
			1		2		3		
Sterilizing	Time when ST is attained	drain/vent							
		fastest load item							
		slowest load item							
	Time when temperature falls below ST	drain/vent							
		fastest load item							
		slowest load item							
	Holding time	drain/vent							
		fastest load item							
		slowest load item							
		temperature maximum							
		pressure maximum							
		pressure minimum							
		actual ST							
Sensors located in the positions shown on the attached sheet reference No……									
			Test 1		Test 2		Test 3		
Drying and Vacuum break	drying	duration							
		pressure minimum							
		pressure maximum							
	Vacuum break	duration							
Duration of the cycle									
Comments									
……									
……									
This is a summary of the data obtained during performance qualification for loading condition reference……... sterilized in sterilizer serial number…… Test Person signature…… print name …… date……...									

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Porous Load Sterilizers – User Daily Record

Tests to be carried out in accordance with SHTM2010.

Hospital/Location	Week beginning	Week No.
Department	Ref.No	Ser.No

	VACUUM LEAK RATE TEST-EMPTY CHAMBER							**BOWIE-DICK TEST**					
								Pack type			Indicator sheet type		
	Cycle number	Pressure when pump stopped	Pressure below 50mbar	Pressure after 5 minutes P1	Pressure after further 10 minutes P2	Leak rate per minute (P2-P1)/10	Leak rate <1.3 mbar/min	Cycle number	Drain temp. sterilizing	Chamber pressure sterilizing	Indicator sheet result	Tested by (initials)	Certified fit for use by User
Monday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Tuesday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Wednesday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Thursday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Friday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Saturday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Sunday		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
Retests													
day		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		
day		mbar	Yes/No	mbar	mbar	mbar	Yes/No		°C	bar	Pass/Fail		

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

Sample Copy

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Porous Load Sterilizers – Weekly Record

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	Door Pressure Interlock [ ]
Door Seal [ ]	Door Safety Edge [ ]	Door Closed Interlock [ ]

VACUUM LEAK RATE TEST-EMPTY CHAMBER		Cycle number
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes P1		millibar
Pressure after further 10 minutes P2		millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

AUTOMATIC CONTROL / BOWIE DICK TEST						Pack / Indicator Type			
Start cycle t1=0	Cycle number			Evacuation to mbar in min seconds					
Pulse number	1	2	3	4	5	6	7	8	9	10
Time at peak	:	:	:	:	:	:	:	:	:	:
Max ind. temp °C										
Max press. bar										
Min press. bar										

		Drain temperature		Chamber pressure	
Final evacuation at (t2)	min sec	Indicated	Recorded	Indicated	Recorded
Sterilizing temp at (t3)	min sec	°C	° C	bar	bar
Instrument readings (t3+1)	min sec	°C	° C	bar	bar
Instrument readings (t3+2)	min sec	°C	° C	bar	bar
Instrument readings (t3+3)	min sec	°C	° C	bar	bar

Drying stage starts at (t4)	min sec	Jacket pressure during sterilizing	bar
40 mbar reached at (t5)	min sec	Minimum pressure	mbar
Air replacement starts (t6)	min sec	Maximum chart temperature	°C
Process complete at (t7)	min sec	Indicator sheet result	PASS / FAIL

Final evacuation to sterilizing (t3-t2)	min sec	Air removal time (t2-t1)	min sec
Time at sterilizing (t4-t3)	min sec	Sterilizing stage time(t4-t2)	min sec
Time to reach 40mbar (t5-t4)	min sec	Drying stage time (t6-t4)	min sec
Air replacement time (t7-t6)	min sec	Total cycle time (t7-t1)	min sec

AIR DETECTOR FUNCTION TEST		Pack Type Sheets / Towels
Leak rate setting to reject cycle millibar/min (from Yearly test results)		
Cycle number	Air detector setting	Air detector reached
Result of test	REJECT / ACCEPT	SATISFACTORY / UNSATISFACTORY

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

Sample Copy

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Porous Load Sterilizers – Quarterly Record

To be filled in along with Weekly Test Sheet to complete a Quarterly Test.
Tests to be carried out in accordance with SHTM2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

VACUUM LEAK RATE TEST-EMPTY CHAMBER			Cycle number
Test carried out after connection of temperature and pressure sensors			
	Indicated	Measured	
Pressure when pump stopped after min sec			millibar
Pressure below 50 millibar	YES/NO	YES/NO	
Pressure after 5 minutes P1			millibar
Pressure after further 10 minutes P2			millibar
Leak rate per minute (P2-P1)/10			millibar
Leak rate <1.3 millibar/min	YES/NO	YES/NO	PASS / FAIL

VERIFICATION OF CALIBRATION OF STERILIZER INSTRUMENTS/SMALL LOAD TEST							
Verification of calibration of test instrument before tests carried out				SATISFACTORY / UNSATISFACTORY			
Readings to be taken during the sterilizing hold period				Cycle number			
	Indicated values		Recorded values		Measured values		
Time	Chamber pressure	Drain Temp.	Chamber Pressure	Drain Temp.	Chamber Pressure	Drain Temp	Load Temp
Start	bar	°C	bar	°C	bar	°C	°C
+1 minute	bar	°C	bar	°C	bar	°C	°C
+2 minutes	bar	°C	bar	°C	bar	°C	°C
+3 minutes	bar	°C	bar	°C	bar	°C	°C
Maximum temp.above pack °C			Max.temp. above pack after 1 minute °C				
Calibration of instruments within limits YES/NO			If not,then note inaccuracies below, and action.				
Outstanding inaccuracies							
If any calibration has been changed during this quarterly test,note below with initial error							
Equilibration time less than 15 seconds YES/NO			Drying vacuum below 40 millibar YES/NO				
Drying stage more than 3 minutes YES/NO			Sheets/Towels sensibly dry after cycle YES/NO				
Verification of calibration of test instrument after tests carried out			SATISFACTORY / UNSATISFACTORY				
Result of test SATISFACTORY/UNSATISFACTORY							

VACUUM LEAK RATE TEST-EMPTY CHAMBER		Cycle number
Test carried out after removal of temperature and pressure sensors		
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes P1		millibar
Pressure after further 10 minutes P2		millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Porous Load Sterilizers – Yearly Record

To be filled in along with Weekly and Quarterly Test Sheets to complete a Yearly Test. Tests to be carried out in accordance with SHTM 2010

Hospital / Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 134°C during sterilizing should cause cycle fail [ ]		
Chamber safety valve free YES / NO	Jacket safety valve free YES / NO	Power failure [ ]
Steam pressure low [ ]	Water pressure low [ ]	Air pressure low [ ]

AIR DETECTOR PERFORMANCE TEST SMALL LOAD		Pack Type Sheets / Towels
Leak rate setting up to max of 10 millibar/min to give 2°C depression millibar/min		
Cycle number	Air detector disabled.	Air detector reached
Cycle number	Air detector enabled/set at	Air detector reached
Result of cycle REJECT / ACCEPT	Result of test SATISFACTORY / UNSATISFACTORY	

AIR DETECTOR PERFORMANCE TEST FULL LOAD		Pack Type Sheets / Towels
Leak rate setting to give less than 2°C depression and reject cycle millibar/min		
Cycle number	Air detector disabled.	Air detector reached
Cycle number	Air detector enabled/set at	Air detector reached
Result of cycle REJECT / ACCEPT	Result of test SATISFACTORY / UNSATISFACTORY	

THERMOMETRIC SMALL LOAD TEST	Cycle number	SHTM 2010 Pt.3 Para 13.14 met YES/NO
Comments		

THERMOMETRIC FULL LOAD TEST	Cycle number	SHTM 2010 Pt.3 Para 13.24 met YES/NO
Comments		

PERFORMANCE REQUALIFICATION TESTS AS REQUIRED BY USER	
Load Details	
Thermocouple locations	
Cycle number	Sterilizing conditions met YES/NO
Dryness of load SATISFACTORY/UNSATISFACTORY	Comments

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

COMMENTS

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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POROUS LOAD STERILIZERS	**Sheet 1 of 2**
PERFORMANCE REQUALIFICATION RECORD (PRQ)	**Week No…….**

Plant reference number…….	Validation file reference……..
Date of tests……	Sterilizer serial number…….
Performance qualification reference……	Loading condition reference……

Task	Schedule reference	Result	Valid until	Initial
Commissioning				
Yearly test valid				
Performance qualification				
*microbiological				
thermometric				
Performance requalification				
* microbiological				
thermometric				

* is required if biological tests were carried during validation

Test instruments

File reference……..Calibration certification number……Calibration due…….

Error at the sterilizing temperature:-

Sensor number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
before PRQ test												
after PRQ test												

Data from the tests have been compared with the data in the validation file performance qualification reference……. and it is confirmed as being comparable within the limits specified.

Test Person signature……. print name……. date……..

Audited by:-

Authorised Person signature…….. print name……. date……..

I have compared the results from these tests with the data in the validation file for performance qualification reference …… and I have also reviewed data in the batch records with the Test Person, Maintenance Person and Authorised Person. I am satisfied that this loading condition can be processed in sterilizer serial number…….

User Signature……. print name…… date……

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POROUS LOAD STERILIZERS	**Sheet 2 of 2**
PERFORMANCE REQUALIFICATION RECORD (PQ)	**Week No…….**

Plant reference number…….	Validation file reference……..
Date of tests……	Sterilizer serial number……...
Performance qualification reference……	Loading condition reference……..

Summary of thermometric tests

			Test 1	Test 2	Test 3	
Cycle number						
Air removal	Negative pulsing	duration				
		number				
		pressure minimum				
		pressure maximum				
	Positive pulsing	duration				
		number				
		pressure minimum				
		pressure maximum				
Sterilizing temperature (ST) (Set)						
Holding time (Set)						
		Location of each sensor	Test and sensor number			
			1	2	3	
Sterilizing	Time when ST is attained	drain/vent				
		fastest load item				
		slowest load item				
	Time when temperature falls below ST	drain/vent				
		fastest load item				
		slowest load item				
	Holding time	drain/vent				
		fastest load item				
		slowest load item				
		temperature maximum				
		pressure maximum				
		pressure minimum				
		actual ST				

Sensors located in the positions shown on the attached sheet reference No……

			Test 1	Test 2	Test 3	
Drying and Vacuum break	drying	duration				
		pressure minimum				
		pressure maximum				
	Vacuum break	duration				
Duration of the cycle						

Comments

……
……
……

This is a summary of the data obtained during performance qualification and performance requalification for loading condition reference…….. sterilized in sterilizer serial number……

Test Person signature…… print name …… date……..

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STERILIZER MODIFICATION AND REPAIR RECORD

Service provider	Department
Sterilizer	Plant ref. No.

Modification/repair	Revalidation file reference	Maintenance Person/Contractor signature	Date completed

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2. Procedures for the procurement, validation, revalidation and operational management of sterilization.

Fluids Sterilizer – Weekly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	Door Pressure Interlock [ ]
Door Seal [ ]	Door Safety Edge [ ]	Door Closed Interlock [ ]

AUTOMATIC CONTROL TEST					MPR Ref. No.					
Container type		Container size			Number of containers					
Product in containers									Glass/Plastic	
Batch number		Cycle number			Timer setting/Profile number					
	Time	Indicated values				Recorded values				
Start t1=0 Load 1 at °C Load 2 at °C	Min:sec	Chamber Pressure.	Spray Pressure	Drain/ vent Temp.	Load Temp.	Chamber Pressure	Drain/ vent Temp	Load 1 Temp.	Load 2 Temp.	
Load(s) at 80 °C	(t2) :	bar	bar	°C	°C	bar	°C	°C	°C	
Drain 115/121 °C	(t4) :	bar	bar	°C	°C	bar	°C	°C	°C	
Load at 115/121 °C	(t6) :	bar	bar	°C	°C	bar	°C	°C	°C	
t6+5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C	
t8-5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C	
Sterilizing ends	(t8) :	bar	bar	°C	°C	bar	°C	°C	°C	
Load at 80/90° C	(t9) :	bar	bar	°C	°C	bar	°C	°C	°C	
Cooling ends (t11) :	Cycle complete(t12) :	Load spread max/min / °C Below 80/90 °C YES/NO								
MPR/Test comparison	MPR	Limits	Test	Within Limits	Comments					
Heat up stage (t6-t2)	:	+/- 20%	:	YES/NO						
Drain at 115/121 (t8-t4)	:	+/- 10%	:	YES/NO						
Sterilizing stage (t8-t6)	:	+/- 10%	:	YES/NO						
Cooling stage (t9-t8)	:	+/- 20%	:	YES/NO						
Calibration within limits YES/NO	If not, then note inaccuracies below, and action									
Outstanding inaccuracies										
Comments on test										
Result of test SATISFACTORY/UNSATISFACTORY										

HEAT EXCHANGER INTEGRITY TEST (if applicable)	
Pressure 10 minutes after closing valves bar	Pressure after further 10 minutes bar
Pressure drop bar	Result of test SATISFACTORY/UNSATISFACTORY

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Fluids Sterilizer – Quarterly Maintenance Schedule

To be filled in along with Weekly Test Sheet to complete a Quarterly Test.
Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SIMPLIFIED THERMOMETRIC TEST			**MPR Ref. No.**
Verification of calibration of test instrument before tests carried out			SATISFACTORY / UNSATISFACTORY
Container type	Container size		Number of containers
Product in containers			Glass/Plastic
Batch number	Cycle number		Timer setting/Profile number

Measured values in shaded boxes - Load 1 in position slowest to reach sterilizing temperature and Load 2 in position slowest to reach 80°C(glass) or 90°C(plastic) during cooling.

	Time	Indicated values				Recorded values			
Start t1=0 Load 1 at °C Load 2 at °C	Min:sec	Chamber Pressure.	Spray Pressure	Drain/ vent Temp.	Load Temp.	Chamber Pressure	Drain/ vent Temp	Load 1 Temp.	Load 2 Temp.
Load(s) at 80 °C	(t2) :	bar	bar	°C	°C	bar	°C	°C	°C
Load(s) at 80 °C	(t3) :		bar			bar	°C	°C	°C
Drain 115/121 °C	(t4) :	bar	bar	°C	°C	bar	°C	°C	°C
Drain 115/121 °C	(t5) :		bar			bar	°C	°C	°C
Load at 115/121 °C	(t6) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 115/121°C	(t7) :		bar			bar	°C	°C	°C
t6+5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t6+5 minutes	:		bar			bar	°C	°C	°C
t8-5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t8-5 minutes	:		bar			bar	°C	°C	°C
Sterilizing ends	(t8) :	bar	bar	°C	°C	bar	°C	°C	°C
Sterilizing ends	(t8) :		bar			bar	°C	°C	°C
Load at 80/90°C	(t9) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 80/90° C	(t10) :		bar			bar	°C	°C	°C

Cooling ends (t11) :	Cycle complete(t12) :	Load spread max/min / °C Below 80/90 °C YES/NO

MPR/Test comparison	MPR	Limits	Test	Within Limits	Measured values	Test
Heat up stage (t6-t2)	:	+/- 20%	:	YES/NO	Heat up stage (t7-t3)	:
Drain at 115/121 (t8-t4)	:	+/- 10%	:	YES/NO	Drain at 115/121 (t8-t5)	:
Sterilizing stage (t8-t6)	:	+/- 10%	:	YES/NO	Sterilizing stage (t8-t7)	:
Cooling stage (t9-t8)	:	+/- 20%	:	YES/NO	Cooling stage (t10-t8)	:

Calibration within limits YES/NO	If not, then note inaccuracies below, and action
Outstanding inaccuracies	
If any calibration has been changed during this quarterly test, note below with initial error	
Comments on test	
Verification of calibration of test instrument after tests carried out	SATISFACTORY / UNSATISFACTORY
Result of test SATISFACTORY/UNSATISFACTORY	

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Fluids Sterilizer – Yearly Maintenance Schedule

To be filled in along with Weekly Test Sheet to complete a Yearly Test. May require more than one PRQ Test. Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 115/121°C during sterilizing should cause cycle fail [ ]		Chamber safety lift at bar
Steam pressure low [ ]	Water pressure low [ ]	Air pressure low [ ] Power failure [ ]

PERFORMANCE REQUALIFICATION TEST		MPR Ref. No.	
Container type	Container size	Number of containers	
Product in containers			Glass/Plastic
Batch number	Cycle number	Timer setting/Profile number	

Measured values in shaded boxes - Load 1 in position slowest to reach sterilizing temperature and Load 2 in position slowest to reach 80°C(glass) or 90°C(plastic) during cooling.

	Time	Indicated values				Recorded values			
Start t1=0 Load 1 at °C Load 2 at °C	Min: sec	Chamber Pressure.	Spray Pressure	Drain/ vent Temp.	Load Temp.	Chamber Pressure	Drain/ vent Temp	Load 1 Temp.	Load 2 Temp.
Load(s) at 80 ° C	(t2) :	bar	bar	°C	°C	bar	°C	°C	°C
Load(s) at 80 °C	(t3) :		bar			bar	°C	°C	°C
Drain 115/121 ° C	(t4) :	bar	bar	°C	°C	bar	°C	°C	°C
Drain 115/121 °C	(t5) :		bar			bar	°C	°C	°C
Load at 115/121 °C	(t6) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 115/121°C	(t7) :		bar			bar	°C	°C	°C
t6+5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t6+5 minutes	:		bar			bar	°C	°C	°C
t8-5 minutes	:	bar	bar	°C	°C	bar	°C	°C	°C
t8-5 minutes	:		bar			bar	°C	°C	°C
Sterilizing ends	(t8) :	bar	bar	°C	°C	bar	°C	°C	°C
Sterilizing ends	(t8) :		bar			bar	°C	°C	°C
Load at 80/90°C	(t9) :	bar	bar	°C	°C	bar	°C	°C	°C
Load at 80/90° C	(t10) :		bar			bar	°C	°C	°C

Cooling ends (t11) : | Cycle complete(t12) : | Load spread max/min / °C Below 80/90 °C YES/NO

MPR/Test comparison	MPR	Limits	Test	Within Limits	Measured values	Test
Heat up stage (t6-t2)	:	+/- 20%	:	YES/NO	Heat up stage (t7-t3)	:
Drain at 115/121 (t8-t4)	:	+/- 10%	:	YES/NO	Drain at 115/121 (t8-t5)	:
Sterilizing stage (t8-t6)	:	+/- 10%	:	YES/NO	Sterilizing stage (t8-t7)	:
Cooling stage (t9-t8)	:	+/- 20%	:	YES/NO	Cooling stage (t10-t8)	:

Calibration within limits YES/NO	If not, then note inaccuracies below, and action
Outstanding inaccuracies	
If any calibration has been changed during this yearly test, note below with initial error	
Comments on test	
Result of test SATISFACTORY/UNSATISFACTORY	

COOLANT QUALITY TEST	Carried out by
Result of test (residue concentration) mg/litre	Result less than 40mg/litre YES/NO

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Unwrapped Instrument and Utensils Sterilizer – Daily/Weekly Maintenance Schedule

Tests to be carried out in accordance with SHTM2010.

Location	Week beginning	Week
Department	Ref.No	Ser.No

AUTOMATIC CONTROL TESTS SHTM2010 recommends an empty chamber but in order to reduce testing time it is now considered acceptable that a production load of instruments can be used instead.

		During sterilizing hold period		Sterilizing hold Time		
	Cycle number	Temperature	Pressure	min:sec	Result of test	Certified fit for use by User
Monday		°C	bar	:	PASS/FAIL	
Tuesday		°C	bar	:	PASS/FAIL	
Wednesday		°C	bar	:	PASS/FAIL	
Thursday		°C	bar	:	PASS/FAIL	
Friday		°C	bar	:	PASS/FAIL	
Saturday		°C	bar	:	PASS/FAIL	
Sunday		° C	bar	:	PASS/FAIL	
		° C	bar	:	PASS/FAIL	

RESERVOIR WATER CHANGES (where applicable). See SHTM 2031- Drain, rinse and refill with Sterilized Water for Irrigation.

	Cycle number when water changed	Comments	Water changed by
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

WEEKLY SAFETY CHECKS	Tick if Satisfactory	Door Pressure Interlock [ ]
Door Seal [ ]	Door Safety Edge [ ]	Door Closed Interlock [ ]
TESTED BY	Date	SATISFACTORY /UNSATISFACTORY

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

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PLANNED PREVENTATIVE MAINTENANCE

Unwrapped instrument and utensil sterilizer

Quarterly/Yearly Maintenance Schedule

The User or maintenance Person should tick each task when it has been completed.

EO	MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
Q – QUARTERLY **Y – YEARLY INTERVALS**					
Service the following items within the contract and at the frequency indicated and check for safe operation					
1.	Check fuses and connections on the electrical mains or plug				*
2.	Replace faulty indicator lamps.	*	*	*	*
3.	Check the gauges and their calibrations. Recalibrate as required	*	*	*	*
4.	Examine the door seal(s) and replace if damaged	*	*	*	*
5.	Examine the door closure mechanism and lubricate.	*	*	*	*
6.	Check the door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine all pipe work connections and components for leaks. Repair as required	*	*	*	*
8.	Weekly safety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly safety checks as SHTM 2010 Part 3				*
10.	Safety valve check	*	*	*	*
11.	Examine the condenser in the reservoir/ and discharge from chamber vent	*	*	*	*
12.	Examine electrical connections for security	*	*	*	*
13.	Examine timers and check their settings	*	*	*	*
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions.	*	*	*	
15.	Carry out yearly maintenance tasks and check vessel in accordance with the scheme of inspection and the manufacturer's instructions				*
16.	Check the thermal sensor(s) and recorder and recalibrate if necessary				*
17.	Carry out yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all covers & note the cycle count number	*	*	*	*
19.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED	*	*	*	*
20.	Weekly Satisfactory Not satisfactory	*	*	*	*
21.	Quarterly Satisfactory Not satisfactory	*	*	*	*
22.	Yearly Satisfactory Not satisfactory				*
23.	Complete the log book and summary sheets	*	*	*	*
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the user	*	*	*	*

*Tasks to be undertaken at frequency indicated by * and as appropriate by*

Maintenance Person sterilizers, Manufacturer, Service contractor

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Dry Heat Sterilizer – Weekly Maintenance Schedule

Hospital/Location	Week number	
Department	Ref.No	Ser.No

Note:-Where the load probe cannot be placed in a load item the “Chamber at T°C” time should be used instead of “Sterilizing stage” time for MPR comparison.(See Yearly Test Form)

Date	Batch No.	Product or load description	Container type/size	Number of containers	Timer setting	Cycle counter	Time load /chamber at sterilizing temp	Load temp during sterilizing	Chamber temp during sterilizing	Heat up time within MPR limits	Sterilizing time within MPR limits	Cooling time within MPR limits	Comments and operator initials
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	
							:	°C	°C	Yes/No	Yes/No	Yes/No	

Review of batch records for week by User and Test Person. If no production runs have been carried out, the Test Person should carry out an Automatic Control Test and fill in the details above.

Weekly safety checks Door seal condition [ ] Door temperature interlock [ ]

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person Date	User Date

Sample Copy

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Dry Heat Sterilizer – Quarterly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	
Door Seal [ ]	Cooling interlock [ ]	Door Closed Interlock [ ]

AUTOMATIC CONTROL TEST	Production load.	Cycle number
Calibration SATISFACTORY/UNSATISFACTORY	Fill in details on weekly test sheet DHS1	

PERFORMANCE REQUALIFICATION	MPR Ref. No.

Load details		
Container type	Container size	Number of containers
Product in containers		
Batch number	Cycle number	Timer setting
Sterilizing temperature 160/170/180 °C =T°C	Temp controller setting(s)	

Measured values are in shaded boxes. Where the load probe of the sterilizer cannot be put into the load, use chamber at 80°C for t2, leave the t6 row blank, and use t4 and t7 instead of t6 in the MPR/Test comparison.

	Time	Indicated values			Recorded values	
Start t1=0	Min: sec	Chamber Temp.(B)	Load Temp.	Pressure drop across filter	Chamber Temp. (A)	Load Temp.
Load at 80°C	(t2) :	°C	°C		°C	°C
Load at 80°C	(t3) :	°C	°C		°C	°C
Chamber at T°C	(t4) :	°C	°C		°C	°C
Chamber at T°C	(t5) :	°C	°C		°C	°C
Load at T°C	(t6) :	°C	°C		°C	°C
Load at T°C	(t7) :	°C	°C		°C	°C
t6+5 minutes	:	°C	°C		°C	°C
t6+5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Load at 80°C	(t9) :	°C	°C		°C	°C
Load at 80°C	(t10) :	°C	°C		°C	°C
Cooling ends (t11) :		Cycle complete (t12) :			Load below 90°C YES/NO	

MPR/Test comparison	MPR	Limits	Test	Result		
Heat up stage (t6-t2)or(t4-t2)	:	+/- 20%	:	Yes/No		
Chamber at T°C (t8-t4)	:	+/- 10%	:	Yes/No		
Sterilizing stage (t8-t6)or(t8-t7)	:	+/- 10%	:	Yes/No		
Cooling stage (t9-t8)	:	+/- 20%	:	Yes/No		

Calibration within limits YES/NO	Comments
Comments on test	
Result of test SATISFACTORY/UNSATISFACTORY	

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person Date	User Date

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Dry Heat Sterilizer – Yearly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	
Door Seal [ ]	Cooling interlock [ ]	Door Closed Interlock [ ]

AUTOMATIC CONTROL TEST	Production load.	Cycle number
Calibration SATISFACTORY/UNSATISFACTORY	Fill in details on weekly test sheet DHS1	

PERFORMANCE REQUALIFICATION				MPR Ref. No.		
Load details						
Container type		Container size			Number of containers	
Product in containers						
Batch number		Cycle number			Timer setting	
Sterilizing temperature 160/170/180 °C =T°C				Temp controller setting(s)		
Measured values are in shaded boxes. Where the load probe of the sterilizer cannot be put into the load, use chamber at 80°C for t2, leave the t6 row blank, and use t4 and t7 instead of t6 in the MPR/Test comparison..						
	Time	Indicated values			Recorded values	
Start t1=0	Min:sec	Chamber Temp(B).	Load Temp.	Pressure drop across filter	Chamber Temp. (A)	Load Temp.
Load at 80°C	(t2) :	°C	°C		°C	°C
Load at 80°C	(t3) :	°C	°C		°C	°C
Chamber at T°C	(t4) :	°C	°C		°C	°C
Chamber at T°C	(t5) :	°C	°C		°C	°C
Load at T°C	(t6) :	°C	°C		°C	°C
Load at T°C	(t7) :	°C	°C		°C	°C
t6(or t7)+5 minutes	:	°C	°C		°C	°C
t6(or t7)+5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
t8-5 minutes	:	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Sterilizing ends	(t8) :	°C	°C		°C	°C
Load at 80°C	(t9) :	°C	°C		°C	°C
Load at 80°C	(t10) :	°C	°C		°C	°C
Cooling ends (t11) :		Cycle complete (t12) :			Load below 90°C YES/NO	
MPR/Test comparison		MPR	Limits	Test	Result	
Heat up stage (t6-t2)or(t4-t2)		:	+/- 20%	:	Yes/No	
Chamber at T°C (t8-t4)		:	+/- 10%	:	Yes/No	
Sterilizing stage (t8-t6)or (t8-t7)		:	+/- 10%	:	Yes/No	
Cooling stage (t9-t8)		:	+/- 20%	:	Yes/No	
Calibration within limits YES/NO				Comments		
Comments on test						
Result of test SATISFACTORY/UNSATISFACTORY						

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

CHAMBER OVERHEAT CUT-OUT TEST Maximum chamber temperature °C (should be <200 °C)
AIR FILTER INTEGRITY TEST Result % (should be <0.001%)

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person Date	User Date

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Low Temperature Steam and Formaldehyde Sterilizer – Daily/Weekly Maintenance Schedule

LTS.F	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY		**D**	**W**		
Service the following items within the contract and at the frequency indicated. Check for safe operation & correct readings				**U**	**M**
1.	Check all sterilizer services are turned on and correct readings are indicated on controls & gauges	S M T W Th F Sa			
2.	Check the log book & production records together with the routine microbiological test for LTSF. Complete as required	S M T W Th F Sa			
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	S M T W Th F Sa			
4.	Check the chamber & clean as detailed for the type of material chamber is constructed from.	S M T W Th F Sa			
5.	Check the chamber discharge strainer. Remove & clean as required.	S M T W Th F Sa			
6.	Check the door system as required by the scheme of inspection. Clean the door seal & its contact surface.	S M T W Th F Sa			
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4.	S M T W Th F Sa			
8.	Replace faulty indicator lamps	S M T W Th F Sa			
9.	Check gauges & digital indicator(s). If faulty repair or change as required.	S M T W Th F Sa			
10.	Check the door safety interlocks & control systems as required by the scheme of inspection. Lubricate the closure mechanism as required.	S M T W Th F Sa			
11.	Examine all pipe work connections & components for leaks. Repair as required.	S M T W Th F Sa			
12.	Examine door seal(s). Replace if damaged	S M T W Th F Sa			
13.	Weekly safety checks as per HTM 2010 Part 3	S M T W Th F Sa			
14.	Carry out weekly maintenance tasks & check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	S M T W Th F Sa			
15.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT RECORDS WITH USER	S M T W Th F Sa			
16.	Daily tests Satisfactory Not Satisfactory Weekly tests satisfactory Not Satisfactory	S M T W Th F Sa			
17.	Complete the log book.	S M T W Th F Sa			
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User.	S M T W Th F Sa			

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency indicated by person U = User M = Maintenance

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PLANNED PREVENTATIVE MAINTENANCE

Low temperature steam and formaldehyde sterilizer

Quarterly/Yearly Maintenance Schedule

The Maintenance Person should tick each task when it has been completed.

LTS.F	MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
Q – QUARTERLY **Y – YEARLY INTERVALS**					
Service the following items within the contract and at the frequency indicated and check for safe operation					
1.	Check fuses and connections on the electrical mains or plug				*
2.	Replace faulty indicator lamps.	*	*	*	*
3.	Check the gauges and their calibrations. Recalibrate as required	*	*	*	*
4.	Examine the door seal(s) and replace if damaged	*	*	*	*
5.	Examine the door closure mechanism and lubricate.	*	*	*	*
6.	Check the door safety interlocks as required by the scheme of inspection	*	*	*	*
7.	Examine all pipe work connections and components for leaks. Repair as required	*	*	*	*
8.	Weekly safety checks as SHTM 2010 Part 3	*	*	*	
9.	Yearly safety checks as SHTM 2010 Part 3				*
10.	Safety valve check and formalin container vent	*	*	*	*
11.	Examine the condenser	*	*	*	*
12.	Examine electrical connections for security	*	*	*	*
13.	Examine timers and check their settings	*	*	*	*
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions.	*	*	*	
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions				*
16.	Check the thermal sensor(s) and recorder and recalibrate if necessary				*
17.	Carry out yearly tests in accordance with SHTM 2010 Part 3				*
18.	Refit all covers & note the cycle count number	*	*	*	*
19.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED	*	*	*	*
20.	Weekly Satisfactory Not satisfactory	*	*	*	*
21.	Quarterly Satisfactory Not satisfactory	*	*	*	*
22.	Yearly Satisfactory Not satisfactory				*
23.	Complete the log book and summary sheets	*	*	*	*
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User	*	*	*	*

*Tasks to be undertaken at frequency indicated by * and as appropriate by Maintenance Person sterilizers, Manufacturer, Service contractor*

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Ethylene oxide sterilizer – Daily/Weekly Maintenance Schedule

The User or Maintenance Person should tick each task when it has been completed.

EO	MAINTENANCE SCHEDULES				
D = DAILY W = WEEKLY		**D**	**W**		
Service the following items within the contract and at the frequency indicated. Check for safe operation & correct readings				**U**	**M**
1.	Check all sterilizer services are turned on and correct readings are indicated on controls & gauges	S M T W Th F Sa			
2.	Check the log book & production records together with the routine microbiological test for each production cycle. Complete as required	S M T W Th F Sa			
3.	Check the chart recorder or data logger. Fit new chart; replenish ink or fit new ink cartridge as required	S M T W Th F Sa			
4.	Check the chamber & clean as detailed for the type of material chamber is constructed from.	S M T W Th F Sa			
5.	Check the chamber discharge strainer. Remove & clean as required.	S M T W Th F Sa			
6.	Check the door system as required by the scheme of inspection. Clean the door seal & its contact surface. Report any damage to the Maintenance Person	S M T W Th F Sa			
7.	Carry out detailed periodic daily tests in accordance with HTM 2010 Part 3 Table 4f.	S M T W Th F Sa			
8.	Check the ethylene oxide cylinder(s) & monitoring equipment. Change as required. Report defects to the Maintenance Person.	S M T W Th F Sa			
9.	Check gauges, digital indicator(s) & indicator lamps. If faulty repair or change as required.	S M T W Th F Sa			
10.	Check the door safety interlocks & control systems, lubricate the door closure mechanism as required by the scheme of inspection.	S M T W Th F Sa			
11.	Examine all pipe work connections & components for leaks. Repair as required.	S M T W Th F Sa			
12.	Examine door seal(s). Replace if damaged	S M T W Th F Sa			
13.	Weekly safety checks as per HTM 2010 Part 3	S M T W Th F Sa			
14.	Carry out weekly maintenance tasks & check the pressure vessel in accordance with the scheme of inspection and manufacturer's instructions	S M T W Th F Sa			
15.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED. INSPECT RECORDS WITH USER	S M T W Th F Sa			
16.	Daily tests Satisfactory Not Satisfactory Weekly tests satisfactory Not Satisfactory	S M T W Th F Sa			
17.	Complete the log book.	S M T W Th F Sa			
18.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User.	S M T W Th F Sa			

User and Maintenance Person, Manufacturer, Service contractor

Tasks to be undertaken at frequency indicated by U = User M = Maintenance person

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PLANNED PREVENTATIVE MAINTENANCE

Ethylene Oxide Sterilizer
Quarterly/Yearly Maintenance Schedule

The Maintenance Person should tick each task when it has been completed.

EO		MAINTENANCE SCHEDULES	1st Q	2nd Q	3rd Q	4th Y
Q – QUARTERLY **Y – YEARLY INTERVALS**						
Service the following items within the contract and at the frequency indicated and check for safe operation						
1.	Check fuses and connections on the electrical mains or plug					*
2.	Replace faulty indicator lamps.		*	*	*	*
3.	Check the gauges and their calibrations. Recalibrate as required		*	*	*	*
4.	Examine the door seal(s) and replace if damaged		*	*	*	*
5.	Examine the door closure mechanism and lubricate.		*	*	*	*
6.	Check the door safety interlocks as required by the scheme of inspection		*	*	*	*
7.	Examine all pipe work connections and components for leaks. Repair as required		*	*	*	*
8.	Weekly safety checks as SHTM 2010 Part 3		*	*	*	
9.	Yearly safety checks as SHTM 2010 Part 3					*
10.	Safety valve check		*	*	*	*
11.	Examine the heat exchanger and the discharge vent from the chamber		*	*	*	*
12.	Examine electrical connections for security		*	*	*	*
13.	Examine timers and check their settings		*	*	*	*
14.	Carry out detailed periodic quarterly maintenance tasks in accordance with the scheme of inspection and manufacturer's instructions.		*	*	*	
15.	Carry out yearly maintenance tasks and check the pressure vessel in accordance with the scheme of inspection and the manufacturer's instructions					*
16.	Check the temperature sensor(s), humidity sensor(s), and the pressure sensor(s) & recalibrate if necessary					*
17.	Carry out yearly tests in accordance with SHTM 2010 Part 3					*
18.	Refit all covers & note the cycle count number		*	*	*	*
19.	CARRY OUT PERIODIC & AUTOMATIC CONTROL TEST(S) AS REQUIRED		*	*	*	*
20.	Weekly Satisfactory	Not satisfactory	*	*	*	*
21.	Quarterly Satisfactory	Not satisfactory	*	*	*	*
22.	Yearly Satisfactory	Not satisfactory				*
23.	Complete the log book and summary sheets		*	*	*	*
24.	Notify the user of any defect or safety hazard. Complete the service records. Hand over to the User		*	*	*	*

*Tasks to be undertaken at frequency indicated by * and as appropriate by Maintenance Person sterilizers, Manufacturer, Service contractor*

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Laboratory Sterilizer – Daily Test Sheet

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Week beginning	Week
Department	Ref.No	Ser.No

TAKE READINGS DURING FIRST PRODUCTION CYCLE OF THE DAY						
	Cycle number	During sterilizing hold period		Sterilizing hold	Result of test	Certified fit for use by User
		Temperature	Pressure	time min:sec		
Monday		°C	bar	:	PASS/FAIL	
Tuesday		°C	bar	:	PASS/FAIL	
Wednesday		°C	bar	:	PASS/FAIL	
Thursday		°C	bar	:	PASS/FAIL	
Friday		°C	bar	:	PASS/FAIL	
Saturday		°C	bar	:	PASS/FAIL	
Sunday		°C	bar	:	PASS/FAIL	
		°C	bar	:	PASS/FAIL	

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

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Laboratory Sterilizer – Weekly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	
Door Seal [ ]	Door Safety Edge [ ]	Door Closed Interlock [ ]
Chamber Safety Valve Free [ ]	Jacket Safety Valve Free [ ]	Door Pressure Interlock [ ]

VACUUM LEAK RATE TEST-EMPTY CHAMBER		Cycle number
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes P1		millibar
Pressure after further 10 minutes P2		millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

AUTOMATIC CONTROL TEST			Cycle counter number	
The cycle selected should be rotated between those in routine use.				
Description of cycle selected(include number if applicable)				
Description of load				
Sterilize temperature	Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)				
Timer settings (if applicable)				
Position of load probe (include type of bottle and contents for fluids cycles)				
Start t1=0				
Sterilizing achieved	Sterilizing ends	Cooling/drying ends	Cycle complete	
(t2) :	(t3) :	(t4) :	(t5) :	
Take readings during sterilizing hold period				
Indicated values			Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO	
Calibration within limits YES/NO			If not, then note inaccuracies below, and action	
Outstanding inaccuracies				
For fluids loads , load temp below 80/90°C at end of cycle YES/NO				
Comments on test				
Result of test SATISFACTORY/UNSATISFACTORY				

FAULTS-NEW OR EXISTING-ALSO ENTER IN PLANT HISTORY RECORD

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
Test Person	Date	User	Date

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Laboratory Sterilizer – Quarterly Maintenance Schedule (Sheet A)

To be filled in along with Quarterly Test Sheets B and C to complete a Quarterly Test.

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

SAFETY CHECKS	Tick if Satisfactory	
Door Seal [ ]	Door Safety Edge [ ]	Door Closed Interlock [ ]
Chamber Safety Valve Free [ ]	Jacket Safety Valve Free [ ]	Door Pressure Interlock [ ]

VACUUM LEAK RATE TEST-EMPTY CHAMBER		Cycle number
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes P1		millibar
Pressure after further 10 minutes P2		millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

VACUUM LEAK RATE TEST-EMPTY CHAMBER			Cycle number
Test carried out after connection of temperature and pressure sensors			
	Indicated	Measured	
Pressure when pump stopped after min sec			millibar
Pressure below 50 millibar	YES/NO	YES/NO	
Pressure after 5 minutes P1			millibar
Pressure after further 10 minutes P2			millibar
Leak rate per minute (P2-P1)/10			millibar
Leak rate <1.3 millibar/min	YES/NO	YES/NO	PASS / FAIL

VACUUM LEAK RATE TEST-EMPTY CHAMBER		Cycle number
Test carried out after removal of temperature and pressure sensors		
Pressure when pump stopped after min sec		millibar
Pressure below 50 millibar	YES/NO	
Pressure after 5 minutes P1		millibar
Pressure after further 10 minutes P2		millibar
Leak rate per minute (P2-P1)/10		millibar
Leak rate <1.3 millibar/min	YES/NO	PASS / FAIL

THERMAL DOOR LOCK OVERRIDE TEST	SATISFACTORY/UNSATISFACTORY

CALIBRATION : If any calibration has been changed during this quarterly / yearly test, note below with initial error	
Verification of calibration of test instrument before tests carried out	SATISFACTORY / UNSATISFACTORY
Verification of calibration of test instrument after tests carried out	SATISFACTORY / UNSATISFACTORY

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Laboratory Sterilizer – Quarterly Maintenance Schedule (Sheet B)

To be filled in along with Quarterly Test Sheets A and C to complete a Quarterly test

This sheet to be used for any other cycles available but not tested on Quarterly Sheet C.

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

AUTOMATIC CONTROL TEST			Cycle counter number		
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	Cycle complete
(t2) :		(t3) :		(t4) :	(t5) :
Take readings during sterilizing hold period					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			Comments		
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

AUTOMATIC CONTROL TEST			Cycle counter number		
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	Cycle complete
(t2) :		(t3) :		(t4) :	(t5) :
Take readings during sterilizing hold period					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			Comments		
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Laboratory Sterilizer – Quarterly Maintenance Schedule (Sheet C)

To be filled in along with Quarterly Test Sheets A and B to complete a Quarterly test

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

THERMOMETRIC TEST FOR SMALL LOAD			Cycle counter number		
Small plastic discard, or fabrics, or glassware (choose first cycle in list available on autoclave).					
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	Cycle complete
(t2) :		(t3) :		(t4) :	(t5) :
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			If not, then note inaccuracies below, and action		
Outstanding inaccuracies					
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

PERFORMANCE REQUALIFICATION			Cycle counter number		
Fluid discard, or culture media, or free steaming (choose first cycle in list available on autoclave).					
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature		Sterilize time		Sterilize pressure	
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved		Sterilizing ends		Cooling/drying ends	Cycle complete
(t2) :		(t3) :		(t4) :	(t5) :
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			If not, then note inaccuracies below, and action		
Outstanding inaccuracies					
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Laboratory Sterilizer – Yearly Maintenance Schedule

To be filled in along with Quarterly Test Sheets A, Band Cto complete a Yearly test.

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 134/121/115°C during sterilizing should cause cycle fail [ ]		
Chamber safety lift at bar	Jacket safety lift at bar	Power failure [ ]
Steam pressure low [ ]	Water pressure low [ ]	Air pressure low [ ]

THERMOMETRIC TEST FOR FULL LOAD			Cycle counter number		
The cycle selected should be rotated between those in routine use.					
Description of cycle selected(include number if applicable)					
Description of load					
Sterilize temperature	Sterilize time		Sterilize pressure		
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Position of load probe (include type of bottle and contents for fluids cycles)					
Start t1=0					
Sterilizing achieved	Sterilizing ends		Cooling/drying ends	Cycle complete	
(t2) :	(t3) :		(t4) :	(t5) :	
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Drain/vent temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			If not, then note inaccuracies below, and action		
Outstanding inaccuracies					
For fluids loads , load temp below 80/90°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
TEST PERSON	DATE	USER	DATE

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Culture Media Preparator Sterilizer – Weekly Maintenance Schedule

Hospital/Location	Week number	
Department	Ref.No	Ser.No

Date	Batch No.	Product	Volume	Timer setting	Cycle counter	Time chamber at sterilizing temp	Indicated temp during sterilizing	Recorded temp during sterilizing	Sterilizing time within limits	Comments and operator initials
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	
						:	°C	°C	Yes/No	

The Test Person should carry out an Automatic Control Test and fill in the details above, in addition to the weekly safety checks. The time at sterilizing temperature should be checked with a stopwatch.
Weekly safety checks Seal condition [ ] Lid temperature interlock [ ] Lid closed interlock [ ]
Safety Valve free [ ]

TEST RESULT SATISFACTORY/UNSATISFACTORY		STERILIZER IS FIT/UNFIT FOR USE	
Test Person	Date	User	Date

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Culture Media Preparator Sterilizer Yearly Maintenance Schedule

Tests to be carried out in accordance with SHTM 2010.

Hospital/Location	Date	Week
Department	Ref.No	Ser.No

YEARLY SAFETY CHECKS	Tick if Satisfactory	Additional to weekly checks.
Drop below 121/115°C during sterilizing should cause cycle fail or timer reset[ ]		
Chamber safety lift at bar	Jacket safety lift at bar	Power failure [ ]

THERMOMETRIC TEST FOR FULL LOAD			Cycle counter number		
Type of culure medium			Volume of liquid		
Sterilize temperature			Sterilize time		
Temperature controller settings (if applicable)					
Timer settings (if applicable)					
Start t1=0					
Sterilizing achieved	Sterilizing ends		Cooling ends	Cycle complete	
(t2) :	(t3) :		(t4) :	(t5) :	
Take readings during sterilizing hold period : measured values in shaded boxes.					
Indicated values				Recorded values	
Load temp.	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
°C	°C	bar	bar	°C	bar
°C	°C	bar	bar	°C	bar
Sterilizing hold period (t3-t2) :			Sterilizing conditions met YES/NO		
Calibration within limits YES/NO			If not, then note inaccuracies below, and action		
Outstanding inaccuracies					
Door safety hood unable to be opened until load temps below 80°C at end of cycle YES/NO					
Result of test SATISFACTORY/UNSATISFACTORY					

REHEAT AND DISPENSING TEST			Cycle counter number		
Type of culture medium			Volume of liquid		
Reheat temperature setting °C			Dispensing temperature setting °C		
Start t1=0					
Take readings at start, middle and end of dispensing period.					
Indicated values				Recorded values	
	Load temp.	Chamber pressure	Jacket pressure	Recorded temp	Recorded pressure
Start	°C	bar	bar	°C	bar
Middle	°C	bar	bar	°C	bar
End	°C	bar	bar	°C	bar
Indicated temp within 2 °C of set temp YES/NO			Indicated chamber pressure zero YES/NO		
Medium does not solidify YES/NO					
Outstanding inaccuracies					
Result of test SATISFACTORY/UNSATISFACTORY					

TEST RESULT SATISFACTORY/UNSATISFACTORY	STERILIZER IS FIT/UNFIT FOR USE
Test Person Date	User Date

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Scottish Health Technical Memorandum 2031

(Part 1 of 1)

Clean steam for sterilization

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NHSScotland, P&EFEx, June 2001

Executive summary

The quality of steam supplied to a sterilizer can have a major influence on the efficacy of the sterilization process, the quality of the sterile product and the longevity and serviceability of the sterilizer and its associated equipment. Where concern for steam quality has traditionally focused on its physical characteristics - notably dryness and the presence of non-condensable gases - new European Standards supporting legislation governing the manufacture of medical devices require more comprehensive control of the purity of the sterilizing environment.

This SHTM discusses the nature, effects and sources of chemical and biochemical contaminants in steam, and proposes a readily achievable purity specification for “clean steam” to be used for sterilization. The specification is designed to meet regulatory requirements for medicinal products and medical devices without incurring excessive expenditure.

Clean steam is defined as steam whose condensate meets the purity requirements of Water for Injections BP (including a limit on pyrogens) with additional specifications to protect against corrosion of materials used in the construction of sterilizers and medical devices.

Practical guidance is given on the generation of clean steam from the following sources:

a. from the existing mains steam supplies commonly used in hospitals;

b. from dedicated clean-steam generators;

c. in sterilizers with an internal steam supply, such as transportable sterilizers for unwrapped instruments and utensils.

With minor modifications and adjustments to operating practices, it should be possible to obtain clean steam from the majority of mains steam services currently installed in NHS hospitals. However, the necessary assurance that the supply continues to meet clean-steam specifications will require frequent testing of steam and feed water samples and close supervision of plant normally outside the control of the user of the sterilizer.

In the longer term, a dedicated clean-steam generator, solely supplying one or more sterilizers, is likely to prove a more reliable and economical source of clean steam.

Advice is given on the validation and periodic testing of clean-steam supplies, with guidance on methods of taking steam and water samples for analysis. Confirmation that a supply complies with the clean-steam specification requires a number of laboratory tests, most of which are based on those of the British Pharmacopoeia and are well within the capacity of any hospital pharmacy.

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1. Responsibilities

Introduction

1.1 This chapter reviews the roles of the key personnel associated with the operation of a sterilizer and summarises their responsibilities with regard to clean steam.

Key personnel

1.2 The following key personnel are referred to in this SHTM. Further information, including qualifications and general areas of responsibility, can be found in SHTM 2010: Part 1.

1.3 **Management** is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of personnel, for the organisation in which the sterilizer is employed.

1.4 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive, laboratory director or other person of similar authority. In small, autonomous installations the user may take on this function.

1.5 The **User** is defined as the person designated by Management to be responsible for the management of the sterilizer.

1.6 In a hospital the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the Production Manager (see paragraph 1.13) in charge of the entire manufacturing process.

1.7 The **Authorised Person (Sterilizers)** is defined as a person designated by Management to provide independent auditing and advice on sterilizers and sterilization and to review and witness documentation on validation. The shorter term “Authorised Person” is used in this SHTM.

1.8 The Institute of Healthcare Engineering and Estate Management (formerly the Institute of Hospital Engineering) is the registration authority for Authorised Persons. The address is given in Appendix 1.

1.9 The **Test Person (Sterilizers)** is defined as a person designated by Management to carry out validation and periodic testing of sterilizers. The shorter term “Test Person” is used in this SHTM.

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1.10 The **Maintenance Person (Sterilizers)** is defined as a person designated by Management to carry out maintenance duties on sterilizers. The shorter term “Maintenance Person” is used in this SHTM.

1.11 The **Microbiologist (Sterilizers)** is defined as a person designated by Management to be responsible for advising the user on microbiological aspects of the sterilization of non-medicinal products. The shorter term “Microbiologist” is used in this SHTM.

1.12 The **Competent Person (Pressure Vessels)** is defined as a person or organization designated by Management to exercise certain legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a sterilizer described in the Pressure Systems Safety Regulations 2000. The shorter term “Competent Person” is used in this SHTM.

1.13 The **Production Manager** is defined as a person designated by Management to be responsible for the production of medicinal products.

1.14 The **Quality Controller** is defined as a person designated by Management to be responsible for quality control of medicinal products with authority to establish, verify and implement all quality control and quality assurance procedures. (A similar role may be defined for the manufacture of medical devices, but this is rarely the practice in hospitals.)

Responsibilities regarding clean steam

1.15 The **Authorised Person** will be able to advise the user on all aspects of the production and use of clean steam for sterilization.

1.16 The **User** will need to:

a. appreciate the nature of contaminants in steam supply (especially pyrogens), their possible adverse effects and their sources;

b. understand the requirements of legislation on medicinal products and medical devices as regards sterilization;

c. be familiar with the current and impending standards on steam sterilization and their implications for steam quality;

d. understand the difference between process steam, clean steam and BS EN 285 steam and the appropriate applications of each;

e. understand the rationale for the clean steam specification;

f. understand the engineering principles required for the delivery of clean steam and how they may be realised for mains steam, dedicated steam generators and sterilizers with internal reservoirs;

g. with appropriate advice, decide whether clean steam is required for any sterilizer unit and if so, what is the best means of achieving it;

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h. after the required engineering work is complete, be satisfied that the chosen system is capable of supplying clean steam;

i. appoint and liaise with a suitable laboratory for the analysis of steam and feed water samples;

j. arrange for the steam supply to be formally validated;

k. on completion of the validation tests, confirm that the sterilizer is fit for use with the steam supply;

l. arrange for periodic maintenance of any steam generating and distribution plant under the user's control;

m. arrange for periodic tests of the steam quality at intervals coinciding with periodic tests on the sterilizer.

1.17 The **Test Person** will need to:

a. understand the operation of the apparatus for taking samples of steam condensate for field analysis (Chapter 6) and be trained in the method of its use;

b. be aware of the correct procedures for collecting, preserving and handling samples;

c. be trained in the measurement of electrical conductivity of water samples using a portable meter.

1.18 The **Maintenance Person** will need to:

a. if maintaining transportable sterilizers, be aware of the guidance on cleaning and rinsing in Chapter 4;

b. if maintaining clean-steam generators, be suitably trained and aware of the guidance in Appendix 2.

1.19 The **Microbiologist** will be able to advise on all microbiological aspects of clean steam, including avoidance of bacterial contamination and control of pyrogens.

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2. Contamination in steam supplies

Introduction

2.1 Recent years have seen a growing awareness of the need to improve the quality of steam used for sterilization, spurred on in part by regulatory requirements for medicinal products and medical devices, but also by increasing concern about the harmful effects that even minute quantities of contaminants may have upon patients.

2.2 This chapter discusses the adverse effects that impurities in the steam supply may have on patients, equipment and the sterilizer itself, identifies the products most likely to be susceptible to contamination and reviews the means by which various contaminants find their way into steam for sterilization.

Why does contamination matter?

2.3 As will be discussed in Chapter 3, quality assurance in the manufacture of medicinal products and medical devices requires that the quality of the steam used in sterilization be known and controlled. The following sections identify a number of specific contaminants which are known to have adverse effects and whose presence in steam is therefore undesirable.

Adverse effects on patients

2.4 Even small amounts of unwanted substances may be harmful to patients. The danger arises because certain medicinal products and medical devices may introduce contaminants directly into parts of the body that are normally protected by skin or mucous membranes. Water that is safe to drink, for example, may not be safe if injected into the bloodstream. Patients are particularly vulnerable to contaminants carried on sterile instruments precisely because such instruments are used to bypass the body's normal defences.

2.5 Several contaminants are known to have adverse effects on patients.

a. **Metals:** Many of these are toxic (some are cumulative poisons) and therefore their presence is undesirable. Metals of particular concern include cadmium, lead, mercury and other heavy metals.

b. **Organic compounds:** Many of these are biologically active and therefore undesirable. The chief compounds of concern are filming amines and other chemicals that may be used in boiler treatment (see paragraph 2.29).

c. **Micro-organisms:** Organisms of concern include all pathogens and all Gram-negative bacteria (which are sources of pyrogens).

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d. **Pyrogens:** These are bacterial endotoxins, predominantly derived from Gram-negative bacteria, which can cause severe reactions when administered intravenously (see paragraph 2.6).

e. **Particulate materia:** Solid particles can lead to a number of adverse effects if injected into the body.

2.6 Pyrogens are of particular concern because, unlike other contaminants, there are no controls on the levels of pyrogens in public water supplies from which steam is generated. Moreover, they are extremely heat-stable and are only destroyed after prolonged exposure to high temperatures (3 hours at 180°C or 30 minutes at 250°C). They are not inactivated by any of the standard sterilization processes employed for medical devices and medicinal products. Control of pyrogens, then, is a priority for steam sterilization. Detailed information about pyrogens may be found in Appendix 3.

Adverse effects on materials

2.7 As well as the obvious risks to patients, contaminants in steam may have a damaging effect on the materials of load items and the sterilizer itself.

2.8 Reactive contaminants in the steam may cause corrosion or otherwise impair the longevity or function of the product. Reactions may occur when contaminants interact directly with the product, or indirectly with materials that will subsequently come into contact with the sterilized product.

2.9 The steam also comes into direct contact with the internal surfaces of the sterilizer pressure vessel and associated equipment and instrumentation. Contaminants within the steam may react with the materials of construction and cause corrosion of the equipment or otherwise impair its longevity or function.

2.10 The reaction of steam with surfaces in contact is affected by its pH. In general steam of a low pH (acidic) will react with and dissolve metals. A pH of approximately 7 (neutral) is ideal and deviations towards alkaline (to e.g. pH 8) is acceptable.

2.11 Contaminants of concern include the following.

a. **Alkaline earth metals** cause “hardness” which can lead to build-up of lime scale on load items, in the sterilizer chamber and in pipework. Most problems are caused by calcium and magnesium, and to a lesser extent strontium.

b. **Iron**, whether in metallic or ionic form, is corrosive to stainless steel.

c. **Chlorides** in the presence of oxygen lead to pitting corrosion and (to a lesser extent) crevice corrosion in stainless steel. The effects can be controlled by limiting the amount of oxygen in the feed water (see paragraph 4.48).

d. **Phosphates** and silicates act to concentrate chloride ions and so promote their corrosive effects.

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2.12 Clearly the materials used in the construction of load items and of the sterilizer itself will determine which contaminants are of greatest importance in each case. BS EN 285 offers guidance on materials of construction suitable for all steam sterilizers.

2.13 Steam sampling systems also must be constructed of materials which will not react with, and hence contaminate, the sample being collected. Suitable equipment is discussed in Chapter 6.

Products vulnerable to contamination

2.14 Any product may become contaminated when the steam supplied to sterilizers comes into direct contact with it. Contaminants in the steam are deposited on the product as the steam condenses during the heating-up stage. The amount of steam condensing, and hence the amount of contamination deposited, is proportional to the heat capacity of the load item which in turn is proportional to its mass and the specific heat capacity of the material from which it is made. A massive metal item will therefore receive much more contamination than a light plastic item of similar size and shape heated to the same temperature.

2.15 The amount of contamination remaining at the end of the cycle, however, will depend on how much condensate is retained at the surface of the product. Where condensate can drain freely from unwrapped items, a small fraction of the deposited contaminants will be held in a thin film of water and the total amount remaining when the film is evaporated will be proportional to the exposed surface area of the item. Where condensate is trapped in cavities or held in the packaging close to the surface, the amount of contamination retained will be proportionally greater.

2.16 To some extent, packaging materials for steam processes (except fluids in sealed containers) have a filtering effect which protects against contamination. Particulate matter is normally trapped on the outer wrapping (giving rise to discoloured packs) but smaller particles and all molecules will pass through with the steam and be transferred to the product as the steam condenses on it. Performance requirements for packaging materials may be found in BS EN 868.

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2.17 Whether such contamination has any adverse effect depends upon the nature and intended use of the product. Vulnerable products are:

a. those which would permit direct transfer of contaminants to the patient, including:

(i) medicinal products;

(ii) porous goods such as dressings and swabs;

(iii) surgical instruments and utensils;

b. those which would permit indirect transfer of contaminants to a patient, such as equipment used in pharmaceutical manufacturing (see paragraph 2.18 below);

c. those which would be impaired or inactivated by the presence of one or more of the possible contaminants. These include:

(i) certain medicinal products;

(ii) laboratory products for in-vitro diagnostic use.

2.18 Various items of equipment used in the manufacture of sterile pharmaceuticals and medical devices are sterilized before use. It is important that during sterilization these items are not tainted with contaminants which may be transferred to the product being manufactured, whether that product is terminally sterilized or produced aseptically. Such items of equipment may include mixing vessels, filling heads, sterilization grade filters, filling lines, pipes and tubing for material transfer, connectors, and so on.

Sources of contamination

2.19 Contaminants delivered to the sterilizer in steam may arise from a number of sources:

a. contaminants present in the public water supply from which the steam is generated;

b. contaminants arising from treatment of the boiler feedwater;

c. contaminants arising in the distribution system carrying steam to the sterilizer.

Public water supply

2.20 While the quality of mains water supplies differs considerably from place to place, it can normally be relied upon to meet the minimum standards set out in The Water Supply (Water Quality) (Scotland) Regulations 1990. These specify more than 50 limits for a wide range of impurities including dissolved minerals, organic compounds and micro-organisms.

2.21 There are no controls, however, on the amounts of atmospheric gases dissolved in mains water, all of which will be present in small and varying

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amounts. Air is the principal non-condensable gas that can impede steam sterilization, and carbon dioxide and oxygen are important contributors to corrosion in boiler systems (see SHTM 2010: Part 2).

2.22 While mains water contains negligible numbers of pathogens and faecal contaminants (such as Escherichia coli) it may contain low numbers of other micro-organisms. Most water authorities use chlorine as a means of microbiological control. The disinfection effect of the chlorine may be largely lost, however, by the time the water reaches the point of use.

2.23 Water taken from the mains and subsequently kept in storage tanks before use may have significantly higher counts than the original mains water. Although bacteria tend to settle out on prolonged storage in reservoirs or lagoons, the intermittent throughput in storage tanks maintains their buoyancy and can cause counts to rise rapidly. Particularly in the summer months counts as high as 105–106 ml^{-1} may not be uncommon. This is of particular concern for sterilization since some 98% of the bacteria found in water supplies are reported to be Gram-negative bacteria, which are the predominant source of pyrogens (see Appendix 3).

2.24 There are no requirements for suppliers to measure or control the level of pyrogens in mains water.

Boiler feedwater treatment

2.25 Further contaminants may be introduced either deliberately or inadvertently as a result of treatments applied to mains water before it can be used as boiler feedwater.

2.26 Dealkalisation treatments can raise the levels of dissolved air and carbon dioxide.

2.27 Base-exchange water softeners remove calcium and magnesium ions from the water and replace them with sodium ions (see paragraph 4.43). Sodium levels will therefore be raised in mains water softened by this method. The use of brine to regenerate the ion-exchange beds may temporarily raise the level of chloride.

2.28 Bacterial growth may occur in water softening, deionisation or reverse osmosis plant unless the manufacturer's operating and maintenance procedures are strictly adhered to. While bacteria will not survive the steam generating process, the pyrogens they produce could be delivered to the sterilizer.

2.29 Any chemicals added to the boiler water may be carried into the steam as contaminants either in droplets of water entrained in the steam during the evaporative process or as volatile components present as gases. Filming amines (such as hydrazine), commonly used to protect condensate return systems, are toxic and should not be used where the steam is to be used for sterilization.

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Steam distribution system

2.30 Steam is chemically aggressive; the purer the steam the more reactive it is. Reaction with pipework and valves can lead to contamination of the steam with corrosion products such as magnetite (Fe_3O_4). Often in the form of fine particulates, these products are not readily removed by the strainers normally installed in steam services. Users of old installations may have occasionally noted black or reddish brown discoloration of packaging material by particles of magnetite shed from the walls of the steam pipes.

2.31 The hydrogen liberated by the formation of magnetite (400 ml for each gram of iron) may contribute appreciably to the amount of non-condensable gases in the steam delivered to the sterilizer, especially in new installations with long pipe runs.

2.32 Contamination is also likely to arise at points where water can collect, such as dead-legs, gauges and poorly maintained traps. Trapped water can result in rust, which can be shed into the steam as particles, and bacterial growth, which can lead to the formation of bio-films which periodically generate high levels of contamination as they slough off.

2.33 Guidance on avoiding contamination from mains steam distribution systems may be found in paragraphs 4.20 – 4.24.

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3. Steam quality requirements

Introduction

3.1 This chapter discusses the purity requirements for steam to be used in sterilization, with special emphasis on the grade of “clean steam” recommended for general use within the NHS.

Regulatory requirements

3.2 The move towards higher quality steam for sterilization has been brought about, in the main, by regulatory requirements for the manufacture of medicinal products and, more recently, sterile medical devices (see SHTM 2010: Parts 1 and 4 for a summary of the relevant legislation). In both cases there is a clear principle that products should not be adulterated with unwanted or unspecified compounds during sterilization, or any other stage in processing. Such an objective can only be attained if the physical, chemical and biological properties of steam coming into contact with the product are known and controlled.

Medicinal products

3.3 Annex 1 of the ‘The Rules governing medicinal products in the European Community: Volume IV: Good manufacturing practice for medicinal products’ states “*Care should be taken to ensure that steam used for sterilization is of suitable quality and does not contain additives at a level which could cause contamination of product or equipment*.”

3.4 The steam quality need not be very high where the product does not come into direct contact with the steam. This is the case for aqueous products processed in fluid sterilizers, provided that the method of sealing the containers has been validated and shown to have a quantified risk of failure and that failed containers can be readily identified and removed (see SHTM 2010: Part 4 for details). However, such assurance normally requires a degree of testing and monitoring of containers that may not be justified in smaller hospital pharmacies. It may be more cost-effective to ensure that the steam is of sufficient quality that a failure of a seal will not have adverse effects on the product.

3.5 Further guidance on legislation governing medicinal products may be obtained from the Medicines Control Agency whose address may be found in Appendix 1.

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Medical devices

3.6 Annex I of the Medical Devices Directive, implemented by the Medical Devices Regulations 1994, lists a number of “essential requirements” for the manufacture of medical devices. Section 7.2 requires that devices are “*designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product*.” This has clear implications for the quality of steam used in sterilization processes.

3.7 The Directive is supported by the European Standard on validation and monitoring of moist heat sterilization (EN 554) which requires that the *“purity of the sterilizing environment in contact with the medical device shall not affect the safety of the product*.” (Reference should also be made to BS EN 554).

3.8 In practically all steam sterilization processes, the medical device comes into direct contact with the steam and therefore the quality of the steam must be known and controlled. Steam quality is also of concern in ethylene oxide sterilizers in which steam is used for humidification and therefore, again, comes into direct contact with the medical devices.

3.9 Further guidance on legislation governing medical devices may be obtained from the Medical Devices Agency. The address may be found in Appendix 1.

Requirements of SHTM 2010

3.10 SHTM 2010 is the NHS in Scotland Property and Environment Forum's guide to sterilization in Scotland. Part 3 describes steam quality tests for determining the non-condensable gas content, dryness and superheat values of steam supplied to porous load sterilizers, LTSF and LTS disinfectors. The steam quality specified is as follows:

a. the volume of non-condensable gases should not exceed 3.5 ml for every 100 ml of displaced water when measured by the method given in SHTM 2010: Part 3 (this is not equivalent to a fraction of 3.5% by volume of the steam, as incorrectly implied in BS EN 285 and elsewhere);

b. the superheat measured on expansion of the steam to atmospheric pressure should not exceed 25°C when measured by the method given in SHTM 2010: Part 3;

c. the dryness value should be not less than 0.9 (or, if only metal loads are to be processed, not less than 0.95) when measured by the method given in SHTM 2010: Part 3.

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3.11 This specification, which complies with both BS EN 285 and BS 3970: Part 1, addresses the basic requirements for assurance that the sterilization process is carried out under moist heat conditions, without excessive moisture, and without random, localised, impairment of the sterilization conditions caused by excessive amounts of non-condensable gases. The condensate from the steam should be clear, colourless and free from oil and particulates. To meet this specification steam should be generated by boiler plant which is designed, operated and maintained in accordance both with the recommendations of SHTM 2010 and of the manufacturer. Experience shows that these requirements are readily met in the majority of hospitals.

3.12 Saturated steam, which is clean and substantially free from moisture and non-condensable gases, is the minimum standard required for all sterilization processes.

3.13 The SHTM 2010 requirements, however, say little about the purity of steam for sterilization. From the discussion of the adverse effects of contaminants (see Chapter 2) it is apparent that different minimum specifications could be devised for each of the possible applications and for each of the available sterilization processes. Ideally one would review the nature and intended use of the process, together with any constraints imposed by the materials of which the distribution system and sterilizer are constructed, and select a specification appropriate to the particular circumstances. For specialised products it may be necessary to specify limits for a particular contaminant not considered in this general guidance. Such procedures would be grossly impractical, however, for the wide range of products processed in hospitals.

3.14 Although steam of the highest possible purity may be suitable for all applications it is significantly more expensive to produce than steam of a lower standard. Chemically pure steam is also highly corrosive.

3.15 There is a clear need for a steam purity specification that would meet regulatory requirements and which could be attained in hospitals without excessive expenditure. The rest of this chapter discusses three proposed grades of steam: process steam, BS EN 285 steam and clean steam. They are summarised in Table 1.

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Table 1: Classification of steam quality

Steam quality	Description	Sterilizer applications
Process steam	All-purpose steam supply, not optimised for sterilization.	Fluid sterilizers with validated closure systems Laboratory sterilizers (make safe cycles).
Clean steam	Steam whose condensation meets the specification for clean steam in Table 2.	Porous load, unwrapped instruments, LTS and LTSF sterilizers processing medical devices. Fluid sterilizers without validated closure systems Ethylene oxide sterilizers processing medical devices (steam for humidification) Laboratory sterilizers (loads vulnerable to contamination)
BS EN 285 steam	Steam whose condensate meets the specification for BS EN 285 steam in Table 3.	Not required in the NHS

Note: Clean steam may be used for all sterilizer applications

Process steam

3.16 “Process steam” is defined here as general-purpose steam whose quality has not been optimised for sterilization.

3.17 Where it is not intended to be in direct contact with medical devices, medicinal or culinary products, no specific physical, chemical or biological contamination limits are set. The steam may contain various volatile additives (such as those intended to inhibit corrosion in condensate return pipes) which are unacceptable for topical, enteral or parenteral administration to human beings.

3.18 Process steam intended for use as a heating medium in culinary applications, where it is in direct contact with food products or food contact surfaces, is sometimes known as “potable steam”. The condensate from such steam should then meet the purity requirements of drinking water.

3.19 The recommendation of this SHTM is that process steam, as defined above, is not acceptable for sterilizers in which medicinal products and medical devices are in contact with steam and therefore vulnerable to contamination. It may also be unacceptable for certain loads processed in laboratory sterilizers, but may be used where discard loads only are to be processed (see Table 1).

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BS EN 285 steam

3.20 BS EN 285 is the standard on large steam sterilizers (essentially porous load machines). When EN 285 was being developed in the first instance, it was considered desirable to include recommendations on the quality of steam with which a sterilizer should be designed to operate. The result was a specification both for steam condensate and feedwater that would ensure that the steam environment in the chamber would not "impair the sterilization process or harm the sterilizer or sterilized load." Identical recommendations are likely to appear in a future standard on sterilizers for unwrapped instruments and utensils. BS EN 1422, which sets out requirements for EO sterilizers, also recommends limits on impurities in steam used for humidification, although the permitted levels are generally higher than those of BS EN 285.

3.21 "BS EN 285 steam" is defined here as steam whose condensate complies with the specification recommended in BS EN 285 and reproduced in Table 3. It should be emphasised that steam of this quality is a recommendation and not a requirement. Sterilizer plant may conform fully to BS EN 285 without meeting the recommended specification for steam purity.

3.22 While BS EN 285 steam is appropriate for its intended use, it was not designed to meet the requirements of the legislation and standards on medicinal products and medical devices. It is not regarded as suitable for use in NHS hospitals for the following reasons:

a. BS EN 285 steam is designed primarily to protect materials, not patients; it does not, for example, set limits on pyrogens;

b. steam of this purity is chemically aggressive and will attack many materials, including iron, steel and copper, commonly found in existing steam distribution systems, sterilizers and sterilizer loads;

c. it is unlikely that steam of this purity can be generated and delivered with the steam systems currently used in NHS hospitals without excessive engineering costs.

3.23 There appear to be few, if any, sterilizer applications in which BS EN 285 steam would be preferable to "clean steam" as discussed below. The recommendation of this SHTM is that BS EN 285 steam is unnecessary for sterilizers in use in the NHS.

Clean steam

3.24 The concept of "clean steam" has been developed to meet all regulatory requirements while meeting a reasonable standard of purity that can be readily attained in hospitals without excessive expenditure.

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3.25 The recommendation of this SHTM is that clean steam should be provided for all clinical sterilizers where the steam may come into direct contact with medical devices, medicinal products or equipment intended for use in the manufacture of medicinal products or medical devices. It may also be required for use with laboratory sterilizers where the product is sensitive to contamination. It is expected that clean steam will in due course become the norm for all sterilization applications in the NHS.

3.26 Clean steam is defined as steam whose condensate meets the specification given in Table 2. This specification is compared with those for drinking water and BS EN 285 steam in Table 3.

Table 2: Specification for clean steam.

Determinand	Value	Recommended test for compliance
Based on Sterilized Water for injections BP:		
Acidity or alkalinity	NQ	BP test. Tests for pH are not an acceptable substitute
Ammonium	0.2 mg litre^{-1}	BP test or other suitable method
Oxidisable substances	NQ	BP test
Calcium and magnesium	NQ	BP test. Tests for hardness are not an acceptable substitute
Heavy metals substitute	0.1 mg litre^{-1}	BP test. Tests for individual elements are not an acceptable substitute.
Chloride	0.5 mg litre^{-1}	BP test or other suitable method.
Nitrate	0.2 mg litre^{-1}	BP test or other suitable method.
Sulphate	NQ	BP test.
Residue on evaporation	30 mg litre^{-1}	BP test. Conductively measurement is not an acceptable substitute.
Pyrogens	0.25 EU ml^{-1}	BP test.
Based on BS EN 285:		
Phosphate	0.1 mg litre^{-1}	Any suitable method.
Silicate	0.1 mg litre^{-1}	Any suitable method.
Routine monitoring only:		
Electrical conductivity at 25^{o}C	35 μS cm^{-1}	See Appendix 4 and Chapter 7.

NQ=not quantified; BP=British Pharmacopoeia; EU=endotoxin unit.

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3.27 The purity requirements are defined in terms of physical, chemical and biochemical properties and are independent of any engineering measures that may be needed to attain them. The quality specified is to be determined at the point of delivery to the sterilizer. Provided that a suitable quality can be attained and sustained, and that the process has been validated, the source of steam can be selected on economic grounds.

3.28 Test schedules to demonstrate compliance of a condensate sample are discussed in Chapter 5, with sampling methods in Chapter 6 and methods of analysis in Chapter 7.

3.29 The rationale for the clean steam specification is discussed below under the headings of health and safety, sterilizer protection and routine monitoring.

Health and safety

3.30 Rather than make detailed assessments of the health and safety implications of all possible steam contaminants and determine safe levels for each, this SHTM adopts Water for Injections BP (identical to Water for Injections PhEur) as a suitable standard that clean steam condensate should meet. WFI has been in use throughout Europe and elsewhere for many years as the basis for pharmaceutical preparations to be administered intravenously. Steam condensate meeting the requirements of WFI can therefore be regarded as free of harmful contaminants.

3.31 The British Pharmacopoeia (BP) defines two grades of WFI: Water for Injections in Bulk (for use in the manufacture of medicinal products) and Sterilized Water for Injections (essentially WFI in Bulk that has been bottled and sterilized, and intended for dilution of medicinal products for injection). Clean steam is based upon the requirements for Sterilized WFI; experimental measurements with WFI in Bulk show that it is too acidic for the materials used in sterilizers.

3.32 The BP defines WFI both in terms of its means of production and in terms of a number of tests for specified contaminants.

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Table 3: Comparison of clean steam with drinking water and BS EN 285 steam

Determinand and unit	Maximum permitted values		
	Drinking water (a)	Clean steam condensate (b)	EN 285 steam condensate (c)
Acidity or alkalinity	-	NQ	-
Degree of acidity(pH)	*5.5 -9.5*	-	*5 - 7*
Ammonium, NH_4 (mg litre^{-1})	0.5	0.2	-
Calcium & magnesium (mg litre^{-1})	300	NQ	-
Total hardness, $CaCO_3$ (mg litre^{-1})	*> 150 (d)*	-	*2.0 (e)*
Heavy metals (mg litre^{-1})		0.1 (f)	
Iron, Fe (mg litre^{-1})	*0.2*	-	*0.1*
Cadmium, Cd (mg litre^{-1})	*0.005*	-	*0.005*
Lead, Pb (mg litre^{-1})	*0.05*	-	*0.05*
Heavy metals (mg litre^{-1}) other than Fe, Cd, Pb		-	*0.1 (g)*
Chloride, Cl (mg litre^{-1})	400 (h)	0.5	0.1
Nitrate, NO_3 (mg litre^{-1})	50	0.2	-
Sulphate, SO_4 (mg litre^{-1})	250	NQ	-
Oxidisable substances	-	NQ	-
Residue on evaporation (mg litre^{-1})	1500 (h)	30	1
Silicate, SiO_2 (mg litre^{-1})	-	0.1	0.1
Phosphate, P_20_5 (mg litre^{-1})	10 (i)	0.1	0.1
Conductivity at 20°C (μS cm^{-1})	1500 (h)	35 (j)	3
Bacterial endotoxins (EU ml^{-1})	-	0.25	-
Appearance		Clear, colourless	Colourless, clean without sediment

Entries in italics are not applicable to clean steam.

NQ. not quantified

a. Source: The Water Supply (Water Quality) (Scotland) Regulations 1990
b. See paragraphs 3.24 onward
c. Source: BS EN 285
d. Expressed in BS EN 285 as 0.02 mmol litre^{-1}
e. Expressed in the Regulations as > 60 mg litre^{-1} Ca
f. See paragraph 3.38
g. Identity of heavy metals not specified
h. 12-month average.
i. Expressed in the Regulations as 2.2 mg litre^{-1} P
j. At 25°C

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3.33 First, WFI "is obtained by distilling potable water or Purified Water from a neutral glass, quartz or suitable metal still fitted with an effective device for preventing the entertainment of droplets; the apparatus must be correctly maintained to ensure the production of apyrogenic water." A high degree of purity is clearly implicit in this statement. For example, a sample of tap water treated chemically to remove only the impurities specified in the BP would not be WFI. For the purposes of this SHTM, the guidance on clean steam generation in Chapter 4 is deemed to meet the distillation requirement for WFI.

3.34 Second, Sterilized WFI is required to comply with a number of tests designed to confirm that a given water sample contains less than a certain amount of a specified contaminant. Test procedures are given in the BP and reproduced here in Appendix 4.

3.35 It has to be said that these tests are not entirely satisfactory as a specification for clean steam. They employ traditional reagent methods which rely upon the observation of colour changes, and are poor at determining the extent to which a sample deviates from specification. Moreover, limits are not always quantified: concentrations are quoted for some contaminants but not others. For this reason it has not been possible to set numerical limits for all the contaminants in Table 2. On the other hand, the tests can be carried out in any hospital pharmacy and do not require the facilities of a specialised analytical laboratory.

3.36 Where no concentration is quoted (*acidity* or *alkalinity, calcium and magnesium, oxidisable substances* and *sulphate*), the only safe way of ensuring that a sample meets the WFI specification is to conduct the test described in the BP; there are no generally accepted equivalent concentrations.

3.37 Where the BP does quote an equivalent concentration, however (*ammonium, nitrate, chloride* and *residue on evaporation*), the way is open to employing a variety of modern analytical techniques to demonstrate compliance (see Chapter 7), though the stated concentrations are not precise and should be treated with caution.

3.38 While the BP quotes a concentration for *heavy metals* (expressed as Pb), the test responds to different metals in varying degrees and it is not possible to express the BP limit as a simple sum of individual elements. For this reason the BP test alone should be used to ascertain compliance; alternative methods are not recommended (see paragraphs 7.18–7.20 for more details).

3.39 The limit for *pyrogens* is 0.25 endotoxin units (EU) ml^{-1} (see Appendix 3 for a discussion on the meaning of the endotoxin unit). The BP test for pyrogens (bacterial endotoxins) is the LAL test described in Appendix 4.

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3.40 It is likely that these traditional tests will be replaced by more precise quantitative tests in the future. If so, the requirements for clean steam will be modified accordingly. *Clean steam should always comply with the current pharmacopoeial specification for Sterilized Water for Injections*.

Sterilizer protection

3.41 The WFI specification is designed to ensure that water can be administered safely by injection and is therefore regarded as a suitable minimum standard for health and safety purposes. It is not, however, concerned with effects on materials, and so additional specifications have been added to lessen the corrosion problems discussed in Chapter 1.

3.42 The levels at which *phosphate* and *silicate* begin to contribute to corrosion are poorly understood and little experimental work has been done. The levels in Table 2 have therefore been taken from the BS EN 285 specification without modification.

3.43 The BP test for *chloride* is considered adequate to limit its corrosive effects on stainless steel.

Routine monitoring

3.44 For the reasons explained in Chapter 7, *electrical conductivity* is a convenient diagnostic tool for routine monitoring of steam quality once the system has been validated. The BP does not specify a conductivity for Sterilized WFI. While it is possible to determine a corresponding value experimentally, experience shows that the evaporative residue in steam samples is considerably lower than the BP value of 30 mg litre^{-1} and therefore a correspondingly lower conductivity would be appropriate for routine monitoring. A figure of 35 µS cm^{-1} has been adopted as a reasonable upper limit for contaminants that may be found in the steam supply. Conductivity is to be measured only during field testing of the steam supply and is not specified where samples are subject to a full laboratory analysis.

3.45 The drinking water and BS EN 285 conductivities are specified at 20° C, which is below room temperature in many sterilizer installations. A standard temperature of 25° C has been chosen for clean steam because it can normally be attained without the need for refrigeration.

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4. Clean steam in practice

Introduction

4.1 This chapter discusses the principles by which steam conforming to the clean-steam specification of Chapter 3 may be generated. It offers practical guidance on how to achieve clean-steam standards for sterilizers supplied by mains steam, sterilizers supplied by a dedicated clean-steam generator and for sterilizers (such as transportables) which generate steam from an internal reservoir.

4.2 Full costings should be obtained when the relative merits of different steam supplies are being assessed. The cost of the testing required to demonstrate that a mains steam system can consistently produce clean steam may amount to a considerable fraction of the capital cost of a dedicated clean-steam generator.

How steam is made

4.3 At first sight it may be surprising that there should be any contaminants in steam at all. Steam is generated by boiling, in which liquid water is converted into a gas. One might expect that any impurities in the water would be left behind, as in distillation, while pure steam in the form of H_2O molecules was delivered to the sterilizer.

4.4 Boiling occurs at a temperature where evaporated water vapour has sufficient pressure to displace the water immediately below the surface to form bubbles of steam. (At lower temperatures evaporation occurs only from the surface.) The bursting of bubbles from the surface of the boiling water is accompanied by the ejection of small droplets of water. *These droplets contain the same dissolved and suspended solids that are present in the water in the boiler*. They are readily entrained in the flow of steam and thus carry contaminants to the sterilizer. Even if the water droplets subsequently evaporate, the contaminants will still be present in the form of solid particles.

4.5 “Priming” is a related phenomenon where significant quantities of the boiler water can sporadically be carried over into the steam. This is often as a result of a sudden increase in the demand for steam, which reduces the pressure above the water and effectively lowers the boiling point, so increasing the violence of bubbling. A too-high level of water in the boiler can also lead to priming. Priming can be reduced by standard good operating practice, such as running the boiler at or near its maximum permissible pressure, using pressure-reducing valves where the demand causes a reduction in pressure in the distribution system, and maintaining correct water levels.

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4.6 High concentrations of impurities in the boiler water also promote carry-over. They reduce the surface tension and so increase the agitation of the water surface. They can also cause the formation of a stable foam above the water surface leading to severe carry-over. Slugs of water are intermittently discharged from the boiler along with the steam, severely prejudicing the quality of the steam.

4.7 A crucial aspect of boiler design, therefore, is to ensure the best possible separation and removal of such entrained moisture.

Summary of requirements for clean steam

4.8 From the above considerations and the discussions in Chapter 1, the requirements for generating clean steam can be summarised as follows:

a. feedwater should be as free as possible of contaminants, especially those specified for clean steam in Table 2;

b. the boiler should be designed to prevent water droplets being carried over into the steam;

c. the boiler should be operated to prevent foaming and priming;

d. the distribution system carrying steam from the boiler to the sterilizer should be resistant to corrosion.

4.9 It is apparent that a boiler system designed and operated to provide minimal carry-over of entrained water droplets will be able to maintain a low level of contaminants in the steam even where the quality of feedwater is poor. Feedwater treatment, then, may not be the decisive factor in the ability of a system to deliver clean steam. However, if the feedwater is of low quality, even small deviations from optimum operating conditions may result in large amounts of contaminants being carried over and delivered to the sterilizer. The designer of a robust clean-steam supply will therefore ensure that all the above requirements are met.

4.10 A suggested process for assessing how a clean steam supply may be achieved is illustrated in Figure 1.

Clean steam from the mains steam supply

4.11 Recent tests have shown that clean steam can be obtained from well-designed, constructed and operated conventional boilers and distribution systems of the type found in most NHS hospitals. If steam from this source is chosen, it is essential to demonstrate compliance and identify maintenance and boiler treatment regimes necessary for reproducibility.

4.12 Where a central supply does not deliver steam of acceptable standard, it is possible that the quality may be sufficiently improved by changes in operating practice and relatively minor engineering modifications. However, it is unlikely

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to be economical to embark on extensive remedial works such as the introduction of new feedwater treatment plant or the replacement of distribution pipework. It may be more cost-effective to install a dedicated clean-steam generator solely to supply sterilizers (see paragraph 4.26 onwards).

Boiler design and operation

4.13 The first step in assessing whether clean steam can be supplied from the mains is to examine the design and operation of the boiler plant.

4.14 An important consideration is the proportion of boiler feedwater that is fresh “make-up” water rather than steam condensate returned from the distribution system. In most large hospitals where steam is supplied centrally only a small fraction of the steam demand is due to sterilizers (which discharge most of their condensate to waste) and therefore the bulk of the condensate is returned to the boiler. This makes it more feasible to control the level of contaminants in the boiler. While the nature of the feedwater treatment is also of importance, the requirements for clean steam are unlikely to be achieved if the proportion of make-up feedwater exceeds 15%.

4.15 The level of total dissolved solids (TDS) in the boiler water is an important factor both in the prevention of foaming (see paragraph 4.6) and for the contaminants that may be present in the entrained water droplets. Acceptable TDS levels if clean steam is to be produced are typically below 2000 ppm. While some control of TDS concentration can be exercised by appropriate feedwater treatments, the boiler usually has a “blow-down” facility to allow accumulated sludge to be expelled from the bottom of the vessel. The water level gauge and TDS sensor element should also be blown down at regular intervals.

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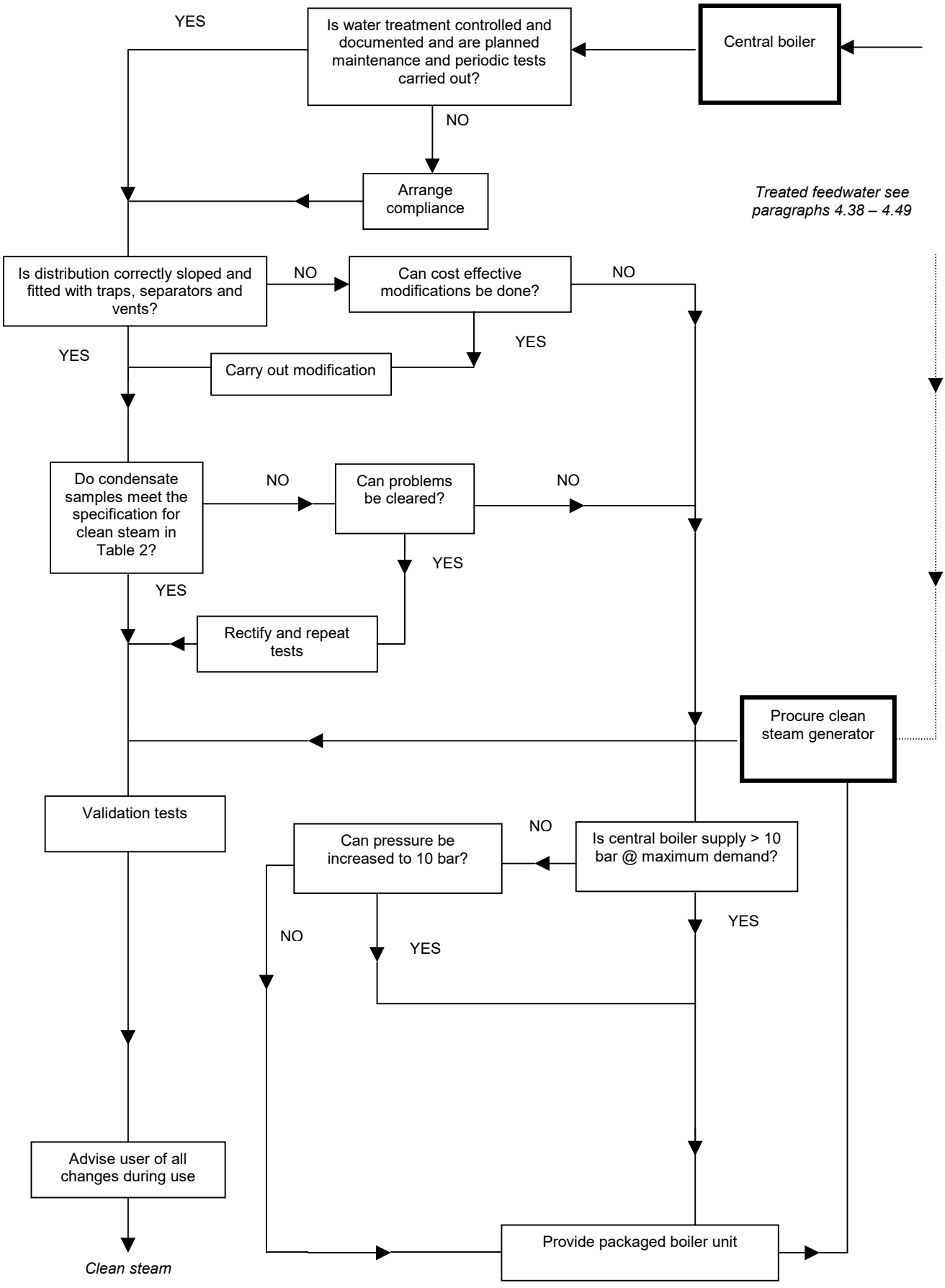
Figure 1: How to provide clean steam



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4.16 Filming amines, which are often added to feedwater to prevent corrosion of condensate return pipes, are toxic and are not acceptable for boilers supplying clean steam for sterilizers. If it is not possible for the boiler to be operated without filming amines, then another source of steam must be found.

4.17 While the boiler is unlikely to have been designed with the requirements of clean steam in mind, it should nonetheless have some means of preventing water being carried over into the steam. The chief precaution against carry-over is good practice in operating the boiler so that foaming and priming do not occur (see paragraph 4.5). Discussion with boiler-room staff will ascertain the degree to which operating procedures are successful in this regard.

4.18 Steam sampling points on the boiler, as discussed in Chapter 5, are desirable and should be installed if they are not already fitted.

4.19 As the operational management of the steam supply will normally be outside the user's control, the user will also need to assess whether the boiler-room management are aware of the principles of clean steam and whether the necessary cooperation will be forthcoming (see paragraph 4.25d). Well-trained and knowledgeable boiler personnel, and clean and tidy working conditions, are all good signs.

Distribution system

4.20 The distribution system also influences the quality of steam delivered to the sterilizer. The design of distribution systems suitable for the delivery of dry, saturated steam is considered in SHTM 2010; Part 2.

4.21 A purpose-built distribution system for clean steam would normally be constructed of stainless steel. However, when a large conventional installation has been in use for a number of months, a hard protective layer of oxide (magnetite) may have formed on the inside of the steam pipes (see paragraph 2.30). Providing the steam condensate is neutral or alkaline, this coat will remain intact and permit the use of the pipework for the distribution of clean steam. Acidic condensate in the presence of moist air, however, can break down the layer leading to corrosion which may then be shed as contaminating particles.

4.22 As a precaution, final steam filters capable of removing all particles down to 5 µm in size should be installed on all distribution systems.

4.23 It is important that the distribution system is free of dead-legs and other places where condensate may become trapped. During periods when the steam supply is off, such accumulations may become a focus of microbial growth. The trapped water may then be swept up into the steam when the supply is restored. Although the micro-organisms may be killed by the steam, pyrogens will not be inactivated at the temperature of the steam and may be delivered to the sterilizer.

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4.24 Other key points for a distribution system suitable for clean steam include:

a. correctly sized automatic air vents throughout the pipework distribution system to minimise the amount of air and other non-condensable gases delivered to the sterilizer;

b. properly sized and selected steam traps to remove condensate;

c. steam pipeline velocities kept below 25 m s^{-1} to allow steam traps to remove entrained moisture effectively and to prevent condensate being drawn out of them;

d. steam separators near the steam take-off on boiler plant prone to generating wet steam;

e. strainers to protect control valves, steam traps, etc.

Quality assurance

4.25 Where a mains steam supply is found to be capable of meeting the clean-steam specification, users should assess whether the steam quality can be maintained under all operating conditions. There are several points to consider.

a. Frequent testing of the steam at the sterilizer will be required to provide assurance that the clean-steam specification is consistently met.

b. Competing demands on the steam service from other units in the hospital may degrade the steam quality at the sterilizer.

c. Steam quality is apt to vary through the year as the boiler room responds to changing seasonal demands.

d. An otherwise effective clean steam supply may quickly deteriorate if appropriate periodic maintenance is not carried out.

e. Arrangements should be made for the user to be warned of imminent engineering modifications, maintenance and changes in steam generation, distribution and operating practice. If changes are likely to be made without the user's knowledge, the supply cannot be considered a reliable source of clean steam.

Clean steam from a clean-steam generator

4.26 A dedicated clean-steam generator, whether supplying one or several sterilizers, is the recommended solution where clean steam cannot be reliably obtained from the mains supply. Since the bulk of the condensate from sterilizers is discharged to waste and not returned to the boiler, such generators may have to run on practically 100% make-up feedwater.

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4.27 A dedicated system must therefore:

a. minimise the amount of non-condensable gases and other contaminants in the boiler feedwater;

b. prevent liquid water leaving the boiler and being delivered in the steam;

c. prevent microbial growth in any storage tank or pipework;

d. be constructed from materials resistant to corrosion and particle shedding, such as low-carbon stainless steel (type 316L).

4.28 The capacity of the generator should be sufficient to meet both maximum and minimum demands while still maintaining the requirements for dryness and non-condensable gases specified in SHTM 2010: Part 3 (see paragraph 3.10).

Moisture separation

4.29 An essential component of a clean-steam generator is a means of separating entrained water droplets from the steam before it is delivered to the sterilizer. The baffles used in some conventional boilers are not normally adequate for this purpose, but good results have been obtained on experimental machines using cyclonic separators which essentially spin-dry the steam by causing it to rotate at high speeds.

4.30 The manufacturer will have measured the efficiency of moisture removal by spiking the feedwater with high levels of endotoxin (at least 10^3 EU ml^{-1}) and testing samples of the steam for endotoxin levels by means of the LAL test (see Appendix 4). (This work should be undertaken only by personnel with appropriate training and experience.) Tests on an experimental clean-steam generator have shown that reduction factors greater than 105 can be consistently achieved.

4.31 Adequate moisture removal should be maintained over the entire range of steam demand, typically up to 200 kg h^{-1} for each sterilizer.

Heating

4.32 A single 500-litre porous-load sterilizer requires a steam generator capable of converting energy at a rate of up to 50 kW. A group of sterilizers will require a proportionately higher heating power.

4.33 Where existing sterilizers are supplied from a central boiler the ideal solution is to install a generator heated by mains steam. The steam generator is then effectively a steam-to-steam calorifier, in which the mains steam is used only to heat the feedwater and does not come into contact with the clean steam for the sterilizer. Primary steam requirements for this type of calorifier will normally be 300 kg h^{-1} for each sterilizer at a minimum pressure of 10 bar and operating on 100% condensate return. Where mains steam is not available, a small packaged boiler may be a convenient source of steam for heating, but should not itself be regarded as a source of clean steam.

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4.34 Generators may be heated by electricity, but size for size, an electrically heated generator cannot match a steam-to-steam generator for heating power. Experience shows that the pressure in the boiler cannot be maintained at a high enough level to ensure adequate removal of droplets by the cyclonic method described above. Gas-fired heating is not recommended for stainless-steel boilers.

Materials

4.35 The boiler and other parts of the generator that come into contact with feedwater or steam should be constructed of corrosion-resistant stainless steel (such as low-carbon 316L grade).

4.36 Pipework connecting the clean-steam generator to the sterilizer should be also constructed in stainless steel. Since the generator can be sited close to the sterilizer, it is a false economy to re-use existing sections of the steam supply system.

4.37 While existing sterilizers should not be harmed by a carefully-designed clean-steam system, steam-contact surfaces of iron, mild steel or copper should be avoided in new machines. In most cases this will require contact surfaces to be fabricated in stainless steel as specified in BS EN 285.

Feedwater treatment

4.38 Since there is no return of chamber condensate from the sterilizer, the quality of feedwater is crucial to the performance of a clean-steam generator. It is especially critical for those generators that operate on a straight-through principle and have no reservoir of water within the boiler.

4.39 Water drawn from the public supply may be hard, that is containing significant concentrations of the salts of the alkaline earth metals (chiefly calcium and magnesium), and may also have traces of other contaminants which need to be removed. To assess the need for water treatment, users are recommended to obtain an analysis of the mains water from the supply company. Under The Water Supply (Water Quality) (Scotland) Regulations 1990 such an analysis must be supplied to customers on request and free of charge.

4.40 Although the stated water quality may be relied on most of the time, gross contamination of water supplies may occasionally occur due to engineering works and treatment failures. Users should take adequate precautions to protect any installed equipment from damage in such circumstances.

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4.41 Full water treatment consists of three stages:

a. softening (to remove scale-forming contaminants which may harm the boiler);

b. purification (to remove other undesirable contaminants);

c. degassing (to remove corrosive and non-condensable gases).

4.42 The need for softening treatment will depend on the hardness of the local water supply. Where the water is soft it may be possible to achieve the clean steam requirements without further treatment. In such cases users should be aware that the quality of the steam will vary with the quality of the water supply, and that frequent monitoring will be required to ensure that the clean steam specification is maintained.

4.43 In hard-water areas a base-exchange softening plant will normally be required. In this process calcium and magnesium ions are exchanged for sodium ions in a zeolite column (permutite process). The columns are periodically regenerated by flushing with brine (sodium chloride). It is important that the flushing is carried out in accordance with the manufacturer's instructions to prevent chloride ions being introduced into the softened water.

4.44 Microbial growth may occur in the columns unless the equipment is correctly operated and scrupulously maintained. Although mains water should be free of micro-organisms, a recirculating system should be fitted to maintain a flow of water through the columns at times of low demand. The softened water should be monitored regularly for microbial content. Periodic sanitising of the columns may be required and in-flow filters and regular decontamination may be needed to prevent colonisation. Although the brine flushing process should destroy most micro-organisms, bacteria such as *Bacillus* species and *Staphylococcus aureus* are tolerant of high salt concentrations.

4.45 Steam generators that are highly efficient at removing water droplets may be able to attain clean-steam standards without the need for further purification of the feedwater, but this can only be determined by experiment. Until clean-steam technology has been further developed and proven, users are recommended to consider installing feedwater purification plant.

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4.46 Purification may be achieved either by reverse osmosis or deionisation. In reverse osmosis (RO), water is forced through a semi-permeable membrane which filters out contaminants to a high degree of efficiency. In deionisation (DI), ions and charged particles are removed either by electric fields or by ion exchange in resin beds. Although RO cannot normally attain the degree of purity possible with DI methods, it is more than adequate for feedwater intended for purpose-built clean-steam generators. Moreover:

a. RO is cheaper to install and to run than DI;

b. RO removes particulate matter, organic molecules and pyrogens that DI cannot;

c. RO water is less corrosive to steel and copper than DI water;

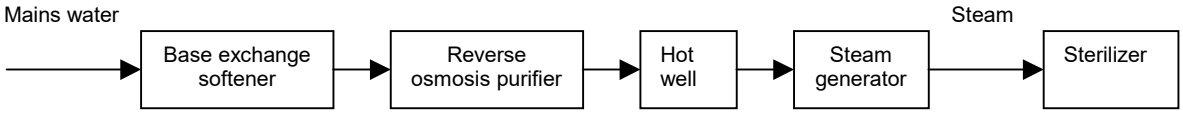
d. maintenance requirements are less demanding than for DI units.

4.47 When seeking quotations for the supply of water purification plant, the user should ensure that the manufacturer is aware of the intended use of the purified water and establish that it will not be corrosive to the materials of the clean-steam generator.

4.48 Further treatment of the feedwater to remove dissolved gases will be necessary. This is usually achieved by pre-heating the water in a “hot well” maintained at temperatures of 80–190°C (at atmospheric pressure) to drive dissolved gases out of solution. The hot well is often provided by the manufacturer of the steam generator as an integral part of the unit.

4.49 A schematic illustration of a complete water treatment system is shown in Figure 2.

Figure 2: Typical feedwater treatment for a clean steam generator



Internally generated clean steam

4.50 A large number of sterilizers in use in the NHS generate steam from a reservoir of water within the machine. Examples of such machines include:

a. transportable sterilizers (bench-top) for unwrapped instruments and utensils;

b. small EO sterilizers in which water is used to generate steam for humidification;

c. certain laboratory sterilizers with internal reservoirs.

4.51 These machines can be readily converted to clean steam, although demonstrating compliance poses severe difficulties. While it may be possible

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to modify a sterilizer so that steam samples may be taken from the chamber, the amount of steam generated in each cycle is so small that the volume of condensate obtained is insufficient for the required laboratory tests.

4.52 The problem is compounded since manufacturers have traditionally provided neither steam sampling points nor drainage valves on transportable sterilizers. Users should consider specifying such features when procuring new sterilizers. For the foreseeable future, however, assurance of clean steam conditions in the chamber must rely on good operating practice rather than the testing of samples.

Feedwater quality

4.53 The first consideration is the quality of the feedwater. Because there is normally nothing in these sterilizers to prevent entrained moisture or carried-over water reaching the load from the reservoir, the purity of the steam must be assumed to differ little from that of the water in the reservoir. If the feedwater itself complies with the clean steam specification then, provided that the sterilizer chamber and reservoir are known to be clean and free of corrosion, the steam generated from it can also be presumed to be clean. *The quality of feedwater, then, is critical to the attainment of clean-steam conditions in the chamber*.

4.54 It follows from the definition of clean steam (see paragraphs 3.24–3.45) that the feedwater for these sterilizers should meet the purity requirements of Sterilized Water for Injections BP.

4.55 The situation is complicated, however, as soon as production loads are introduced into the chamber. Most sterilizers with an internal reservoir are designed to hold sufficient water for several operating cycles. After each cycle the condensate, together with any contaminants introduced with the load items, will be drained down into the reservoir. After a few cycles the level of contaminants in the feedwater may be so high that the steam generated from it no longer meets clean-steam specifications.

4.56 The possibility of pyrogens accumulating in the reservoir is of particular concern. Some pyrogens will be washed down from load items, while others may arise from bacterial growth, especially where the sterilizer is unused for long periods between refills. Even if such bacteria are subsequently killed by the sterilization process, pyrogens will not be inactivated and will be deposited on the next load. The level of pyrogens in the steam may exceed the permitted maximum for clean steam even though Sterilized WFI was used as the original feedwater.

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A practical approach

4.57 By following good operational practice and using Sterilized WFI it is possible to meet in full the requirements for clean steam. Whilst good operational practice should also be employed in the maintenance and cleaning of the reservoir and chamber, the use of Sterilized WFI may not always be justified.

4.58 Small transportable (benchtop) steam sterilizers are used in various healthcare premises, ranging from chiropody clinics to primary care premises in which, increasingly, minor surgical procedures are performed. The procedures for which sterilized instruments from a small steam sterilizer are used, therefore, vary widely. In some circumstances, the user may decide that Sterile Water for Irrigation may be a suitable alternative to Sterilized WFI. Sterile Water for Irrigation is sterilized nonpyrogenic distilled water, intended to be used for cleaning and irrigating body surfaces, wounds and body cavities. It differs from Sterilized WFI primarily in having a higher maximum endotoxin limit (0.5EU per ml compared with 0.25EU per ml for WFI). It is readily available in 1 litre, or larger, packs and at a similar price to the retail price for distilled water.

4.59 At the end of each working day the reservoir and chamber should be drained and left dry. The contents of part-used containers of sterilized feedwater should be discarded.

4.60 Small ethylene oxide sterilizers using steam for humidification are more likely to process products for complicated procedures, and Sterilized WFI is recommended.

4.61 Similarly, laboratory sterilizers with internal reservoirs used to process products vulnerable to contamination, or sterilizers processing medicinal products with unproven closure systems, should utilise Sterilized WFI.

Good operating practice

4.62 In view of the above considerations, it is clear that the key to achieving clean steam in this type of sterilizer lies in appropriate operating procedures, adhered to rigorously.

4.63 Sterile Water for Irrigation should be used during validation tests of a new sterilizer, at the time of all periodic or revalidation tests.

4.64 The following procedure should be used during validation tests of a new sterilizer, at the time of the yearly or revalidation tests, and where a sterilizer has not previously been used to generate clean steam:

a. where practicable, examine all internal surfaces (reservoir, chamber, connecting pipework and other surfaces in contact with steam or feedwater) for signs of dirt, obstructions, scaling and corrosion; if present, consult the manufacturer for advice on cleaning and repair and remedy accordingly;

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b. rinse all internal surfaces several times with Sterile Water for Irrigation, checking that the discarded water is clear, uncoloured and free of particulates;

c. fill the reservoir with Sterile Water for Irrigation to the level recommended by the manufacturer and run an operating cycle with an empty chamber; drain the reservoir;

d. if the sterilizer is to be used immediately, refill the reservoir with Sterile Water for Irrigation to the level recommended by the manufacturer; otherwise rinse all internal surfaces twice with Sterile Water for Irrigation and leave dry.

4.65 In routine operation the following procedures should be observed:

a. ensure that all load items are scrupulously clean and dry before being placed in the chamber;

b. when the reservoir is to be replenished, drain the contents, rinse all internal surfaces twice with distilled water and once with Sterile Water for Irrigation; refill the reservoir with Sterile Water for Irrigation to the level recommended by the manufacturer;

c. at the end of the working day, or whenever the sterilizer is to be unused for several hours, drain the reservoir, rinse all internal surfaces once with distilled water and once with Sterile Water for Irrigation and leave dry;

d. when the sterilizer is to be used again, rinse all internal surfaces once with Sterile Water for Irrigation and refill the reservoir with Sterile Water for Irrigation to the level recommended by the manufacturer.

4.66 A guiding principle is that water is not allowed to remain standing in the reservoir for more than a few hours. If water has inadvertently been allowed to stand for a long period, or is suspected to have become contaminated, drain the reservoir and repeat the rinsing procedure in paragraph 4.64b.

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5. Testing for compliance

Introduction

5.1 This chapter discusses the testing regimes necessary for the initial validation of a clean-steam supply and for subsequent periodic testing. Methods for taking samples are given in Chapter 6 and their analysis is discussed in Chapter 7.

Where to take samples

5.2 For a thorough assessment of the quality of the steam supply, samples of water and steam should ideally be taken throughout the steam-generating and distribution system from incoming water to steam at the sterilizer, though such extensive sampling will rarely be needed in practice. Examples of points at which water and steam samples may be taken include:

a. *mains water*; which after suitable treatment will be used as feedwater to the boiler;

b. *treated water*; which may include one or more distinct treatment stages. Samples should be taken from the inlet and outlet pipes as close as possible to the treatment plant. To monitor the various stages of water treatment samples should be taken after each stage.

c. *feedwater*; the water admitted to the boiler from the hot well, but without any dosing treatments admitted simultaneously or separately to the boiler;

d. *boiler water*; the water in the boiler prior to blow-down;

e. *boiler steam*; the steam leaving the boiler;

f. *steam for use in sterilizer*; the steam delivered to the sterilizer, sampled at the steam service pipe.

5.3 The sampling points should be chosen so that the samples obtained will allow, when required, the identification and quantification of significant changes which may occur in contamination levels at each stage in the process. For example, sampling before and after a base-exchange water softener may reveal an increase in bacterial endotoxin levels from a contaminated ion-exchange column. A full set of sampling points at strategic locations will allow such problems to be investigated with a minimum of disruption, even though most of them will rarely be used in routine operation. Guidance on the design and use of sampling points is given in Chapter 6.

5.4 The design and construction of the system will determine how many sampling points would be of value. For a mains system supplying a large hospital, all the above points may be desirable. For a sterilizer with an adjacent, dedicated

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clean-steam generator supplied from a simple treatment plant, fewer would be needed.

Validation and periodic testing

5.5 Validation tests should normally be carried out on the following occasions:

a. on initial validation of the steam-raising and distribution plant;

b. on initial validation of the sterilizers served by the steam plant, if not the same occasion;

c. on yearly testing or revalidation of the sterilizers;

d. where there is operational evidence that the steam quality may have deteriorated;

e. after any significant modification of the steam plant or its operation which might adversely affect the quality of the steam.

5.6 Periodic tests should be carried out on quarterly testing of the sterilizers.

5.7 As a minimum, samples for validation should always include both the feedwater and the steam for use in the sterilizer. Testing the steam without testing the water from which it is raised can lead to a false sense of security. For example, high levels of pyrogens in the feedwater will not necessarily produce contamination in the steam when the boiler is operating under loads which do not induce carry-over or priming. But during normal operation this could occur and therefore the contamination in the feedwater would require urgent investigation and remedial action.

5.8 Once a clean-steam supply has been validated, periodic testing of steam quality will be necessary for assurance that the clean-steam specification continues to be met. Quarterly testing of electrical conductivity is recommended here (see paragraphs A4.39–A4.48), but the frequency will depend upon the particular application and the consistency of control established from historical data. Other tests may be desirable if one or more of the possible contaminants is critical for the process or product.

Mains steam supply

5.9 Formal validation should be carried out once the user is satisfied that the chosen system is capable of supplying clean steam and boiler operating procedures have been established. Much exploratory testing may be required before this point is reached.

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Validation test

5.10 The user should consult boiler room records to establish how the demand on the boiler varies through a typical working day (in a large hospital sterilizers themselves are likely to contribute only a small fraction of this load). The object is to ensure that times of highest and lowest demand can be reliably identified so that representative steam samples can be taken.

5.11 Because of the large amount of steam contained within a mains distribution system, it may take several minutes for steam produced in the boiler to arrive at the sterilizer. The quality of the steam at the sterilizer, then, may not be representative of the quality at the boiler. In particular, the steam in the pipes may have been generated under more favourable conditions at a time of less extreme demand and therefore be of higher quality, so invalidating the tests. On the other hand, steam that has been standing in the pipes is more likely to have received contamination from the distribution system. For these reasons users should take care to ensure that the steam sample was indeed generated when the boiler was operating at the presumed demand. This may require the pipework feeding the plant room manifold to be flushed with fresh steam immediately before samples are taken. In practice the samples should be satisfactory if the boiler demand has been steady for several minutes and remains steady while the flushing takes place and the samples are taken.

5.12 Two samples each of both feedwater and steam at the sterilizer should then be taken:

a. at a time of highest demand;

b. at a time of lowest demand.

5.13 Samples should consist of:

a. a full set of duplicate samples for laboratory analysis as described in paragraphs 6.18–6.25;

b. a field sample as described in paragraphs 6.8–6.17.

5.14 Where more than one sterilizer is supplied from the same steam manifold, the steam samples should be taken at the sterilizer furthest downstream from the boiler. It is not necessary to sample the steam at each sterilizer.

5.15 Samples should be subject to a full laboratory analysis as described in Chapter 7. The field sample should be tested for electrical conductivity on site as described in Appendix 4.

5.16 If the steam samples do not conform, the feedwater analysis should be examined to determine whether the failure could be remedied by a simple adjustment of the treatment regime. If not, further samples may need to be taken at other points in paragraph 5.2 to establish where the problems are arising.

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5.17 When validation has been completed successfully, the mains supply may be used as a source of clean steam for sterilization. Users, however, should proceed with caution until sufficient experience has been gained to build confidence in the system. During the first year of clean-steam operation, the validation tests should be repeated at intervals chosen to coincide with the peak variations in seasonal demand. Such additional tests will provide further assurance that the system is capable of meeting the clean-steam specification under all normal operating conditions. If any tests fail during this period corrective action should be taken and the tests repeated.

Periodic tests

5.18 Periodic testing of the steam supply (testing of feedwater is unnecessary) should be carried out quarterly to coincide with the quarterly tests scheduled for the sterilizer. The test should consist of a conductivity measurement of a field sample (see Appendix 4). Provided that the conductivity value remains below the limit established during validation, the steam supply may be regarded as continuing to meet the clean-steam requirements. Failure of the periodic test requires further investigation, however, normally by a full laboratory analysis of both feedwater and steam.

5.19 Revalidation should be carried out once a year, to coincide with the yearly testing of the sterilizer.

Dedicated clean-steam generator

5.20 A dedicated clean-steam generator supplying one or more sterilizers does not suffer competing demands from other equipment and is more likely to be within the user's control. Consistency of steam quality can therefore be demonstrated more readily than for a mains steam supply.

Validation test

5.21 Validation can normally be carried out as soon as the contractor has installed the equipment and completed his own installation tests.

5.22 The user should first establish the conditions under which the steam generator will be subject to the highest and lowest demand. Depending on the design of the steam plant, it is possible for either to constitute the worst-case conditions for carry-over of moisture. For example, a large plant designed to supply several sterilizers and relying on a cyclonic separator for removal of entrained water droplets may be inefficient at the lower velocities generated by a single sterilizer on light load. The other extreme requires the generator to operate at the lowest pressure and at the highest demand rate which would be expected under normal use.

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5.23 The highest demand on the boiler usually occurs when all sterilizers are operating simultaneously. However the period of peak demand is brief (steam admission into the chamber) and it is difficult to synchronise the operating cycles so that the peaks coincide for long enough to allow a sample to be taken.

5.24 An alternative method is to vent steam from the relief valve on the plant room manifold. Users should first ensure that the steam will be discharged to a safe position outside the building (see SHTM 2010: Part 2 for guidance). By its very nature, the relief valve is designed to limit pressure in the system under all conditions and therefore creates a demand on the boiler that is greater than the maximum demand of the sterilizers. If steam samples collected under these conditions comply with clean-steam specification then the User can be confident that the generator will cope with the demand of the sterilizers. If not, then the generator may still comply if loaded at the lesser demand of the sterilizers. Further testing will be required.

5.25 A third possibility is to install a discharge valve on the steam manifold designed to simulate the peak demand of all sterilizers operating at the same time.

5.26 Lowest demand in normal operation typically occurs when a single sterilizer is on stand-by, with steam only being used to heat the jacket. However, since that steam will not come into contact with load items, its quality is not critical and it matters little whether it is clean or not. It may be better to regard the lowest demand as occurring during the holding time of a single sterilizer.

5.27 Unlike the mains systems discussed in paragraph 5.10, the amount of steam contained within the distribution system will be small, the steam produced in the boiler will arrive at the sterilizer almost instantly, and the steam sample collected can be assumed to be representative of that created in the boiler.

5.28 Two samples each of both feedwater and steam at the sterilizer should then be taken:

a. under conditions of highest demand;

b. under conditions of lowest demand.

5.29 Samples should consist of:

a. a full set of duplicate samples for laboratory analysis as described in paragraphs 6.18–6.25;

b. a field sample as described in paragraphs 6.8–6.17.

5.30 Where more than one sterilizer is supplied from the same steam generator, the steam samples should be taken at the sterilizer furthest downstream. It is not necessary to sample the steam at each sterilizer.

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5.31 Samples should be subject to a full laboratory analysis as described in Chapter 7. The field sample should be tested for electrical conductivity on site as described in Appendix 4.

Periodic tests

5.32 Periodic testing of the steam supply (testing of feedwater is unnecessary) should be carried out quarterly to coincide with the quarterly tests scheduled for the sterilizer. The test should consist of a conductivity measurement of a field sample (see Appendix 4). Provided that the conductivity value remains below the limit established during validation, the steam supply may be regarded as continuing to meet the clean-steam requirements. Failure of the periodic test requires further investigation, however, normally followed by a full laboratory analysis of both feedwater and steam.

5.33 Revalidation should be carried out once a year, to coincide with the yearly testing of the sterilizer.

Internally generated clean steam

5.34 As explained in paragraph 4.50, transportable sterilizers pose problems in demonstrating compliance with clean steam due to the difficulty of obtaining adequate steam samples. For this reason, no validation or periodic tests are specified for these sterilizers.

5.35 Users should follow the good practice guidance given in paragraphs 4.63−4.67. In particular, the cleaning and rinsing procedure described in paragraph 4.65 should be carried out on validation, revalidation and yearly testing of the sterilizer.

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6. Sampling

Introduction

6.1 This chapter discusses methods for taking water and steam samples for both field and laboratory analysis.

6.2 Field samples will normally be taken and analysed by the Test Person in the course of testing the sterilizer. Laboratory samples may be taken either by personnel from the receiving laboratory or by the Test Person if qualified to do so.

Sampling points

6.3 As discussed in Chapter 5, sampling is required in each part of the system where the composition of the water or steam may need to be confirmed, or where changes in composition may need to be determined. Sampling points should be designed and constructed to ensure that:

a. the sample taken is as nearly as possible representative of the water or steam being sampled in that section of the system;

b. the sample can be taken without contaminating it;

c. the sample can be taken safely.

6.4 When possible, samples should be taken from flowing rather than static parts of the system. For example, for sampling a tank the samples are best taken from the inflow or outflow pipes but not from the static reservoir in the tank.

6.5 Where boiler water is to be sampled the position of the sampling point must be chosen with care. The composition of water at various locations in the boiler may show considerable variation. For boilers with forced circulation the sampling point is best located on the discharge side of the pump.

6.6 It is good practice to install coolers to ensure that representative samples of the boiler water may be taken safely.

6.7 Guidance on the design and construction of sampling points is given in BS 6068: Section 6.7.

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Sampling for field analysis

6.8 This method is suitable for taking steam and water samples to be tested for electrical conductivity during periodic tests. It should not be used for samples intended for laboratory analysis.

Apparatus

6.9 Figure 3 shows the apparatus connected to a pitot tube identical to the one specified for the steam quality tests in SHTM 2010: Part 3. The pitot is fitted to the steam supply pipe near the sterilizer. This standard pitot is not suitable for the system for laboratory samples described below (see paragraph 6.18) so Figure 4 shows an alternative pitot which may be used for all steam testing. If this pitot is used for field samples or the tests in SHTM 2010: Part 3, the ball valve, nipple and socket should be removed.

6.10 Steam is led through a length of polypropylene tubing and is condensed as it passes through a bath of cold or iced water.

6.11 This apparatus is suitable for use for samples which are to be analysed immediately, such as for periodic tests for electrical conductivity. It is not suitable for samples intended for more sensitive analysis in the laboratory since the polypropylene is contra-indicated for several of the determinands of interest. It is also unsuitable where samples are to be taken for pyrogen testing since the polypropylene tubing cannot withstand the extended exposure to high temperatures needed to ensure that all components of the sampling system are free from pyrogens (see paragraph 6.22).

Method

6.12 Clean the polypropylene sample bottle and the polypropylene tube with dilute hydrochloric acid and rinse several times with distilled water. Detergents should not be used. Leave them to dry.

6.13 If the pitot is not already fitted, isolate the steam supply and vent the pipe of pressure. Fit the pitot tube into the pipe and secure the polypropylene tube to it with a clip.

6.14 Restore the steam supply and allow steam to vent through the polypropylene tube for at least 5 minutes to restore the steam service to its stable operating temperature. Ensure that the condensate drains freely. Close the steam valve.

6.15 Coil part of the polypropylene tube into sufficient number of coils to ensure condensation of steam, place it in the 8-litre container and retain it in place. Fill the container with enough cold water (ice may be added if required) to immerse the coils.

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6.16 Open the steam valve. The steam will condense in the coils and condensate will emerge from the end of the tube. Allow the first 50 ml of condensate to discharge to waste and then collect approximately 250 ml in the sample bottle.

6.17 Seal and label the bottle. The electrical conductivity should be measured promptly as described in Appendix 4.

Sampling for laboratory analysis

6.18 This method is suitable for taking all required samples, including those to be subjected to full laboratory analysis including the test for pyrogens.

Apparatus

6.19 The apparatus is shown in Figure 5. All components, including the condenser and valves, are constructed in stainless steel. The tubing is made in short sections which are connected by compression joints to form the required length and configuration. The sections are short enough to allow each element to be thoroughly cleaned, sterilized and depyrogenated before use.

6.20 The standard pitot used with the field sampling apparatus described above is not designed to take compression fittings and so cannot be used with this apparatus. It should be replaced with the modified pitot and ball valve shown in Figure 4.

6.21 The apparatus is suitable for taking samples for all the determinands of interest. It may be used for steam condensate or water samples throughout the steam-raising system. In theory there is a risk of some contamination of the sample from metals which could be extracted from the stainless steel. However the grade of steel chosen is no more reactive than those used in the construction of steam pipes and equipment. If, for whatever reason, the steam reacts with the sampling apparatus it will also have reacted with the installed system.

Method

6.22 All the stainless steel components should be depyrogenated by processing in a dry-heat sterilizer at a sterilization temperature of 180°C for 3 hours. If a suitable oven is available they may alternatively be baked at 250°C for 30 minutes (dry-heat sterilizers cannot attain this temperature).

6.23 Clean and prepare sample bottles according to the instructions from the receiving laboratory. Normally, two sets will be used for steam samples and one for control samples. Ensure that the bottles are labelled as described in paragraph 6.36.

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Figure 3: Steam sampling system for field analysis

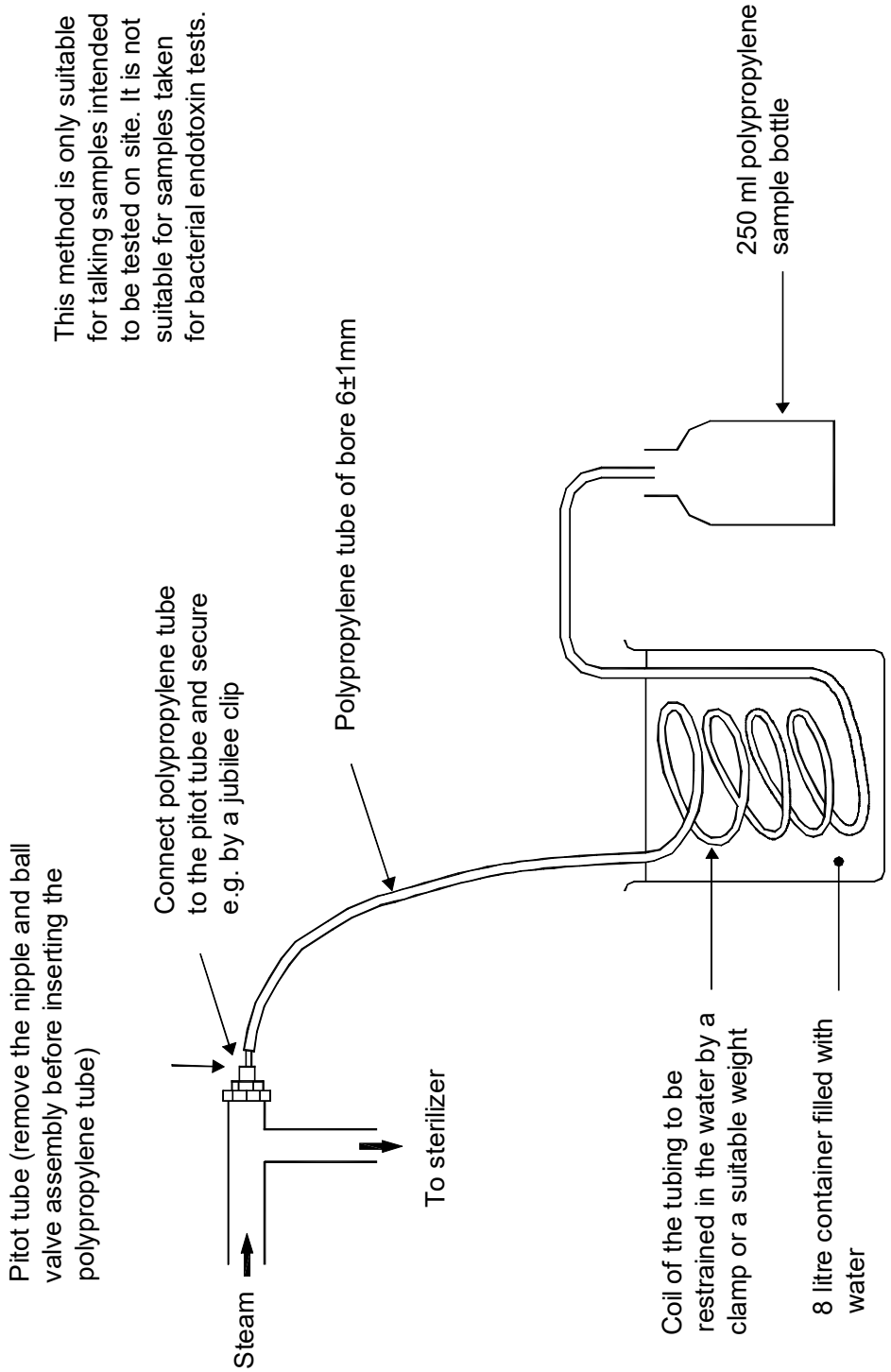

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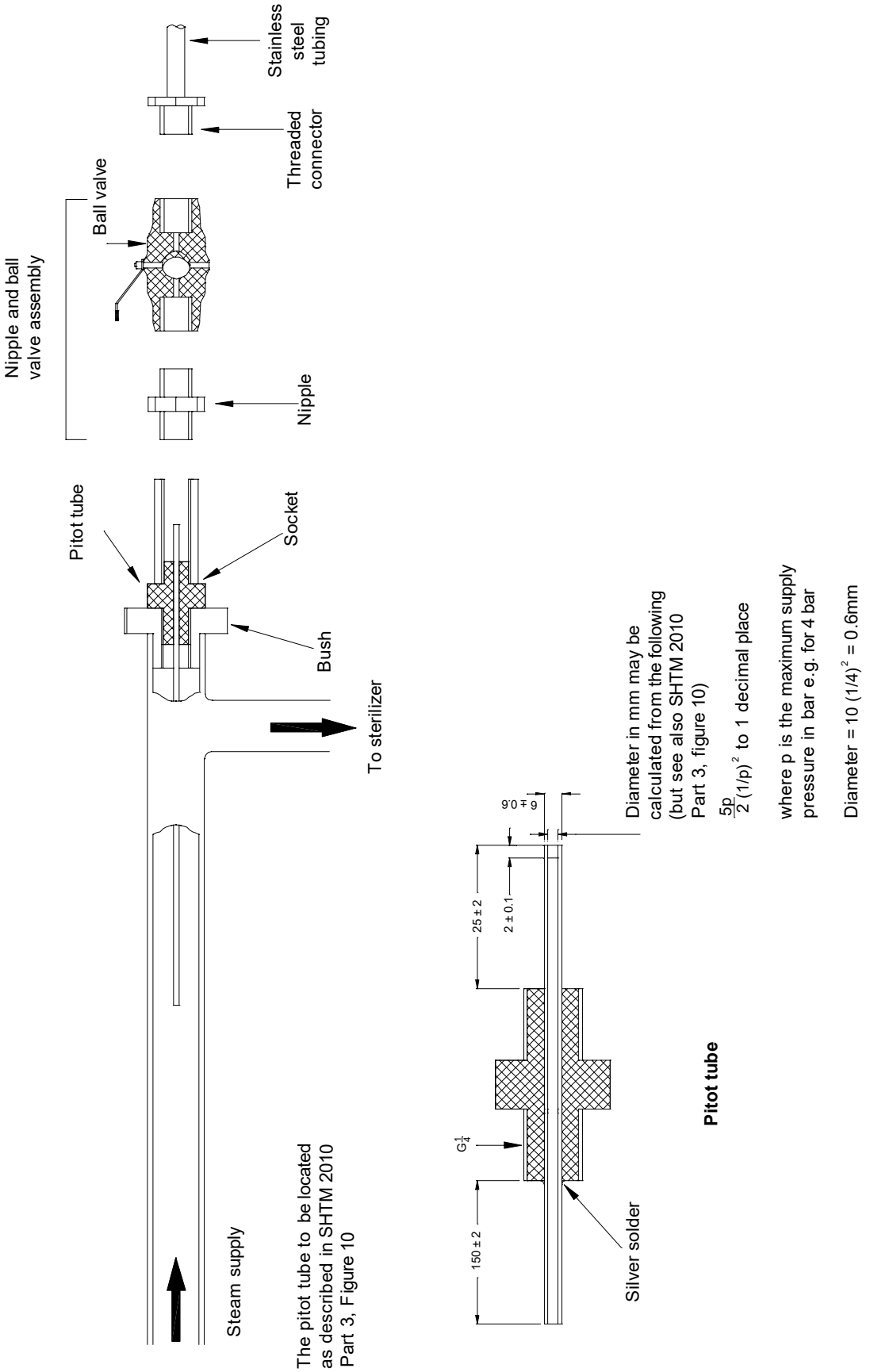
Figure 4: Typical pitot sampling tube assembly



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6.24 Open the valve on the pitot. The steam will condense in the coil and condensate will emerge from the end of the tube. Allow the first 50 ml of condensate to discharge to waste and then collect samples in the first two sets of bottles.

6.25 The third set of bottles should be filled with distilled water of known quality, which should be preserved and analysed in the same manner as the two sets of steam samples. These negative control samples provide evidence that the choice of container, cleaning system and preservative is appropriate.

Handling of samples for laboratory analysis

6.26 As soon as a steam or water sample is taken, it is important that its physical, chemical and biological properties remain stable until it arrives at the laboratory for analysis. The conditions in which the sample should be kept are determined by the contaminants for which the water is to be tested. The material of the sample container is also important since it may interact with substances in the water; plastic is suitable for some parameters, glass for others.

6.27 General guidance on these points is given below; more specific advice may be found in BS EN ISO 5667-3 and BS 6068-6.3. The laboratory carrying out the analysis will normally provide all the necessary containers, preservatives and labels with full instructions for their use.

Containers

6.28 There is no one material suitable for all contaminants of interest. Containers may be made variously from polyethylene, polystyrene, polypropylene, glass or borosilicate glass. The receiving laboratory should supply the appropriate containers with full instructions for their use.

6.29 Each type of container requires a different cleaning procedure to ensure that samples are not contaminated by residues. Again, the instructions of the receiving laboratory should be followed.

6.30 Observe the laboratory's instructions on filling and closing the bottles. Most bottles should be filled to the brim and then stoppered or capped to ensure that as little air as possible remains above the sample. A small air space should be left above samples to be frozen.

Sample preservation

6.31 The purpose of preservation is to transfer the sample to the laboratory in a manner which, as far as may be practicable, maintains the concentration and state of the contaminant of interest unchanged from the moment the sample was taken.

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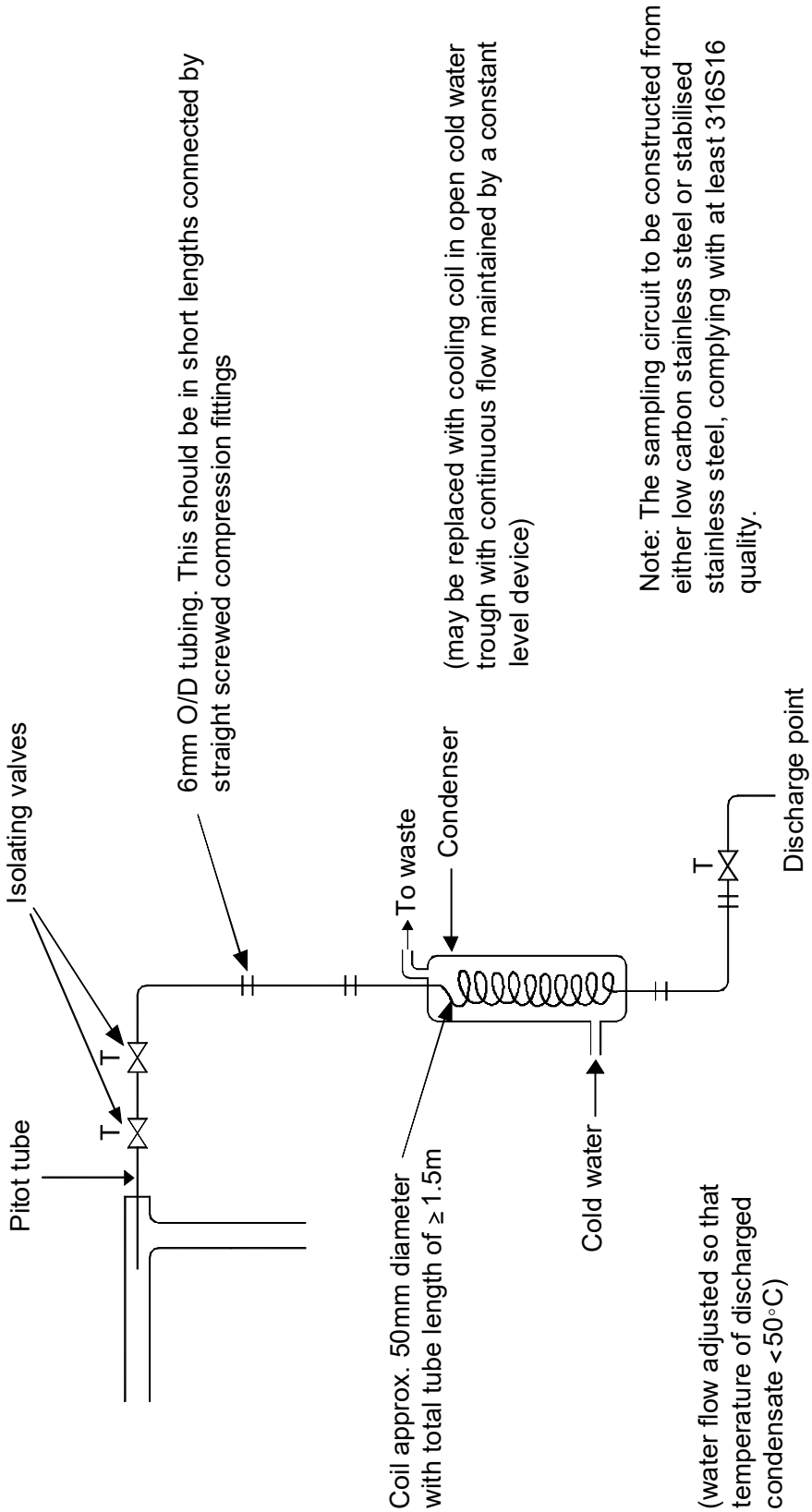
Figure 5: Steam sampling system for laboratory analysis



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6.32 There are many possible interactions which can occur that will adversely affect the sample. The contaminant of interest may:

a. polymerise or, if already a polymer, depolymerise;

b. react with other constituents of the sample;

c. react with atmospheric oxygen or carbon dioxide becoming dissolved in the sample;

d. be consumed, modified or be produced in higher concentrations by micro-organisms growing in the sample;

e. react with, or be adsorbed or absorbed by, the material of which the container is constructed.

6.33 The extent to which these and other reactions will modify the sample is a function of several factors. The sample itself, and the extent and nature of any contaminants present, will determine which reactions and changes may occur. The more contaminated a sample is the more likely it is that changes will occur. The temperature during transport and storage, the exposure to light, the material of which the container is made and any special precautions used in the preparation of the container, and the elapsed time before analysis will all have a significant effect.

6.34 While it is desirable for all samples to be cooled (normally at 2−5°C) some will require the addition of an acid preservative and others will need to be frozen. The receiving laboratory will specify the preservative treatment for each container and supply suitable reagents where necessary.

6.35 Few preservative treatments for the contaminants specified for clean steam are valid for more than 24 hours and some for a much shorter time. Prompt despatch and analysis are therefore essential.

Identification of samples

6.36 Each container must be legibly and unambiguously labelled with a water-resistant label at the time of sampling. The laboratory will supply suitable labels and instructions. The information to be noted will normally include:

a. the establishment at which the sample was taken;

b. the date and time at which the sample was taken;

c. the name of the person taking the sample;

d. clear identification of hazardous materials present (e.g. acids used as a preservative);

and either

e. a reference number, which unambiguously relates to contemporaneous notes of the following information;

or

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f. the sampling point;

g. the nature of the sample (e.g. condensed steam);

h the determinand(s) for which the sample is to be analysed;

i. any preservative treatment;

j. notes on any observations pertinent to the analysis, such as an event not in accordance with the sampling procedure which may affect the analysis.

Packaging and transport

6.37 The samples should be packaged securely in containers providing suitable protection from breakage or external contamination during transport. The containers should be kept as cool as possible during transport. For transporting small quantities of samples, domestic cool boxes provide suitable protection and cooling.

6.38 The transport container should be accompanied by a list of the samples being sent, and a duplicate retained. The list should be sufficiently comprehensive to allow confirmation of the identity of each sample in the consignment.

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7. Analysis of samples

Introduction

7.1 This chapter discusses the means by which a sample of steam condensate may be analysed for compliance with the clean-steam specification. The tests are equally suitable for testing samples of steam or water from elsewhere in the steam supply system, provided the limitations of the pharmacopoeial tests are understood (see paragraph 3.35).

7.2 The methods of collecting samples are discussed in Chapter 6.

Testing of samples

7.3 The quality of a water sample cannot be assessed merely by visual inspection. To determine whether a steam sample conforms with the requirements for clean steam it is necessary to carry out tests for all the determinands listed in Table 2.

7.4 Appendix 4 describes all the tests, with the exception of phosphate and silicate (see paragraph 7.23) required to analyse a sample for compliance. These tests are taken from the British Pharmacopoeia and should be well within the capacity of any hospital pharmacy. Although they do not require expensive analytical equipment, they are intended to be used by trained personnel in a properly equipped laboratory and are not suitable for on-site determinations under field conditions.

7.5 Laboratories invited to carry out these tests should be accredited to a recognised standard.

7.6 The field test for electrical conductivity is also described in Appendix 4. Note that it is required to be preceded by the BP test for acidity or alkalinity, which may also be carried out in the field.

Reporting of results

7.7 The report obtained from the laboratory in respect of each test should contain the following information:

a. the exact identity of the water sample;

b. the date and time the sample was received;

c. the date and time at which the test was commenced;

d. the storage conditions if (b) and (c) are not the same date;

e. the determinand for which the sample was analysed;

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f. for non-quantitative tests, a statement as to whether the result complies with specification;

g. for quantitative tests:

(i) the numerical value expressed in the unit specified (see paragraph 7.11) for each of the duplicate determinations;

(ii). the mean of the results of the duplicate determinations and the uncertainty which may be associated with the final result;

h. a description of any sample pre-treatment;

i. a description of the method used, including reference to specific items of equipment, calibration standards, etc;

j. any deviations from the method or other facts which might reasonably be expected to influence the result obtained; and should be signed both by the analyst responsible for carrying out the determinations and the analyst or quality controller responsible for checking the report.

Alternative methods

7.8 Where numerical values are given in Table 2, laboratories may offer alternatives to the BP tests of equivalent or greater accuracy and sensitivity if these are methods which they routinely use. (Users should note that such methods will generally be more expensive than the BP tests.) Experienced analysts with appropriately equipped laboratories may favour the use of one of the many instrumental analytical techniques available. Instrumental methods which provide the same or better precision than the BP tests are suitable. See paragraph 7.23 for guidance on phosphate and silicate.

7.9 For any given determinand there will usually be several methods which are suitable and cover the range of concentrations of interest. The choice of method will be determined by a number of factors including availability of equipment, previous experience with the method, cost, sensitivity to interfering substances which may be present in the sample, etc. Significance should be given to:

a. the limit of detection, which must be lower than the specified limit for the contaminant;

b. the accuracy of the method, which will be of particular importance in observing changes in quality;

c. the likely presence of interfering substances in the samples to be tested.

7.10 For further guidance see *General principles of sampling waters and associated materials*, 2nd edition, in the series, *Methods for the examination of waters and associated materials*.

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Comments on the tests

7.11 Since there are several ways in which numerical results from any given analysis may be presented, the user should specify that the results are quoted in the units used in the clean-steam specification in Table 2 so that the sample can readily be compared with the specification.

7.12 The following sections give background information on interpreting the results of some of the clean-steam tests and explains the relationships between them.

Concentrations; residue on evaporation

7.13 The levels of some of the impurities in Table 2 are expressed as mass concentrations in units of milligrams per litre (mg $litre^{-1}$). An alternative unit seen occasionally is milligrams per kilogram (mg kg^{-1}) which is identical to parts per million by mass (ppm). Since one litre of pure water has a mass of almost exactly one kilogram, these units may be taken to be numerically equivalent for steam condensate. Hence:

1 mg $litre^{-1}$ = 1 mg kg^{-1} = 1 ppm = 0.0001% by mass.

7.14 Alternatively, concentrations may be expressed in moles or millimoles per litre (mol $litre^{-1}$, mmol $litre^{-1}$), where one mole is equal to Avogadro's number of entities (atoms, molecules or ions). A concentration of one mole per litre is known as a "molar" (M) solution. To convert to a mass concentration, the relative molecular mass (RMM, formerly known as "molecular weight") of the entity is required. Thus:

(Mass concentration / mg $litre^{-1}$) = (RMM / g mol^{-1}) × (molar concentration/mmol $litre^{-1}$).

7.15 It is important to understand precisely what the reported concentration represents, since the same units are often used in different ways to express the results of the same analytical procedure. For example in the determination of phosphate the results may be reported as mg $litre^{-1}$ of P, P_2O_5 , or PO_4 (see paragraph 7.24). Although the three values will be different, they represent the same experimental result.

7.16 The sum of the concentrations of individual ionic species must always be less than the concentration of total dissolved solids (measured as residue on evaporation). Unfortunately the BP tests are not sufficiently quantitative to allow this check to be made. However, the residue figure should be consistent with the electrical conductivity as described in paragraph 7.28 onwards.

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Acidity and alkalinity

7.17 The test for WFI in Bulk corresponds approximately to a pH in the range 4.2 to 7.0. Since a pH of 7.0 represents a neutral solution, the test requires the sample to be acidic. This is unacceptable for steam condensate, since acidic conditions promote corrosion of materials. For this reason the clean-steam specification adopts Sterilized WFI as a purity standard; the acidity-alkalinity test then corresponds to a much more acceptable pH in the approximate range 6.8 to 8.4.

Heavy metals

7.18 In the BP test for heavy metals the sample is concentrated by a factor of 10 by evaporation and then calibrated against a standard solution containing 1 mg litre^{-1} of lead ions. The test fails if the sample contains a sufficient concentration of heavy metals to produce a more intense brown colour than the standard solution subjected to the same test. The colour is not easy to discern and so the test should be carried out in conditions of good controlled lighting.

7.19 In normal circumstances the test will react to metals which form acid-insoluble sulphides, but the BP gives no indication of which metals will be detected. Table 4 shows the result of experimental work to determine the sensitivity of the test to various metals (Healthcare Science Ltd 1996). This shows that only lead, copper and silver can be detected at the 0.1 mg litre^{-1} limit, mercury must be present at 1.5 mg litre^{-1} before it is detected. Cadmium and zinc give a pale yellow colour (but not brown) at 0.6 mg litre^{-1} and zinc gives a pale white opalescence at 1.2 mg litre^{-1}. The test is insensitive to antimony, iron, nickel, cobalt, manganese and tin.

Table 4: Sensitivity of the BP test for heavy metals.

Metal	Concentration in sample (mg litre^{-1})
Lead	0.1
Copper	0.1
Silver	0.1
Bismuth	0.6
Mercury	1.5

The table gives the concentration of each metal that will cause the same reaction as 0.1 mg litre^{-1} of lead.

7.20 It is therefore not possible to express the 0.1 mg litre^{-1} figure as an equivalent sum of concentrations of individual metals. For this reason the test cannot be replaced by more precise quantitative tests for individual elements.

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Pyrogens

7.21 In the BP test for pyrogens, the water sample is incubated with a reagent known as LAL (Limulus amoebocyte lysate) derived from the horseshoe crab, *Limulus polyphemus*. If a clot forms, the amount of endotoxin in the sample may be estimated from the known sensitivity of the lysate. The limit of detection is 0.03 EU ml^{-1}.

7.22 The test should not be confused with the alternative “test for pyrogens”, also described in the BP, which is carried out on live rabbits.

Phosphate and silicate

7.23 These contaminants differ from the others in that they are not listed in the pharmacopoeial specification for Water for Injections. Consequently there are no simple BP tests that can be used to demonstrate compliance. A suitable analytical method for phosphate may be found in BS EN 1189 and BS 6068-2.28 (ammonium molybdate spectroscopic method) and for phosphate and silicate in *Phosphorous and silicon in waters, effluents and sludges* 1992 in the series *Methods for the examination of waters and associated materials*.

7.24 Conversion factors for different expressions of phosphate are as follows:

1.00 mg $litre^{-1}$ P = 3.07 mg $litre^{-1}$ PO_4 = 4.58 mg $litre^{-1}$ P_2O_5.

Electrical conductivity

7.25 Pure water, which contains no ions except H^+ and OH^- (formed by the dissociation of H_2O) is a poor conductor of electricity. Any dissolved ionic species will raise the conductivity of the water sample. Measurement of the conductivity therefore provides a simple means of measuring the concentration of ionic species. That is why conductivity is so useful in monitoring steam quality.

7.26 The SI unit of conductance (reciprocal of resistance) is the *siemens* (S) which has the same dimensions and magnitude as the older unit, the *mho* (or reciprocal ohm). The SI unit of conductivity is the *siemens per metre* (S m^{-1}) but the practical unit for aqueous solutions (and the unit used in this SHTM) is the *microsiemens per centimetre* (µS cm^{-1}). This gives a numerical value of conductivity which is the same order of magnitude as the concentration of dissolved ionic species expressed in milligrams per litre.

1 mS m^{-1} = 10 µS cm^{-1}.

7.27 A number of factors affect the measurement of conductivity. These include:

a. the ionic species present (the particular ions, and the extent to which they become hydrated);

b. polarisation; gases produced at the surface of the electrodes will increase the electrical resistance and rapidly reduce the current to near zero. This

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can be avoided by the use of an alternating voltage which prevents the build-up of gases at the electrodes;

c. temperature; for which the relationship with conductivity is non-linear. Temperature compensation is therefore essential.

7.28 When a water sample contains predominantly ionisable solids in solution, and the composition of the various constituents is reasonably constant, the conductivity is proportional to the concentration of total dissolved solids (TDS) for concentrations up to 10 000 mg litre^{-1}. A measured conductivity is multiplied by a suitable conversion factor to give an estimate of the TDS in mg litre^{-1}. The conversion factor can be derived experimentally for waters of consistent ionic composition by making direct comparison of the measured mass of total dissolved solids and the electrical conductivity. It should be emphasised that TDS values estimated this way are not as reliable as direct measurements by gravimetric methods and reported as *residue on evaporation.*

7.29 Conductivity meters calibrated directly in TDS mg litre^{-1} are available, but readings should be not be taken at face value. The conversion factor being used must be established and shown to be appropriate.

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Appendix 1: Useful addresses

Scotland

Property and Environment Forum Executive,
4th Floor, St Andrew House, 141 West Nile Street, Glasgow G1 2RN
Tel: 0141 548 3446
Fax: 0141 553 4109

Scottish Centre for Infection and Environmental Health,
Clifton House, Clifton Place, Glasgow G3 7LN
Tel: 0141 300 1100
Fax: 0141 300 1170

Scottish Healthcare Supplies,
Trinity Park House, South Trinity Road, Edinburgh EH5
Tel: 0131 552 6255
Fax: 0131 552 6535

Health and Safety Executive (East),
Belford House, 59 Belford Road, Edinburgh EH4 3UE
Tel: 0131 247 2000
Fax: 0131 247 2121

Health and Safety Executive (West),
375 West George Street, Glasgow
Tel: 0141 275 3000
Fax: 0141 275 3100
Health and Safety Executive Information Line Tel: 0870 154 5500

UK health agencies

NHS Estates,
1 Trevelyan Square, Boar Lane, Leeds LS1 6AE
Tel: 0113 254 7000

Medicines Control Agency,
Market Towers,
1 Nine Elms Lane, London SW8 5NQ
Tel: 0171 273 3000

Medical Devices Agency,
Hannibal House,
Elephant and Castle, London SE1 6TQ
Tel: 0171 972 8000
Internet address: mda_mail@mda.win-uk.net

Public Health Laboratory Service,
Central Public Health Laboratory,
61 Colindale Avenue, London NW9 5HT
Tel: 0181 200 4400

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Other organisations

Institute of Healthcare Engineering and Estate Management,
2 Abingdon House, Cumberland Business Centre, Northumberland Road,
Portsmouth PO5 1DS
Tel: (02392) 823186

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Appendix 2: Operation and maintenance of clean-steam generators

Introduction

A2.1 Clean-steam generators are steam boilers and are subject to the Pressure Systems Safety Regulations 2000.

A2.2 Users should ensure that operation and maintenance of the generator is carried out correctly, both to ensure safety and also to maintain the quality of the steam.

A2.3 Steam generators are subject to a written scheme of examination for pressure vessels.

A2.4 Guidance on the design, maintenance, testing and operation of steam generators may be found in HSE Guidance Note PM 5*, Automatically controlled steam and hot water boilers*.

A2.5 The advice of the boiler manufacturer about water supply, water treatment, blowing down and other operational practices should be strictly observed.

A2.6 Failure to provide adequate supervision, with consequential inadequate control of water quality and insufficient blow-down, has resulted in such severe corrosion of steam generators that in some cases internal parts have collapsed and operators have been put in danger.

Operation

A2.7 A risk assessment should be undertaken to establish the level of supervision required. While it is not acceptable for steam generators to be left continuously unattended, it is not necessary for an operator to be present at all times. The amount and frequency of attention necessary in each case will depend largely on the nature of the water supply, water treatment arrangements and the intensity of use. The operator, who may also be the sterilizer operator, should be adequately trained.

Maintenance

A2.8 Because there is little condensate return to these steam generators, their feedwater is usually almost 100% make-up, and as a result the concentrations of dissolved and suspended solids in the boiler water quickly build up to very high levels. Such boilers are provided with a “blow-down” facility to expel

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deposits of sludge from the bottom of the boiler. It is essential that an effective blow-down regime is established and adhered to. There are three possibilities:

a. continuous blow-down - sludge is expelled continuously;

b. automatic intermittent blow-down - sludge is expelled automatically under the control of a conductivity device;

c. manual intermittent blow-down - sludge is expelled manually under the control of the operator.

A2.9 With manual blow-down there is a risk of affecting the steam quality if this is undertaken at a time when there is a high demand for steam. For this reason manual blow-down should be undertaken at times of light load, preferably when none of the sterilizers are operating. Continuous and automatic blow-down systems need to be carefully managed to ensure they do not affect steam quality.

A2.10 Guidance on blow-down may be found in HSE Guidance Note PM 60, *Steam boiler blow-down systems* (PM 60).

A2.11 Generator vessels constructed from stainless steel will be subject to the same risk of stress corrosion cracking encountered in stainless steel sterilizer chambers (see SHTM 2010: Part 4) To minimise the risk, the manufacturer's guidance on feedwater quality should be followed.

A2.12 A record of all tests and maintenance should be kept in the machine's plant history file.

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Appendix 3: Pyrogens

Bacterial endotoxins

A3.1 Bacterial endotoxins are a group of compounds, derived predominantly from Gram-negative bacteria, which give rise to high temperatures and fever-like reactions when injected into man and other mammals. This febrile reaction is referred to as *pyrexia* and compounds which can cause this reaction when injected are known as *pyrogens*. Bacterial endotoxins are not the only pyrogenic compounds but they are by far the most common and are also of the greatest significance in sterile product manufacture.

A3.2 The majority of bacterial endotoxins causing a pyrogenic reaction are lipo-polysaccharides (LPS) from the outer membrane of Gram-negative bacteria. They consist of a lipid A molecule with long polysaccharide side chains. The toxicity resides in the lipid portion of the molecule. The lipid moiety is hydrophobic and on its own would be insoluble in water but it is rendered soluble by the polysaccharide side chains. (The polysaccharide side chains are the molecules in the bacterial membrane which provide the surface antigens used to characterize individual strains of bacteria.)

A3.3 Organisms other than Gram-negative bacteria may give rise to endotoxins. For example fragments of the cell wall peptidoglycan from β haemolytic *Streptococci* produce a similar pyrogenic reaction.

A3.4 The relative molecular mass (RMM) of the LPS is typically in the range 3 000 –25 000 daltons. However, there is usually significant aggregation of endotoxin molecules in aqueous media; a number of molecules group together with the hydrophobic lipid moieties to the centre and the polysaccharide side chains to the outside. This effective increase in the size of the endotoxin explains why ultrafilters with cut-offs within the range 20 000–100 000 daltons can be used to effect almost complete removal of bacterial endotoxins from solution.

A3.5 Bacterial endotoxins are extremely heat-stable and are only destroyed after prolonged exposure to high temperatures (3 hours at 180°C or 30 minutes at 250°C). They are not destroyed by any of the sterilization processes commonly employed for medical devices and medicinal products.

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Clinical significance

A3.6 In small doses the injection of endotoxins causes pyrexia (fever), transient leukopenia followed by leukocytosis, hyperglycaemia, haemorrhagic necrosis of certain tumours, abortion, altered resistance to bacterial infection, various circulatory disturbances and vascular hyperreactivity to adrenergic drugs. When injected in larger amounts, endotoxins cause shock, usually accompanied by severe diarrhoea; absorption of endotoxin from the bowel is a major cause of terminal irreversibility in haemorrhagic shock.

A3.7 Endotoxins appear to cause pyrexia, not directly but through an endogenous pyrogen released from polymorphonuclear leukocytes.

A3.8 Endotoxins are generally assumed to play a large role in the vascular, metabolic, pyrogenic and haematalogic alterations which occur in severe Gram-negative infections but the evidence is indirect since, unlike most bacterial exotoxins, no specific protective antibody is available.

A3.9 Subcutaneous injection of microgram quantities of endotoxins produces a mild inflammatory reaction but, when the injection is repeated with the same or a different endotoxin 24 hours later, the originally injected site becomes haemorrhagic within a few hours. This reaction (the Shwartzman reaction) is accentuated by the presence of cortisone. A similar programme of injections given intravenously to rabbits causes bilateral cortical necrosis of the kidneys and death.

A3.10 Many sterile medical devices are intended for use on wounds where the dermis may have been breached. The sterile product may thus come into direct contact with the vascular system and if endotoxins are present may cause a pyrogenic reaction.

Detection and measurement

A3.11 The classic method of detection of pyrogens in pharmaceutical products is by measurement of the temperature rise in rabbits to which the substance has been administered. This method does not readily permit assay of the amount of endotoxin present. However it is sensitive to all pyrogenic substances, whether or not they are bacterial endotoxins.

A3.12 In-vitro assay, which depends on the gelation of extracts of lysed blood cells of the horseshoe crab *Limulus polyphemus*, can be used quantitatively and will detect picogram quantities of lipopolysaccharide (endotoxin) in the so-called LAL test (Limulus amoebocyte lysate). A modification of the LAL test to provide a chromogenic test has been made, which allows reading of the endotoxin concentration by spectrophotometry. A turbidimetric method, which requires dedicated capital equipment, is also available as a quantitative method. Sensitivities as low as 0.001 EU ml^{-1} are available.

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A3.13 There is considerable variability in endotoxins derived from different bacterial species and it is difficult to set limits of permissible amount in terms of mass per unit volume. The US Food and Drugs Administration devised a unit of potency, the *endotoxin unit* (EU), to overcome this problem. The units are related to the endotoxin derived from *Escherichia coli* assigned by comparison with a USP reference endotoxin. The 1st International Standard for Endotoxin, established in 1986, consists of lyophilised endotoxin from *E. coli* 0113:H10:K(-)ve with trehalose (normally supplied in ampoules containing 14 000 EU). This, or another suitable preparation (such as the European Pharmacopoeia Biological Reference Preparation) the activity of which has been determined in relation to the International Standard using a gelation method, permits standardisation of the sensitivity of the lysate.

Generation of bacterial endotoxin

A3.14 Endotoxins arise, almost without exception, from the cell wall of Gram-negative bacteria. This is present both on the surface of the living bacteria and as persistent fragments of dead bacteria. As previously noted the endotoxins are thermally very stable.

A3.15 Gram-negative bacteria include a wide range of organisms, for example:

a. the sheathed bacteria e.g. *Sphaerotilus spp* which are large rods in a mucilagenous sheath found anchored to the substrate in running water (also called sewage fungus);

b. some 17 genera of budding or stalked bacteria such as *Caulobacter*;

c. the aerobic rods and cocci which include:

   Pseudomonas spp, which are ubiquitous;
   Xanthomonas spp, common plant pathogens;
   Halobacterium spp, which live in saturated brine;
   Brucella spp, etc;

d. the facultative anaerobes:

   Escherichia, indicator of faecal contamination;
   Salmonella, Shigella, intestinal pathogens;
   Erwinia, plant pathogen;
   Enterobacter, Serratia, Proteus, soil and aquatic;
   Vibrio, commonly marine aquatic;

e. the obligate anaerobes of the family *Bacteroidaceae*, *Bacteroides*, *Fusobacterium*.

A3.16 These, or any other Gram-negative species, will inevitably give rise to endotoxins. However there are other organisms, such as β haemolytic *Streptococci*, where the cell wall peptidoglycan produces the same reaction as endotoxins from Gram-negative bacteria.

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A3.17 The quantity of endotoxin produced per cell varies from about 4 femtograms (fg) in bacteria growing in very pure water to as much as 16 fg for those grown under nutrient-rich conditions. For *E. coli*, 0.03 EU ml^{-1} corresponds to approximately 0.003 ng per ml of endotoxin. Allowing that each cell produces approximately 6 fg of endotoxin then 500 bacteria per ml would give rise to 0.03 EU ml^{-1}.

A3.18 None of the sterilization processes used routinely for the preparation of pharmaceuticals, medical devices or surgical instruments will destroy or remove endotoxins once they are present. The only method of control therefore is to prevent the growth of significant numbers of Gram-negative bacteria within the product or in any component or material which directly comes into contact with it.

A3.19 Gram-positive bacteria, with the exceptions noted above, do not produce endotoxins. The Gram-positive bacteria include organisms such as the family *Micrococcaceae*, which contains the genera *Staphylococcus* and *Micrococcus*, and the spore formers of the genera *Bacillus* and *Clostridium*. It is among these organisms that those species most resistant to radiation and thermal sterilization are found.

Regulatory requirements

A3.20 Pharmacopoeial specifications for water include several different grades of which the two principal grades are Purified Water and Water for Injections (WFI).

A3.21 In the European Pharmacopoeia (EP) WFI is required to be prepared from potable water or purified water “by distillation in an apparatus of which the parts in contact with the water are of neutral glass, quartz or suitable metal and which is fitted with an effective device to prevent the entrainment of droplets. The apparatus must produce water free from pyrogens and to ensure this correct maintenance is essential. The first portion of the distillate obtained when the apparatus begins to function is discarded.”

A3.22 The United States Pharmacopoeia (USP), however, permits the use of reverse osmosis for the preparation of WFI. In all other respects the limits set, and the test to determine compliance, are essentially similar.

A3.23 USP XXII suggests an aerobic viable count limit of 500 cfu/ml for potable water and 100 cfu/ml for purified water (although normal practice would be not to accept >50 cfu/ml for purified water).

A3.24 WFI (both USP and EP) is required to be free from pyrogens and there is a specified limit for bacterial endotoxins of < 0.25 EU ml^{-1}.

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A3.25 Where a product, such as a wound irrigation solution, is required under the terms of the product licence to be “non-pyrogenic” the endotoxin standard for WFI would apply even though the product is not actually for parenteral administration.

Requirements for clean steam

A3.26 The requirement for parenterally administered medicinal products to be free from pyrogens is immediately apparent. It is not always recognised, however, that a similar requirement exists for medical devices or that the steam sterilization process can be a source of pyrogen contamination.

A3.27 In the sterilization of solid goods (as opposed to aqueous fluids) steam in the sterilizer chamber condenses on the surface of the goods. This condensation process is necessary to heat the goods to the required temperature and provide the moist conditions necessary for rapid sterilization. At the end of the sterilization stage the condensate is evaporated from the load by reducing the pressure in the sterilizer chamber (drying vacuum) to produce a cooler, dry load.

A3.28 Bacterial endotoxin carried in the steam supply will be deposited with the condensate and tends to become concentrated on the surface of the goods when the condensate is evaporated off during the vacuum drying stage. In consequence, items intended for use in invasive procedures, or for use in the preparation or administration of parenteral products, should be sterilized in a sterilizer which is supplied with “pyrogen-free” steam.

A3.29 For practical purposes steam for use in sterilizers may be regarded as pyrogen-free when a condensed, representative, sample meets the European Pharmacopoeial standard for Water for Injections, i.e. less than 0.25 EU ml^{-1}.

A3.30 Two factors are of greatest importance in ensuring that the steam supply is pyrogen free:

a. the quality of the feedwater to the steam raising plant, high levels of pyrogens or high bacterial counts in the feedwater will ensure that limited carry-over of water as droplets in the steam will make a significant contribution to the pyrogen level;

b. the performance of the steam raising plant, in particular that its design, construction and mode of operation ensure that there is the minimum carry-over of entrained droplets of water.

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Summary

A3.31 The following key points summarise the topics discussed above:

a. most pyrogens are bacterial endotoxins;

b. endotoxins are lipopolysaccharides formed by the cell wall of Gram-negative bacteria;

c. endotoxins are very stable molecules and are not destroyed by normal sterilization processes;

d. 90% of the bacteria growing in purified waters are Gram-negatives;

e. pyrogen testing was traditionally done by administering the substance to rabbits and observing whether there is a temperature rise;

f. endotoxin testing may be done *in-vitro* using the Limulus Amoebocyte Lysate (LAL) test;

g. the endotoxin limit for WFI (EP) is < 0.25 EU ml^{-1};

h. endotoxins are also of significance for medical devices, surgical equipment and equipment used to prepare parenteral medicinal products;

i. if the steam when condensed is within the endotoxin limit for WFI (EP) it may be regarded as “pyrogen-free”;

j. control of pyrogens in the steam is achieved by appropriate control of the boiler and its feedwater.

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Appendix 4: Tests for clean steam

Introduction

A4.1 This appendix contains procedures for the testing of steam condensate samples for compliance with the clean-steam specification of Chapter 3. The tests for chemical purity and the test for bacterial endotoxins are derived from the tests for Water for Injections in the British Pharmacopoeia. A procedure for the field measurement of electrical conductivity is also given.

Laboratory tests for chemical purity

A4.2 The tests in this section are extracted from the British Pharmacopoeia 1993. They are essentially identical to corresponding tests in the European Pharmacopoeia. The tests should be conducted only by suitably trained persons familiar with pharmacopoeial custom and practice.

A4.3 The following tests are for Sterilized Water for Injections.

Acidity or alkalinity

A4.4 To 20 ml add 0.05 ml of *phenol red solution*. If the solution is yellow, it becomes red on the addition of 0.1 ml of 0.01 M *sodium hydroxide VS*; if red, it becomes yellow on the addition of 0.15 ml of 0.01 M *hydrochloric acid VS*.

NOTE: The method given in the 1993 edition of the BP is incorrect and is amended in the BP Addendum 1995.

Ammonium (0.2 ppm)

A4.5 To 20 ml add 1 ml of *alkaline potassium tetraiodomercurate solution* and allow to stand for 5 minutes. When viewed vertically the solution is not more intensely coloured than a solution prepared at the same time by adding 1 ml of *alkaline potassium tetraiodomercurate solution* to a mixture of 4 ml of ammonium standard solution (1 ppm NH_4) and 16 ml of *ammonia-free water* (0.2 ppm).

Calcium and magnesium

A4.6 To 100 ml add 2 ml of *ammonia buffer pH* 10.0, 50 mg of *mordant black 11 triturate* and 0.5 ml of 0.01 M *disodium edetate*. A pure blue colour is produced.

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Heavy metals (0.1 ppm)

A4.7 In a glass evaporating dish evaporate 150 ml to 15 ml on a water bath. 12 ml of the resulting solution complies with *limit test A for heavy metals*. *Use lead standard solution (1 ppm Pb*) to prepare the standard (0.1 ppm).

A4.8 Limit test A for heavy metals: To 12 ml of the prescribed aqueous solution add 2 ml of *acetate buffer pH 3.5*, mix, add 1.2 ml of *thioacetamide reagent*, mix immediately and allow to stand for 2 minutes. Any brown colour produced is not more intense than that obtained by treating in the same manner a mixture of 10 ml of either *lead standard solution (1 ppm Pb*) or *lead standard solution (2 ppm Pb*), as prescribed, and 2 ml of the solution being examined. The standard solution exhibits a slightly brown colour when compared to a solution prepared by treating in the same manner a mixture of 10 ml of water and 2 ml of the solution being examined.

Chloride (0.5 ppm)

A4.9 When the nominal volume of the final container is 100 ml or less, 15 ml complies with the *limit test for chlorides (0.5 ppm).* Use a mixture of 1.5 ml of *chloride standard solution (5 ppm Cl)* and 13.5 ml of water to prepare the standard. Examine the solutions down the vertical axes of the tubes.

A4.10 Limit test for chlorides: To a solution of the specified quantity of the substance being examined in 15 ml of *water* or to 15 ml of the prescribed solution add 1 ml of 2 M nitric acid, pour the mixture as a single addition into 1 ml of *silver nitrate solution R2* and allow to stand for 5 minutes protected from light. When viewed transversely against a black background any opalescence produced is not more intense than that obtained by treating a mixture of 10 ml of *chloride standard solution (5 ppm Cl)* and 5 ml of water in the same manner.

Nitrate (0.2 ppm)

Sulphate

A4.12 To 10 ml add 0.1 ml of 2 M hydrochloric acid and 0.1 ml of *barium chloride solution R1*. The solution shows no change in appearance for at least 1 hour.

A4.11 To 5 ml in a test tube immersed in ice add 0.4 ml of a 10% w/v solution of *potassium chloride*, 0.1 ml of *diphenylamine solution* and, dropwise with shaking, 5 ml of *sulphuric acid*. Transfer the tube to a water-bath at 50°C and allow to stand for 15 minutes. Any blue colour in the solution is not more intense than that in a solution prepared at the same time and in the same manner using a mixture of 4.5 ml of *nitrate-free water* and 0.5 ml of *nitrate standard solution* (2 ppm NO_3) (0.2 ppm).

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Oxidisable substances

A4.13 Boil 100 ml with 10 ml of 1 M *sulphuric acid*, add 0.2 ml of 0.02 M *potassium permanganate* and boil for 5 minutes. The solution remains faintly pink.

Residue on evaporation (30 ppm)

A4.14 Evaporate 100 ml to dryness on a water bath and dry the residue to constant weight at 100°C to 105°C. For containers with a nominal volume of 10 ml or less, the residue weighs not more than 4 mg (0.004%) and for containers with a nominal volume greater than 10 ml, the residue weighs not more than 3 mg (0.003%).

Laboratory test for pyrogens

A4.15 The following text is based on the bacterial endotoxin test from the British Pharmacopoeia 1993. Additional information pertinent to the analysis of steam condensate samples is given in notes.

A4.16 The test for bacterial endotoxins (LAL test) uses a lysate of amoebocytes from the horseshoe crab, *Limulus polyphemus*. The addition of a solution containing endotoxins to a solution of the lysate produces turbidity, precipitation or gelation of the mixture. The rate of reaction depends on the concentration of endotoxin, the pH and the temperature. The reaction requires the presence of certain bivalent cations, a proclotting enzyme system and clottable protein; these are provided by the lysate.

A4.17 The limit for a given material or preparation is expressed as the maximum allowable endotoxin concentration (MAEC) in endotoxin units per millilitre (EU ml^{-1}) for a defined solution of that material or preparation.

NOTE: The maximum allowable concentration for clean steam condensate is 0.25 EU ml^{-1}.

A4.18 Before carrying out the test for endotoxins on the sample, it is necessary to verify:

a. that the equipment used does not absorb endotoxins;

b. the sensitivity of the lysate; and

c. the absence of interfering factors.

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NOTE: New borosilicate glass test tubes have a relatively high affinity for endotoxin in aqueous solution and may give rise to artificially low readings if used to make dilutions of endotoxin. Strict adherence to the reagent manufacturer's recommendations for choice and preparation of test equipment is necessary.

A4.19 Carry out the test in a manner that avoids microbial contamination. If necessary, treat equipment to eliminate endotoxins.

Reagents

A4.20 **Limulus amoebocyte lysate**. A lysate of amoebocytes from the horseshoe crab, *Limulus polyphemus*. Reconstitute the lysate as stated on the label. For each batch, confirm the stated sensitivity as prescribed under Sensitivity of the lysate. The sensitivity of the lysate is defined as the lowest concentration of endotoxin that yields a firm gel in the test conditions and is expressed in EU ml^{-1}.

NOTE: The LAL reagent is selected for the required sensitivity to endotoxin. 0.125 EU ml^{-1} is used to test for compliance with a maximum allowable endotoxin concentration of 0.25 EU ml^{-1}. The various commercially available LAL reagents differ in product compatibility, inhibition endpoints and buffer capacity. There may also be lot-to-lot variation within supplies from any one manufacturer.

A4.21 **Water BET**. Water that gives a negative result in the conditions prescribed in the test for bacterial endotoxins on the preparation being examined. It may be prepared by distilling water three times in an apparatus fitted with an effective device to prevent the entrainment of droplets or by other means that give water of the requisite quality.

A4.22 **0.1 M hydrochloric acid BET**. 0.1 M *hydrochloric acid* that has been prepared using *water BET*. After adjustment to pH 6.5 to 7.5 with 0.1 M *sodium hydroxide BET* it gives a negative result in the conditions of the test.

NOTE: The reconstituted lysate may be subdivided into suitable aliquots and frozen and stored at -20°C or below for up to 3 months. Frozen lysate should only be thawed once.

A4.23 **0.1 M sodium hydroxide BET**. 0.1 M *sodium hydroxide* that has been prepared using *water BET*. After adjustment to pH 6.5 to 7.5 with 0.1 M *hydrochloric acid BET* it gives a negative result in the conditions of the test.

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Standard preparation

A4.24 The Standard Preparation is the 1st International Standard for Endotoxin, established in 1986, consisting of freeze-dried endotoxin from Escherichia coli 0113:H10:K(-ve) with trehalose (supplied in ampoules containing 14 000 EU), or another suitable preparation the activity of which has been determined in relation to the International Standard using a gelation method. (For this purpose the European Pharmacopoeia Biological Reference Preparation is recommended.)

NOTE: Reconstitute the Standard Preparation according to the manufacturer's instructions. Mix by repeated vortexing and prepare working standards by serial dilution using *water BET* and pyrogen-free dilution tubes.

Procedure

A4.25 Unless otherwise prescribed, prepare the solutions and dilutions used in the test using *water BET*.

NOTE: Lyophilised endotoxin has a threshold limit value of 5 EU kg^{-1} h^{-1}. Over-exposure may result in fever, nausea and shock. Avoid inhalation of the powder and injection of the reconstituted solution.

A4.26 If necessary, adjust the solution being examined to pH of 6.5 to 7.5 using 0.1 M *hydrochloric acid BET*, 0.1 M *sodium hydroxide BET* or a suitable buffer.

NOTE: The "solution being examined" may be the sample, dilutions of the Standard Preparation, control solutions, as appropriate.

A4.27 Add a volume of the lysate appropriate to the chosen receptacle (for example a slide or tube) to each of the requisite number of such receptacles maintained at 36°C to 38°C.

NOTE: Reaction tubes are recommended. The volume of lysate added should be 0.1 ml.

A4.28 At intervals that will permit the examination of each receptacle and the recording of each result, add to each receptacle an equal volume of the solution being examined and immediately mix gently with the lysate.

A4.29 Incubate the reaction mixture, without vibration and avoiding loss of water by evaporation, for a constant period that has been found suitable in the chosen experimental conditions (usually 20 to 60 minutes), examine the receptacle and record the result.

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NOTE: Vibration during the incubation period can prevent stable gel formation. An unstirred water bath should be used since vibration from the motor in a stirred bath may interfere with the reaction. The tube should be incubated for 1 hour.

A4.30 A positive result is indicated by the formation of a firm gel that does not disintegrate when the receptacle is gently inverted. A result is negative if such a gel is not formed.

NOTE: Turbidity can be confused with initial stages of gelation. It is essential that all apparent gel formation is verified by demonstrating a stable gel on inversion through 180°.

Sensitivity of the lysate

A4.31 Prepare not fewer than four replicate series each of not fewer than three dilutions of the Standard Preparation such that at least the final dilution in each series gives a negative result. Examine the dilutions, and a negative control solution consisting of *water BET*, as described under *Procedure*. Calculate the average of the logarithm of the lowest concentration of endotoxin in each series of dilutions for which a positive result is found. The antilogarithm of this average gives the estimated lysate sensitivity. The estimated lysate sensitivity is confirmed if it does not differ by more than a factor of 2 from the stated sensitivity. The estimated sensitivity is then used in all tests performed using this lysate.

Interfering factors

A4.32 Operate as prescribed under *Sensitivity of the lysate* but to prepare the dilutions of the Standard Preparation use the sample at the maximum valid dilution calculated from the expression:

$$\frac{\textit{Maximum allowable entoxin concentration}}{\textit{Sensitivity of the lysate}}$$

both values being expressed in EU ml^{-1}.

A4.33 If the sensitivity of the lysate determined in the presence of the sample does not differ by more than a factor of 2 from that determined in the absence of the sample, the latter does not contain factors that interfere in the experimental conditions and it may be examined without further treatment.

A4.34 If the sensitivity of the lysate determined in the presence of the sample differs by more than a factor of 2 from that determined in the absence of the sample, the sample acts as an inhibitor or an activator. The interfering factors must be eliminated by suitable treatment such as dilution, filtration, neutralisation, dialysis or addition of substances that displace absorbed endotoxins. The use

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of a more sensitive lysate permits the use of a greater dilution of the sample and this contributes to the elimination of interference.

A4.35 Ultrafiltration may be used when the interfering factor passes through a filter with a nominal separation limit corresponding to a molecular weight of 10 000 to 20 000. Asymmetrical membrane filters of cellulose triacetate or polysulphone have been found to be suitable. The material retained on the filter, which contains the endotoxins, is rinsed with *water BET* or a suitable buffer and endotoxins are recovered in *water BET* or a suitable buffer. The test volume and the final volume used to recover the endotoxins are determined for each preparation being examined.

A4.36 Establish that the chosen method effectively eliminates interference without removing endotoxins by repeating the test for interfering factors using the sample to which the Standard Preparation has been added and which is has then been submitted to the chosen treatment.

Test for bacterial endotoxin in the sample

A4.37 Carry out the method described under *Procedure* in duplicate using the maximum valid dilution of the sample which has been treated if necessary to eliminate interfering factors. Examine at the same time a negative control consisting of *water BET* and two positive controls each of which contains the Standard Preparation at a concentration corresponding to twice the stated sensitivity of the lysate and one which contains the sample (treated if necessary to eliminate interfering factors after the addition of the Standard Preparation) at the concentration being used in the test. The test is not valid unless the negative and both positive controls give the appropriate results.

Interpretation of results

A4.38 The sample complies with the test if a negative result is found for both test mixtures. The sample does not comply with the test if a positive result is found for both test mixtures. If a positive result is found for one test mixture and a negative result for the other, repeat the test; the sample complies with the test if a negative result is found for both test mixtures.

NOTE: For a given batch of lysate of calibrated sensitivity λ EU ml^{-1}, a positive result will indicate the presence of endotoxin within the range 0.5 λ to 2 λ EU ml^{-1}.

Field test for electrical conductivity

A4.39 The only test of steam condensate or feedwater that can be reliably carried out on site is a test for electrical conductivity. Guidance on the interpretation of conductivity measurements is given in Chapter 7.

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A4.40 A portable conductivity meter is required, accurate to 1% over a range which includes 1.0 to 30 µS cm^{-1} with a resolution of 0.1 µS cm^{-1}. It should be temperature-compensated over the range 0°C to 40°C, so that it gives readings standardised to 25°C. The instrument should be designed to measure the conductivity of very pure water.

A4.41 Commercially available meters usually have temperature compensation set at 2% per °C either as standard or as a default value. The compensation effect is often user-adjustable over the range 0-5% per °C, but unless there are unusual local circumstances (such as a particularly ubiquitous contaminant) the temperature compensation value should be set at 2% per °C.

A4.42 Several standard conductivity reference solutions are also required, preferably with conductivities which bracket the expected value. A range of such standards, including pure water standards (also known as absolute water) is available commercially, standardised at 25°C and traceable to national standard reference materials. The standards should be allowed to equilibrate to room temperature in the area in which the tests will be conducted.

A4.43 Carry out the BP test for acidity or alkalinity (see paragraph A4.4). If the sample is fresh condensate, there is no need to boil the sample as described in the test. If the sample complies with the test, then it may be tested for conductivity.

A4.44 Wash the meter probe with Purified Water BP or with the sample water. Measure the conductivity of the standards. Use the results to calibrate the meter in accordance with the manufacturer's instructions.

A4.45 Measure the temperature of the sample. For effective temperature compensation, this test is best carried out with both sample and standards near a temperature of 25°C. If the sample is hotter, allow it to cool until the temperature is approximately 25°C.

A4.46 Wash the meter probe either with Purified Water BP or with the sample water. Measure the conductivity of the sample.

A4.47 The test should be considered satisfactory if the measured conductivity:

a. does not exceed the value specified for clean steam in Table 2;

b. is consistent within experimental errors with the value measured during validation.

A4.48 If the conductivity has risen substantially from the value determined during validation, the cause should be identified and corrected.

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Glossary

The following terms have been used in this SHTM. Chapter or paragraph references to where more information may be found are given in brackets. Cross-references are shown in bold.

bacterial endotoxins
A group of compounds derived predominantly from **Gram-negative** bacteria, which give rise to high temperatures and fever-like reactions when injected into mammals. Also known as **pyrogens** (Appendix 3).

blow-down
The process of removing sludge from a boiler by using the internal pressure to expel it from a valve in the bottom of the vessel (4.15, A2.8).

carry-over
The delivery of substantial quantities of liquid water in steam due to **priming** or **foaming** (4.5).

clean steam
Steam whose **condensate** meets the purity requirements of **Water for Injections BP** with additional limits for phosphate and silicate (3.24).

clean-steam generator
A boiler designed to produce **clean steam** (4.26).

condensate
Water formed by the condensation of steam.

Conductivity
A measure of the ability of a material to pass an electric current. Reciprocal of resistivity (7.25).

cyclonic separator
A device forming part of a **clean-steam generator** that removes entrained water droplets from steam by causing the steam to rotate at high speed (4.29).

degassing
A pre-heating treatment of boiler **feedwater** to reduce the amount of **non-condensable** gases in the steam supply (4.48).

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deionisation (DI)
A water purification process in which ions and other electrically charged particles are removed from solution either by the influence of an electric field or by ion exchange columns (4.46).

dryness value
A dimensionless quantity, approximating to the dryness fraction, derived to determine whether steam is of the correct dryness for sterilization purposes. A dryness value of 1.0 represents saturated steam (3.10).

BS EN 285 steam
Steam whose **condensate** meets the recommended purity requirements for steam contained in BS EN 285 (3.20).

endogenous infection
Infection due to re-activation of organisms in a dormant focus.

endotoxin unit (EU)
A measure of the potency of **bacterial endotoxins** in relation to those derived from E. coli (A3.13).

feedwater
Water that is to be used for the generation of steam.

foaming
The production of a head of foam within a boiler, often due to a raised level of **total dissolved solids**, which is drawn off with the steam so leading to a wet and contaminated steam supply (4.6).

Gram-negative
A class of bacteria that do not take Gram's stain and which are also sources of **bacterial endotoxins (pyrogens)** (A3.14).

hot well
A tank in which **feedwater** is maintained at a high temperature to drive off dissolved gases before it is admitted to a boiler (4.48).

make-up water
Freshly treated water often mixed with returned steam **condensate** to make feedwater for a boiler.

medical device
Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be

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assisted in its function by such means (source: EU Council Directive 93/42/EEC) (3.6).

medicinal product
Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions in human beings or in animals is likewise considered a medicinal product (source: EU Council Directive 65/65/EEC) (3.3).

non-condensable gas
Gases which cannot be liquefied by compression under the range of conditions of temperature and pressure used during the **operating cycle** of a sterilizer (3.10).

packaged boiler
A small local boiler used to supply steam for a **clean-steam generator** (4.33).

parenteral
Of a **medicinal product**, administered by means other than through the digestive tract, and especially by injection.

pitot
A metal tube of narrow bore inserted along the axis of a steam pipe and designed to extract a sample of steam for testing or collection (6.9).

potable steam
Process steam intended for culinary applications and meeting the purity requirements of drinking water (3.18).

priming
Of a boiler, the delivery of steam containing water in suspension due to violent boiling or frothing (4.5).

process steam
Steam whose quality is not optimised for sterilization (3.16).

pyrogen
A **bacterial endotoxin** that causes a rise in body temperature and which is not destroyed by steam **sterilization** (Appendix 3).

residue on evaporation
The mass of solid remaining when a given volume or mass of aqueous solution is evaporated. Unit: mg litre^{-1} or ppm. See also **total dissolved solids** (7.16).

reverse osmosis (RO)
A water purification process in which impurities are filtered out by forcing the water through a semi-permeable membrane (4.46).

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Sterilized Water for Injections BP (Sterilized WFI)
A grade of **Water for Injections BP** designed for dilution of sterile medicinal products intended for subsequent intravenous administration (3.31).

Sterile Water for Irrigation
Sterile Water for Irrigation is a sterile, nonpyrogenic preparation of Water for Injections BP, containing no antimicrobial agent or other substances.

total dissolved solids
The mass of solid material dissolved in a given volume or mass of aqueous solution. Unit: mg litre^{-1} or ppm. See also **residue on evaporation**.

Water for Injections BP
A pharmaceutical preparation designed for administration by injection consisting of distilled water that meets the purity specifications of the British Pharmacopoeia (3.30).

Water for Injections in Bulk BP
A grade of **Water for Injections BP** designed for use in the manufacture of medicinal products that are to be terminally sterilized and intended for administration by injection (3.31).

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Abbreviations

BET	Bacterial Endotoxins
BP	British Pharmacopoeia
BS	British Standard
°C	Degree Celsius
Ca	Calcium
$CaCO_3$	Calcium carbonate
cfu/ml	Calony forming units/millimetre
CIBSE	Chartered Institute of Building Services Engineers
Cl	Chlorine
DI	De-ionised (referring to water)
EEC	European Economic Community
EN	European Norm
EO	Ethylene oxide
EU	European Union
	Endotoxin unit
EU ml^{-1}	Endotoxin units per millilitre
EP	European Pharmacopoeia
H_2O	Water/water vapour
HMSO	Her Majesty's Stationary Office
HSE	Health and Safety Executive
HTM	Heath Technical Memorandum
kgh^{-1}	kilogram per hour
kW	kilowatt
LAL	Limulus amoebocyte lysate
LPS	Lipopolysaccharides
LTS	Low temperature steam
LTSF	Low temperature steam and formaldehyde
M	Molar
mgl^{-1}	milligram per litre
ml	millilitres
mm	millimetre
mmol l^{-1}	millimol per litre
ms^{-1}	metres per second
mSm^{-1}	milli Siemen per metre
ng	nanograms
NH_4	Ammonium
NHS	National Health Service
OD	Outside diameter
P	Phosphorus
Pb	Lead
P&EF	Property and Environment Forum
P&EFEx	Property and Environment Forum Executive
pH	The inverse of the logarithm…..etc.
Ph Euro	Pharmacopoeia European

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P_2O_2	Phosphate
PO_4	Phosphate
ppm	Parts per million
RO	Reverse osmosis
SI	System International
	Statutory instrument
SHG	Scottish Health Guidance (note)
SHTM	Scottish Health Technical Memorandum
TDS	Total dissolved solids
USP	United States Pharmacopoeia
WFI	Water for injections BP
:m	micron (a unit of length equal to one millionth of a metre)
:Scm^{-1}	micro Siemens per centimetre
<	greater than
<	less than

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
	Registered Establishments (Scotland) Act	HMSO	1998	
	Water (Scotland) Act	HMSO	1980	
SI 3146	Active Implantable Medical Devices Regulations	HMSO	1998	
SI 2179 & 187	Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd 1994)	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	

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Publication ID	Title	Publisher	Date	Notes
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 2307	Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)	HMSO	1998	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	Medical Devices Regulations	HMSO	1998	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 3139	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 119	Water Supply (Water Quality) (Scotland) Regulations	HMSO	1990	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
European Union Directives				
65/65/EEC	Approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.	Official Journal of the European Communities (OJEC), no 22, 9/2/65, p 369		
90/385/EEC	Approximation of the laws of the Member States relating to active implantable medical devices.	Official Journal of the European Communities (OJEC), L189 20/7/90, p 17		

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Publication ID	Title	Publisher	Date	Notes
91/356/EEC	Laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.	Official Journal of the European Communities (OJEC). L193 17/7/91, p 30		
93/42/EEC	Medical Devices Directorate	Official Journal of the European Communities (OJEC), L169 12/7/93, p 1		
British Standards				
BS EN 868	**Packaging materials and systems for medical devices which are to be sterilized** **Part 1**: General requirements and test methods **Part 2**: Sterilization wrap. Requirements and test methods **Part 3**: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (Specified in EN 868-5). Requirements and test methods. **Part 4**: Paper bags. Requirements and tests methods **Part 5**: Heat and self-sealable pouches and reels of paper and plastic film construction. Requirements and test methods **Part 6**: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation. Requirements and test methods **Part 7**: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation. Requirements and test methods **Part 8**: Reusable sterilization containers for steam sterilizers conforming to EN 285. Requirements and test methods	BSI Standards	 1997 1999 1999 1999 1999 1999 1999 1999	Draft

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS EN 868	**Part 9**: Uncoated non-woven materials of polyolefines for use in the manufacture of heat-sealable pouches, reels and lids. Requirements and test methods	BSI Standards	2000	Draft
	Part 10: Adhesive coated non-woven materials of polyolefines use in the manufacture of heat-sealable pouches, reels and lids. Requirements and test methods.		2000	
BS 3970	**Sterilizing and disinfecting equipment for medical products** **Part 1**: Specification for general requirements	BSI Standards	1990 (1996)	
BS EN 550	**Sterilization of medical devices. Validation and routine control of ethylene oxide sterilization**	BSI Standards	1994	
BS EN 554	**Sterilization of medical devices. Validation and routine control of sterilization by moist heat.**	BSI Standards	1994	
BS EN 285	**Sterilization: Steam sterilizers: Large sterilizers.**	BSI Standards	1997	
BS EN 1422	**Sterilizers for medical purposes: ethylene oxide sterilizers. Requirements and test methods**	BSI Standards	1998	
BS 6068	**Water quality** **Part 0**: Introduction	BSI Standards	1995	
	Part 2: Physical, chemical and biomedical methods **Section 2.28**: Method for the determination of phosphorus: ammonium molybdate spectrophotometric method.		1986 (1991)	
	Part 6: Sampling **Section 6.3**: Guidance on the preservation and handling of samples. **Section 6.7**: Guidance on sampling of water and steam in boiler plants.		1986 (1990) 1994	
Scottish Health Technical Guidance				
SHTN 2	Domestic hot and cold water systems for Scottish Healthcare Premises	P&EFEx	2001	CD-ROM
SHTM 2007	Electrical services supply and distribution	P&EFEx	2001	CD-ROM

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Publication ID	Title	Publisher	Date	Notes
SHTM 2010	Sterilization	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2030	Washer-disinfectors	P&EFEx	2001	CD-ROM
SHGN	'Safe' hot water and surface temperatures	P&EFEx	2001	CD-ROM
SHPN 1	Health Service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 4	General Purposes Estates and Facilities Model Safety Permit-to-Work System	EEF	1997	
	NHS in Scotland – PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland Firecode				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
UK Health Technical Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	

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Publication ID	Title	Publisher	Date	Notes
Miscellaneous References				
	British Pharmacopoeia. Medicines Commission	HMSO	1993	
	British Pharmacopoeia Addendum. Medicines Commission	HMSO	1995	
	CIBSE Guides and Commissioning Codes, A, R and W	CIBSE	1986 1991 1994	
	European Pharmacopoeia. 3rd edition		1996	
	General principles of sampling waters and associated materials (methods for the exhibition of waters and associated materials)	Strasbourg Council of Europe Publishing	1996	
MES C14	Model Engineering Specifications Sterilization	NHS Estates	1996	
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	Rules governing medicinal products in the European Community. Volume IV: Good manufacturing practice for medicinal products. (CO-71-91-760-EN-C)	Commission of the European Communities (HMSO)	1992	
	United States Pharmacopoeia	United States Pharma-copoeial Convention	1994	Updated by supple-ments

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Scottish Health Technical Memorandum 2040

(Part 1 of 6)

Overview and management responsibilities

The control of legionellae in healthcare premises – a code of practice

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IMPORTANT NOTE
LEGIONELLA
SHTM 2040 and the HSC Approved Code of Practice and Guidance (L8) 2000

HSC's Approved Code of Practice came into effect on 8 January 2001. At this time i.e. December 2001 the UK Health Department's Guidance HTM 2040 (SHTM 2040 in Scotland) has not been aligned with the ACOP. Work is ongoing but it is unlikely that HTM 2040 and SHTM 2040 will be updated until late 2002 and launched on a UK basis.

L8 takes cognisance of 'hospitals' but requires considerable interpretation for practical application. The revised UK Health Department Guidance will undertake to address this issue.

In the meantime this version of SHTM 2040 must be read as subordinate to the new ACOP.

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NHSScotland, P&EFEx, December 1999

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1. Introduction

General

1.1 The guidance contained in this part is applicable to new and existing sites, and is for use at various stages during the inception, design, upgrading, refurbishment, extension and maintenance of a building.

1.2 The approach should be to remove all potential sources of seeding, growth and spread of legionellae. Where this ideal cannot be achieved in existing situations, steps should be taken to control and prevent legionellae by sound operational management.

1.3 The control of legionellae is a continuing responsibility. The effectiveness of precautionary measures should be continually monitored, and a continuing programme to ensure awareness should be devised. Although knowledge of legionellosis has improved markedly in recent years there is a continuing misunderstanding about the method of dissemination. Many people are under the impression that cooling towers are the only source of legionellae in building service systems. All water systems are capable of colonisation by legionellae, and taps are just as capable of generating an aerosol as showers or, indeed, cooling towers.

1.4 The biggest risk is complacency leading to the deterioration of water hygiene to the extent that an outbreak of the disease occurs.

1.5 The general manager/chief executive has the responsibility of ensuring that designated staff are appointed.

1.6 This SHTM does not include advice on water supplies for clinical equipment such as dialysers, nebulisers and respiratory humidifiers or for water services for pharmacy and dental departments. Users of clinical humidifiers and nebulisers are reminded that sterile water, not tap water, should be used and that they should be emptied and cleaned thoroughly following each period of use. All equipment with water reservoirs should be stored dry. Water for any other purpose should meet any identifiable local requirements, but users must recognise that any water system may provide a suitable environment for legionellae and other water-borne organisms.

1.7 SHTM 2027; *Hot and cold water supply, storage and mains services* should be consulted for guidance on the general design and operation of water systems in healthcare premises.

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Application to premises

1.8 Precautions to prevent outbreaks of legionnaires' disease are required even in those premises which have to date not been infected. The guidance should be used for all sites where there is in-patient or out-patient accommodation, for example hospitals, clinics, health centres and Blood Transfusion Service premises.

Priorities

1.9 Premises designed since 1988 should be in compliance with SHTM 2040; The control of legionellae in healthcare premises – a code of practice, with reference to SHHD/DGMs (1988)50; (1989)35; 1989(77); 1990(51) and 1991(15).

1.10 All existing premises should be regularly reviewed to identify where they do not meet the advice of this SHTM. A realistic programme should be prepared to eradicate any shortfall. Priority should be given to patient areas, although the exact priority will depend on local circumstances.

NOTE: Reference must be made to Health and Safety Commission, 'Legionnaires' disease, The control of legionella bacteria in water system – Approved Code of Practice and Guidance' issued 2000.

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2. Statutory obligations

Health and Safety at Work

2.1 Employers have a general duty, under the Health and Safety at Work etc Act 1974, to ensure, so far as is reasonably practicable the health, safety and welfare of their patients, employees and visitors. These duties are legally enforceable, and the Health and Safety Executive (HSE) have successfully prosecuted occupiers of premises under this statute for outbreaks of legionnaires' disease. It falls upon both the owners and occupiers of premises to ensure that there is a management regimen for the proper design, installation and maintenance of plant, equipment and systems. Failure to have a proper system of work and adequate control measures can also be an offence even though an outbreak has not occurred.

Control of Substances Hazardous to Health (COSHH) Regulations

2.2 Also relevant are the Control of Substances Hazardous to Health (COSHH) Regulations 1999 which came into force in 1999. In the context of hot and cold water supply, storage and mains services, these regulations apply to micro-organisms, including legionellae, which could create a health hazard. These regulations also apply to the chemicals which may be used to control the growth of organisms in water supply.

Reporting requirements under health and safety legislation

2.3 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 came into force on April 1996. These place a responsibility on employers to report cases of work related disease to the HSE. The list of reportable diseases includes a number of infections which could be related to work within health services and includes legionellosis.

The Public Health (Infectious Diseases) Regulations 1975 requires that a properly appointed officer shall inform the Chief Medical Officer of any serious outbreak of the disease which to his knowledge has occurred. Reference should also be made to Public Health (Notification of Infectious Diseases) Scotland Regulations (1988) and amendment regulations 1989.

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NOTE: Further advice is given in the Scottish Infection Manual: 'Guidance on Core Standards for the control of infection in Hospitals, health care premises and at the community interface' issued by the Public Health Policy Unit Room 401, St. Andrews House, Scottish Executive Health Department, Edinburgh EH1 3DG.

Water Supply Regulations

2.4 The Water Supply (Water Quality) (Scotland) Regulations 1990 (as amended) apply to water stored and distributed within any hospital which is used for drinking and any domestic purpose.

2.5 The Private Water Supplies (Scotland) Regulations 1992 (Statutory Instrument No. 2790) cover private water supplies (Boreholes and Wells).

NOTE: Legionellosis is a notifiable disease: 'The European Community Directive Relating to the Quality of Water Intended for Human Consumption'; Council Directive 80/778/EEC.

Food Safety Act

2.6 The Food Safety Act 1990 covers for water used for food preparation or food manufacture, and also includes water used for drinking.

NOTE: Reference should also be made to Food Safety (General Food Hygiene) Regulations 1995, and Food Safety (Temperature Control) Regulations 1995.

Approved Code of Practice

2.7 The Health and Safety Commission have published 'Legionnaires disease, The control of legionella bacteria in water systems – Approved Code of Practice and Guidance 2000'. This single publication replaces the 1995 ACOP and the technical guidance HSG 70. This has allowed information to be consolidated, with the aim of making it easier to read and understand the duties under the law.

2.8 The health service, with responsibility for the wider aspects of public health and the operation of NHS premises, is expected to be particularly vigilant. The courts will expect a higher standard of care from public bodies, given the resources available to them and the greater risks to the occupants of these premises. Though the number of outbreaks of legionnaires' disease is relatively small, outbreaks are considered to be avoidable. Management must also acknowledge that incidents or outbreaks cause widespread

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concern especially if associated with healthcare premises. Investigation of these outbreaks has shown that they are generally related to a breakdown in management systems. Design flaws and defects have also been implicated as the cause of some outbreaks.

2.9 Hence, managers need to satisfy themselves, by monitoring, that the procedures are being implemented. It is not sufficient merely to devise procedures.

2.10 It is a widely held misconception that wet cooling towers are the only source of the disease, and that a building without such a tower presents no risk. All water systems are liable to colonisation by legionellae.

2.11 The prohibition of wet cooling towers is not envisaged; in some instances, they provide the only practicable solution. The relevant statutory requirement is to assess risk and the measurements to prevent (or where it is not reasonably practicable to prevent, to minimise) the risk from exposure to legionellae.

2.12 The Notification of Cooling Towers and Evaporative Condensers Regulations 1992 requires the registration of cooling towers and evaporative condensers to the local authority.

NOTE: Directors of environmental health are required to maintain a register of cooling towers and whirlpool spas in association with the Health and Safety Executive.

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3. Management responsibility

Management accountability

3.1 The chief executive or general manager has overall responsibility for all aspects of the quality of water supplies within his/her organisation.

3.2 The procedures instituted should be such as to demonstrate that any person on whom the statutory duty falls has fully appreciated the actual and potential risks of legionellae. Though compliance with this guidance may be delegated to staff, or undertaken by contract, accountability cannot be delegated.

3.3 Regular assessments should be made at least annually, using this guidance, to establish the extent of risk. Shortfalls should be clearly recorded and the proposed control measures, with timescales, developed. A review should be undertaken whenever there is a substantial change in physical environmental conditions.

3.4 The objective must be to institute management procedures to ensure that compliance is continuing and not notional. The prime purpose of the assessment is to be able to demonstrate that management has identified all the relevant factors, has instituted corrective or preventative action, and is monitoring that the plans are being implemented.

3.5 This guidance should be applied to all healthcare premises, however small, where there is a duty of care under the Health and Safety at Work etc Act 1974. Smaller premises, such as clinics, present a risk in the same way as a major hospital. Intermittently used areas, for example premises not used over the weekend, may present ideal environments for the growth of legionellae.

NOTE: Reference should be made to Part 6 of this SHTM 'Supplementary guidance applicable to intermittently used healthcare premises'.

Role of infection control team

3.6 The infection control team (legionella) should be nominated in writing by the chief executive or general manager for advising on and monitoring infection control policy for legionnaires' disease. The infection control team (legionella) should be involved in the production of the policy and management procedures for the control of legionellae. Similarly, the team has a key role in formulating the plans for its implementation.

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NOTE: Reference should be made to the Scottish Infection Manual 1998: 'Guidance on Core Standards for the Control of Infection in Hospitals, Health Premises and at the Community Interface' issued by the Public Health Policy Unit Room 401, St. Andrews House, Edinburgh, Scottish Executive Health Department, Edinburgh EH1 3DG.

3.7 Additionally, the policy should be acceptable to the control of infection team and any amendment to that policy must be agreed by the team.

Nominated person

3.8 A nominated person (legionella), possessing adequate professional knowledge and with appropriate training, should be nominated in writing by the general manager or chief executive to devise and manage the necessary procedures for the prevention of legionnaires' disease. The persons will be required to liase closely with other professionals in various disciplines. In addition, the person should possess a thorough knowledge of the control of legionellae and would ideally be a Chartered Engineer.

NOTE: Training courses on minimising the risk of legionellae in water systems are available from The Property and Environment Forum Executive.

3.9 This person's role, in association with the infection control team and maintenance staff, involves:

a. advising on the potential areas of risks and identifying where systems do not comply with this guidance;

b. advising on the necessary continuing procedures for the prevention of legionellae;

c. monitoring the implementation and efficacy of those procedures;

d. approving and identifying any changes of those procedures;

e. maintaining adequate records.

3.10 Implementation of an effective maintenance policy must incorporate the creation of fully detailed operating and maintenance documentation and the introduction of a logbook system. The "nominated person" should appoint a deputy to whom delegated responsibilities may be given. The deputy should act for the nominated person on all occasions when the nominated person is unavailable.

3.11 The nominated person should be fully conversant with the design principles and requirements of water systems and should be fully briefed in respect of the causes and effects of contamination with legionella. The appointment of an engineer as the nominated person is appropriate in that the responsibility can extend to the operation and maintenance of the associated plant. It is

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recognised that the nominated person cannot be a specialist on all matters and must be supported by specialists in specific subjects such as water treatment and microbiology, but he/she must undertake responsibility for calling upon and co-ordinating the activities of such specialists.

Hazard assessment

3.12 Legionellae, which causes legionellosis, are naturally widespread in water systems. It is exceptional for a water supply, either public or private, to be entirely free from aquatic organisms, and for this reason it is important that appropriate measures are taken to guard against conditions which may encourage microbial multiplication. Provided water is derived from the public mains and its quality is preserved in the storage and distribution system by correct design, installation and maintenance, it can be regarded as being microbiologically acceptable for use without further treatment. Strict adherence to the guidance in this SHTM will not eradicate legionellae, but there will be reduction in the risk of an outbreak.

3.13 The number of organisms which cause infection has not been reliably determined and is likely to vary from person to person. However, all patients are at risk, and those who are immunocompromised can be particularly susceptible.

3.14 Particularly susceptible patients will be those found in departments concerned with:

a. head/neck cancer;
b. bone marrow transplant;
c. renal dialysis;
d. leukaemia;
e. organ transplant;
f. AIDS.

3.15 Outbreaks have been linked to the inhalation of infected aerosols. Most people recognise that showers and wet cooling towers generate aerosols. Less well known is that a ‘fog’ of aerosols is generated when a bath or basin is filled. Aerosols can be generated from any water outlet, and no water outlet can be considered free from potential risk. Hence baths, spa baths and hydrotherapy pools also represent hazards. If the water is contaminated, the possibility of the organism being entrained in the aerosol increases.

3.16 These aerosols are buoyant and can remain suspended in the air for a relatively long time. Any air movement will distribute them over quite large distances. Recently it has been shown that the organism can survive even after the “wet” layer of the aerosol has dried.

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3.17 For certain immuno-compromised patients there may be other routes of infection. However, since these represent minimal risk, the SHTM does not deal with these aspects.

Prevention

3.18 It has been suggested that the following “chain of causation” must exist for legionellosis to be acquired:

a. an environmental reservoir;
b. opportunity for multiplication;
c. a mechanism for dissemination;
d. virulence to the human host;
e. inoculation of an infectious dose;
f. host susceptibility.

(See Figure 1, Chain of causation.)

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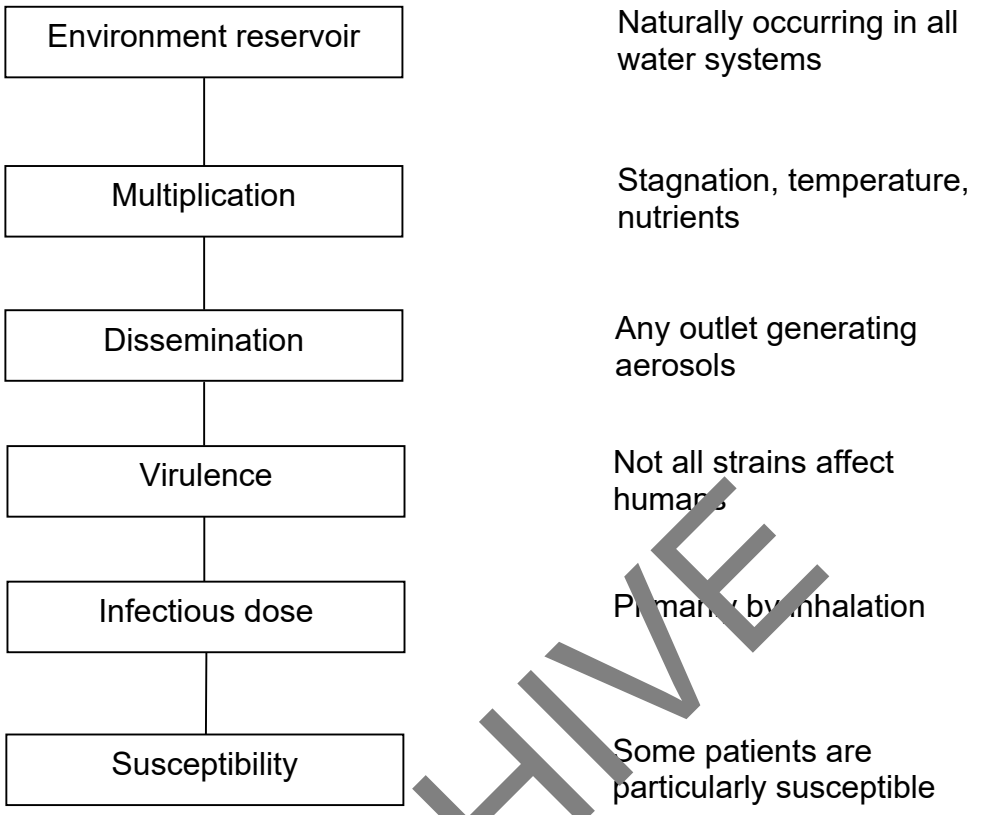
Figure 1: Chain of Causation



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3.19 Employing this hypothesis, the key preventative measures that may be applied are those which break the chain of causation. Strict procedures for water supply hygiene and disinfection are essential and particular attention should be paid to outlets.

NOTE: Refer to EH M(92)3 and SHPN2.

3.20 Simple precautions to achieve this objective are:

a. removing all taps and outlets and associated pipework which are not needed, due to disuse or under-use;

b. ensuring that the hot water from the calorifier is at or above 60°C and that it does not fall below 50°C in the circulation pipework;

c. keeping the length of the pipework carrying blended water at 24-45°C to the minimum (never more than 2 m);

d. reducing the length of dead-legs or spurs from the main hot water circulation system to the minimum (maximum 5 m);

e. avoiding water stagnation;

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f. introducing an appropriate level of maintenance and ensuring correct and safe operation;

g. maintaining the cleanliness of water systems;

h. using adequate water treatment in wet cooling towers;

i. keeping storage cisterns clean and sealed from extraneous matter and insulating where necessary to maintain temperatures below 20°C;

j. reducing the amount of water stored (24 hours maximum).

3.21 Where systems are known to be of uncertain quality or where consistent problems have been identified, a regimen of additional water treatment systems may be appropriate.

Monitoring and record keeping

3.22 Based on this guidance and the results of the risk assessment, a written operational plan should be devised. This should clearly identify who has overall accountability for the premises, and who is responsible for devising and carrying out the procedures. The record should include the systems, plant and equipment which pose a potential threat, and a detailed schedule of the preventative maintenance procedures. Finally, provision should be made in the plan for evaluation of the efficacy of the measures.

Water supply and distribution

3.23 It is exceptional for a water supply, either public or private, to be entirely free from aquatic organisms, and consequently it is important that appropriate measures are taken to guard against conditions that may encourage microbial multiplication. Legionellae, like other opportunist pathogens including *Aeromonas hydrophila* and *Pseudomonas aeruginosa*, are common in the environment and as such can seed treated water systems during construction.

3.24 Micro-organisms can also be introduced during refurbishment, repair, alteration or during routine inspection and sampling.

3.25 Hospital sites are generally large and often contain complex storage reservoirs and distribution systems similar to those operated by the water authorities. The water authorities or a specialist consultant can assist with the design, specification, tendering and commissioning of such water systems.

3.26 Wherever possible, publicly supplied mains water should not be mixed with private supplies. Each should be separately identified. Where mixing does occur it must be protected by a Type A air gap.

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Water treatment regimen

3.27 The regimen of water treatment chosen should be agreed by the infection control doctor (legionellae) and the nominated person (legionellae). The regimen should be of proven efficacy, and substances and products to be used in contact with potable water supplies must be listed in the current edition of the Water Bylaws Scheme's (WBS) Water Fittings and Materials Directory (WFMD).

NOTE: Reference should be made to SHTN 2. The WRc, byelaws scheme is not in itself sufficient. For new materials CCM committee or WRc Medenham (J Fawells Dept.) approval on toxicity levels is required.

3.28 Chemical conditioning systems which are used in conjunction with potable water systems should be selected very carefully. Addition of any substance must not cause a breach of any requirement in the Water Supply (Water Quality) (Scotland) Regulations, and any system for introducing a substance must be listed in the current edition of the WFMD.

3.29 Consideration should be given as to whether or not the process kills only the organisms flowing through the equipment (leaving no residual disinfecting agent in the water) or whether agents are released into the water circuits.

3.30 Further care should be taken to ensure that adequate filtration and/or reverse osmosis is used to provide a pure water supply free of contaminants for water serving clinical processes, for example dialysis equipment.

Air conditioning

3.31 Air-conditioning and ventilation systems have been shown to provide a route for distributing contaminated air throughout a building. Particular attention should be paid to the humidification process. Ductwork should be examined for evidence of "ponding", that is, places where water has collected.

NOTE: Refer to SHTM 2025; *Ventilation in Healthcare Premises*.

Design and build contracts

3.32 An outbreak of legionnaires' disease has been associated with healthcare premises built under the "design and build" type of contract, under which the client retains no clerk of works on-site and there is no "commissioning" period on completion of the work. It is essential to ensure that, immediately before occupation, the measures outlined in this SHTM have been taken for disinfection and maintenance of temperatures. A nominated person (legionellae) should be appointed immediately before handover. (Adequate

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documentation, including “as-fitted” drawings, should be available at the time of handover.)

NOTE: Refer to SHTN No. 1, PCD.

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4. Epidemiology

General

4.1 Although legionnaires' disease was first recognised in July 1976, when an outbreak occurred among delegates attending an American Legion Convention in Philadelphia, the cause of the outbreak was not identified until January 1977 when the Center for Disease Control in Atlanta reported the isolation of the aetiological agent which they named *Legionella pneumophila*. Diagnostic tests were developed which revealed earlier outbreaks of the disease and sporadic cases dating back to the 1940s. Thus the infection was not new, but had escaped recognition.

4.2 Legionnaires' disease is an illness characterised mainly be pneumophila. Typically it begins quite abruptly with high fever, chills, headaches and muscle pain. A dry cough soon develops, and most patients suffer difficulty with breathing. About one-third of patients also develop diarrhoea or vomiting and about half become confused or delirious. The case fatality rate is similar to that of most other types of pneumonia.

4.3 *L. pneumophila* can also cause a short febrile (feverish) illness without pneumonia known as Pontiac fever. Since *L. pneumophila* was originally isolated, several other species of legionella capable of causing pneumonia have been described in the UK and elsewhere. The 1988 outbreak of non-pneumonic legionellosis at Lochgoilhead in Scotland, now referred to as Lochgoilhead fever, was attributed to the species *L. micdadei*. Legionellosis is the generic term used to cover legionnaires' disease, Pontiac fever and Lochgoilhead fever.

4.4 To date, at least 37 different species of legionellae are recognised. The species most commonly associated with disease outbreaks is *L. pneumophila*. Fourteen different serogroups of *L. pneumophila* have been described, *L. pneumophila* serogroup 1 being most commonly associated with cases of legionnaires' disease in the UK.

4.5 There are various sources of the organism and various routes of transmission to humans. Domestic hot water services in large buildings have been shown to be the most common source, but evaporative cooling towers serving the air-conditioning plant in these types of establishment have also been implicated. A poorly maintained whirlpool spa has also been show to be a source, as have individual wall-mounted humidifiers and nebulisers using tap water.

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4.6 In all these instances, the infection is considered to have been acquired by inhalation of small water droplets carrying the bacteria. Aerosols containing such droplets may be generated by running taps or showers and during the normal operation of cooling towers and evaporative condensers. Survival of the bacterium in an aerosol is enhanced if the ambient relative humidity is greater than 65% and if it is sheltered from direct sunlight. Viable bacteria contained within aerosols may travel great distances.

4.7 The incubation period (the time between exposure to the organism and the development of first symptoms) may range from 2-10 days. There is no record of person-to person spread of infection. The bacterium is not highly virulent, but may infect individuals who are susceptible. In most outbreaks fewer than 5% of people exposed to the source of infection have contracted legionnaires' disease, although in some hospital units such as renal and oncology wards, greater attack rates have been reported.

Risk of infection

4.8 The principle route of infection is through inhalation of the bacteria into the lungs. The risk increases with increasing numbers of inhaled bacteria. Other infection routes may include ingestion and external wounds.

Source of bacteria

4.9 The bacterium is ubiquitous, surviving and multiplying in water. It is widespread in natural fresh water including rivers, lakes, streams and ponds and may also be found in wet soil. Airborne dispersal may occur when water droplets are created. There is a strong likelihood of very low concentrations of the bacteria existing in all open water systems including those of building services. There is also a risk where earthworks are taking place near to open windows or intakes to air-conditioning/ventilation systems.

4.10 The risk is related to the number and types of bacteria in the water at the point of use.

Aerosol generation

4.11 Contaminated water presents a risk when it is dispersed into the air as an aerosol. This risk increases with reduced droplet size for two reasons. First the smaller the droplet, the longer it remains airborne. Second, small droplets (5 microns diameter or less) penetrate deeply into the lung and cannot easily be expelled. However, larger droplets can evaporate and become smaller ones, still containing the initial number of organisms. Aerosols are produced merely by water streams breaking up after striking a surface or by a bubble bursting on the water surface.

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4.12 In both a cooling tower and an evaporative condenser, water is distributed over large areas of wetted surfaces to create intimate contact between air and water, increasing the opportunity for the formation of aerosols. Water services are also capable of generating aerosols from the impact of tap water hitting wash-basins, sinks and baths, and from showers.

4.13 In whirlpools and spas the refreshing agitation of the water is achieved by the combination of air jets and pulsating water flow. Splashing of water and bursting of the air bubbles as they break through the water surface creates an aerosol immediately above the water surface.

4.14 The risk increase with the number of “infected” droplets in the aerosol generated, especially if the size of the droplet in the aerosol is within the range 2 to 5 microns in diameter.

Number of inhaled bacteria

4.15 Two factors determine the number of bacteria actually inhaled:

a. the concentration of bacteria in the air:

   (i) this is determined both by the concentration of bacteria in the water and by the amount of contaminated water dispersed into a given air volume. The concentration of live bacteria in the air falls rapidly with distance from the source. Where a cooling tower and the fresh-air inlet to a building are both at roof level, it may be possible for contamination from the tower to reach the air inlet and hence enter the building;

   (ii) the quantity entering will depend primarily on the separation distance between the tower and the fresh-air inlet. Increasing this distance of separation and locating the air inlet upwind (prevailing wind) of the tower will help to reduce the likelihood of water droplets containing legionellae from entering the building;

b. the duration of exposure to the contaminated air;

   (i) exposure in a shower is usually limited to few minutes, while exposure in a spa is usually longer. Exposure to airborne legionellae distributed in a building from a contaminated cooling water system may take place whenever the tower is operating, which may be most of the day during the summer;

   (ii) the risk increases with the number of legionellae in the air and with the respiratory rate of the individual, and the length of time the person is exposed. The chances of legionella infections occurring increase with the number and susceptibility of people exposed.

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Susceptibility of individuals

4.16 While previously healthy people may develop legionnaires' disease, there are a number of factors which increase susceptibility:

a) increasing age, particularly above 50 years (children are rarely infected);

b) sex: males are three times more likely to be infected than females;

c) existing respiratory disease which makes the lungs more vulnerable to infection;

d) illnesses, such as cancer, diabetes, kidney disease or alcoholism, which weaken the natural defences;

e) smoking, particularly heavy cigarette smoking, because of the probability of impaired lung function;

f) patients on renal dialysis, or on immuno-suppressant drugs which inhibit the body's natural defences against infection.

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5. Ecology

5.1 The following conditions have been found to influence the colonisation and growth rate of legionella:

a. water temperatures in the range 20-45°C favour growth. It is uncommon to find proliferation below 20°C, and the organisms do not survive long above 60°C. The optimum laboratory temperature for the growth of the organism is 37°C , that is, body temperature. Organisms may, however, remain dormant in cool water, multiplying only when the temperature reaches a suitable level;

NOTE: The death curve is logarithmic with time for a given temperature.

b. the presence of sediment, sludge, scale and organic material provides a good nutrient source for legionellae. Evidence suggests that the presence of iron oxide (rust) also favours the growth of the organism;

c. legionellae have been shown to colonise certain types of water fitting, pipework and material used in the construction of water systems. The presence of such materials and of large quantities of sediment may provide nutrients for legionellae and can make eradication difficult;

d. other commonly encountered organisms in water systems such as algae, amoebae and other bacteria may serve as an additional nutrient source for legionellae. Algal slime may provide a stable habitat for multiplication and survival. Legionellae have been shown to proliferate rapidly in association with slime water-borne amoebae;

e. exposure to direct sunlight may inhibit the growth of legionellae while stimulating the growth of algae and the formation of slimes;

f. biofilms are thought to play an important role in harbouring and providing favourable conditions in which legionellae can grow;

NOTE: A biofilm is a slime which develops on surfaces in contact with water.

g. stagnant water encourages colonisation.

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Appendix: Management checklist

Legionellosis risk assessment

1. Appoint infection control doctor (legionella) and nominated person (legionella).

NOTE: A logbook recording the action taken on this checklist is recommended.

2. Produce record of drawings and schematics for all water systems. The drawings/schematic should show:

NOTE: Existing drawings should be checked for accuracy.

a. layout and arrangement of all calorifiers and pumps;
b. layout and arrangement of all cisterns, humidifiers and cooling towers;
c. all other water systems, such as hydrotherapy pools, which may present a legionellosis hazard;
d. dead-legs and blind ends, with lengths and diameter indicated;
e. operation and check points for cross-referencing with operational instructions and temperature records.

There should also be adequate documentation which details the engineering design intent and maintenance and operation procedures.

3. Identify work needed to be carried out for compliance with this SHTM and HSC(L8)2000. This will require:

a. tracing all water pipework;
b. measuring the time taken to achieve recommended temperatures at hot and cold water outlets;
c. measuring temperatures at all cisterns, calorifiers, humidifiers and cooling towers, and at other strategic points to check compliance;
d. checking layout and arrangement of cisterns, calorifiers, pumps, humidifiers, cooling towers and other water systems which may present a legionellosis hazard;
e. identifying little-used outlets and associated pipework which could be removed.

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4. Develop schemes for risk minimisation and control in order of priority, having considered cost, risk and difficulty.

5. List all buildings in priority order of non-compliance and potential risk.

6. Devise an agreed management programme for the minimisation of risks identified in (5) above. This should be an action plan identifying resources and time-scales.

7. Manage the programme described in (6) above and identify compliance failures for remedial action.

8. Review the programme at yearly intervals to record progress in implementing the programme. All changes to the water systems and functional content should be recorded and evaluated.

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References

NOTE:
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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	The Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
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	Electricity Act	HMSO	1989	
	The Food Safety Act	HMSO	1990	
	Registered Establishments (Scotland) Act	HMSO	1998	
	The Water (Scotland) Act	HMSO	1980	
	Health and Safety at Work etc Act	HMSO	1974	
SI 346	The Active Implantable Medical Devices Regulations	HMSO	1992	
SI 2179 & 187	The Building Standards (Scotland) Regulations	HMSO	1990	
	The Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
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SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations	HMSO	1988 (amd 1990)	
SI 3080	Electromagnetic Compatibility (Amendment) Regulations	HMSO	1994	
SI 2372	Electromagnetic Compatibility Regulations	HMSO	1992	

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Publication ID	Title	Publisher	Date	Notes
	Food Safety (Temperature Control) Regulations	HMSO	1995	
	Food Safety (General Food Hygiene) Regulations	HSMO	1995	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	The Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2225	The Notification of Cooling Towers and Evaporative Condensers Regulations	HMSO	1992	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2169	The Pressure Systems and Transportable Gas Containers Regulations	HMSO	1989	
SI 574	The Private Water Supplies (Scotland) Regulations	HMSO	1992	
	The Public Health (Notification of Infectious Disease) (Scotland) Regulation	HMSO	1988	
	The Public Health Act (Infectious Disease) Regulations	HMSO	1975	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 1333	The Water Supply (Water Quality) (Scotland) Regulations (amendment)	HMSO	1991	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 6700	Specification for design, installation, testing and maintenance services supplying water for domestic use within buildings and their curtilages	BSI Standards	1997	
BS 7206	Specification for unvented hot water storage units and packages	BSI Standards	1990 (1997)	
BS 6920	Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on water quality	BSI Standards	1996	
BS 7592	Sampling for Legionellae organisms in water and related materials	BSI Standards	1992	
European Union Directives				
80/778/EEC	The Quality of Water Intended for Human Consumption	EEC		
Scottish Health Technical Guidance				
SHTM 2005	Building management systems	EEF	1999	CD-ROM
SHTM 2023	Access and accommodation for engineering services	EEF	1999	CD-ROM
SHTM 2024	Lifts	EEF	1999	CD-ROM
SHTM 2025	Ventilation in healthcare premises	EEF	1999	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	EEF	1999	CD-ROM
SHGN	'Safe' hot water and surface temperatures	EEF	1999	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	EEF	1999	CD-ROM
SHTN 4	General Purposes Estates and Functions Model Safety Permit-to-work Systems	EEF	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
	NHS in Scotland – Scotconcode Scottish Infection Manual: Guidance on core standards for the control of infection in hospitals, healthcare premises and at the community interface	EEF	1999	Version 3
NHS in Scotland Firecode				
HTM 81	Fire precautions in new hospitals	EEF	1998	CD-ROM
HTM 82	Alarm and detection systems	EEF	1998	CD-ROM
HTM 83	Fire safety in healthcare premises: general fire precautions	EEF	1998	CD-ROM
HTM 84	Fire safety in NHS residential care properties	EEF	1998	CD-ROM
HTM 85	Fire precautions in existing hospitals	EEF	1998	CD-ROM
HTM 86	Fire risk assessment in hospitals	EEF	1998	CD-ROM
HTM 87	Textiles and furniture	EEF	1998	CD-ROM
Fire Practice Note 3	Escape bed lifts	EEF	1998	CD-ROM
Fire Practice Note 4	Hospital main kitchens	EEF	1998	CD-ROM
Fire Practice Note 5	Commercial enterprises on hospital premises	EEF	1998	CD-ROM
Fire Practice Note 6	Arson prevention and control in NHS healthcare premises	EEF	1998	CD-ROM
Fire Practice Note 7	Fire precautions in patient hotels	EEF	1998	CD-ROM
Fire Practice Note 10	Laboratories on hospital premises	EEF	1998	CD-ROM
UK Health Technical Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
MES	Model Engineering Specifications	NHS Estates	1997	As required
	The colonisation of water in United Kingdom transplant units with Legionella bacteria and Protozoa and the risk to patients	HEEU	1995	
	Pseudomonas Aeruginosa in whirlpool baths	HEEU	1997	

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Publication ID	Title	Publisher	Date	Notes
Public Health Laboratory Services				
	Spa pool working party	PHLS	1994	
	Hygiene for hydrotherapy pools	PHLS	1990	
	Hygiene for spa pools: guidance for their safe operation	PHLS		
Miscellaneous References				
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Chemical Disinfection in Hospitals (second edition)	PHLS	1993	
	Water Byelaws Scheme's (WBS) Water Fittings and Materials Directory (WFMD).			
	Department of rehabilitation: a design guide	DHSS	1974	
	The central sterilization club, hygiene for hydrotherapy pools	PHLS	1990	
	A guide to pre-commission cleaning of water systems	BSRIA	1991	

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Scottish Health Technical Memorandum 2040

(Part 4 of 6)

Validation and verification

The control of legionellae in healthcare premises – a code of practice

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IMPORTANT NOTE
LEGIONELLA
SHTM 2040 and the HSC Approved Code of Practice and Guidance (L8) 2000

HSC's Approved Code of Practice came into effect on 8 January 2001. At this time i.e. December 2001 the UK Health Department's Guidance HTM 2040 (SHTM 2040 in Scotland) has not been aligned with the ACOP. Work is ongoing but it is unlikely that HTM 2040 and SHTM 2040 will be updated until late 2002 and launched on a UK basis.

L8 takes cognisance of 'hospitals' but requires considerable interpretation for practical application. The revised UK Health Department Guidance will undertake to address this issue.

In the meantime this version of SHTM 2040 must be read as subordinate to the new ACOP.

Disclaimer

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1. Introduction

1.1 The guidance contained in this part is applicable to new and existing sites, and is for use at various stages during the inception, design, upgrading, refurbishment, extensions and maintenance of a building.

1.2 The approach should be to remove all potential sources of seeding, growth and spread of legionellae. Where this ideal cannot be achieved in existing situations, steps should be taken to control and prevent legionellae by sound operational management.

1.3 The control of legionellae is a continuing responsibility. Effectiveness of precautionary measures should be continually monitored, and a continuing programme to ensure awareness should be devised. Although knowledge of legionellosis has improved markedly in recent years, there is a continuing misunderstanding about the method of dissemination. Many people are under the impression that cooling towers are the only source of legionellae in building service systems. All water systems are capable of colonisation by legionellae, and taps are just as capable of generating an aerosol as showers or indeed cooling towers.

1.4 The biggest risk is complacency leading to the deterioration of water hygiene to the extent that an outbreak of the disease occurs.

1.5 Good practice design alone will not prevent outbreaks of legionellae.

1.6 The SHTM does not include advice on water supplies for clinical equipment such as dialysers, nebulisers and respiratory humidifiers, nor for sterile water services for pharmacy departments. Users of clinical humidifiers and nebulisers are reminded that sterile water, not tap water, should be used and that they should be emptied and cleaned thoroughly following each period of use. All equipment with water reservoirs should be stored dry. Water for any purpose should meet functional and local requirements, but users must recognise that any water system may provide a suitable environment for legionellae and other water-borne organisms and systems should therefore be designed to take account of this.

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2. Validation and verification considerations

Commissioning and testing of hot and cold water systems

2.1 The hot and cold water service systems should be commissioned and tested in accordance with BS 6700 and SHTM 2027; *Hot and cold water supply, storage and mains services*. BS 6700 details procedures to ensure that:

a. materials and equipment installed comply with other British Standards and are not otherwise unsuitable;

b. the work is done entirely within the specification for the scheme;

c. the installation complies in every respect with current water byelaws and regulations and the requirements of British Standards;

d. all the requirements of current legislation are met, both during construction of the installation and when it is completed, particularly with regard to the Health and Safety at Work etc Act 1974.

NOTE: The Trust Infection Control Team should be advised of the testing. Further information on the role of the Infection Control team is given in the Scottish Infection Manual – Guidance on Core Standards for the Control of Infection in hospitals, healthcare premises and in the community interface (1998).

2.2 "As installed" drawings and operating/maintenance instructions must be supplied at the time of handover. Schematics will also be useful. Certified records of pressure testing and disinfection should also be made available.

Pressure testing

2.3 Pressure testing must be carried out before disinfection. Except where otherwise specified, testing of underground pipelines should be carried out in accordance with BS 5886, CP 312 and CP 2010-2, as appropriate for the pipeline material.

2.4 Open pipes should be capped and valves closed to avoid contamination. After pressure testing it will be impracticable to drain the system completely.

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Disinfection

2.5 The system should be disinfected in accordance with BS 6700. Disinfection should be carried out within seven days of the system being brought into use unless:

a. hot water temperatures are maintained;

b. cold water temperatures are maintained;

c. regular (every seven days) flushing is carried out.

NOTE: The contract should specify this for the period that the system is under the contractor's control. Refer to SHTN 2 for details.

2.6 Once filled, systems should not be drained unless full disinfection is to be undertaken before the system is brought into use again.

2.7 For design and build contracts, the brief must include the requirement that adequate certification of disinfection is provided by the contractor. On other contracts, tests must be witnessed and certified. During the post-handover period prior to occupation it is the client's responsibility to ensure system temperatures are maintained and regular flushing is carried out, or to implement full re-disinfection.

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Temperature testing

2.8 These tests should be performed prior to contractual handover and bringing the system into use. Separate temperature measuring and recording equipment should be used, that is, independent of any building management system. It will be necessary to have systems fully operational and to simulate typical draw off of water.

NOTE: Reference should be made to SHTM 2027 Part 4, 'Validation and verification' for guidance.

2.9 Tests should include:

a. measuring the incoming water temperature at the main water meter;

b. testing the inlet, outlet and surface water temperatures of cisterns and cold water feed/header tanks for the hot water calorifiers. The temperature should not be greater than 2°C above that measured at (a);

c. testing the flow and return temperatures of calorifiers and boilers. These should not be less than 60°C and 50°C respectively;

d. testing the temperature at hot and cold water draw-off points, at sinks, wash-hand basins and baths, etc. A steady state temperature of

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between 50°C and 60°C at hot water draw-off should be reached within one minute. At cold water draw-off a temperature of not greater than 2°C above the temperature measured at (a) should be reached within one minute.

Discharge of waste water used during disinfection procedures within buildings

2.10 External bodies responsible for sewers should be informed before chlorinated water used for disinfecting an installation is discharged. Additional disinfection guidance is given in HSC(L8) 2000 The control of legionella bacteria in water systems – Approved Code of Practice and Guidance. It is preferable, therefore, to establish and agree procedures beforehand; this may simply involve the dilution of the discharge or de-chlorination.

2.11 When required, de-chlorination can be achieved using either sulphur dioxide or sodium thiosulphate (20 g of sodium thiosulphate crystals is required to de-chlorinate 500 litres of water containing 20 mg/l free chlorine).

2.12 If possible, it may be preferable to add the sodium thiosulphate to the chlorinated water at the point of discharge into the foul sewer rather than into systems. This will avoid the need for draining and washing systems of any residual chemical which would otherwise mop up any chlorine that may be present in the water.

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3. Cold water systems

General

3.1 The requirements for disinfection subsequent to flushing out to remove debris, etc, are essentially those given in BS 6700. Further guidance is available in 'A Guide to Pre-Commission Cleaning of Water Systems', issued by BSRIA, 1991, which deals with the design/installation considerations, system flushing and chemical cleaning. Background notes on disinfection by chlorine are given in SHTM 2040, 'Good practice guide'; Appendix 1.

3.2 Alternative disinfectants may be used provided satisfactory disinfection is achieved. The infection control team should be consulted.

3.3 Proprietary solutions of disinfectant should be used in accordance with the manufacturers' instructions and will have to take due regard of the requirements under COSHH and other health and safety regulations.

3.4 A suitable proprietary test kit should be used for site measurements of residual disinfection agents.

3.5 Disinfection should not be undertaken before materials, for example linings in cisterns, have fully cured.

Installations outside buildings

3.6 Pipework under pressure from the mains should be disinfected through an injection point and the disinfectant residual measured at the end of the pipeline. It is normal water industry practice to use a chlorine dose of not less than 20 mg/l (ppm) and, because the nature of the installation is likely to lead to unavoidable contamination, it is usual practice to leave the chlorine solution in the pipes for 24 hours before thoroughly flushing out with fresh water. Junctions which are to be inserted into existing pipelines should be disinfected prior to installation.

3.7 All disinfection of pipework under pressure from the mains must be carried out in accordance with the requirements of the local water undertaking. Failure to ensure close liaison between the contractor and the water authority during design, construction, pressure testing or commissioning could present a potential risk of back-siphonage of contaminated materials or chemicals into the public water supply. Site supervision to ensure compliance with any requirements specified by the local water authority is strongly recommended.

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Cold water installations within buildings

3.8 All cistern(s) should be internally cleaned to remove all visible dirt and debris. Cistern(s) and distributing pipework should be drained, filled with fresh water and then drained completely. The cistern(s) should then be refilled and their supply servicing valves closed. On re-fitting it is normal practice to add high doses of sodium hypochlorite to the water in the cistern(s), for example to give a calculated chlorine concentration of 50 ± 10 mg/l (ppm) in the water and leave the water to stand for one hour. Whatever disinfection method is used, the concentration should be adjusted if necessary. The use of a high dose ensures an adequate residual concentration to allow proper disinfection of the downstream services. Each tap or fitting should then be opened, progressively away from the cistern(s), and water discharged until the disinfectant is detected. Each tap or fitting should then be closed, and the cistern and pipes left charged for a further one hour. The tap(s) furthest from the cistern(s) should be opened and the level of disinfectant in the water discharged from the tap(s) measured. If the levels set in the British Standards are not achieved the disinfection process should be repeated.

3.9 As soon as possible after disinfection the distribution pipework should be drained and thoroughly flushed through with fresh water and re-filled. Appropriate hazard warnings should be placed on the taps throughout the building during disinfection procedures.

3.10 After disinfection, microbiological tests for bacterial colony counts at 22°C and 37°C and coliform bacteria including Escherichia coli for drinking water should be carried out under the supervision of the infection control team to establish that the work has been satisfactorily completed. Water samples should be taken from selected areas within the distribution system. The system should not be brought into service until the infection control team certifies that the water is of potable quality.

Storage cisterns

3.11 Cold water storage cisterns are installed in the majority of hospital buildings/departments. A maximum of 24 hours total on-site storage capacity is recommended. The quantity of water stored should be carefully assessed in relation to the daily requirement in order that a reasonable rate of turnover is achieved. Storage of unnecessarily large quantities of potable water will result in low rates of turnover and a consequent deterioration in the quality of water. The storage capacity should be reduced where it is known or established that it is excessive and where it is practicable to do so. An example would be where there are two cisterns in parallel, one of which can be left empty and blanked-off (pipe sections should be removed). Alternatively, the steady water level in the cisterns should be lowered. This can be done most easily if the float controlling the water supply has a

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thumbscrew adjustment as prescribed in BS 1212: Part 2. The design capacity should not allow for future extensions.

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4. Hot water services

Hot water installations within buildings

4.1 Cold feed cisterns, hot water calorifiers, water heaters, direct-fired HWS boilers and distribution pipework should be disinfected in accordance with paragraphs 3.8 to 3.11; no heat source should be applied during the disinfection procedure, including final flushing.

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5. Evaporative cooling towers

General

5.1 The following paragraphs give general guidance on the operation and maintenance of cooling towers.

5.2 Before the identification of legionellae and its association with evaporative cooling systems, cooling towers were maintained for maximum service life. The aim of maintenance was to minimise fouling, thus ensuring optimum thermal efficiency.

5.3 Most evaporative cooling systems are uncomplicated in construction, simple in operation and usually located close to the refrigeration plant. Significant deterioration is possible, therefore, before plant inefficiency becomes evident.

5.4 It is essential that the utmost care and diligence is exercised in the operation and maintenance of cooling towers. The operation, maintenance and water treatment of evaporative cooling systems must be considered with regard to the associated health risks, in addition to operational efficiency.

Operating and maintenance documents

5.5 Operating and maintenance documents must be available for each installation and must be complete at the time of handover. If unavailable, operating and maintenance documents must be prepared by the user and should include the following:

a. the design intent description, usually prepared by the designer and including the system function and its description. It should also include the design requirements in respect of water treatment regimen, flow rates, static and dynamic pressures, thermal capacities, system volumes, operating temperatures, control sensor locations, operating set points and all other relevant information. If commissioning information is not available it will be necessary to recommission the plant in order to prepare records of the operational parameters of the entire system;

b. a description of how the plant and system as a whole are set to work and how they are shut down;

c. a fault diagnosis schedule, description of the alarm/warning system and details of courses of corrective/diagnostic action in event of a fault condition. The schedule should also include a checklist and give guidance on checking possible causes of complaint originating from the occupier;

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d. manufacturer's installation instructions and literature;

e. spares information;

f. operation instructions for individual items of plant;

g. maintenance information for individual items of plant and maintenance frequencies;

h. record drawings of the installation;

i. plantroom and system schematic diagrams (framed copies should be mounted in the respective plantrooms);

j. lubrication charts with frequencies;

k. valve charts showing valve number, type and purpose and, where applicable, design flows/settings/pressure drops;

l. logbooks.

NOTE: Schedule 3 of the Consumer Protection Act 1987 required that sufficient information is made available to the operator for him/her to safely operate the plant.

Logbooks

5.6 The purpose of a logbook system is to improve the efficiency and effectiveness of installation and maintenance, and also to provide a record of various tasks and observations so that the plant history can be reviewed at any time by the maintenance engineer. It will prove essential to the maintenance engineer in the operation of a planned plant maintenance scheme, and, if properly followed, will prevent unacceptable conditions developing as a result of ineffective maintenance.

5.7 The logbook should:

a. identify the installation requiring attention, in this case an evaporative cooling system, and should describe its form, function and how it operates;

b. record the results of the initial commissioning and any recommissioning so that observations made during maintenance checks can be compared;

c. define the maintenance task or observation required and the frequency;

d. provide for the recording of maintenance observations and results and for comments to be made in respect of any defect seen during the inspection. This facility should exist for each item of plant individually and for overall system observations;

e. provide preliminary guidance on fault diagnosis and checking to assist with immediate on-site correction or adjustment;

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f. provide for, and make reference to, any separate observation sheet required to record extensive or abnormal observations which cannot be noted on the routine inspection sheets;

g. facilitate cataloguing and cross-referencing to other logbooks for plant/installations on the same site (for example, the refrigeration plant, the chilled water installation, the air-conditioning plant and the heat source).

Operational checks

5.8 This section of the SHTM is intended to assist maintenance staff in the planning of operational and functional checks. It identifies typical tasks and recommends observation frequencies. It is only a general guide, as it is not possible to cover all aspects which relate to a specific installation.

NOTE: As an aid to the preparation of a suitable logbook system, a sample logbook for an evaporative cooling system is included in SHTM 2040, 'Good practice guide'.

5.9 Details of operational and functional tasks must be drawn up for each site by the "nominated person". These, together with the completion of log sheets, will enable a proper historical record to be compiled of all works carried out and observations made.

5.10 Frequencies are indicated for initial guidance only, as they will vary to suit a particular site, its location, the design parameters and particular provisions, for example manual operation rather than automatic control methods.

5.11 The user's needs must be considered before commencing any operational or maintenance tasks. Where standby or dual facilities are not provided, the timing of these tasks must be carefully planned to minimise inconvenience.

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6. Air-conditioning and mechanical ventilation

General

6.1 Air-conditioning and ventilation plant and ductwork should be inspected at the access point(s) quarterly to see that it is clean and to report on its general condition.

Fresh air inlet

6.2 In the case of existing installations the use of portable smoke generators or smoke bombs may be helpful in observing the discharge plume from cooling towers and discharges from extract systems in order to assess any potential risk.

NOTE: The wind conditions will vary from day to day and sufficient tests to provide a representative sample will be necessary. The tests should be repeated with the cooling tower fan(s) both on and off.

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Publication ID	Title	Publisher	Date	Notes
	Food Safety (Temperature Control) Regulations	HMSO	1995	
	Food Safety (General Food Hygiene) Regulations	HSMO	1995	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	The Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2225	The Notification of Cooling Towers and Evaporative Condensers Regulations	HMSO	1992	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2169	The Pressure Systems and Transportable Gas Containers Regulations	HMSO	1989	
SI 574	The Private Water Supplies (Scotland) Regulations	HMSO	1992	
	The Public Health (Notification of Infectious Disease) (Scotland) Regulation	HMSO	1988	
	The Public Health Act (Infectious Disease) Regulations	HMSO	1975	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 1333	The Water Supply (Water Quality) (Scotland) Regulations (amendment)	HMSO	1991	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 6700	Specification for design, installation, testing and maintenance services supplying water for domestic use within buildings and their curtilages	BSI Standards	1997	
BS 7206	Specification for unvented hot water storage units and packages	BSI Standards	1990 (1997)	
BS 6920	Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on water quality	BSI Standards	1996	
BS 7592	Sampling for Legionellae organisms in water and related materials	BSI Standards	1992	
European Union Directives				
80/778/EEC	The Quality of Water Intended for Human Consumption	EEC		
Scottish Health Technical Guidance				
SHTM 2005	Building management systems	EEF	1999	CD-ROM
SHTM 2023	Access and accommodation for engineering services	EEF	1999	CD-ROM
SHTM 2024	Lifts	EEF	1999	CD-ROM
SHTM 2025	Ventilation in healthcare premises	EEF	1999	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	EEF	1999	CD-ROM
SHGN	'Safe' hot water and surface temperatures	EEF	1999	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 2	Domestic hot and cold water systems for Scottish Health Care Premises	EEF	1999	CD-ROM
SHTN 4	General Purposes Estates and Functions Model Safety Permit-to-work Systems	EEF	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
	NHS in Scotland – Scotconcode Scottish Infection Manual: Guidance on core standards for the control of infection in hospitals, healthcare premises and at the community interface	EEF	1999	Version 3
NHS in Scotland Firecode				
HTM 81	Fire precautions in new hospitals	EEF	1998	CD-ROM
HTM 82	Alarm and detection systems	EEF	1998	CD-ROM
HTM 83	Fire safety in healthcare premises: general fire precautions	EEF	1998	CD-ROM
HTM 84	Fire safety in NHS residential care properties	EEF	1998	CD-ROM
HTM 85	Fire precautions in existing hospitals	EEF	1998	CD-ROM
HTM 86	Fire risk assessment in hospitals	EEF	1998	CD-ROM
HTM 87	Textiles and furniture	EEF	1998	CD-ROM
Fire Practice Note 3	Escape bed lifts	EEF	1998	CD-ROM
Fire Practice Note 4	Hospital main kitchens	EEF	1998	CD-ROM
Fire Practice Note 5	Commercial enterprises on hospital premises	EEF	1998	CD-ROM
Fire Practice Note 6	Arson prevention and control in NHS healthcare premises	EEF	1998	CD-ROM
Fire Practice Note 7	Fire precautions in patient hotels	EEF	1998	CD-ROM
Fire Practice Note 10	Laboratories on hospital premises	EEF	1998	CD-ROM
UK Health Technical Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
MES	Model Engineering Specifications	NHS Estates	1997	As required
	The colonisation of water in United Kingdom transplant units with Legionella bacteria and Protozoa and the risk to patients	HEEU	1995	
	Pseudomonas Aeruginosa in whirlpool baths	HEEU	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Public Health Laboratory Services				
	Spa pool working party	PHLS	1994	
	Hygiene for hydrotherapy pools	PHLS	1990	
	Hygiene for spa pools: guidance for their safe operation	PHLS		
Miscellaneous References				
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Chemical Disinfection in Hospitals (second edition)	PHLS	1993	
	Water Byelaws Scheme's (WBS) Water Fittings and Materials Directory (WFMD).			
	Department of rehabilitation: a design guide	DHSS	1974	
	The central sterilization club, hygiene for hydrotherapy pools	PHLS	1990	
	A guide to pre-commission cleaning of water systems	BSRIA	1991	

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Scottish Health Technical Memorandum 2040

(Part 5 of 6)

Good practice guide

The control of legionellae in healthcare premises – a code of practice

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IMPORTANT NOTE
LEGIONELLA
SHTM 2040 and the HSC Approved Code of Practice and Guidance (L8) 2000

HSC's Approved Code of Practice came into effect on 8 January 2001. At this time i.e. December 2001 the UK Health Department's Guidance HTM 2040 (SHTM 2040 in Scotland) has not been aligned with the ACOP. Work is ongoing but it is unlikely that HTM 2040 and SHTM 2040 will be updated until late 2002 and launched on a UK basis.

L8 takes cognisance of 'hospitals' but requires considerable interpretation for practical application. The revised UK Health Department Guidance will undertake to address this issue.

In the meantime this version of SHTM 2040 must be read as subordinate to the new ACOP.

Disclaimer

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NHSScotland, P&EFEx, December 1999

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Appendix 1: The use of sodium hypochlorite solutions for chlorination of cooling water systems in hospitals

1.1 Chlorine is an excellent and fast-acting biocide, widely used for controlling microbial growth in cooling waters of wet, evaporative heat exchangers. However, it is essential to note the following four facts, which determine its efficiency during use.

a. chlorine has no detergent cleansing powers. It is essential that slime and debris are removed by thoroughly cleansing before chlorine is used, otherwise micro-organisms will survive disinfection as a result of the physical shielding afforded by these slimes;

b. chlorine is a highly reactive chemical and will very rapidly combine with organic matter, ammonium compounds and any oxidisable materials (for example ferrous and manganous salts, hydrogen sulphide) present in the water or on wetted surfaces. These reactions will greatly reduce, or even neutralise completely, the disinfecting power. In practice, the level of free available residual chlorine (that is, that available for disinfection) will always be less than that calculated from the dose added, and will decline progressively after addition. For these reasons, chlorine should only be used in systems which are already clean, and the level of free available residual chlorine in the water must always be checked after adding chlorine and allowing it to become completely mixed with the circulating water;

c. chlorine should not be used with other biocides, since they may neutralise each other, unless they are known to be compatible;

d. the disinfecting effect is greater at pH values at or below the neutral pH value of 7.0. Temperature will also affect the efficacy. At pH values above 8.0 the disinfecting power is greatly reduced. This is because the disinfecting activity is mainly brought about by hypochlorous acid (HOCl), which exists in pH-dependent equilibrium with hypochlorite ions (OCl-), in solution. For example, in water at 30°C and pH 7, 71% free available residual chlorine will exist as hypochlorous acid, whereas at pH 9 there will only be 2.4% hypochlorous acid, and 97.6% will be in the form of hypochlorite ion OCl-, which is not as powerful a disinfectant as HOCl (see Figure 1, Effect of pH on chlorination (as HOCl)).

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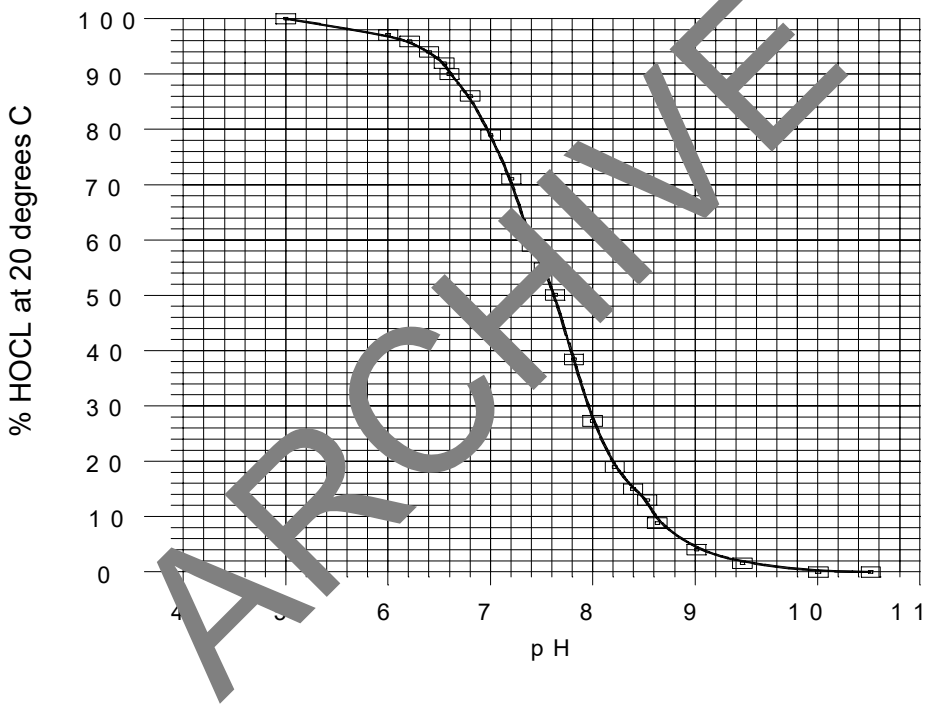
Sodium hypochlorite and available chlorine

1.2 Sodium hypochlorite solutions are the most suitable for chlorinating hospital and other cooling waters. Other chemicals such as bleaching powder ("chloride of lime"), "high-test hypochlorite" or "slow-release tablets" (chloroisocyanurate compounds) are less convenient to prepare or use, and liquefied chlorine gas is too hazardous.

1.3 Sodium hypochlorite solutions are sold containing 10-15 percent available chlorine. They contain sodium hydroxide which helps to prevent degradation of the sodium hypochlorite during storage. The commercial preparation has a pH value of about 11 and also contains sodium chloride.

Figure 1: Effect of pH on chlorination (as HOCl)



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1.4 It is conventional to express the strengths of chlorine compounds and similar oxidising disinfectants in terms of "available chlorine". This is for analytical convenience, since it provides a common reference of oxidising power for various chemicals used in the disinfecting of water (for example chlorine, hypochlorous acid, hypochlorite ion, chloramines, chlorine dioxide and sulphur dioxide. Chlorine itself (Cl_2) is assumed to be 100 percent available.

1.5 Commercial sodium hypochlorite contains 10-15 percent (w/v) available chlorine, representing a dilution of about 10 to 7 times respectively.

1.6 In tests of treated water for the presence of available residual chlorine, the hypochlorous acid and hypochlorite ion both react by oxidation, so both are

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measured. This makes it easy to determine the dose of available chlorine added by calculating the dilution (as shown in Table 1).

1.7 This table does not allow for deterioration in strength of the hypochlorite solution, or for chlorine demand within the water and cooling circuit. Hence, the actual concentration of free residual chlorine in the water must always be checked after the dose has been added and properly mixed with the cooling water.

Care in storage and use of sodium hypochlorite solutions

1.8 Solutions must be stored in a dark, cool, well-ventilated place and handled with care according to instructions on the label. They must not be stored or mixed with other chemicals such as acids, ammonia, ammoniacal compounds or cleaning materials because of the risks of evolution of poisonous, chlorine gas and the spontaneous formation of explosive nitrogen trichloride. The solutions are caustic, causing burns to the eyes and skin, are poisonous and will rapidly bleach and rot clothing and woodwork and corrode metals. They must only be placed in glass or plastic containers. When handled, waterproof protective clothing and eye shields must be worn. Any splashes on the eyes, skin or clothing should be washed off immediately with plenty of cold water. If swallowed, medical advice should be sought immediately. Further information on the safe handling of sodium hypochlorite solutions is given in the Department of Environment's publication, 'Swimming Pool Disinfection Systems Using Sodium Hypochlorite – Guidelines for Design and Operation' (DOE, 1979).

Chlorination of hospital cooling water systems to suppress bacterial growth

Routine chlorination as an alternative to other biocides

1.9 If chlorine (or biocide) is/are not added to the cooling-water circuits, legionellae and other micro-organisms may become established because of the favourable operating temperature range and if sufficient nutrients are present. Nutrients may be derived from such sources as contaminated make-up water, dust, leaves, bird droppings and from decaying microbial slime. Low concentrations of free available residual chlorine will prevent growth of legionellae and other micro-organisms, thereby preventing the build up of slimes even if nutrients are present in the water. The concentration of free available residual chlorine needed to suppress microbial growth will depend upon the quality of the water being circulated and the condition of the pipework.

1.10 It is essential that the chosen level is maintained since the free chlorine will be absorbed constantly by organic matter and microbial growth in the system

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– and lost by chemical degradation when the water cascades through the tower packing. Experience has shown that control is achieved when the free available residual chlorine level is maintained constantly at 1-2 mg/l, and to avoid corrosion, a level of 3mg/l is the maximum which should be permitted.

1.11 Where continuous dosing and control is not possible, it may be possible to maintain a similar level of control by dosing intermittently (not less frequently than weekly), to achieve an initial level of 10 mg/l as free available residual chlorine, after allowing for the solution to become completely mixed with the cooling water. If the level falls below 1 mg/l before the next dosing, the frequency of dosing should be increased.

Periodic cleaning and disinfection of the cooling circuit

1.12 Because sodium hypochlorite in solution has no detergent or penetrative properties, the aim must be to use thorough mechanical cleaning with brushing and rinsing to remove the slime and debris before the system is disinfected and returned to service. The procedure outline in this SHTM is based upon practical engineering and microbiological experience such as described by Colbourne *et al* (1978).

1.13 The procedure recognises that disinfection is a function of both time and concentration. Practical experience in water supply industry for disinfection of pipelines and storage reservoirs, within buildings and in ships, has shown that satisfactory disinfection of cleaned structures can be obtained if the concentration x time product (CT) is at least 50 mg h/l. To achieve this degree of treatment, the dose of available chlorine added, as calculated from Table 1, must be considerably in excess, to allow for chlorine demand. Table 2 indicates the actual dose of chlorine available which may have to be added to achieve a CT product of 50 mg h/l. Experience has shown that when doses of 20 mg/l or less are used, there is a risk of disinfection failure because of the effect of chlorine demand.

1.14 Provided that the procedure has been followed correctly, there is no benefit in extending the contact period. Indeed, if the procedure has been applied incorrectly and the level of chlorine is less than that required, increasing the contact time would create conditions where untreated water stagnate in a water system, thereby allowing time for bacterial growth. There is a risk of accelerating corrosion/deterioration of the materials of construction if chlorinated water is left to stand in pipework overnight on a repeated basis.

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Table 1: Approximate amounts of commercial sodium hypochlorite solution (10% (w/v) available chlorine) to be added to achieve a given dose

Required dose of available chlorine (mg/l)	Volume of sodium hypochlorite to be added		
	ml/m^3	fluid oz 1000 gal	ml/1000 gal
1	10	1.6	45
5	50	8	227
10	100	16	454
50	500	80	2270

Table 2: Examples of the dose of available chlorine which may be needed initially to achieve disinfection to a concentration x time product of 50 mg h/l

Dose to be added		Typical measured free available residual chlorine (mg/l)		
As chlorine mg/l	As hypochlorite 10% w/v available chlorine (ml/m^3)	Contact period (h)	immediately after addition	after contact period
50	500	1	40-50	30
40	400	1.5	30-40	25
30	300	2	20-30	15
20	200	3.5	10-15	5
15	150	5	5-10	5

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Appendix 2: Questionnaire: Assessment of serviceability of existing cooling systems

1. Are they registered with local authority?

2. Siting of cooling tower

   a. Is the cooling tower located near a fresh-air intake to an air conditioning or ventilation system?

   b. Is it possible for wind to carry the cooling tower discharge vapour towards the windows of a nearby area or department where there are patients?

   c. Is the siting such that good access is available for maintenance purposes?

   d. Is the siting or tower configuration such that the wind could cause reversal of air flow and spray to carry over from the air-inlet louvres?

3. Cooling tower

   a. Are all the internal parts of the cooling tower readily accessible, or can they be rendered so?

   b. Is corrosion apparent either internally or externally?

   c. Is fouling apparent within the tower?

   d. Is debris, sludge or slime apparent in the tower water?

   e. Are the drift eliminators closely fitting and firmly seated in their support grid?

   f. Is the pack, or any other part of the tower, manufactured from natural materials such as timber?

   g. Are natural rubbers used as seals or gaskets in the spray system or elsewhere?

   h. When operating at full load, is excessive drift visible from the tower discharge?

   i. Is there a coarse strainer located over the outflow pipe from the tower?

   j. Is the drain from the pond piped to discharge above a gulley connected to the foul water drain system?

   k. Is the overflow from the pond piped to discharge above a gulley connected to the foul water drainage system?

   l. Is there a readily accessible pond water sampling point available?

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m. Is there a readily accessible water sampling point available to sample tower make-up water?

n. Is there a strict water treatment programme in operation to control:

(i) Total Dissolved Solids (TDS);

(ii) pH;

(iii) total hardness;

(iv) chlorides;

(v) scale;

(vi) slime;

(vii) water treatment chemical/additive levels;

(viii) corrosion;

(ix) sludge;

(x) algae;

(xi) micro-organisms?

o. Is the tower and the entire distribution system cleaned and disinfected at the correct intervals?

p. Is there a regular maintenance programme and recording/logbook system in operation?

q. Is a water meter installed on the feed to the make-up valve? Is it accurate?

4. The distribution system

a. Is the pipework distribution system clearly visible and accessible?

b. Is the pipework system easily dismantled for inspection or is it provided with inspection points?

c. Is there a risk of water stagnation in the pipeline strainer assembly? (This can occur with duplicate sets if precautions against stagnation are not taken.)

d. Is there a risk of water stagnation in the maintenance bypass across the 3-way control valve? (This will occur if the bypass valve is fully closed. Flow should be encouraged or the bypass removed.)

e. Where duplicate pumps are installed, do they alternate on a daily basis?

f. Are there adequate manual drain points installed, with drain discharge lines piped to discharge above a gully connected to the foul water drainage system?

g. Are there adequate, readily accessible water sampling points installed in the distribution system?

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h. Is the automatic TDS drain line piped to discharge above a gulley connected to the foul water drainage system?

i. Are there adequate thermometers and pressure gauges installed to enable the system performance to be monitored and understood?

j. Is a regular maintenance programme and recording/logbook system in operation?

k. Does an internal inspection of the condenser and pipework system indicate fouling is present?

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Appendix 3: The course of action if an outbreak of legionnaires' disease is suspected

3.1 The nominated person will usually be informed of a suspected case of legionnaires' disease possibly associated with healthcare premises by either the outbreak control team or the local Consultant in Communicable Disease Control (CCDC). If a case is suspected, then the hospital outbreak team will normally work in association with the Directors of Public Health and the Scottish Centre For Infection and Environmental Health and the local CCDC to search for the source of the causative organism. It is essential that systems are not drained or disinfected before samples have been taken. The nominated person's role is an important one – guiding the team to the various water systems within the building and, in particular, to the points from which the samples can be taken. Easy access to these sampling points is essential.

NOTE: The hospital outbreak control team (the team) should include the consultant in communicable disease control.

3.2 The investigation will concentrate upon all potential sources of legionella infection, including:

a. the domestic hot and cold water distribution system;
b. wet spray cooling water systems;
c. showers or spray washing equipment;
d. drainage systems and traps;
e. spas, whirlpool baths or therapy pools;
f. humidifiers in ventilation systems;
g. cooling coils in air-conditioning systems;
h. fountains and sprinklers.

3.3 To assist in such investigations, the nominated person must be able to provide details of all associated equipment, including all documentation. He/she must assist by advising the investigating team on the extent of the servicing on the site, and by locating taps and sample points.

3.4 The nominated person must also identify the locations of any medical equipment used for dental care, respiratory therapy and within haemodialysis units, etc.

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3.5 Off-site information will also be required, such as whether there have been any local excavation or earthmoving works, alterations to water supply systems, or drainage systems or any other factors which may have a bearing on the site.

3.6 The address and telephone number of the nearest weather station will be required – this is likely to be a local airport, university or college department.

3.7 The team is responsible for identifying the cause of infection, and will advise on cleaning, disinfection, any modifications, and long-term control measures.

NOTE:
Reference Laboratory – Legionella
Scottish Legionella Reference Laboratory
Stobhill Hospital NHS Trust
Glasgow G21 3UW
Tel 0141–201–3000
Fax 0141–201-3887.

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Appendix 4: Sample logbook

Logbook No……

Establishment ……..
……..

Site ……..
……..
……..
……..

Installation Evaporative cooling water system
Located……..……...
Serving……..……...

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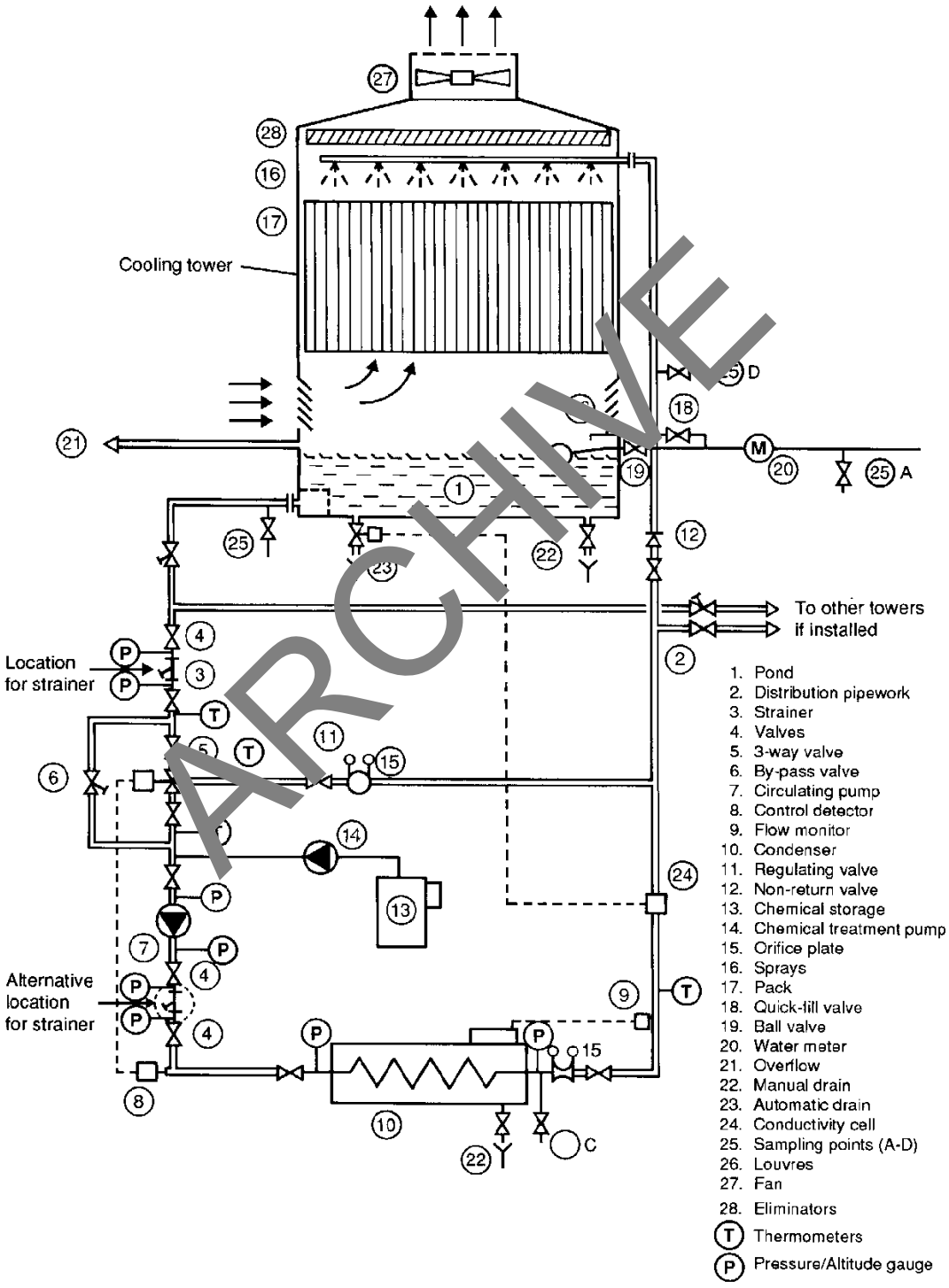
Establishment……...Logbook

Site……..…Page No 1

Installation……..…Serial No 1

Frequency…….

Typical evaporative cooling tower system arrangement



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Establishment……...Logbook

Site……..…Page No 1

Installation……..…….Serial No 2

Frequency…….

Operation

Water is circulated to the condenser at a constant temperature of 25°C. This temperature is achieved by modulation of the 3 way control valve (item 5) missing proportions of water from the cooling tower or bypass line as controlled by the detector (Item 8).

Schedule of commissioning data

Cooling tower rating……...kW
Air on 28°C db 21°C wb Air off…..°C db……...°C wb
Air volume……..……..m3/ Pressure difference…….Pa
Water temperature on……..°C
off……°C
Water flow rate……...l/s

Circulating pump

Flow rate……..l/s Suction pressure……...bar
Static pressure……..bar Discharge pressure……..bar

Refrigeration condenser

Rating ……kW
Water on……°C
off……°C
Pressure drop……..kPa

System volume

Pipework distribution…….litres
Cooling tower…….litres
Total volume……...litres

Plant operating times

Hours per day……..hrs
on……hrs
off……hrs
Days per week……..……days
Weeks per year…..……...weeks
State normal operating season _____ from _____ to _____

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System circulation time

Total volume in litres = ….mins*
Pump flow rate l/s x 60

*** Due to short-circuiting within the pond, a complete change of pond water cannot be guaranteed within this theoretical period, which should be used as a guide only.**

Total dissolved solid (TDS) control

Desired control level……μs/m^2
Method of control for example conductivity control

Chemical treatment system A

Chemical formulation……..……..
Holding tank volume……litres
Pump duty……/hr @ ……..…kPa
Method of control……..…

Chemical treatment system B

Chemical formulation……..……..
Holding tank volume……litres
Pump duty……/hr @ ……..…kPa
Method of control……

Chemical treatment system C

Chemical formulation……..……..
Holding tank volume……litres
Pump duty……/hr @ ……..…kPa
Method of control……

Chemical treatment system D

Chemical formulation……..……..
Holding tank volume……litres
Pump duty……/hr @ ……..…kPa
Method of control……

Chemical treatment system E

Chemical formulation……..……..
Holding tank volume……litres
Pump duty……/hr @ ……..…kPa
Method of control……

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Establishment……...Logbook

Site……..….Page No 2

Installation……..……Serial No 1

Frequency W & M

Evaporative cooling system operational checks

(W = weekly, M = monthly)

Note as applicable: S = satisfactory; N/S = not satisfactory
Record defects over page

Item	Design Data	Frequency	Date of inspection							
1. Refrigeration M/C:										
a) water in/out °C		**W**								
b) temp. diff. °C		**W**								
c) current drawn A		**W**								
d) pressure drop kPa		**W**								
e) observations										
2. Condenser water pump										
a) outlet press bar		**W**								
b) suction press bar		**W**								
c) diff. pressure bar		**W**								
d) duty/standby		**W**								
e) hours run Pump 1		**W**								
f) hours run Pump 2		**W**								
g) full load current A		**W**								
h) observations										
3. Control valve (range 0-10)										
a) valve position (0-10)		**W**								
b) temp. from tower °C		**W**								
c) temp. at detector °C		**W**								
d) manual operation		**W**								
e) observations		**W**								
Inspector's signature										

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Item	Design Data	Frequency	Date of inspection							
4. Tower										
a) pond inspection		**W**								
b) ball valve operation		**W**								
c) fan/speed r.p.m.		**W**								
d) fan current		**W**								
e) air on °C wb		**W**								
f) fan operation check		**W**								
g) casing check		**W**								
h) moisture carry over		**W**								
i) overflow check		**W**								
j) strainer check		**W**								
k) pond heater current operational check		**W**								
l) sump current drawn		**W**								
m) drift eliminator check		**M**								
n) pack check		**M**								
o) discharge ducting check (if applicable)		**M**								
p) NR damper check (if applicable)		**M**								
q) spray/spare/trough check		**M**								
r) inlet louvre check		**M**								
s) observations										
5. Circulation system										
a) strainer pressure		**M**								
b) drains		**W**								
c) valves		**W**								
d) vents		**W**								
e) pipework		**W**								
f) leaks		**W**								
g) flow to tower (with 3 way valve fully open)		**M**								
h) flow to system (with 3 way valve fully recirc.)		**M**								
i) flow monitor check		**W**								
j) observations		**W**								
Inspector's signature										

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 3

Installation……Serial No 1

Frequency…….

Operational tests on make-up water from evaporative cooling systems

Note as applicable: S = satisfactory; N/S = not satisfactory

Name of water undertaking……..…Tel No ……..……..
Name of water treatment contractor……....Tel No ……

Control parameters

Typical water usage……..litres
Normal tolerances ± ……litres
Total hardness…… pH……..
Conductivity…… Chlorides…..……...

Where installed, name of water softener device……..…...

Date	Water meter reading	Water used litres	Total hardness	Conductivity	pH	TDS	Observations	Initials

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 4

Installation……..….Serial No 1

Frequency…….

Detail sheet for water treatment programme associated with evaporative cooling.

Name of water treatment contractor……..Date…….
Cooling tower duty kW
Design operating conditions……...l/s
On……..……°C Off……..…..°C
Plant operating period…….hrs/day
days/week…….
weeks/year……
Total system water capacity……..litres
Evaporative rate……..l/s Peak daily output……..litres
Pre-treatment plant……
Bleed system control method……(for example conductivity control)

Control parameters:

Conductivity……
TDS……..typical
Chlorine……..typical
pH……typical
Chlorides……

Selected chemical treatment				
Chemical formulation	Initial dose	Maintenance dose	Dosing equipment	
			Dilution rate	Flow rate
A				
B				
C				
D				
E				
F				

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Chemical treatment criteria for proprietary products listed in table below							
System water	Treatment (state A, B, C, D, E, F)	Control units		*Units	Type of test	Remarks
		Min	Max			
Scale controller						
Corrosion inhib.						
Sludge dispensive						
pH						
Methyl orange alkalinity M						
TDS						
Biocide						

*** Criteria concentrations are shown in mg/litre (p.p.m) in terms of $CaCO_3$ unless otherwise stated.**

Table 3 Biological activity					
Bacterial procedure	**General bacterial count organisms per ml**	Remarks			

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Establishment .....Logbook

Site .....Page No 5

Installation .....Serial No 1

Frequency .....

Operational tests on water quality for evaporative cooling system

.....

.....

Name of water treatment contractor .....

Note as applicable: S = satisfactory; N/S not satisfactory

State defect over page.

Date	System water test ppm				Total ALK or pH	System condition S or N/S	Chemical dosed A, B, C, D, E, or F, state chemical and litres	Dosing equipment operation S or N/S	Initials
	Scale controls	Corrosion inhibitor	Sludge dispensiv						

Dosing system operational checks **Frequency - weekly**

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Item	Date of inspection							
1. Chemical treatment system A a) contents of holding tank (litres) b) volume of chemical used (litres/day) c) top up holding tank and record new volume (litres) d) pump operational check e) control device check f) pump duty check g) observations S or N/S								
2. Chemical treatment system B a) contents of holding tank (litres) b) volume of chemical used (litres/day) c) top up holding tank and record new volume (litres) d) pump operational check e) control device check f) pump duty check g) observations S or N/S								
3. Chemical treatment system C a) contents of holding tank (litres) b) volume of chemical used (litres/day) c) top up holding tank and record new volume (litres) d) pump operational check e) control device check f) pump duty check g) observations S or N/S								
Inspector's signature								

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 6

Installation……Serial No 1

Frequency Weekly

Maintenance sheet for cooling tower fans

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect on the observation sheet

Job Description	Date of inspection							
1. Cooling tower No ……								
a) isolate electrical supply to fan								
b) isolate condenser water pumps and/or valve to tower being serviced								
c) remove fan guard and wipe clean motor, drive shaft and general parts to be serviced								
d) adjust thrust and collar bearings								
e) lubricate fan bearing with …… shots of grease type ……								
f) lubricate motor bearing with …… shots of grease type ……								
g) check oil level in drive gearbox and top up as necessary using oil type……								
h) lightly grease shafts and parts exposed to vapour as appropriate								
i) if belted drive, check belt tension and adjust as necessary								
j) reassemble guard and bring plant back into service								
k) check ball valve assembly for correct operating level and adjust as necessary								
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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 7

Installation……Serial No 1

Frequency 3 monthly

Maintenance sheet for cooling tower
3 monthly tasks

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect in the observation sheet

Job Description	Date of inspection							
1. Cooling tower No …….. **a) isolate electrical supply to tower** **b) isolate condenser water pumps and/or valve to tower being serviced.** **c) remove fan guard, wipe clean, inspect for rust spots, rub down apply rust inhibitor and paint. When replacing guard lightly grease holding bolts.** **d) clean fan casing, impeller, housing, holding bolts and framework. Inspect all steelwork for rust spots, rub down, apply rust inhibitor and paint. Apply protective grease to bolts and parts exposed to vapour.** **e) remove dirt eliminators, brush and wipe clean, apply hose as necessary. Inspect for signs of fouling. If fouling is present apply chemical dispersant and remove. Similarly clean eliminator support grid and housing. Inspect for signs of rust, rub down, apply rust inhibitor and paint.** **When complete replace eliminators taking care to place the correct way up, to align and seal to prevent moisture by-passing.**								
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Job Description	Date of inspection							
f) remove all spray nozzles and clean. Replace all suspect grommets and washers. **If trough distribution system, remove trough and wipe clean, hose as necessary and rod through all nozzles.** **Inspect distribution pipe for signs of rust, rub down, apply rust inhibitor and paint.** **g) remove pack from tower and clean by scraping, wiping , brushing and application of hose. (Method to be sympathetic to material.) If fouling is present use chemical dispersant to remove fouling or if more appropriate dispose of media and replace with new. Similarly clean inside of tower casing and pack support grid. Inspect for signs of rust, rub down, apply inhibitor and paint. When complete take care with replacement to ensure by-passing does not occur.** **h) clean louvres and screens. Inspect for signs of rust, rub down, apply inhibitor and paint.** **i) isolate ball valve and pond outflow pipe.** **Drain pond.** **Clean out debris and sediment, hose out pond until clear.** **Remove strainer and scrub clean.** **Clean outflow pipe orifice.** **Hose through all drain lines and sampling pipes.** **If fouling is present use chemical dispersant and remove.** **When clean and dry inspect pond for signs of rust, rub down, apply inhibitor and paint.**								
Engineer's signature								

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 7

Installation……Serial No 2

Frequency 3 monthly

Maintenance sheet for cooling tower
3 monthly tasks

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect in the observation sheet

Job Description	Date of inspection							
j) clean ball valve assembly and adjust operating level as necessary. **k) inspect immersion heater for signs of leaks and repair as necessary.** **Clean immersion heater coil and use chemical dispersant to remove any fouling.** **Inspect weather proofing on all trace heating and insulation, and repair where damaged** **Check tightness of all cable terminations**								
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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 7

Installation…….Serial No 3

Maintenance sheet for cooling tower
3 monthly tasks

Frequency 3 months and as necessary

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect in the observation sheet

Job Description	**Date of inspection**							
1. Fan assembly **a) drain oil from gear box and replace using oil type …….**								
2. Ball valve								
a) replace ball valve washer and readjust as necessary each alternate 3 months.								
3. Seasonal cleaning & disinfection								
a) carry out disinfection of make-up tank and distribution pipework as required by Code of Practice. Record quantity and sodium hypochlorite used for disinfection (litres). **Record residual chlorine level after 1 hour standing circulation (p.p.m.)** **b) carry out disinfection of tower and distribution system as required by Code of Practice. Record quantity of sodium hypochlorite used for disinfection (litres).** **Record residual chlorine level after 4 hour circulation period (p.p.m.).** **c) bring system back into service.**								
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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 8

Installation……Serial No 1

Frequency months

Maintenance sheet for condenser water circulation system monthly tasks

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect in the observation sheet

Job Description	**Date of inspection**							
1. Condenser water circulation Pump No 1 a) isolate electrical supplies locally. b) remove guards, inspect for rust and make good as necessary. c) wipe clean motor, shaft, pump casing and parts as appropriate. d) check all bearings and adjust as necessary. e) lubricate pump bearings with …. shots of grease type …….. f) check belt drives for correct alignment and tension and adjust as required. g) check pump glands for excessive leakage, adjust or replace as required. h) clean drip cups and rod through as required. i) check tightness of all holding down bolts and anti-vibration mountings. Realign if required. j) bring pump back into service.								
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Job Description	Date of inspection							
2. Condenser water circulation Pump No 2 Where dual pump installations exist draw up additional maintenance sheet and implement maintenance function.								
3. Dosing pump for chemical A a) check pump bearing and where not sealed for life oil or grease to manufacturers instructions. b) disconnect pump discharge and run for set time discharging contents into measuring container to check duty remains satisfactory. c) tighten pump holding down assembly on top of chemical treatment tank.								
4. Dosing pump for chemical B Where more than one dosing is installed draw up maintenance sheets for each system and implement maintenance function.								
5. Strainer a) remove strainer basket, insert standby basket, bring service back on line, empty and clean basket.								
6. Pressure gauges and thermometers a) clean all glass dial gauges and mercury in glass stem thermometers to ensure clarity of reading.								
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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 8

Installation……Serial No 2

Frequency 6 monthly

Maintenance sheet for condenser water circulation system – 6 monthly tasks

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect in the observation sheet

Job Description	**Date of inspection**							
1. Valves a) clean all valve spindles of dust or deposits. b) operate valve through two full cycles from fully closed and reset to precise original position. c) inspect gland and adjust gland nut as required. Repack gland if required. d) lubricate valve as required by manufacturer.								
2. 3-Way control valve a) check valve spindle for signs of wear and distortion. Replace as necessary. b) check glands and adjust as necessary. c) check terminals and tighten or check pneumatic tubing and tighten nipples if necessary.								
3. Automatic air vents a) isolate feed to AAV, dismantle, remove float and clean float and needles. Clean ports and needle seats. b) blow through discharge lines.								
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Job Description	Date of inspection							
4. Drains and sample points a) open all drain lines and sample points to blow clear. Check discharges to ensure lines freely drain over gully to waste.								
5. Strainer a) remove flow monitor, inspect and operate paddle. Chemically clean and replace. b) check and tighten cable terminals.								
6. Flow monitor a) gain access to NRV clack and inspect for freedom of operation scoring or erosion. Renew disc if required and reassemble.								
7. Conductivity cell a) remove conductivity cell from pipeline, inspect and clean as recommended by manufacturer.								
8. Thermometers a) check all thermometers pockets for thermoconductivity paste and replenish as required.								
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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Establishment……...Logbook

Site……..…Page No 8

Installation……Serial No 3

Maintenance sheet for condenser water circulation system yearly or as necessary

Frequency yearly or as necessary

When maintenance task is satisfactorily completed the operative is to tick the box opposite. If task cannot be completed due to mechanical failure, insert a cross in the box opposite and note defect in the observation sheet

Job Description	Date of inspection							
1. Internal pipe inspections a) when system is drained for seasonal cleaning, remove inspection flanges and note condition of pipe interior.								
2. Pressure gauges a) remove pressure gauges and recalibrate or exchange for a recalibrated gauge.								
3. Condenser a) remove end plates. Clean off any signs of corrosion from tube plates and treat as recommended by manufacturer. b) rod through all tubes with the rodding brush and apply hose to clean out debris. c) reassemble and put into service.								
4. Thermometer pockets a) remove all thermometer pockets and inspect for fouling. If required, chemically clean pocket. b) replace pocket, repack with thermoconductivity paste and insert thermometer.								
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Defects schedule				
Date	**Observations**	**Noted**	**Diagnosed cause of defect**	**Initials**

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Appendix 5: Empty times for cooling tower ponds (approx.)

Pond litres	Capacity (gals)	Cooling tower drain valves sizes mm (inch)									
		25 (1.0)		38 (1.5)		50 (2.0)		63 (2.5)			
		Tank depths		Tank depths		Tank depths		Tank depths			
		0.5m	1.0 m	0.5 m	1.0 m	0.5 m	1.0 m	0.5 m	1.0 m		
150	(35)	5 min	-	-	-	-	-	-	-		
259	(57)	8 min	5 min	5 min	-	-	-	-	-		
345	(76)	11 min	8 min	7 min	-	-	-	-	-		
968	(213)	30 min	20 min	15 min	10 min	10 min	5 min	5 min	-		
1,500	(330)	50 min	35 min	20 min	15 min	15 min	10 min	10 min	5 min		
2,800	(616)	1 hr 30 min	1 hr 00 min	40 min	30 min	25 min	15 min	15 min	10 min		
5,500	(1,210)	3 hr 00 min	2 hr 00 min	1 hr 15 min	1 hr 00 min	45 min	30 min	30 min	20 min		
8,500	(1,870)	4 hr 30 min	3 hr 00 min	2 hr 00 min	1 hr 30 min	1 hr 15 min	45 min	45 min	30 min		
11,000	(2,420)	6 hr 00 min	4 hr 00 min	2 hr 30 min	2 hr 00 min	1 hr 30 min	1 hr 00 min	1 hr 00 min	40 min		

Times assume no hose and gate valve.

Notes

1. Ball type valves should be specified to minimise "clogging".
2. The drain from the gully must be of sufficient size to take the flow from the pond.

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Appendix 6: Cooling towers – operational checks

6.1 These tasks should be carried out weekly. Usually, visual inspection is sufficient.

Evaporative cooling system operational checks

6.2 The specimen logbook, page 2, details the checks and tasks to be covered. It is expected that the engineer will exercise discretion (as to the degree of involvement) where weekly charts are indicated. The tasks listed entail observation from close inspection and do not require dismantling or draining of plant, etc. (More detailed examination is covered under routine maintenance.) For instance, a "pond inspection" on a weekly basis is intended to be a visual inspection of the pond to establish the following:

a. correct operating water level;

b. water appears clean and free from slime, with no foreign matter floating or submerged.

Make-up water operational checks

6.3 Readings and tests as shown in the logbook, page 3, should be carried out on a weekly basis. The readings are required to ensure that the minimum amount of water is used, and that water temperature is maintained to reduce the risk of microbial growth and to suit the chemical treatment programme.

System water operational tests

6.4 The tests given in the logbook, page 5, should be carried out weekly to ensure proper control of the water treatment programme so as to restrict the development of *Legionella pneumophila*, the accumulation of scale, slime, sludge, etc.

Equipment checks

6.5 Each item of equipment should be checked using the senses of sight, touch, smell and hearing as applicable. This type of check will complement the readings taken from instruments and will allow comprehensive details to be recorded on the log sheet. Where such checks show that corrective measures can be carried out quickly and efficiently at the time of the inspection (using minimal tools and equipment), this should be done. Where

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the checks identify more time-consuming remedial action, with the use of specific plant and materials, the work should be carried out at the earliest opportunity following inspection. A preventive planned maintenance scheme should avoid the need for unforeseen, substantial maintenance tasks being identified through the weekly inspections.

6.6 Typical observation checks are listed below:

a. pond:
   (i) check water level is properly marked on the pond and is maintained;
   (ii) check overflow is clear;
   (iii) check ball valve flow and proper shut-off;
   (iv) check water for leaves and foreign matter;
   (v) check for slime and signs of scaling;
   (vi) check for leaks;
   (vii) check for signs of corrosion, for example rusting, algae blistering, oxidisation, etc.
   (viii) check clear visibility of sump;
   (ix) check screen in pond and clean as necessary;
   (x) check drains are free;
   (xi) check discharge from pack for uniformity;

b. tower casing:
   (i) check rattles and vibration;
   (ii) check the casing for water and air leaks while in operation;
   (iii) check for drift from tower discharge;
   (iv) check for signs of corrosion, for example rusting, blistering, oxidisation, etc.
   (v) check paint or protective coating for damage;
   (vi) check louvres and screens for leaves, growth and other deterioration;

c. tower intervals:
   (i) check pack for correct location, alignment, seal and absence of distortion;
   (ii) check pack for condition and signs of deterioration, scale, algae slime, poor water flow/coverage;
   (iii) check casing and inside structure for signs of corrosion, rusting, blistering and oxidisation;

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(iv) check sprays, sparge or troughs for efficient operation and uniformity of distribution of water over pack when operating;

(v) check drift eliminator for correct location, alignment and lack of distortion and seal;

(vi) check drift eliminator for signs of deterioration, scale, algae, slime or blockage;

d. cooling tower fan:

(i) check for noise vibration and free running;

(ii) check drive method where applicable for correct adjustment, alignment and operation;

(iii) check cage, guard and screen for corrosion and proper location and fixing;

(iv) check motor full-load current and record;

(v) check condition of impeller, shaft, housing, scroll, shaft, bearing and supports, etc;

e. sump immersion and trace heating:

(i) check power available and isolator position;

(ii) check operation manually;

(iii) check thermostat setting;

f. pipework distribution system:

(i) check for signs of leaks;

(ii) check for signs of corrosion;

(iii) check for vibration;

(iv) vent all air cocks and check all AAVs and discharge lines;

(v) check all drains are operable and gulleys are clear;

g. manual valves and cocks:

(i) check all valve glands for leaks or solid deposits collecting around spindle;

(ii) check for the correct setting of all valves (fully open, closed, partially open, etc.);

h. automatic 3-way control valves and associated equipment:

(i) check 3-way control valve fully operational;

(ii) check 3-way valve maintenance bypass valve is closed save for bleed facility;

(iii) check for positive shut-off as applicable;

(iv) re-establish automatic control, calibrate detector and set to design temperature;

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i. strainer:

(i) compare system flow to bypass flow and assess if strainer might be partially blocked;

(ii) check that spare strainer basket is available;

j. circulating pump:

(i) check each pump for smooth running and freedom from noise and vibration;

(ii) check bearings from grease and high temperature;

(iii) check shaft and drives for signs of wear;

(iv) check belts and pulley for correct alignment and tension belts;

(v) check guards for proper fixing and absence of vibration and corrosion;

(vi) check clearance of guards for free operation;

(vii) check glands for excessive leakage and check drip lines are clear and free draining to gulley;

(viii) operate stop cocks and auto-change facility as applicable;

(ix) operate each pump via on/off/auto switch to prove operation;

(x) measure suction and discharge pressures, record and compare with design. Increase in pressure difference will indicate reduction in flow, possibly caused by strainers or condenser tube fouling. Note observations;

(xi) record hours run for each pump;

(xii) check pump mounting condition and effectiveness;

(xiii) check foundations, securing bolts and pump alignment with pipework and assess any movement creeping;

k. condenser:

(i) vent condenser via air cocks to relieve any air pockets;

(ii) measure condenser water inlet and outlet pressures and record;

(iii) record condenser pressure differential and compare with design and flow as measured in (h) above and assess any fouling;

(iv) record water entry and leaving temperatures;

(v) record refrigeration machine full-load current associated with water temperature difference and compare with manufacturer's chart to assess load-cross check with flow and temperature difference readings taken;

l. flow monitor

(i) stop/start pumps and check free operation and ready switching of flow monitor;

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(ii) check refrigeration machine shuts down on no-flow;

(iii) check action of “delay-on” timer to refrigeration circuit and others as applicable;

m. dosing system(s) – for each system:

(i) check contents of drum(s) and note volume remaining;

NOTE: Checking frequency will depend on dosing rates and capacity for the chemical containers/drums, for example, small containers may be exhausted in as little as three days.

(ii) top up drum(s) with water treatment chemicals and record new volume of contents;

(iii) manually operate dosing pump(s) and check for correct operation and freedom from vibration, etc;

(iv) manually override controller(s) to cycle pump(s) automatically, check controller calibration, reset and leave under automatic control;

NOTE: Initially while plant is settling down, then after less frequently.

(v) check dosing pump(s) duty/calibration manually;

(vi) check setting and operation of any timers.

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
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	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	The Food Safety Act	HMSO	1990	
	Registered Establishments (Scotland) Act	HMSO	1998	
	The Water (Scotland) Act	HMSO	1980	
	Health and Safety at Work etc Act	HMSO	1974	
SI 346	The Active Implantable Medical Devices Regulations	HMSO	1992	
SI 2179 & 187	The Building Standards (Scotland) Regulations	HMSO	1990	
	The Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
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SI 1057	Electricity Supply Regulations	HMSO	1988 (amd 1990)	
SI 3080	Electromagnetic Compatibility (Amendment) Regulations	HMSO	1994	
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Publication ID	Title	Publisher	Date	Notes
	Food Safety (Temperature Control) Regulations	HMSO	1995	
	Food Safety (General Food Hygiene) Regulations	HSMO	1995	
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SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	The Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2225	The Notification of Cooling Towers and Evaporative Condensers Regulations	HMSO	1992	
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SI 2169	The Pressure Systems and Transportable Gas Containers Regulations	HMSO	1989	
SI 574	The Private Water Supplies (Scotland) Regulations	HMSO	1992	
	The Public Health (Notification of Infectious Disease) (Scotland) Regulation	HMSO	1988	
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SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	

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Publication ID	Title	Publisher	Date	Notes
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 1333	The Water Supply (Water Quality) (Scotland) Regulations (amendment)	HMSO	1991	
SI 3004	Workplace (Health, Safety and Welfare) Regulations	HMSO	1992	
British Standards				
BS 6700	Specification for design, installation, testing and maintenance services supplying water for domestic use within buildings and their curtilages	BSI Standards	1997	
BS 7206	Specification for unvented hot water storage units and packages	BSI Standards	1990 (1997)	
BS 6920	Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on water quality	BSI Standards	1996	
BS 7592	Sampling for Legionellae organisms in water and related materials	BSI Standards	1992	
European Union Directives				
80/778/EEC	The Quality of Water Intended for Human Consumption	EEC		
Scottish Health Technical Guidance				
SHTM 2005	Building management systems	EEF	1999	CD-ROM
SHTM 2023	Access and accommodation for engineering services	EEF	1999	CD-ROM
SHTM 2024	Lifts	EEF	1999	CD-ROM
SHTM 2025	Ventilation in healthcare premises	EEF	1999	CD-ROM
SHTM 2027	Hot and cold water supply, storage and mains services	EEF	1999	CD-ROM
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SHTN 4	General Purposes Estates and Functions Model Safety Permit-to-work Systems	EEF	1997	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
	NHS in Scotland – Scotconcode Scottish Infection Manual: Guidance on core standards for the control of infection in hospitals, healthcare premises and at the community interface	EEF	1999	Version 3
NHS in Scotland Firecode				
HTM 81	Fire precautions in new hospitals	EEF	1998	CD-ROM
HTM 82	Alarm and detection systems	EEF	1998	CD-ROM
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UK Health Technical Guidance				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
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	The colonisation of water in United Kingdom transplant units with Legionella bacteria and Protozoa and the risk to patients	HEEU	1995	
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Public Health Laboratory Services				
	Spa pool working party	PHLS	1994	
	Hygiene for hydrotherapy pools	PHLS	1990	
	Hygiene for spa pools: guidance for their safe operation	PHLS		
Miscellaneous References				
	Model Water Byelaws: Dept. of the Environment	HMSO	1986	
	Chemical Disinfection in Hospitals (second edition)	PHLS	1993	
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Scottish Health Technical Memorandum 2040

(Part 6 of 6)

The control of legionellae in healthcare premises

Supplementary guidance applicable to intermittently used healthcare premises

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IMPORTANT NOTE
LEGIONELLA
HTM 2040 and the HSC Approved Code of Practice and Guidance (L8) 2000

HSC's Approved Code of Practice came into effect on 8 January 2001. At this time i.e. December 2001 the UK Health Department Guidance HTM 2040 (SHTM 2040 in Scotland) has not been aligned with the ACOP. Work is ongoing but it is unlikely that HTM 2040 and SHTM 2040 will be updated until late 2002 and launched on a UK basis.

L8 takes cognisance of 'hospitals' but requires considerable interpretation for practical application. The revised UK Health Department Guidance will undertake to address this issue.

In the meantime this version of SHTM 2040 must be read as subordinate to the new ACOP.

Disclaimer

The contents of this document are provided by way of guidance only. Any party making any use thereof or placing any reliance thereon shall do so only upon exercise of that party's own judgement as to the adequacy of the contents in the particular circumstances of its use and application. No warranty is given as to the accuracy of the contents and the Property and Environment Forum Executive, which produced this document on behalf of NHSScotland Property and Environment Forum, will have no responsibility for any errors in or omissions therefrom.

The production of this document was jointly funded by the Scottish Executive Health Department and the NHSScotland Property and Environment Forum.

NHSScotland, P&EFEx, December 1999

Contents

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1. Introduction

General

1.1 Scottish Health Technical Memorandum (SHTM) 2040; *The control of legionellae in healthcare premises – a code of practice*, provides guidance for those with responsibilities in this area. However, Scottish Health Technical Memorandum 2040 is considered to be perhaps more applicable to continuous occupied healthcare sites and to the types of building services likely to be present, than to intermittently used healthcare sites offering a range of out-patient services.

1.2 This supplement seeks to provide a framework for the assessment of the risk of legionellae infection which derives from intermittently used healthcare premises and prescribes appropriate control measures which may be put in place. This document provides guidance on the measures to be taken to ensure safe intermittent operation of domestic hot water plant and hot and cold water supply services.

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Application to premises

1.3 The guidance offered in this supplement is applicable for all intermittently used healthcare sites. These sites are considered to be premises such as health centres, clinics, offices etc. which are not used on a 24 hour basis.

1.4 There may be instances however, where staff may occupy intermittently used healthcare premises for longer periods of time such as an overnight stay. If during this period of occupancy, there is known to be “zero” demand on the hot water services provided to the premises, the guidance in this supplement is considered to be appropriate. However, should hot water services be required by staff during a period of occupancy such as an overnight stay, more comprehensive control measures are required as detailed in the main text of Scottish Health Technical Memorandum 2040.

Priorities

1.5 All intermittently used healthcare premises should be reviewed regularly to identify where they do not meet the standards outlined in this guidance. A realistic programme should be prepared to eliminate any shortfall.

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2. Overview and management responsibilities

Statutory requirements

2.1 It is the responsibility of management to ensure that intermittently used healthcare premises comply with all health and safety statutory requirements. These are detailed in the main text of Scottish Health Technical Memorandum 2040.

2.2 Duties under the Health and Safety at Work etc Act 1974 extend to risks from the legionellae arising from work activities. More specifically, the Control of Substances Hazardous to Health Regulations relate to the risks from hazardous micro-organisms, including legionellae, and chemical such as biocides and chlorine. Under these Regulations, risk assessments and the adoption of appropriate precautions are required.

NOTE: Reference should be made to the Scottish Infection Manual – Guidance on core standards for the control of infection in hospitals, healthcare premises and at the community interface for the role of the Infection Control Team.

Management responsibility

2.3 The chief executive or general manager has overall responsibility for all aspects of water supplies within his/her organisation.

2.4 Scottish Health Technical Memorandum 2040 Part 1 outlines the managerial responsibilities and requirement for the effective management for healthcare premises. The requirements for intermittently used healthcare premises should form part of this overall system.

Nominated person

2.5 A nominated person (legionellae), possessing adequate professional knowledge and with appropriate training, should be nominated in writing for the prevention of Legionnaire's disease in intermittently used healthcare premises.

2.6 The requirements and responsibilities of the nominated person are outlined in the main text of Scottish Health Technical Memorandum 2040 Part 1.

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Site contact

2.7 The person who manages the site should appoint a “site contact” and confirm this in writing to the “nominated person” as defined above. The “site contact” should, on behalf of the “nominated person”, undertake to ensure that specific site information and appropriate routine checks for the premises are completed and duly recorded within the site’s log book.

Epidemiology

2.8 For details of the epidemiology of Legionnaire’s disease refer to the main text of Scottish Health Technical Memorandum 2040 Part 1.

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3. Design considerations

General

3.1 For details of the design requirements and considerations that should be applied to the design up to the contract document, refer to the main text of Scottish Health Technical Memorandum 2040 Part 2, ‘Design Considerations’. All modifications and alterations to the existing systems should comply as far as practicable with the requirements of SHTM 2040. Reference should also be made to Scottish Health Technical Memorandum 2027; *Hot and cold water supply, storage and mains services*.

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4. Validation and verification

General

4.1 For details of the validation and verification requirements and considerations that should be applied, including testing and commissioning aspects, refer to the main text of Scottish Health Technical Memorandum 2040 Part 4, ‘Validation and Verification’.

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5. Operational management

Operational considerations

5.1 A risk assessment diagram has been devised to assist in assessing the risk from legionellae in relation to the range of equipment and facilities likely to be available in intermittently used healthcare premises.

NOTE: Refer to Appendix 2: Intermittently used healthcare premises – checklist for assessing the risk from legionellae.

5.2 Assistance in identifying whether the facility under review is categorised as an intermittently used healthcare premises for the purposes of this document, is provided within this risk assessment diagram.

5.3 Those premises identified as being intermittently used healthcare premises may present a lower risk due to the nature of the systems involved and this document attempts to match the sophistication of the control measure to the complexity of the system. Such controls and inspection frequencies are detailed in the supplementary notes to the risk assessment diagram.

5.4 Those premises identified as being intermittently used healthcare premises, but unable to meet in its entirety the requirements outlined in the risks assessment diagram and supplementary notes are deemed to be of a higher risk. Such premises will require more comprehensive control measures to be put in place. The controls and inspection frequencies to be applied to premises in this category are detailed in the main text of the 'Operational management' part of Scottish Health Technical Memorandum 2040 (Part 3).

5.5 A standard survey sheet specifically for intermittently used healthcare premises and the varying facilities and equipment likely to be provided, has been designed. This form should be completed for each site; this ensures a written record is available for every site under consideration. It is recommended that the user refer to the risk assessment diagram when completing the standard survey sheet.

NOTE: Refer to Appendix 3: Intermittently used healthcare premises – water systems survey sheet.

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Background to risk assessment and monitoring

5.6 In undertaking a suitable and sufficient risk assessment, it is essential that consideration be given to the chances of being exposed to the hazard, coupled with the consequences of the exposure; in this instance the hazard being the contraction of legionellae infection.

5.7 Systems susceptible to colonisation by legionellae and which incorporate the potential to create and disseminate water droplets should be identified and the risk they present assessed.

5.8 In completing a risk assessment of intermittently used healthcare premises, the following points have been addressed when developing the diagram for assisting in the assessment of risk in relation to legionellae:

a. the potential for droplet formation;
b. water temperature;
c. the likely risk to those who will inhale water droplets;
d. the susceptibility of the potentially exposed population;
e. means of preventing or controlling risk.

5.9 The majority of intermittently used healthcare premises offer only basic water related services i.e. sanitary accommodation and washing facilities, providing both a hot and cold water supply for staff and patient use.

5.10 Ideal conditions for the colonisation and growth of legionella organisms may occur in intermittently used healthcare premises if water supply is being held in storage and/or pipework in the temperature range of 20°C to 45°C and if water supplies are stagnant for long periods of time.

5.11 Whilst a greater number of susceptible people may indeed access intermittently used healthcare premises, the facilities offered are unlikely to be used other than on an infrequent basis.

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Hazard assessment

5.12 Legionellae, which causes legionellosis, are naturally widespread in water systems. It is exceptional for a water supply, either public or private, to be entirely free from aquatic organisms, and for this reason it is important that appropriate measures are taken to guard against conditions which may encourage microbial multiplication. Provided water is derived from the public mains and its quality is maintained in the storage and distribution system by correct design, installation and maintenance, it can be regarded as being microbiologically acceptable for use without further treatment.

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5.13 Strict adherence to the additional guidance provided in this supplement read in association with the main text of Scottish Health Technical Memorandum 2040 will not eradicate legionellae, but there will be reduction in the risk of an outbreak.

Monitoring and record keeping

5.14 Based on the results of risk assessments completed and the guidance contained in this document, a written operational plan should be devised and regularly reviewed. A realistic programme should be prepared to tackle any area where action is indicated.

NOTE: Refer to Appendix 1: Guidance in developing an operational plan for the management of intermittently used healthcare premises.

5.15 Records of risk assessment completed, and the implementation of the operational plan should be retained throughout the period for which they remain valid, and for at least a further period of two years.

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6. Good practice guide

General

6.1 For details of the course of action if an outbreak of Legionnaire's disease is suspected, refer to 'Overview and management responsibilities' part of Scottish Health Technical Memorandum 2040.

Reference should also be made to the Scottish Infection Manual.

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Appendix 1: Guidance in developing an operational plan for the management of water systems in intermittently used healthcare premises

An operational plan should:

a. Be in written form and available for inspection.

b. Be prepared by or approved by the nominated person (legionella).

c. Detail the frequencies of routine inspection and maintenance. The minimum frequencies are detailed in HSC(L8) 2000. The control of legionella bacteria in water systems – Approved Code of Practice and Guidance. However, the risk assessment may indicate that increased frequencies are appropriate in some cases.

d. Name the nominated person and the site contact.

e. Be reviewed when the risk assessment is reviewed.

f. Detail known weaknesses and identify remedial actions including timescales.

g. Be signed and dated by the nominated person (legionella) and identify the premises to which it applies.

h. Identify the person or persons responsible for each action called for in the plan including checking temperatures, inspection of systems, time controls etc.

A copy of the operational plan should be retained by the nominated person (legionella), the site contact, the Infection Control Team and any other person upon whose actions the successful implementation of the plan depends.

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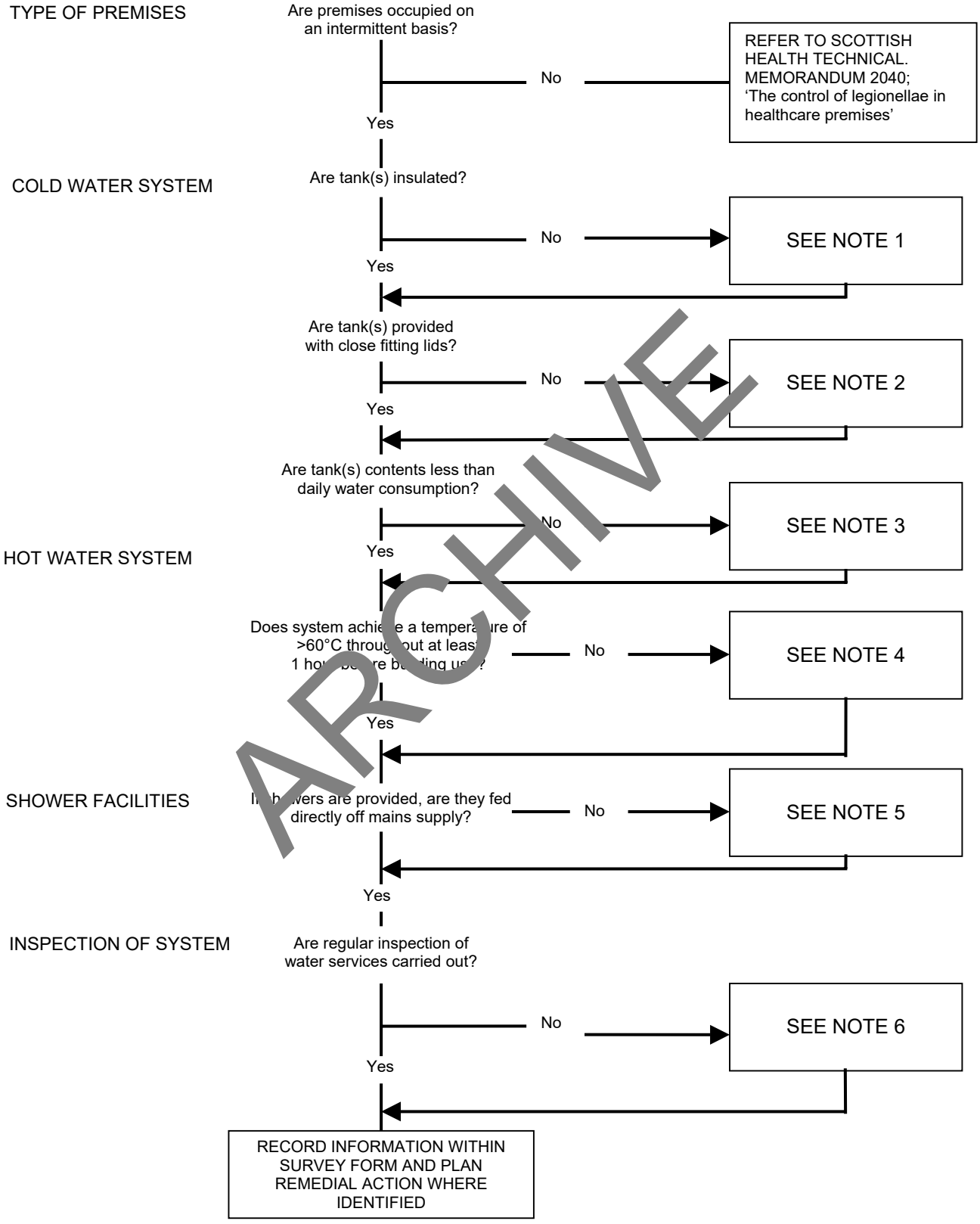
Appendix 2

Intermittently used healthcare premises – checklist for assessing the risks from legionella



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Intermittently used healthcare premises
Checklist for assessing the risks from legionella

Supplementary notes

Note 1 Storage tanks should be insulated to ensure that stored water does not exceed 20°C. Consideration should be given to the location of storage tanks to minimise casual heat gains.

Note 2 Tanks should be provided with close fitting lids secured to the tank. Vents and overflows should be fitted with mesh screens to prevent access by insects and rodents. Tank lids should allow easy access for cleaning and inspection.

Note 3 Water storage should be kept to the minimum required by operational considerations (requirements of Scottish Health Technical Memorandum 2027 or Water Authorities Guidelines) to ensure that water turnover is as high as possible. Reducing storage time reduces the effects of heat gains and helps to maintain temperatures below 20°C.

NOTE: The volume of stored water can be reduced by lowering the water level in the tank.

Note 4 To ensure pasteurisation, stored water must reach a temperature of 60°C throughout the system at least one hour before the water systems to be used and maintained throughout the occupancy. The temperature at the bottom of a calorifier can be significantly below that at the top and this should be taken into account. Calorifiers in which the heating element is not at the bottom will have difficulty in meeting this requirement. Domestic hot water circulators should be sized to ensure that the temperature within the distribution circuit is above 50°C at all points. Where a temperature of 50°C cannot be maintained, alterations to the systems should be considered.

Note 5 Showers fed from the mains with the hot water at point of use are preferred to showers fed from calorifiers. Where point of use heating is used, the amount of heated water left in the system after operation should be minimised. If showers are provided which are not fed directly from the mains supply, calorifier temperature should be maintained at above 60°C 24 hours a day.

Note 6 A system of regular inspections should be used to ensure that the risk of contamination and multiplication of the organism is minimised.

Note 7 Where Thermostatic Mixing Valves are fitted, the operational requirements of Pressure and Temperature ranges of the valve must be established and recorded.

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Appendix 3: Intermittently used healthcare premises water systems survey sheet

General information

Premises name:	
Site contact/manager:	
Date survey completed:	

Building

Hours of use of building (hrs/wk):	
Year built:	
Heated volume of building:	

Cold water storage

Tank material (No. of tanks)	Galvanised steel	
	Epoxy lined	
	Plastic	
	Other specify	
Insulation:	Yes ☐ No ☐ Comments:	
Close fitting lid(s):	Yes ☐ No ☐ Comments:	
Tank water volume:		
Water usage m^3/day:		
Water turnover: $\left(\frac{\text{Tank volume}}{\text{Water usage}}\right)$:		

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Hot water storage/generation

Verification of Temp.>60°C 1 hour before building use? Yes ☐ No ☐.	
Location of heating element (please tick) Top ☐ Middle ☐ Bottom ☐	
Time control: Time setting	On:
	Off:
	On:
	Off:

Distribution system

	Staff: Yes ☐ No ☐ Patient: Yes ☐ No ☐.
Showers: Source of hot water:	Point of use heater ☐ From calorifier ☐
Baths: Patient/staff use:	Yes ☐ No ☐.
Thermostatic Mixing Valves Fitted	Yes ☐ No ☐.

Additional comments

TYPE of TMV etc.....

.....

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	The Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Consumer Protection Act	HMSO	1987	
	Electricity Act	HMSO	1989	
	The Food Safety Act	HMSO	1990	
	Registered Establishments (Scotland) Act	HMSO	1998	
	The Water (Scotland) Act	HMSO	1980	
	Health and Safety at Work etc Act	HMSO	1974	
SI 346	The Active Implantable Medical Devices Regulations	HMSO	1992	
SI 2179 & 187	The Building Standards (Scotland) Regulations	HMSO	1990	
	The Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP 2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 1057	Electricity Supply Regulations	HMSO	1988 (amd 1990)	
SI 3080	Electromagnetic Compatibility (Amendment) Regulations	HMSO	1994	
SI 2372	Electromagnetic Compatibility Regulations	HMSO	1992	

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Publication ID	Title	Publisher	Date	Notes
	Food Safety (Temperature Control) Regulations	HMSO	1995	
	Food Safety (General Food Hygiene) Regulations	HSMO	1995	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 2307	Lifting Operations and Lifting Equipment Regulations (LOLER)	HMSO	1998	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3017	The Medical Devices Regulations	HMSO	1994	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 2225	The Notification of Cooling Towers and Evaporative Condensers Regulations	HMSO	1992	
SI 3139	Personal Protective Equipment (EC Directive) Regulations	HMSO	1992	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 2169	The Pressure Systems and Transportable Gas Containers Regulations	HMSO	1989	
SI 574	The Private Water Supplies (Scotland) Regulations	HMSO	1992	
	The Public Health (Notification of Infectious Disease) (Scotland) Regulation	HMSO	1988	
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SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	

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NEW SOUTH GLASGOW HOSPITALS

SPECIFICATION HOT AND COLD WATER SUPPLY SYSTEMS

Ref: ZBP-XX-XX-SP-500-103

Status: Construction T3

Rev: C

Date: April 2014

WALLACE WHITTLE is a trading name of TUV SUD Ltd
TUV SUD Ltd is a TÜV SÜD Group Company

SPECIFICATION CHECK / REVISION SHEET

Wallace Whittle

PROJECT	**New South Glasgow Hospitals**	**PROJECT NUMBER**	**2900**
SERVICE (S)	**Public Health**	**REF**	**ZBP-XX-XX-SP-500-103**
PERFORMANCE SPECIFICATION TITLE	**Hot and Cold Water Supply Systems**	**DATE**	**February 2012**
PREPARED BY	**MK**	**CHECKED BY**	**SP**

Revision Ref.	Date of Revision	Page N$^{o(s)}$.	Revision Details	Checked By
01	June 2010		Initial Issue for Comment	SP
02	11 August 2010	5,6,11 & 12	Revised following Brookfield's comments	SP
03	August 2011		Issued as T1 Status for comment	SP
A	January 2012	5-13 & 16	Amended as indicated. Issued for Construction T3	AP
B	February 2012	5, 15 & 17	Revised following further review & comments	AP
C	April 2014	-	Amended as indicated in accordance with RDD process	SP

TUV SUD WALLACE WHITTLE
RDD COMMENT/RESPONSES

Document Revision Reviewed	**B**
RDD COMMENTS	**RESPONSE**
Clause 1.0 What level of development is required. Is service not fully designed?	Text amended
Clause 3.0 Presumably these are specified elsewhere?	Refer to separate specifications ZBP-XX-XX-SP-500-104 & ZBP-XX-XX-SP-511-354
Clause 5.0 P.6 Any derogations?	No
General comment with regard to 'Trust'	Text amended
Clause 6.0 Scottish water will only guarantee 1.0 Bar	Text amended
Section S10 Has this been agreed?	Text amended
Section S10 Clause 250 Submit proposals – Has this been done?	Text amended

OVERALL FRAMEWORK OF TENDER DOCUMENTATION
HOT AND COLD WATER SUPPLY SYSTEMS TECHNICAL SPECIFICATION

CONTRACT DOCUMENTATION- PRELIMINARIES

General Preliminaries

HOT AND COLD WATER SUPPLY SYSTEM TECHNICAL SPECIFICATION

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1.0 GENERAL INTRODUCTION

Purpose of Document

This specification is based on the NBS suite of specifications.

The development of the ~~design,~~ manufacture, supply, installation, wiring, setting to work and commissioning of the works described in this document shall be undertaken by the Specialist Sub-contractor and is referred to in this document as “the Sub-contractor”.

To carry out the development of the design, the Sub-contractor shall obtain the necessary supporting documentation including but not limited to that listed in Appendix A.

This specification relates to the Domestic Hot and Cold water services serving the Adult and Children’s Hospitals and the adjacent Energy Centre.

This specification shall be read in conjunction with all other mechanical and electrical engineering services specifications and the architectural drawings.

Carbon Target

The hospitals have a stringent carbon target of 80kg/m^2 per annum and the engineering services have been designed with this strictly in mind. The Sub-contractor shall not deviate from the proposed designs without consulting with the Contractor and providing evidence on how the deviation impacts on energy usage and hence the carbon target.

Pumps

All pumps shall be fitted with IE2 efficiency motors to EN 60034-30:2009 as standard, and suitable for operation in ambient temperatures of 40 degrees C.

2.0 SCOPE

The scope of work covered by this specification shall include, but not be limited to the following:

- Site wholesome water mains.
- The domestic cold water service
- The domestic hot water service.

3.0 SPECIFIC EXCLUSIONS

The following are specifically excluded from the scope of this specification:

- RO Water for Renal use
- RO Water for Endoscopy use
- Fire Hydrant Main
- Water Treatment Equipment
- ~~Laboratory Hot & Cold Water~~

4.0 INTERFACES AND DEMARCATIONS

The domestic hot and cold water services shall be provided as complete working systems serving the Adult and Children's Hospitals. The Sub-contractor shall provide information to other parties including for power supplies and BMS interfaces.

The site water mains shall be provided as complete working systems serving the Adult and Children's Hospital, the Energy Centre and the Laboratory Building.

5.0 APPLICABLE STANDARDS

All elements of the works shall be in accordance with the requirements of current legislation, regulations and industry standards unless otherwise stated.

The domestic hot and cold water systems shall accord with all appropriate Scottish Hospital Technical Memoranda, Codes of Practice and relevant British and European Standards, Scottish Water Regulations *(Byelaws)* and to the approval of the local Water Authority and Appendix A.

The site wholesome water mains shall comply with the requirements of Water for Scotland 2nd Edition 2007, and to the requirements of the Water Authority.

6.0 DESIGN CRITERIA

General the domestic hot and cold water systems shall comply with the Scottish Water Regulations and current Codes of Practice

Electricity Supply Characteristics

LV power characteristics: 400/230 V, 3-phase, 50 Hz, 230 V, 1-phase, 50 Hz.

System Design Conditions

Boosted Wholesome Water	-	*7.7 bar*
Boosted General Purpose Water	-	*7.7 bar*
Incoming Water Pressure	-	*1.0 bar*

7.0 LIAISON

The Sub-contractor shall include for liaison with:-

Health and Safety Professionals. As well as the Health and Safety requirements of *Parts A, B and C of this specification,* the Sub-contractor shall include for close liaison with Health and Safety professionals including the Hospital Board's Health and Safety Advisors and the CDM Co-ordinator and shall comply with the CDM Regulations and all Health and Safety Regulations.

The Contractor. The Sub-contractor shall liaise with the Contractor through whom all communications must flow. Drawings and other documentation will be available via the Contractor. The Sub-contractor shall include for liaison with members of the Contractor's team with an interest in the planning and administration of the domestic hot and cold water supply installations.

Other Sub-contractors. The Sub-contractor shall liaise with other Sub-contractors as necessary to ensure that all interfaces between the domestic hot and cold water supply installations and other systems are allowed for.

The Hospital Board. The Sub-contractor shall include for liaison in conjunction with The Contractor with members of the Hospital Board's team with an interest in the planning and administration of the domestic hot and cold water supply installation.

The Architect. The Sub-contractor shall include for review of the Architect's loaded 1:50 drawings, reflected ceiling plans and wall elevations and shall liaise as necessary with the Architect to assist with the production of these drawings

The Structural Engineer. The Sub-contractor shall liaise with the Structural Engineer and provide them with all necessary information for them to undertake the design.

The Local Water Supply Undertaker. The Sub-contractor shall liaise with the Local Water Supply Undertaker or their licensed agents to ensure that all aspects of the installation comply with the Scottish Water Regulations.

8.0 SYSTEM DESCRIPTION

Site Water Mains

Two separate water main connections for wholesome water shall be taken from the new 250 HPPE Scottish Water main crossing the hospital land from Hardgate Road to Govan Road. The connection locations shall be as shown on Horizons Hydro Engineering Drawing No F25214-400-002 and the two pipe shall run as two separate underground main supplies to the basement tank room of the Adult and Children's Hospital, and as two separate supplies to the Laboratory Building and a single supply from the connection nearest to Govan Road to serve the Energy Centre.

The two respective water main connections to the Scottish Water main shall be metered but shall have a branch connection before the meter to serve an un-metered site fire hydrant main.

Both incoming main meters shall have direct readings and a BMS interface.

The two separate incoming water mains shall not be interlinked at any part of the installation.

Incoming Water Supply to the Adult and Children's Hospital

Wholesome cold water will be derived from 2 No. separate incoming water main supplies entering the basement tank room. Each supply will be capable of isolation by valves within the building. A water meter will be incorporated on each supply within the tank room with direct reading and a BMS interface.

Shared incoming flow from water mains

Both incoming water mains shall be fitted with motorised shut-off valves to enable the two mains to have an equal operational running time to supply water to the storage tanks. The valves shall operate on an alternative eleven hours per 24 hour day and shall have a BMS interface.

Each water supply to each tank shall be fitted with an electrically operated shut-off valve to operate in response to a high level alarm in the tank and thus reduce the amount of water discharged through tank warning and overflow pipes. The shut-off valves shall have a BMS interface.

Emergency By-pass

Provision shall be made in the tank room on both incoming water mains for an emergency by-pass connection from the water mains to the two bulk storage tanks. This provision is to be used in the event of main filter plant failure.

Cold Water Storage Tanks

Bulk potable quality water storage tanks will be located within the basement tank room. The tanks will store 100% of the total main hospital water storage.

The tanks shall be arranged to give two streams of flow with 1/3 of storage capacity in the 2 No. break tanks and 2/3 of storage capacity in the 2 No. main *(bulk)* storage tanks.

The tanks will be insulated and complete with raised ball valve housings, self-draining bases, flushing drain and all necessary connections to comply with Water Authority requirements. Each tank shall have a central division plate.

Ballvalves shall be of the delayed action type valve with pilot valve control kit.

Separate connections will be made from the main cold water storage tank header to the booster sets.

The whole of the domestic water services installation will be boosted in pressure to ensure adequate flow at outlets points, such as showers, etc.

Water Filtration

Twin filtration plant shall be served from the 2 No. break tanks and shall supply filtered water to the 2 No. main storage tanks.

Wholesome Water Booster Sets

Two separate packaged wholesome (potable) grade water booster sets will be provided within the tank room.

Each booster set will comprise:

- Dedicated control panel
- Multiple variable speed duty pumps to maintain a constant discharge pressure.
- Accumulator vessel

Provision for an emergency stool piece shall be allowed between pump delivery/header lines of the two pump sets to enable one pump set to be connected into the other pump set supply in the event of a pump set failure.

General Purpose Water Booster Set

A general purpose water booster set complete with break tank in overhead frame shall be provided in the tank room to serve general use Category 5 risk outlets such as external watering points, hoses etc, to avoid cross contamination with the wholesome (potable) water supply.

The booster set will comprise:

- Dedicated control panel

- 3No Variable speed pumps
- Accumulator vessel.

Water Booster set for Dental Chairs

A small packaged booster set with integrated break tank shall be provided to serve the dental chairs in the Children's Hospital. The unit shall be suitable for locating in a cupboard.

All booster cold water pump sets shall be as detailed in the booster pump schedule and as shown on the drawings.

Domestic Cold Water System

From the bulk storage tanks, the wholesome boosted cold-water service will be routed via the main distribution routes to roof plant level and vertical risers to feed the various departments.

A pressure reducing valve shall be installed on the main distribution pipe into each plant room to allow for balancing of pressures serving the different areas of the hospital.

In the plantrooms, the wholesome boosted cold water service will feed un-vented HWS plant, and a number of direct connections to demand points within the building, including system pressurisation units, and dedicated water service systems storage tanks, via type AB air gaps for prevention of cross contamination.

Subject to compliance with SHTMs or with Hospital Board approval, cold water service outlets which may be subject to misuse or for clinical convenience or temperature maintenance and BREEAM compliance may use proximity switching, timed flows, shut off valves and flow regulation to serve this purpose.

Flexible Supply Hoses for Final Connections

No flexible hoses (or tails) connections shall be used.

Hot Water Service Installation

General

All hot water supply systems will be designed and installed to meet the requirements of SHTM 04-01 Part A and B.

Hot Water System

The hot water distribution system will be designed for 60ºC flow and 55ºC return circulating temperature.

Domestic Hot Water (DHWS) will be generated and stored utilising plate heat exchangers and buffer storage vessels (DHWS plant). The DHWS plant and distribution system will be fed from the boosted water system, and thus be pressurised.

The DHWS plant will be directly heated from the main primary MTHW heating circuit from the Energy Centre. The storage temperature will be controlled through the BMS by 2-port control valves on the primary heating system, along with 2-port direct acting control valves to provide protection override in the case of high hot water flow temperatures.

The DHWS plant system will be capable of achieving higher storage temperatures for carrying out a pasteurising process to minimise contamination from Legionella bacterium within the storage buffer vessel. Each storage buffer vessel and plate heat exchanger will be isolated from the distribution system while the process is carried out.

The DHWS distribution system will be configured with a pumped return to maintain temperatures within the system in accordance with SHTM 04-01. The pumped return system will minimise “dead legs” and reduce water consumption by providing the correct temperature of water at the outlet with minimum delay.

The system will have isolating valves generally as the cold water system. In addition, the return water pipework will be provided with valves that isolate and automatically regulate the flow rate, in order to maintain satisfactory temperatures throughout the system.

The hot and cold water system pressures will be equalised at each service outlet for successful blending of hot and cold water through anti-scalding devices prior to use.

The anti scalding devices will be used throughout the hospital where service outlets provide water for personal hygiene washing. Designated outlets will use unmixed hot water at system temperatures where utensils or garment washing is required.

Subject to compliance with the SHTMs or with Hospital Board approval, hot water service outlets which may be subject to misuse or for clinical convenience may use proximity switching, timed flows and flow regulation for water conservation purposes as described for cold water services.

Hot Water Supply Plant (DHWS plant)

The DHWS plant shall be instantaneous type plate heat exchangers with buffer vessels, to provide instantaneous heated water with reduced storage capacity. The DHWS plant shall be housed in the plant rooms as indicated in the equipment data sheets. All DHWS plant shall be factory assembled onto skids and supplied as fully fitted with buffer vessel, expansion vessel, pumps, control panel, controls and gauges.

Each hot water supply plant (plant) shall be arranged as a bank of 3 No. skids. Each skid shall have its own separate plate heat exchanger (phe), and its own buffer vessel. Each phe and buffer vessel is nominally rated at 50% of the total HWS output capacity for its supply zone to cater for isolation of one unit for maintenance and to provide 50% resilience to the hot water supply.

Refer to Equipment Data Sheets of plant & equipment for further details.

Thermostatic Mixing Valves

These valves are provided on each sanitary fitting that requires the hot water delivery temperature to be limited to a safe working maximum. All valves shall comply with the requirements of NHS Specification DO8; NHS Health Guidance Note (HGN) entitled “Safe Hot Water and Surface Temperatures” and be a WRAS listed pattern.

Types of valves to be used (as defined in the HGN) shall be used as indicated on the attached “Matrix of Hot Water Temperatures and Thermostatic mixing valve requirements for sanitary assemblies”.

In addition, the valves shall be appropriate to the system pressure at point of installation.

Valves shall be supplied with in-built check valves and have tamper-proof adjustment. Connections shall be suitable for stainless steel.

Double check valves to be duplicated at TMVs.

Where the thermostatic mixing valves are not provided the Contractor shall affix a permanent label adjacent to the unprotected hot tap clearly stating “VERY HOT WATER”.

Valves shall be factory pre-set to provide maximum delivery water temperatures as follows:

Bidet	-	38°C
Shower	-	41°C
WHB	-	41°C
Bath	-	44°C

Upon completion of the installation, each valves performance shall be checked in accordance with the requirements of Section 5 of the HGN for commissioning, including all necessary paperwork.

HWS Secondary Pumps

All the domestic hot water systems shall be provided with return water circulation pumps. These shall be run continuously with the standby pump supplied loose to allow removal and replacement of operational unit in the case of a fault.

The buffer vessels shall be provided with their own circulation pumps as part of the equipment package. All pumps shall be as detailed on the pump equipment schedule and as shown on the drawings.

Thermostatic Balancing Valves

Each HWS return loop shall be provided with a thermal balancing valve to ensure the HWS return temperature is maintained at 55°C.

The tamper-proof multi-function thermostatic balancing valves shall be suitable for use in domestic hot water circulation systems and shall include drain point, temperature gauge point and automatic disinfection point.

The valves shall provide a thermal balance in the hot water installation by keeping a constant temperature in the system, thus limiting the flow in the circulation pipes to the minimum required level. The valves shall have a minimum flow rate no greater than 0.02 litres/second.

Water Meters

Water meters shall be provided as indicated on the drawings to measure cold water consumption to various systems and parts of the building.

In addition, meters shall be provided to key ‘cost centres’ such as restaurants, kitchens, retail units, etc.

DOMESTIC WATER FLOW REGULATION

To reduce the overall water consumption of the development, all sanitary fittings shall be furnished with flow regulating devices to both hot and cold supplies to the fitting. These devices shall be factory fitted into the outlet side of the fitting isolating valves, and shall regulate the flow (and thus pressure) of each fitting.

These devices shall be as Arrow Valves Ltd. (Tel. No: 01442-823123).

Alternatively, loose regulators may be provided from the same manufacturer for insertion into the outlet side of the local isolating valve.

MATERIAL & WORKMANSHIP CLAUSES

S10 HOT AND COLD WATER SUPPLY SYSTEMS

GENERAL

All domestic stored water shall be of wholesome quality.

The main domestic water supply tanks have be sized for 24hr storage with a 10% additional margin.

The tanks shall be joined at a header arrangement with each tank capable of being isolated for repair or maintenance.

From the bulk storage tanks, the potable boosted cold-water service will be routed via the main distribution routes to roof plant level and vertical risers to feed the various departments. In the plantrooms, the *wholesome* (potable) boosted cold water service will feed un-vented HWS calorifiers, and a number of direct connections to demand points within the building, including system pressurisation units, and dedicated water service systems storage tanks, via type AB air gaps for prevention of cross contamination.

At each main plant area a pressure-regulating valve will be provided to maintain appropriate water pressure at all levels in the building providing convenience of use and minimizing water consumption.

All specific department areas will be provided with isolation provision, with draining down facilities for maintenance and shutdown.

All main distribution and dropper connections will be provided with isolating valves, with local isolation valves installed to isolate and shut down individual ward/department areas.

It should be noted that domestic supplies can only connect to outlets and equipment that are suitable for potable quality water supplies, in accordance with the *Scottish* Water Regulations.

All items of hot and cold water plant and system controls must be capable of being fully interrogated by the building management system through the independent network protocol.

The hot water distribution system will be designed for 60ºC flow and 55ºC return circulating temperature.

Anti scalding devices shall be used throughout the hospital where service outlets provide water for personal hygiene washing. Designated outlets will use unmixed hot water at system temperatures where utensils or garment washing is required.

Subject to compliance with the SHTMs or with Board approval, hot water service outlets which may be subject to misuse or for clinical convenience may use proximity switching, timed flows and flow regulation for water conservation purposes as described for cold water services.

110 INCOMING WATER SUPPLY

- Water company: Scottish Water/Business Stream
- Volume flow rate: 25 l/s from 2No incoming main supplies respectively.
- Position of incoming mains water supply: As schedule and drawings. Two mains supplies shall be taken from the new main crossing the hospital grounds, one connection from Govan road end and one from Hardgate Road end.

Each main shall be capable of supplying 25l/s.
Site water mains shall be installed in accordance with Water for Scotland 2nd Edition and NJUG requirements for utility .apparatus with regards to depth, colour coding, identification markers, and position, and to the requirements of Scottish Water. Site water mains shall be WRAS approved PE barrier pipe suitable for the site contaminated ground conditions and approved by Scottish Water. All backfill shall be from a clean source. A water meter will be incorporated with direct reading and a BMS interface onto both incoming mains supplies at the location identified by Scottish Water and also sub meters within each building served by the site water mains. All sub meters will be linked to the BMS. All water meters will be fitted with isolation valves and non return valves.

130 PUMPED COLD WATER SUPPLY SYSTEM

Bulk wholesome quality water storage tanks and break tanks will be located within the basement of the hospital building. The tanks will store 100% of the total main hospital water storage.

Separate connections will be made from the cold water storage tank header to the booster sets.

The whole of the domestic water services installation will be boosted in pressure to ensure adequate flow at outlets points, such as showers, etc. duplicate packaged wholesome water grade booster sets will be provided within the tank room.

A separate general purpose water booster set will serve Category 5 outlets.

Each booster set will comprise:-
Dedicated control panel
Multiple variable speed duty pumps to maintain a constant discharge pressure including a standby pump
Accumulator vessel

Water supplies for vending machines, ice makers and chilled drinking water points shall be installed as per drawing with valved-off connections for final connection by others.

All incoming water for wholesome storage will pass through a filtration system with a 0.2 micron capacity.

The filtration plant will be in duplicate and served by duplicate break tanks of one third of total capacity.

Each filtration plant will be capable of supplying full peak water demand to the bulk cold water storage tanks.

- Type: Flooded suction or suction lift to directly pressurize hot and cold water systems.
- Water meters: As shown on drawings.
- Pressure booster sets: As section Y20.
- Pumps: As schedule.

- Storage tank or cistern: Glass fibre reinforced cisterns, as section Y21.
  - Accessories: As schedule and requirement for wholesome water.
- Pipelines:
  - Below ground: As section Y10 and NJUG.
  - Above ground: As section Y10.
- Pipeline ancillaries: As section Y11.
- Thermal insulation:
  - Pipelines: As section Y30.
  - Tanks: As section Y30.
- Vibration isolation: Inertia bases, to acoustic consultant recommendations.
- Sanitary appliances: All taps, shower mixers, and sanitary ware shall be as Architects schedules.
- Drinking water outlets: All domestic water shall be wholesome. Drinking water points shall be shown on drawings..
- Flush control devices: As schedules.
- Water coolers: As schedule and drawings.
- Controls: All items of Cold water plant and system controls must be capable of being fully interrogated by the building management system through the independent network protocol..
- Accessories: As schedule.
- Completion:
  - Cleaning and chemical treatment: Flushing and chemical treatment, as section Y12.
  - Plant and equipment identification: As section Y32 and as SHTM/HTM 04 .
  - Commissioning: Commissioning of cold water supply systems, as section Y50 and as SHTM/HTM 04.

160 INDIRECT HOT WATER STORAGE SUPPLY SYSTEM

Hot water storage shall be via the buffer vessels/Storage calorifiers supplied with the plate heat exchangers. The DHWS distribution system will be configured with a pumped return to maintain temperatures within the system in accordance with SHTM/HTM 04-01, associated HGN Safe Hot Water and Surface Temperatures and SHTM/HTM 04-01. The pumped return system will minimise dead legs and reduce water consumption by providing the correct temperature of water at the outlet with minimum delay.

- Capacity: As schedule.
- Primary heat source: MTHW system Comprising of gas fired hot water boiler and CHP units, as section T20.
  - Primary: Sealed.
- Storage unit: Hot water storage shall be via the buffer vessels/Storage calorifiers supplied with the plate heat exchangers.
- Pumps:
  - Primary hot water supply: Close coupled in line, as section Y20. All parts in touch with the wet system shall be stainless steel.
  - Secondary hot water supply: Close coupled in line, as section Y20 All parts in touch with the wet system shall be stainless steel.
- Pipelines: As section Y10.
- Pipeline ancillaries: As section Y11.
- Thermal insulation:
  - Pipelines: As section Y30.
  - Cylinders: As schedule.
- Controls: All items of Hot water plant and system controls must be capable of being fully interrogated by the building management system through the independent network protocol..
- Sanitary appliances: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.

- Accessories: As schedule.
- Completion:
  - Cleaning and chemical treatment: Flushing and chemical treatment, as section Y12.
  - Plant and equipment identification: As section Y32.
  - Commissioning: Commissioning of Hot water supply systems, as section Y50 and as SHTM/HTM 04.

SYSTEM PERFORMANCE

The hot and cold water supply system shall be install, flushed, cleaned, tested and commissioned as per Water Regulations SHTMs and HTMs. Where any standards or documents contradict one another the Sub-contractor shall contact the Contractor for further guidance.

220 COLD WATER SUPPLY

- Incoming mains water supply:
  - Site factors: Two water mains from the external water main shall run separately in the ground to give security of supply. They shall enter the basement of the Acute/Children's Hospital and run at high level in the basement corridor to enter the basement cold water storage tank room. Each of the supplies will connect to the duplicate break tanks serving the filtration plant to ensure that in the event of a mains failure both break tanks will continue to be supplied by the other incoming water main. From the bulk storage tanks, the wholesome boosted cold-water service will be routed via the main distribution routes to plant level and vertical risers to feed the various departments. See drawings for details.
- Type of system: Pumped from a storage tanks.
- Design parameters: To SHTM/HTM 04-01.
- Daily consumption: As schedule.
- Storage capacity: The main domestic water supply tanks shall be sized for 24hr storage.

250 PIPELINE SIZES

- ~~Sizing: Calculate sizes to meet simultaneous demand for the building in accordance with BS 6700 Appendix D or BS EN 806-3. Submit proposals.~~
- Performance:
  - Water velocity (maximum): 1.3 m/s for hot water and 2.0 m/s for cold water.
  - Filling time (maximum) for cold water storage cistern: As schedule.

PRODUCTS

The Sub-contractor shall supply and install services and equipment to perform as per specification. The Contractor shall submit details of all mechanical equipment for comment and place orders in a timely fashion to ensure delivery as per programme. Where a particular manufacture is specified, the Contractor shall include for that manufacturer. Where considered appropriate, provide for equivalent standard alternatives to be offered for consideration. This must be done in a timely manner and the Sub-contractor shall provide all details including but not limited to:

- detailed description
- Cost comparison
- Technical comparison
- References to standards
- References to SHTM/HTMs

310 DEZINCIFICATION

- Fittings, pipelines and equipment located below ground or in concealed or inaccessible locations: Resistant to dezincification, e.g. gunmetal.

320 WATER METERS

Water meters shall be installed as indicated on drawings. Stool pieces between isolating valves will be provided for temporary removal of the meters during the flushing of the system or when meters are removed for repair.

- Standard: To ISO 4064-1.
- Type: In-line meters. Shall be capable of being read by the clients BMS system. .
- Manufacturer: As schedule.
  - Product reference: As schedule.
- Size: To suit service.
- Pressure class: As schedule.
- Temperature class: To suit service.
- Metrological class: As schedule.
- Connections: As schedule.
- Indicating device: Type 2 - digital.
- Features: Pulsed output for remote monitoring.
- Accessories: To BS EN 14154-2.

375 INSTANTANEOUS WATER HEATERS, PACKAGED PLATE HEAT EXCHANGERS

The package instantaneous water heaters shall be served from the MTHW system. The units shall be arranged in banks of three. With 100% duty 50 % standby with each unit capable of meeting 50% of the total load. Each skid mounted unit shall consist of a heat exchanger, buffer vessel, expansion tank, pumps, valves and control panel.

The Integrated control panel shall incorporate a PID controller with a 7 day timer, an automatic night set-back facility, an anti-legionella pasteurisation cycle facility, common fault volt-free signal, alarm message display, remote operating temperature display, remote temperature setting capability, remote enable/disable, high temperature cut-out (manual reset), low temperature alarm, pump protection and valve output indication

The units shall be selected for quite operation and come complete with vibration isolators. The storage temperature will be controlled through the BMS by control valves on the primary heating system, along with 2-port direct acting control valves to provide protection override in the case of high hot water flow temperatures.

The storage system will be capable of achieving higher storage temperatures for carrying out a pasteurising process to minimise contamination from Legionella bacterium within the storage vessel. Each storage vessel will be isolated from the distribution system while the process is carried out.

- Type: Instantaneous.
- Manufacturer: As schedule.
  - Product reference: As schedule.
- Package unit: Plate heat exchanger complete with primary pump, control valves and control panel.
- Primary medium: Medium temperature hot water.
  - Flow rate: As schedule.
  - Inlet temperature: As schedule.
  - Outlet temperature: As schedule.

- Pressure: As schedule.

- Secondary medium: Water.
  - Feed Boosted.
  - Peak flow rate: As schedule.
  - Outlets: As schedule and drawings.
- Accessories: As schedule. The units shall come as a complete package read for use. .

376 BUFFER VESSEL

Hot water storage shall be via the buffer vessels/Storage calorifiers supplied with the plate heat exchangers.

- Manufacturer: As schedule.
  - Product reference: As schedule.
- Capacity: As schedule.

480 FLUSH CONTROL DEVICES

All taps, shower mixers, and Sanitary ware shall be as Architect’s schedules.

- Manufacturer: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.
  - Product reference: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.
- Flush rate: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.
- Water supply valve: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.
- Sensor unit:
  - Material: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.
- Movement detector: All taps, shower mixers, and sanitary ware shall be as Architect’s schedules.
- Power supply: All taps, shower mixers, and sanitary ware shall be as Architect's schedules.

490 WATER COOLERS

- Manufacturer:
  Water coolers, drinks and vending machines shall be supplied and installed by others. The Sub-contractor shall supply services to the coolers and vending machines at locations shown on drawings and agreed with the Contractor.
  - Product reference: Supplied by others.
- Type: Supplied by others.
- Flow rate: Supplied by others.
- Temperature of delivered water: As SHTM/HTM 04-01.
- Water inlet: As required.
- Power supply: As required.

EXECUTION

The Sub-contractor shall ensure all works carried out shall be done is a safe manner and comply with Health and Safety Regulations. This shall include clean and tidy working and working in confined spaces. Due to the size of the water systems being installed all pressure testing and commissioning equipment shall be cleaned and chlorinated before each use. This is to prevent the systems from being contaminated with pseudomonas.

620 INSTALLATION GENERALLY

- Installation: To BS 6700.
- Performance: Free from leaks and the audible effects of expansion, vibration and water hammer.
- Fixing of equipment, components and accessories: Fix securely, parallel or perpendicular to the structure of the building.
- Preparation: Immediately before installing tanks and cisterns on a floor or platform, clear the surface completely of debris and projections.
- Corrosion resistance: In locations where moisture is present or may occur, avoid contact between dissimilar metals by use of suitable washers, gaskets, and the like.

630 INSTALLING WATER METERS

- Standards: To BS EN 14154-2.
- Interconnection to Building Management and Monitoring System (BMMS): Required.

660 UNVENTED HOT WATER STORAGE DISCHARGE PIPES

- Fall (minimum): 1 in 80.
- Discharge: Via an air break and tundish.
  - Size: At least the diameter of the outlet of the safety device.
  - Tundish discharge: At least one diameter larger than the outlet of the safety device.
  - Discharge point: As shown on drawings.

COMPLETION

The Sub-contractor shall protect the system from damage or interference during the works.

The Sub-contractor shall Test, flush and clean the system as per section Y12, Y50, SHTM/ HTM's and TR/20.

The Sub-contractor shall submit O&M's as required by The Contractor

The Sub-contractor shall provide training as per section Y12, Y40 & Y50.

The Sub-contractor shall provide spares as per section Y12, Y40 & Y50.

The Sub-contractor's defects and liability period shall be as the contract prelims.

910 HYDRAULIC PRESSURE TESTING OF HOT AND COLD WATER SUPPLY SYSTEMS

- Standard: To BS 6700.
- Notice (minimum): 1 week.
- Pressure: 1.5 times working pressure.
- Duration of test: 1 h.

980 DOCUMENTATION

O& M documentation shall be issued at least three months before completion of any part of the contract.
The contents and format shall be agreed with the Contractor. The document shall be issued/uploaded on ZUTEC.

The Sub-contractor shall provide instruction to the clients engineers and maintenance staff in the safe operation of all systems and items of equipment for an adequate and reasonable period of time based on the manufactures' recommendations and best practice. The Sub-contractor shall provide adequate and qualified staff in order to carry out their maintenance and repairs during the defects liability period.

990 OPERATING TOOLS

- Tools: Supply tools for operation, maintenance and cleaning purposes.
- Keys: Supply keys for valves and vents.

APPENDIX A

SUPPORTING DOCUMENTATION

In order to carry out the design, the Sub-Contractor shall require access at least to the documentation listed below.

The following information is, or shall be, available from the Contractor:-

1. Standard General Conditions and Preliminary Clauses
2. ZBP Drawings
3. ZBP Schedules
4. Nightingale Associates: Sanitary Schedule
5. Nightingale Associates: Building Plans
6. Nightingale Associates: Building Sections
7. Nightingale Associates: Wall Elevations
8. ZBP: Automatic Controls and Building Management System Specification :
   ZBP-XX-XX-SP-660-401 to 406
9. ITPD Documentation and Appendices

Drawings for other specialist systems shall be developed by other Sub-contractors during the detailed design period and shall be made available by The Contractor when complete.

Description of Domestic Water System

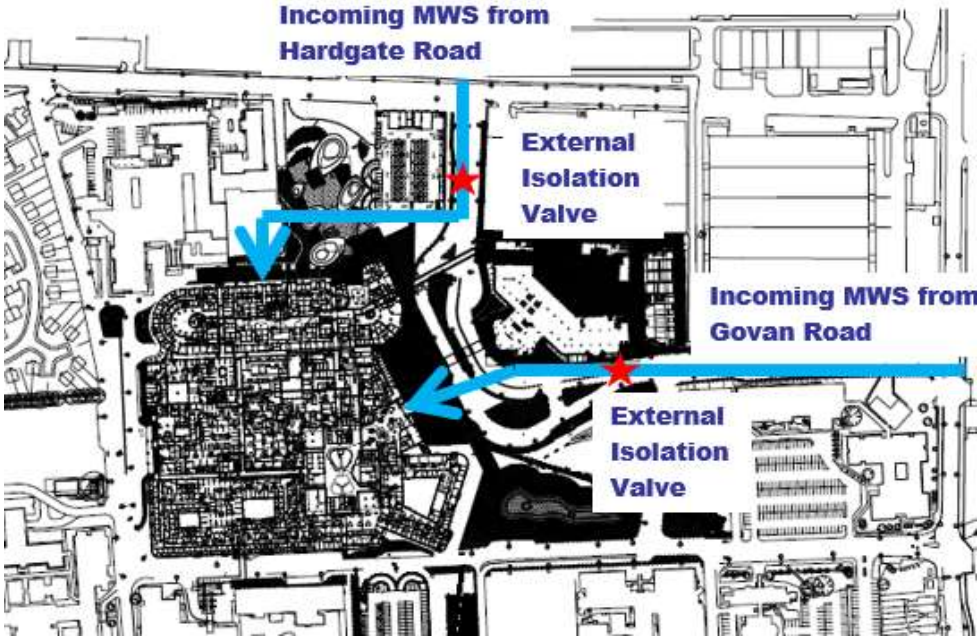
Overview

This description relates to the Domestic Hot and Cold water system serving the Adult and Children's Hospitals at the time it was handed over to GGHB by MPX.

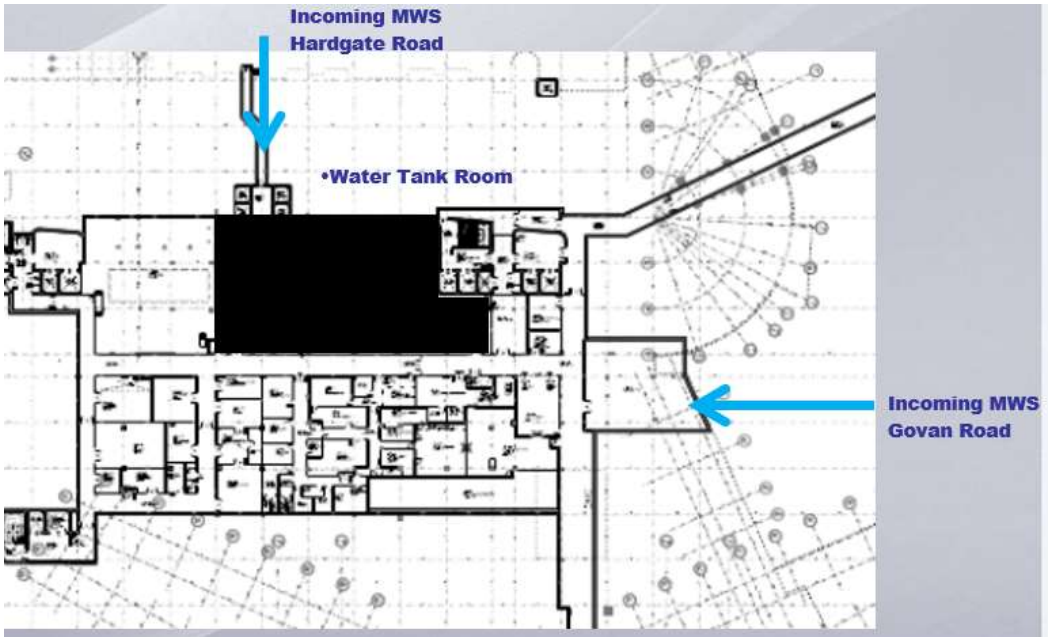
Multiplex understands GGHB have carried out modifications to the water system, but is unaware of the details of those modifications.

The operational procedures, monitoring, control measures and preparedness are matters for GGHB.

Two separate wholesome water main connections are provided from the Scottish Water network. One from Hardgate Road and the other from Govan Road as illustrated below.



The two wholesome cold water supplies are piped underground to the basement tank room of the Adult and Children's Hospital as illustrated below.



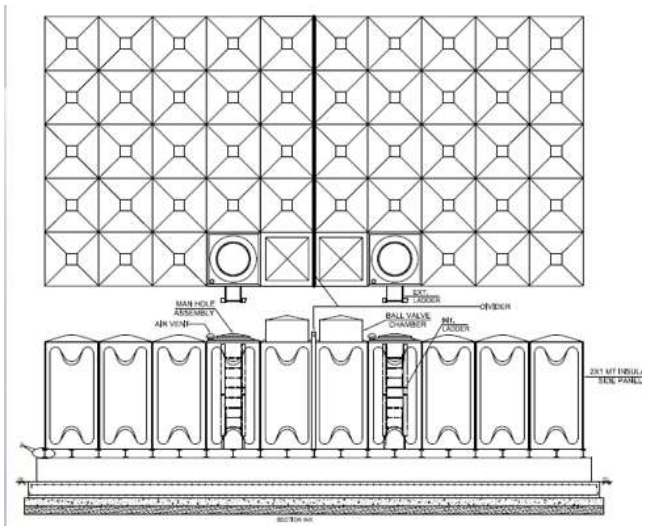
Bulk potable water storage tanks are located within the basement tank room. The tanks store all of the water required for the Adult and Children's Hospital.

Within the basement tank room there are 5no. water tanks.

- The tanks are arranged to give two streams of flow with 1/3 of storage capacity in the 2 break tanks and 2/3 of storage capacity in the 2 main storage tanks.

All cold water storage tanks are two compartment tanks and are piped in such a way as to allow tank maintenance without disrupting the water supply to the building.

The below is a typical example of water storage tanks with compartment divider.



The two wholesome cold water supplies are piped to the break tanks, from these tanks the water is passed through the water filtration plant supplying filtered water to the two main storage tanks.

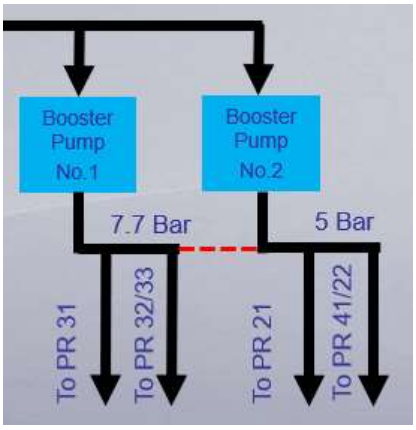
The below is an image of a typical filtration plant.

The whole of the domestic water services installation is boosted in pressure to ensure adequate flow throughout the building.

There are two separate packaged wholesome (potable) grade water booster sets located within the basement water tank room. One serves Plant Room (PR) PR21, PR22 and PR41 and the other serves PR31,PR32 & PR33.

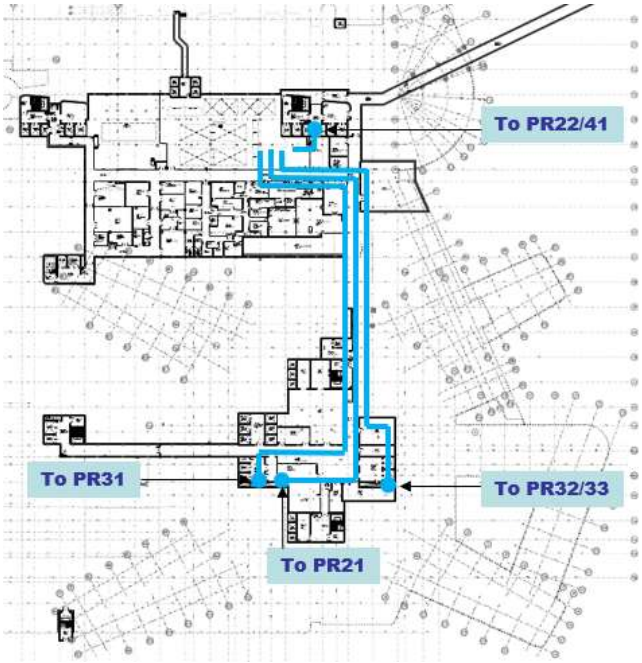
An emergency link is provided between the two booster pump sets to enable one pump set to be connected into the other pump set supply in the event of a pump set failure.

The below is an example of a typical packaged water booster set along with a diagram showing the emergency connection.



There is also a trade water booster set within the basement water tank room. This provides water to high risk outlets such as external watering points, hoses etc to avoid cross contamination with the potable water system.

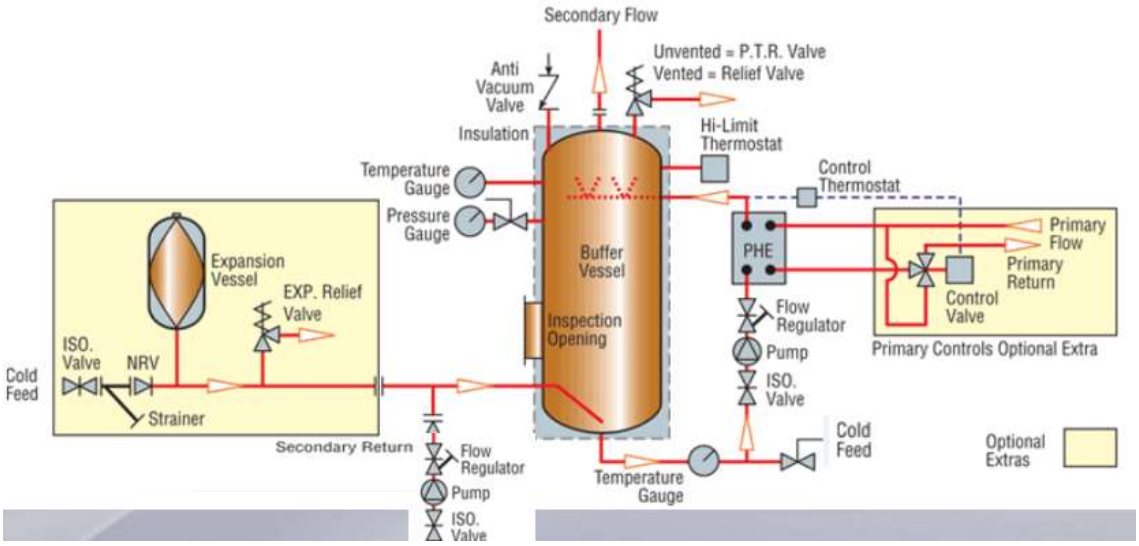
The cold-water service pipework is routed via the basement to vertical risers where the pipework is distributed to the various plantrooms for the generation of hot water. This is illustrated in the below diagram.



Domestic hot water is generated within plantrooms PR21, PR22, PR31, PR32, PR33 & PR41 utilising plate heat exchangers and buffer storage vessels. This provides instantaneous heated water with reduced storage capacity.

The domestic hot water is in-directly heated from the MTHW circuit from the energy centre.

The below image represents a typical arrangement.



The potable cold water service and hot water service is then distributed to outlets within the hospital departments.

The hot water is circulated to the outlet and back to the plate heat exchanger / buffers by a hot water return pump so that temperature is maintained throughout the system. These pumps run continuously.

Below is an image of a typical hot water return pump.

Domestic Water Services Valves

There are various valves installed within the domestic hot and cold water services systems, some examples of the main valves are as follows;

Isolation valves – These are used on both cold and hot water pipework to assist with system isolation for maintenance activity.

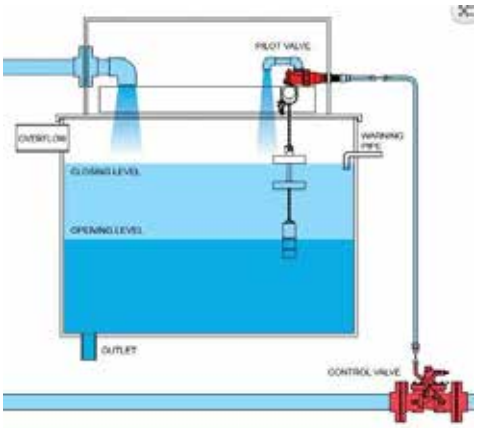
Thermal balancing valves – These are installed on the hot water return pipework to provide isolation for maintenance activity and automatically regulate the water flow rate to maintain temperatures throughout the system.

Multi-Therm
Figure 141 or Figure 143

Multi-Fix
Figure 150 or Figure 151

Pressure reducing valves - The hot and cold water system pressures are equalised by use of pressure reducing valves, these assist with successful blending of hot and cold water through anti-scalding devices prior to use (thermostatic mixing taps).

Cold water tank float valves – Each cold water storage tank is fitted with a Keraflow float valve. This maintains the water level within the tanks. These float valves are adjustable and can be used to reduce the water storage volume if water turnover is slow.



Thermostatic mixing valves – These valves are provided at sanitary fittings and are either separate valves or integral to the taps, these limit the hot water delivery temperature to a safe working maximum.

<u>Domestic Water meters</u>

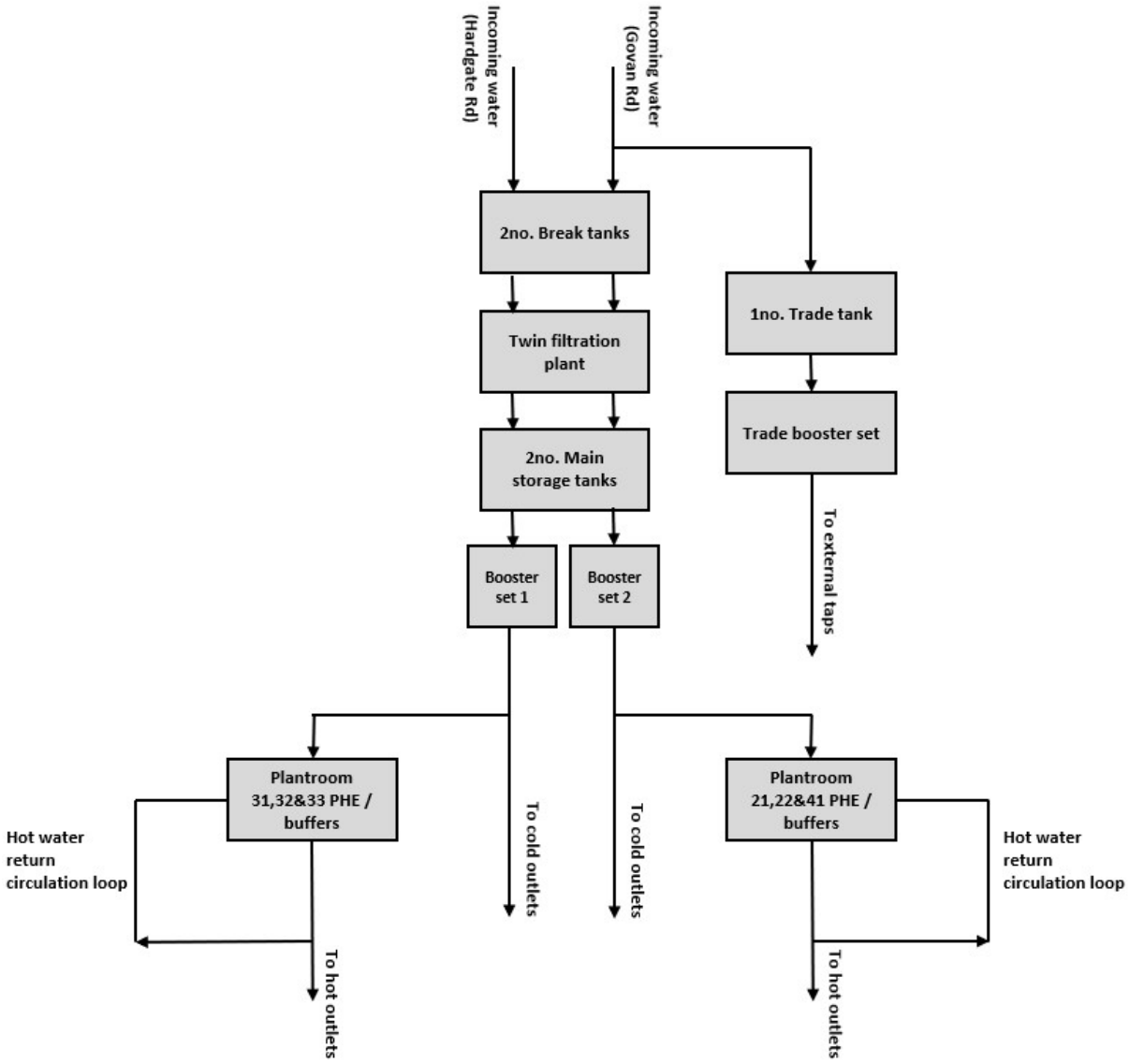
Water meters have been installed on the incoming mains, water supply to each plantroom, cold feed to each of the hot water PHE/buffer plants, kitchen/restaurant supplies, retail unit supplies and renal water plant supplies. All meters are linked back to the BMS to provide remote reading of meters.

Pipework Materials

Pipework ranges in size from 15mm to 200mm in diameter.

- Pipework sizes 15mm to 108mm are of the stainless steel pressfit pipe and fittings type.
- Pipework sizes 150mm to 200mm are of the stainless steel metric tru bore pipe and fittings type.

Simplified flow diagram



Notes

The following are excluded from this description,

- RO Water for Renal use
- RO Water for Endoscopy use

- Fire Hydrant Main

Reverse osmosis (RO) water is an ultrapure water supply for on-line haemodiafiltration treatments. RO water treatment plant is located in plantrooms 21, 31 and 32 and is piped to dialysis stations within various departments.

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Detection of biofilms associated with pitting corrosion of copper pipework in Scottish hospitals

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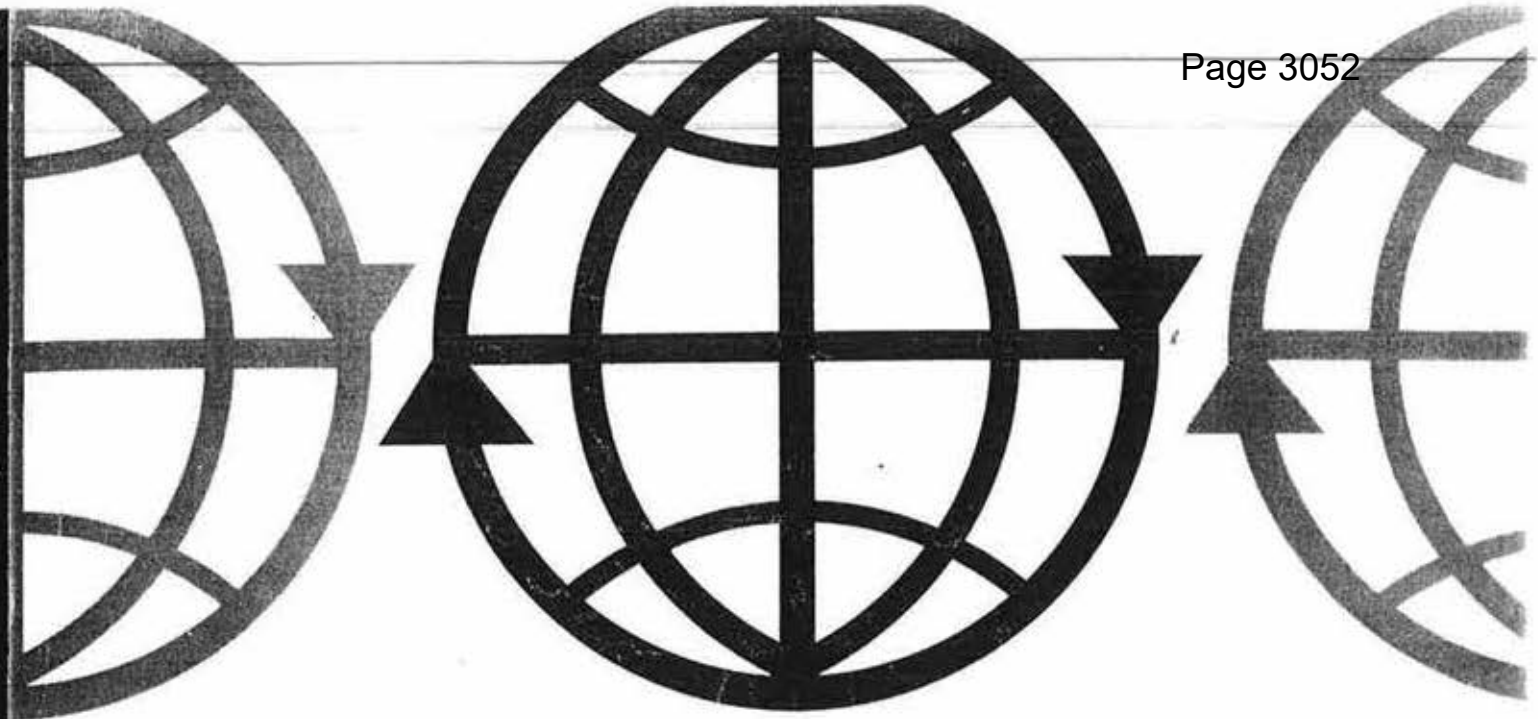

Biocorrosion

Proceedings of a joint meeting between the
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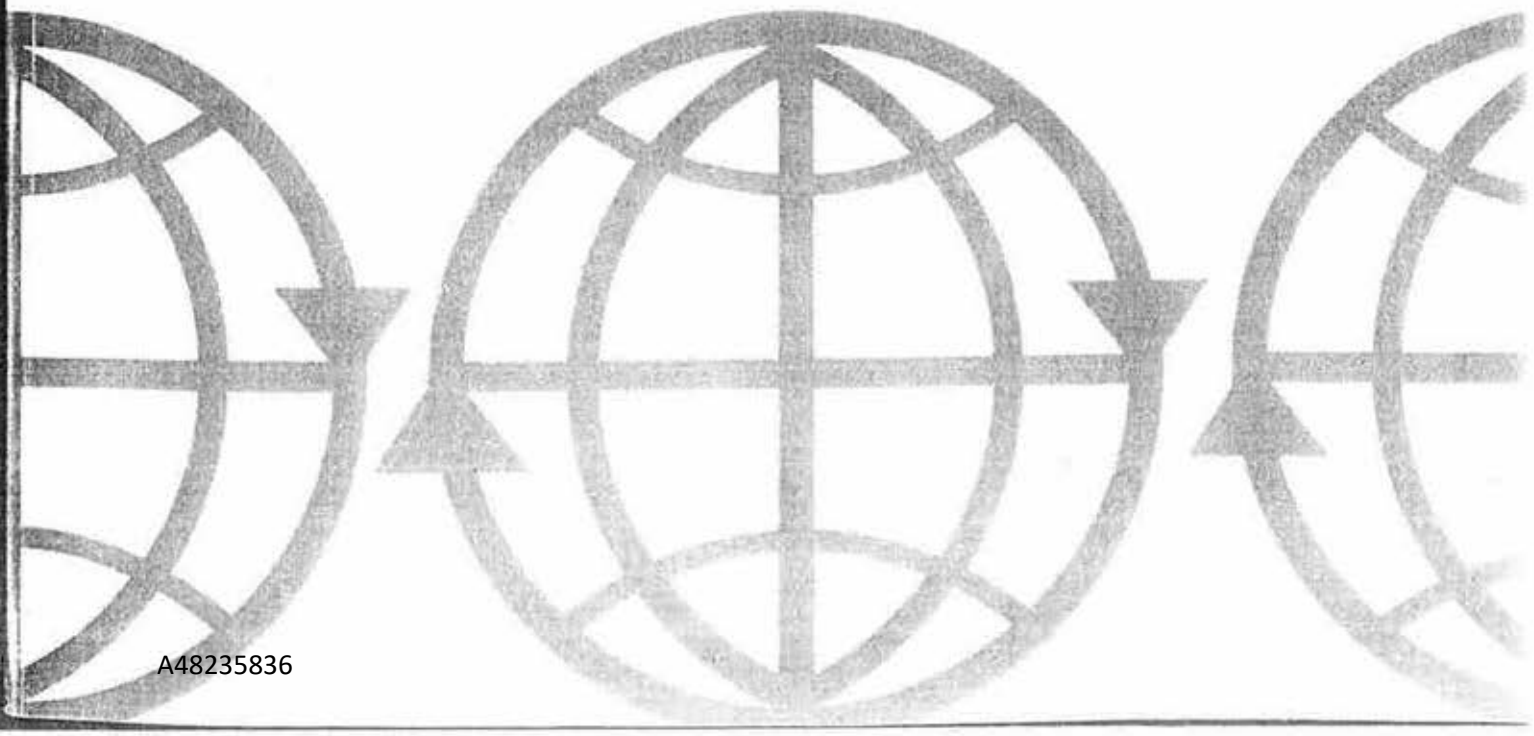
French Microbial Corrosion Group

Edited by C.C. Gaylarde and L.H.G. Morton

Biodeterioration Society
Summer 1988



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It is an international society, open to all with a scientific, technological, practical or commercial interest in biodeterioration and biodegradation.

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DETECTION OF BIOFILMS ASSOCIATED WITH PITTING CORROSION OF COPPER PIPEWORK IN SCOTTISH HOSPITALS

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ABSTRACT

A survey was undertaken of the water quality and plumbing systems of two Scottish hospitals experiencing corrosion of the copper pipework. Waters were also concentrated aseptically from various sites within the hospitals and one metre lengths of copper pipework were withdrawn from the hot water supply for microbiological examination. Extensive pitting corrosion was evident at several sites and a copious biofilm was observed by scanning electron microscopy. Microbiological analysis of the black tubercles covering the perforated areas indicated the presence of anaerobic sulphate-reducing bacteria (SRB) and a variety of aerobes, including *Pseudomonas* and *Alcaligenes* spp., pink-pigmented facultatively methylotrophic bacteria and fungi. Fewer SRB and fungi were detectable in the thinner biofilm associated with the site experiencing minor corrosion but no pitting. The water quality of both the badly and less corroded sites was similar but the hot water supply of the latter was maintained at 60°C whilst the former rarely exceeded 50°C.

Une enquête sur le terrain a été entreprise au niveau de la qualité des eaux et des systèmes de distibution de plusieurs hôpitaux de Glasgow connus ou suspectés pour avoir des problèmes de corrosion au niveau des canalisations en cuivre. Les eaux de plusieurs sites hopitaliers sont concentrées stérilement et un canalisation d'un mètre de long est prélevée du circuit d'eau chaude pour examen microbiologique. On remarque une importante corrosion par piqûres à plusieurs endroits et un biofilm abondant est observé en microscopie électronique à balayage. Les analyses microbiologiques des amas noirs au niveau des surfaces perforées indiquent la présence de bactéries anaérobies sulfatoréductrices (BRS) et

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d'une flore aérobie comprenant des *Pseudomonas* et des champignons. Les eaux concentrées contiennent aussi des BSR et la même flore aérobie bien que peu de champignons soient détectés. Un plus grand nombre de BSR et de champignons ont été trouvés au sein d'un fin biofilm présent sur un site expérimenté ou seulement une corrosion mineure sans piqûres était observée. La qualité des eaux des deux sites plus ou moins corrodés est similaire bien que la première soit maintenue à 60°C tandis que la seconde excède rarement 50°C.

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INTRODUCTION

Copper pipework has a twenty-five year guarantee against manufacturing defects and under normal operating conditions is expected to last the lifetime of the building. Many millions of metres of copper plumbing tubes continue to give excellent service supplying hot and cold water in both domestic and industrial buildings. However, it is now apparent that the plumbing systems of a few institutional buildings in certain soft water areas have suffered severe deterioration. In particular, pitting corrosion has resulted in perforation of copper tube in such diverse areas as Scotland, Saudi Arabia and West Germany, although corrosion in the latter country appears to be of a modified form to that experienced elsewhere. The corrosion process was so well established in some Scottish hospitals that renewed sections of the plumbing system suffered identical pitting in a matter of months. This unique corrosion problem cannot be explained simply in terms of chemical corrosion *per se* and suspicion has fallen on the possible involvement of microorganisms, as exemplified by the role of biofilms in corrosion of the steel legs of drilling platforms in the sea (Hamilton, 1985). In this process, sulphate-reducing bacteria (SRB) in a complex microbial consortium use sulphate in the water as an electron acceptor for anaerobic growth, liberating hydrogen sulphide in the biofilm which attacks the steel and establishes a corrosion cell.

The extent of corrosion of copper tubing in Scottish hospitals is not known but replacement costs could be very high. Moreover, the escape of aerosolised water sprays through perforated tubing poses a potential health risk, particularly if *Legionella* spp. were present in the water or able to grow in biofilms (Colbourne and Dennis, 1988; Keevil *et al.*, 1988) adjacent to the perforations. Even in the absence of such pathogens, aquatic bacteria may, when aerosolised, be involved in processes giving rise to humidifier fever and other lung infections. Indeed, any biofilm which is resistant to the toxic effects of copper may well harbour and protect potential pathogens which are normally inhibited by this metal (Gadd and Griffiths, 1978; Falkinham *et al.*, 1984; States *et al.*, 1984). Growth of individual bacterial species or complex microbial consortia and the development of biofilms is markedly affected by the local environment, including changes in nutrient availability, pH, temperature, oxygen concentration, redox potential and metals concentration (Ellwood *et al.*, 1982; Keevil *et al.*, *1987*, *1988*; *Glenister et al.*, 1988). Accordingly, the aim of this investigation was to assess the water quality and plumbing systems of two Scottish hospitals and establish physico-chemical and microbiological parameters of importance to the corrosion process.

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MATERIALS AND METHODS

Water Supply and Sampling

The soft, peaty water was supplied from an upland catchment (Scottish loch). Water at various points in the plumbing of the hospitals was collected for chemical analysis (Anon, 1979) and determination of assimilable organic carbon (AOC; Stanfield and Jago, 1987). A continuous monitor was installed in one hospital close to the calorifier to study E_h, pH, temperature and dissolved oxygen fluctuations over a 24-hour period. In addition, 10 *l* samples of the incoming mains supply (hydrant), the stores supply (first tap off the holding tank) and water from the calorifiers (first tap off calorifier) or representative of that flowing through the rest of the distribution system (furthest tap in system) were concentrated aseptically by passage through 0.2 μm nylon membrane filters followed by resuspension in 50 ml of the filtrate. Swabs of various taps, cold water holding tanks and calorifier outlets were suspended in 10 ml of the local water supply. The hot water flow to suspect sections of copper pipework was stopped and one metre lengths were cut and immediately sealed at one end with a bung covered with sterile plastic sheet. The tube was filled to the brim with water from that part of the supply and sealed.

Microbiological Analysis

The sealed tubes were reopened in an anaerobic cabinet containing an atmosphere of 80% N_2:10% H_2:10% CO_2 to exclude oxygen that can kill any strict anaerobes present in the samples. The waters were aseptically decanted into sterile containers and some of the pipes were seen to contain large black nodules which were clearly associated with perforations through the metal. These were scraped off with a sterile dental probe and resuspended by vortex mixing in either 5 ml of the membrane-filtered water (Colbourne *et al.*, 1988) obtained from the site or sterile Page's (1967) amoebal saline which was found to be better in the present study for maintaining the viability of the aquatic bacteria. The concentrated waters, resuspended swabs and biofilm were plated (0.1 ml) onto modified Postgate's (1984) Medium agar (to isolate SRB), mineral salts agar containing 0.2% (v/v) methanol (to isolate methylotrophic microorganisms; Colby and Zatman, 1973), minimal R2A agar (to isolate the majority of aerobic and anaerobic microbes and reduce the risk of substrate shock preventing recovery of oligotrophs; Reasoner and Geldreich, 1985) and BCYE agar (to isolate more fastidious aerobes, legionellae and anaerobes; Pasculle *et al.*, 1980). Dilutions of

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samples were also inoculated into SRB anaerobic broth (Micran, Aberdeen) in triplicate to determine the concentration of SRB by the most probable number (MPN) technique. Biofilm was also streaked directly onto the agar media without resuspension. All samples were incubated at 30°C, both anaerobically in 80% N_2:10% H_2:10% CO_2, and aerobically in 5% CO_2 in air. The number and morphology of colony forming units (cfu) were ascertained after three, six and nine days incubation. The isolated bacteria were tentatively identified by their biochemical reactivity using the API (API 20NE, API-Biomerieux, Basingstoke) and automated Vitek (MacDonald Douglas Bactomatic) database systems. Those colonies suspected of being *Legionella* spp. after growth on BCYE agar (by morphology and purple colouration) were subcultured onto GVPC Legionella Selective Agar (Dennis *et al.*, 1984). L. bozemanii was confirmed by fluorescence of colonies under UV irradiation and reaction with a specific antiserum raised in guinea pigs.

Scanning electron microscopy of suspected biofilms was performed according to the method of Keevil *et al.*, (1987) on 1 cm diameter disks which had been cut out along the lengths of the recovered pipe. These disks were also observed for corrosion under a binocular microscope at low magnification. The waters and resuspended biofilms were observed at 1000 x magnification after Gram staining for the presence of microorganisms.

RESULTS

Pipe Corrosion

The interior surfaces of the copper pipework from the first hospital (hospital X) were covered with a heavy film (Fig.1a,b). Large black tubercles in the tubing taken approximately 100 metres from the calorifier (site 1; Fig.1c) were clearly associated with extensive pitting corrosion (Fig.1d), leading to perforations through the tubing and escape of water. Fewer and smaller tubercles with no perforations were observed in tubing from hospital X at a point less than 60 metres from the calorifier (site 2). The pipework of the second hospital (hospital Y) is supplied with water from the same public supply and it also contained a heavy deposit (not necessarily biofilm; see later) but there was little or no evidence of tubercle formation or corrosion (site 3; Fig.1e,f).

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Chemical Analysis

The chemical quality of the water supplying the two hospitals was typical of an upland surface source with a natural colour from the dissolved humic acids of peaty soil (Table 1). The low mineral content and poor buffering capacity resulted in a variable pH of 7.4 - 9.3. These variations are most probably associated with lime dosing at the water treatment works and the passage through the distribution network but they might also indicate changes within the plumbing itself. Apart from pH, water chemistry remained reasonably constant throughout the plumbing but copper concentrations increased approximately 30-fold in the hot water at hospital X where pitting corrosion was severe and 60-fold at hospital Y experiencing little corrosion in the sample observed. These increases may have been due to corrosion processes in the pipework but the copper concentrations are still well within EC limits. Carbon available for microbial growth (AOC) was abundant in the incoming water supply (Table 2). This value increased from approximately 7.8 in the hydrant water supplying the two hospitals to 12.4 in the holding tank of the first hospital which may reflect concentration of organic debris in the tank. By comparison, the AOC of London water (lowland, hard surface water) is typically only 3.0. The AOC decreased to values of 4.8 and 1.4 in the plumbing systems of hospitals X and Y, respectively. This depletion may indicate prolific biofilm activity assimilating the available carbon.

Temperature and Oxygen Analysis

The site survey was undertaken in late autumn so the temperature of the hydrant and tank samples was only 10°C, sufficient for survival but not growth of microorganisms (Table 1). A continuous monitoring system revealed that the temperature of the hospital X hot water rarely exceeded 50°C and was more often at 40°C for many hours (Fig.2). This is contrary to the DHSS Code of Practice (1988) stating the need for maintaining a water temperature of at least 50°C. Even when the first outlets downstream from the calorifier were at 50°C the temperature at outlets more distant decreased (Table 1). In the case of hospital X which experienced severe corrosion the temperature was only 43°C at the distant tap outlet after flushing and was as low as 28°C when no water was flowing. A similar low temperature was noted at the distant outlet in hospital Y when no hot water was flowing. Perhaps significantly, however, the temperature of the flowing hot water was always above 56°C and little or no corrosion of pipework was evident. The generally low temperatures at hospital X experiencing corrosion were complemented with marked variation in the dissolved oxygen concentration: a sharp fall

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Table 1. Chemical analysis of the waters in the plumbing systems of two hospitals experiencing severe (x) or minor (y) pitting corrosion

	Hydrant	Hospital x				Hospital y		
		Tank	1st tap off calor.	Hot tap site 1	Hot tap site 2	1st tap off tank	1st tap off calor.	Hot tap site 3
Temperature - initial	-	10	23	28	17	26	25	26
- after flush	10	-	51	43	48	15	59	56
pH	9.26	8.63	7.86	7.61	7.65	7.12	6.75	6.77
Colour (Hazen)	13	14	13	13	13	12	10	10
mg/l								
Solids	81(81)[a]	44(44)	50(50)	46(46)	37(37)	33(33)	23(23)	28(28)
Hardness ($CaCO_3$)	<20	<20	<20	<20	<20	<20	<20	<20
Carbon dioxide	0.1	0.1	0.1	0.2	0.2	1	1.8	1.8
Organic carbon	1.6	1.6	1.6	1.6	1.6	1.8	1.6	1.4
Dissolved oxygen	11.2	11.3	12.6	11.7	12.3	8.4	-	8.7
Oxidised nitrogen	<0.2	0.2	0.2	<0.2	0.2	<0.2	<0.2	<0.2
Chloride	<5	5	5	<5	5	<5	<5	<5
Sulphate	3	4	4	3	3	3	4	3
Sulphide	<0.003	<0.003	<0.003	<0.003	<0.003	<0.003	<0.003	<0.003
KMnO4 oxidisability	2.4	2.6	2.3	1.7	2.4	1.7	1.7	1.6
Reactive phosphorus	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Reactive SiO_2	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Calcium	5	4	4	3	3	3	3	3
Magnesium	0.6	0.7	0.6	0.6	0.6	0.6	0.6	0.6
Sodium	3.3	3.3	3.3	3.1	3.3	3.1	3.1	3.1
Potassium	0.3	0.3	0.3	0.3	0.3	0.2	0.3	0.2
µg/l								
Aluminium	33	35	33	39	48	26	19	19
Copper	10 (10)	10 (10)	139 (46)	111 (63)	332 (77)	78 (44)	529 (317)	597 (261)
Iron	64 (25)[a]	74 (35)	60 (33)	94 (38)	201 (33)	96 (45)	119 (51)	134 (62)
Lead	<5	<5	<5	<5	<5	<5	<5	<5
Manganese	10 (<10)	<10	<10	<10	24 (<10)	<10	<10	<10
Zinc	12 (10)	20 (12)	10 (10)	16 (13)	25 (13)	69 (54)	90 (90)	173 (173)

The data are expressed as total dissolved plus insoluble concentrations. Numbers in parentheses refer to the dissolved concn. only, were appropriate. [a]The solids and iron concn. of the hospital y mains supply were 32(32) mg/l and 105(32) µg/l, respectively.

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Table 2. Microbiological and assimilable organic carbon analyses of the waters from various sites within the plumbing systems of hospitals experiencing severe (x) or minor (y) corrosion.

	Hospital x						Hospital y			
	Hydrant	Tank	Tank sediment	1st tap off calor.	hot tap site 1	hot tap site 2	1st tap off tank	Vertical calor.	1st tap off calor.	Hot tap site 1
Aerotolerant spp: (cfu/ml)	280*	300	-	1000	1000	80	50	1000	2000	1000
Legionella spp. (cfu/ml)	0	0	0	0	0	0	0	600	0	0
Fungi (cfu/100ml)	2	7	2	0	0	0	12	3	0	0
Sulphate reducing bacteria /100ml	1	6	0	10	6	5	0	0	0	0
Assimilable organic carbon (ATP x 10-10 g/l)	7.4*	12.4	-	4.8	7.8	5.0	3.4	-	1.4	2.2

No coliforms or Pseudomonas aeruginosa were detectable in the waters. *The number of aerotolerant spp. and the AOC value in the mains water of hospital y were 50 cfu/ml and 8.1, respectively.

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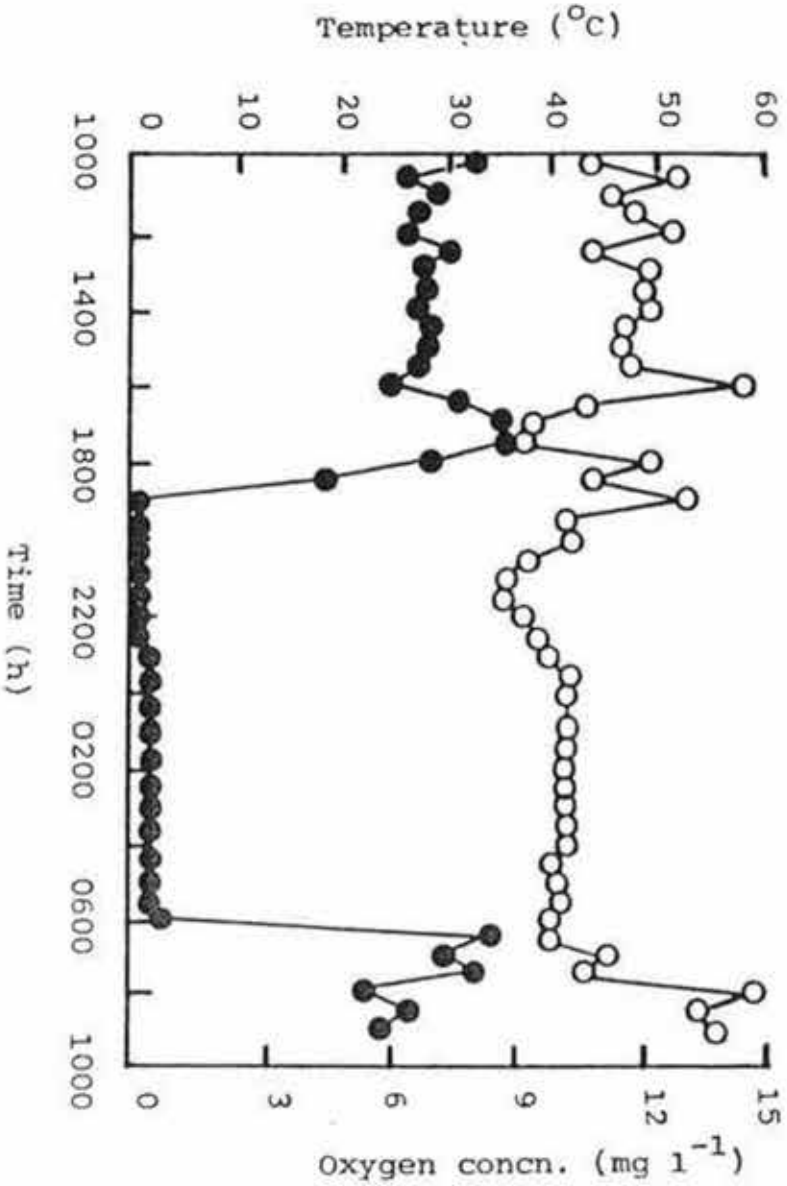

Figure 2 Continuous monitoring of the temperature (O) and dissolved oxygen concentration (●) of the hot water supply at hospital X over a 24 hour tome course

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occurred overnight for 12 out of 24 hours when little water was used, establishing anaerobic conditions in the water column (Fig.1).

Microbiological Analysis

The incoming cold water to both hospitals contained low counts of bacteria (Table 2). The composition of the aerobic microbial flora after up to nine days incubation on agar media comprised mainly slow-growing, Gram-positive streptococci, micrococci, and Gram-negative rods and bacilli which were predominantly white, yellow or red in colouration. Using the API and Vitek databases, some of the Gram-negative species were tentatively identified as *Alcaligenes*, *Achromobacter and Flavobacterium* spp., (white colonies) and *P. paucimobilis* (yellow colonies). Legionellae were recovered from the base of the vertical calorifier in hospital Y: the temperature of the preflush water was only 27°C and a high count of viable bacteria was detected in this sample. After prolonged flushing this count decreased but *Legionella bozemanii* was recovered. Presumably this had been released from biofilm near the outlet by turbulence (Colbourne and Dennis, 1988). Low numbers of fungi were present in samples from the hydrant and tanks at both hospitals. Blackening of SRB broth and anaerobic growth on SRB agar confirmed the presence of low numbers of SRB, probably *Desulfovibrio* spp., in all of the water column samples. The MPN determination was possibly an underestimate of the SRB concentration since more organisms were apparently detected at the higher dilutions. The could be due to dilution of a toxic substance, such as the relatively high copper concentration in the water.

A similar complex flora was detected in swabs (biofilm/deposits) from various sites but samples taken from the taps and tank sediments in both hospitals were negative for SRB. However, pink-pigmented facultative methylotrophs, able to grow aerobically on either R2A or methanol agar, were detected in biofilms but not in the water supply. These bacteria were probably of the genus *Methylobacterium* (Hood *et al.*, 1988). Their niche within the complex consortia might have been established due to release of C_1 compounds from AOC by the focal activity of biofilm.

When the black tubercles associated with perforations in the tubing of hospital X were recovered anaerobically, the presence of many SRB was indicated by the rapid blackening of the indicator medium. These anaerobic bacteria were also visualised as discrete colonies when the

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films were streaked directly onto Postgate's Medium agar. Many aerobic species were found, including fungi which could not be detected (visually or by culture) in the water itself. Scanning electron microscopy of the pitted surfaces revealed a copious biofilm (Fig.3a) which under increased magnification was seen to contain a complex community of rod and coccoid bacteria covered with extracellular polymeric material (Fig.3b). Their presence was confirmed by Gram stain of biofilm homogenised in water. By contrast, no black tubercles (Fig.1f) were visible in the tubing taken from hospital Y and fewer viable SRB and fungi were detected. No perforations were observed at low magnification (Fig.1e). Scanning electron microscopy revealed a much thinner biofilm with few rods and cocci (Fig.3c,d). Their presence was again confirmed in homogenised samples by Gram's stain.

DISCUSSION

Chemical analysis alone of the water supplying the Scottish hospitals could not readily explain the corrosion being experienced. By contrast, the survey indicated a link between the presence of biofilm and pitting corrosion of copper tubing. The more copious the biofilm and the greater the numbers of organisms, the more severe the corrosion. Intriguingly, McEvoy (1985) has described how a fungal isolate from fuel tank sludge, *Cladosporium resinae*, is capable of corroding steel and cupronickel alloys. Although identification of the organisms found in these biofilms has yet to be completed it is apparent that *Pseudomonas* and *Alcaligenes* spp. are present. This is of particular interest since such aquatic species are common in treated waters and produce exopoly-saccharides. The production of these polymers may explain why the biofilm consortia were covered in polymeric material. Recent work by Geesey *et al.*, (1987) has shown that microbial exopolymers can sequest copper, even when purified from the bacteria producing them. This sequestration seems to result in corrosion of the copper surface.

Perhaps as importantly, polymer formation helps to consolidate a biofilm and establish diffusion gradients whereby anaerobes can survive in the layers of the film (near the metal surface) which are depleted of oxygen by the metabolism of aerobic species in the upper layers. Biofilm consolidation can also be encouraged by the presence of fungi whose hyphae spread throughout the biofilm and tenaciously trap bacteria in a mesh-like structure. Interestingly, some of these fungi are resistant

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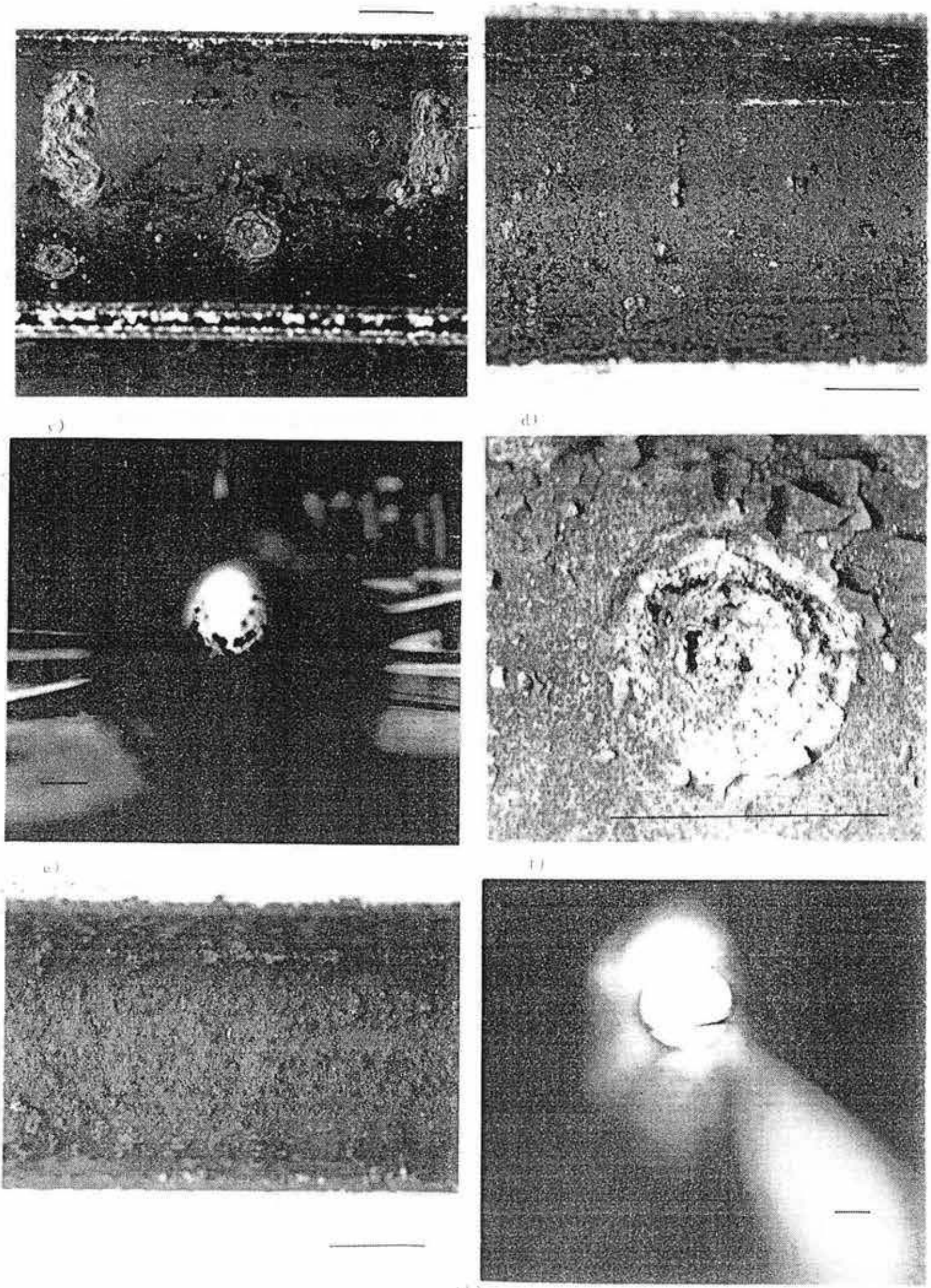
to comparatively high concentrations of copper (McEvoy, 1985), making them attractive candidates as early pioneer colonisers of copper tubing. Thus, it is possible to speculate on the steps which might be involved in biofilm formation and corrosion of copper tubing in soft water areas. The following tentative scheme is proposed:

1. Most surfaces acquire a "pellicle" of absorbed material from the water supply which may modify the physico-chemistry of the surface. Pellicle formation was observed on the copper tube in the present survey. Soft, upland catchment waters such as those supplying the Glasgow area contain natural organic substances derived from the soil, e.g. humic acids (Thurman, 1985). Moreover, the Scottish water contained assimilable organic carbon at levels above those found in harder, lowland river waters and aerobes such as *Pseudomonas* spp. may use the polyphenolic humic acids present as nutrients. Colbourne (1979) and others (see Andreoni and Bestetti, 1988) have shown that pseudomonads in water can utilise a wide range of organic substances as sole carbon sources; the concentration for growth being very low. The pseudomonads produce exopolymers and attach to copper surfaces whose inhibitory effects may be rendered inert due to the pellicle. Polysaccharide production is also believed to protect bacteria against the inhibitory effects of copper. The bacteria may be joined by other species such as fungi which can be copper tolerant and thus a biofilm matrix forms. At this stage, polysaccharide production may sequest copper and initiate an "aerobic corrosion" process.

2. Metabolism by aerobic members of the biofilm consortium reduces the oxygen concentration in the surrounding water (perhaps as demonstrated at hospital X) and permits the proliferation of strictly anaerobic species, such as SRB. This activity also depletes the oxygen within the deeper layers of the biofilm and permits the anaerobes to establish near the metal surface. Sulphate metabolism by the SRB produces hydrogen sulphide which forms copper sulphides and stimulates a corrosion potential, establishing the "anaerobic corrosion" process (Hamilton, 1985).



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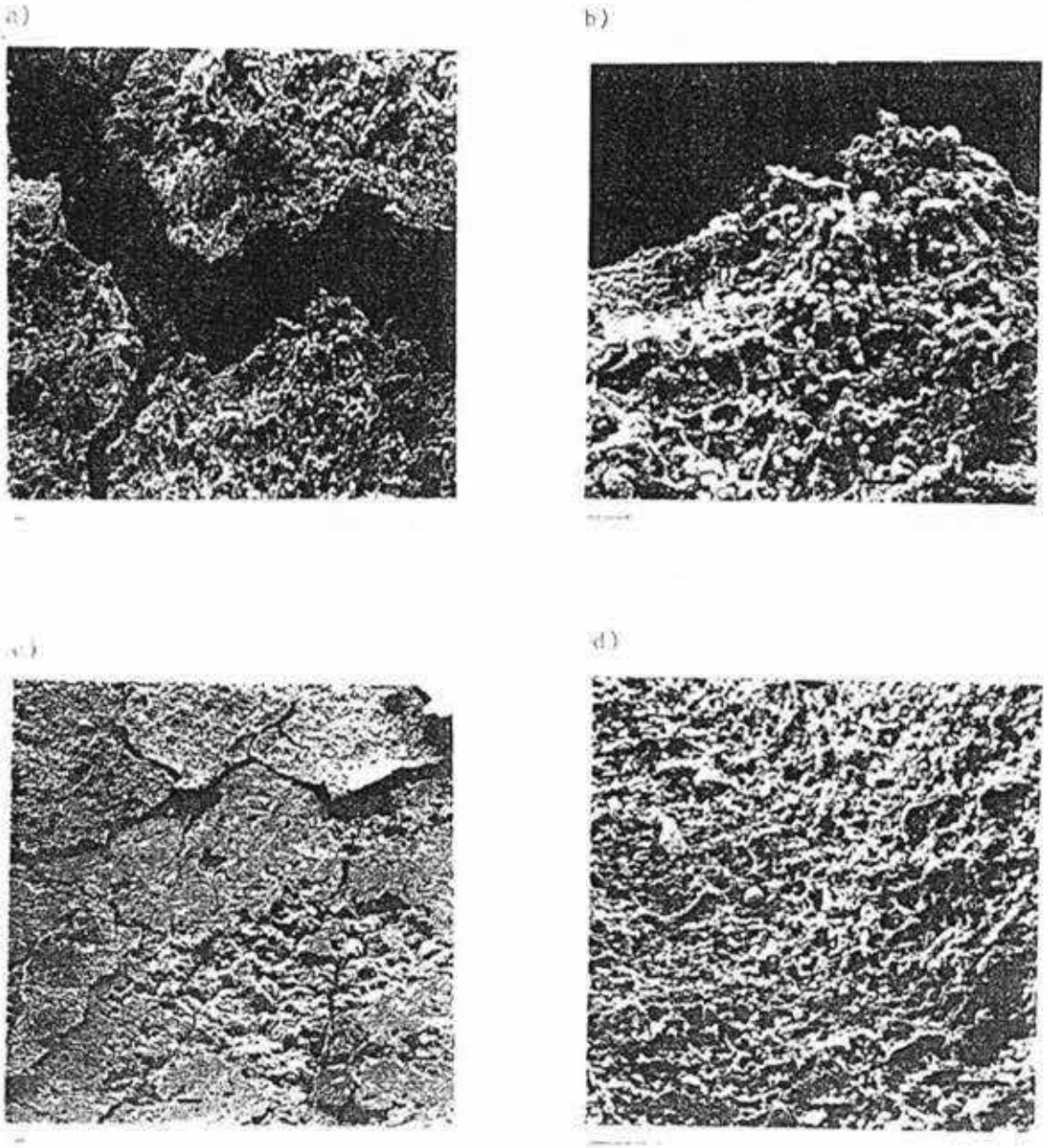

Figure 1 Scanning electron micrographs of biofilms on the internal surfaces of copper pipework supplying hot water to hospital A (a,b) and hospital W (c,d). Marker bars denote 10μm.

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View publication stats

ULTRAFILTRATION UNIT

CONTENTS

DECLARATION OF CONFORMITY

ELGA PROCESS WATER

Orbital House, 3 Redwood Crescent, East Kilbride, G74 5PR

Telephone: +44 (0) 1355 58800
Fax Number: +44 (0) 1355 58801

ULTRAFILTRATION UNIT

Conform to the following EC Directives where required:

The Electromagnetic Compatibility Directive 89/336/EEC
(including any additions or amendments thereafter)

and

The Low voltage Directive (Electrical Safety) 73/23/EEC
(including any additions or amendments thereafter)

and

The Machinery Directive 89/392/EEC
(including any additions or amendments thereafter)

Derek McIntyre

Business Development Manager March 2011

HEALTH AND SAFETY RECOMMENDATIONS

Use caution when working on Elga Process Water equipment. The following items are likely to present possible hazards - chemicals, ion exchange resins, electricity, air pressure, water pressure, hot water and hot surfaces. Please ensure personnel are familiar with these hazards and that adequate precautions are maintained.

CHEMICALS

Chemicals used on Ultrafiltration system during normal use are –

- Elgalite RU3 which is an organic acid cleaner for the Ultrafiltration membranes
- Elgalite UFC13 which is an alkaline detergent also used to clean the Ultrafiltration membranes
- Peracetic Acid used to sanitise the Ultrafiltration system

Refer to safety data sheets supplied with the above products and follow the safety instructions during use.

ELECTRICITY

The unit must be properly earthed and the correct rated fuses should be fitted. Power should be switched off at a remote isolator before commencing work on the equipment.

AIR AND WATER PRESSURE

Elga Process Water equipment operates at pressure and, where possible, this should be reduced before commencing work. Normal protection from freezing should be taken, as ice inside pressure vessels and pipework can cause rupture. Compressed air can be dangerous and great care should taken with its use.

IF IN DOUBT FURTHER INFORMATION ON SAFETY CAN BE OBTAINED FROM ELGA PROCESS WATER SERVICE

INTRODUCTION

GENERAL

Please carefully read these operating and maintenance instructions.

Ensure that the unit is installed by Elga Process Water engineers and operated in accordance with the instructions in this manual. If there are any enquiries regarding the installation, operation or servicing of the unit contact Elga Process Water Service Department.

This manual describes the operation and basic maintenance of the Ultrafiltration unit.

Every effort has been made to maximise the life of the life of the Ultrafiltration membrane incorporated in the Elga UF unit.

The Ultrafiltration skid consists of a vertically mounted ultrafiltration membrane, cleaning in place (CIP) tank, control system, motorised valves, flow meter, pressure gauges and CIP Backflush pump.

IMPORTANT NOTES

Please ensure that the following are regularly checked:

1) That pre-treatment is working reliably
2) The maximum pressure differential across the membrane during service does not exceed 0.8 bar
3) Performance Log Books are kept up to date
4) That routine membrane cleaning is carried out
5) Pressure shock owing to water hammer is avoided during normal operation

In addition, water analyses should be routinely maintained so that wide fluctuations of composition can be quickly identified.

If such fluctuations occur contact Elga Process Water Service for advice.

ELGA PROCESS WATER
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Scotland

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TECHNICAL DATA

UF UNIT

Unit UF/Hydra/60/1/2		
UF Membranes	No.	6
Feed/CIP Pump Motor	kW	5.5
Nominal Recovery	%	92
Output Flow		
During production	l/hr	30000
During Backflush and CIP	l/hr	0
Dimensions and Weights		
Height	mm	2765
Height (including service access)	mm	3265
Depth	mm	1500
Depth (including service access)	mm	2000
Width	mm	3000
Width (including service access)	mm	3500
Shipping Weight	Kg	750
Working Weight	kg	1500
Pipe Connections		
Raw Feed	Ins	3” PN 10/16 Flange
Treated Outlet	Ins	2 1/2” PN 10/16 Flange
Drain	Ins	2 1/2” PN 10/16 Flange

Material Specifications		
UF Housing Module		PVC
UF Housing End Cap		PE
Capillary Membrane		PESM
Raw Water Pipework		ABS & PVC
Purified Water Pipework		ABS & PVC
CIP Tank		PE
CIP/Intermediate Pump		316 Stainless steel multistage centrifugal
Skid		304 Stainless steel
Control Cabinet		Polycarbonate
Feed Water Data		
Supply Quality		Free from suspended matter above 50 micron
Supply Pressure		Flooded Suction
Temperature		Min 5ºC, max 40ºC
pH limits Operation		3-10
Electrical Supply UF/HYDRA/2/6		380/400V/3pH 50Hz – 6.5 kW
Ambient Temperature		
Maximum Ambient Temperature of Plant Room	°C	35

STANDARD SPECIFICATIONS

Performance

Notes:

- Molecular Weight Cut-Off – 100 to 150 kDaltons
- Performance information quoted refers to pre-treatment and post-deionisation applications only. For polishing or special purpose applications please consult Elga.
- It is recommended that the UF plant is protected from suspended solids by a cartridge type prefilter approximately 50 micron rating
- Nominal capacities are based on operation at 10°C. For lower temperatures consult Temperature Correction Table below.

Temperature °C	Temperature Correction Factor
10	1.0
8	0.95
6	0.90
4	0.84

Maximum Operating Pressures

Inlet	Flooded Suction
Maximum trans-membrane pressure in service	0.8 Bar (11.5 psi)
Maximum trans-membrane pressure during backwash	2.5 Bar (35 psi)

Feed Water Temperature and pH Limits

pH	Maximum Temperature
1-3	30ºC (40ºC for short periods for cleaning typically 0.5-1 hour)
3-10	40ºC Normal operation
10-13	30ºC

PROCESS AND PLANT DESCRIPTION

ULTRAFILTRATION

The UF system is a self contained water treatment package that is complementary to the Elga range of media filters, deionisers and reverse osmosis plant.

Owing to the small pore size and geometry of the system, the process is capable of removing contaminants from water without suffering adversely from fouling.

Examples of impurities which can be efficiently removed include suspended solids, colloids (silica, iron, organics etc), and High Molecular Weight Organic molecules.

The system incorporates safety features and automatic controls for ease of operation.

Elga UF plants are skid mounted systems intended for pre-treatment applications and are assembled and wet tested before despatch.

The UF is fully automatic during normal service requiring only the minimum of supervision.

Periodic chemical cleaning is required to restore membrane capacity and prevent long term deterioration in performance. Elga supply a range of chemicals specifically developed for cleaning ultrafiltration membranes operating in the water treatment industry.

Molecular Weight Cut Off (MWCO)

Ultrafiltration is a low pressure membrane separation process employing cross flow and dead ended membranes with pore sizes in the range 10-200 Angstroms.

Systems are rated by their output in litres per hour and the nominal Molecular Weight Cut Off of particles and molecules that will not pass through the membrane.

The membrane module in the Ultrafiltration unit has a MWCO of 100-150 kDaltons and an output of 5000 litres per hour per membrane

Water Recovery

The 'recovery' of a water treatment system is a measure of the proportion of the total input water that is converted to purified water or permeate. A recovery of 10% means that only 1 part in ten of the input water is converted to permeate. At 50% recovery, half of the input water is converted. At 75% recovery, three quarters of the input water is converted to permeate.

The Ultrafilter is operated as a ‘Dead End’ filter for most applications which means that the recovery is 100%. However a small proportion of the permeate is stored and used during periodic backwashing to drain. This then gives an effective recovery of 92%.

Temperature and Pressure

The PESM materials and membrane structure has temperature and pressure limitations of 40ºC and 5 bar respectively when operated on normally pre-treated water. However, the UF should not be operated above 30ºC during alkaline cleaning, and 20ºC during peracetic acid disinfection. Ambient temperature in the plant room should not exceed 35^0C.

OPERATING INFORMATION FOR ULTRAFILTER MEMBRANES

- The membranes fitted to the UF must remain damp at all times. A temporary or possibly permanent loss in performance may result if they are allowed to dry completely.
- If operating specifications are not strictly followed the warranty will be null and void.
- During the first hour of running new membranes, direct product water (permeate) to drain. For critical process applications a longer 'run in' period may be required to completely rinse the membranes.

To prevent bacterial growth and help maintain flux, it is recommended that elements are stored as stated in section Preservation and Freeze Protection, whenever the system is not in use for a period longer than 3 days. Neither non-ionic nor cationic surfactants nor any other chemical not approved in writing by Elga Process Water should be used for membrane cleaning, or come in contact with the UF membranes.

The customer is fully responsible for the effects of unapproved chemicals on the UF membranes; their use will void the element warranty.

PRE-TREATMENT

The UF Membranes in the Ultrafiltration have a finite life with the decline in performance depending mainly on the quality of the treated feedwater and remedial cleaning.

The life of the membranes is optimised by:

- The correct choice of pre-treatment for the feedwater supply.
- Routine maintenance and cleaning when necessary.
- Correct operation.

A full analysis of the feedwater is recommended to provide guidelines for adequate protection of the membranes.

In addition unusual impurities such as oil, grease and organic solvents should not be allowed to enter the unit, otherwise irreversible membrane damage may result.

PRE-TREATMENT TECHNIQUES

One of the following pre-treatment techniques may be required for UF units:

Suspended Matter

A 25 micron particulate filter is fitted as standard to the UF unit. Feed water having a high fouling index or high turbidity may require additional filtration such as suitable sand, or multimedia filter.

Temperature

For optimum performance the Ultrafiltration unit requires a feedwater temperature below 30^{o}C (maximum 40^{o}C). Note that the ambient temperature of the plant room should not exceed 35^{o}C.

PROCESS DESCRIPTION AND HYDRAULIC COMPONENTS

Refer to the flow diagrams in the 'drawings' section of this manual.

Process description

The ultrafiltration membrane is connected to a feed manifold, and concentrate manifold and a permeate manifold

During normal service, water flows into the UF module through either the top of bottom process connection depending on the valve orientation instructed by the controller. Water then flows through the centre of the hollow fibres. The inner surface of the fibres form the membrane separation barriers and water permeates radially outwards through the membranes into the collection shell and permeate manifold.

During service the ultrafiltration modules are operated at 100% recovery, that is no water is rejected from the concentrate side. The overall recovery figure is reduced to approximately 92 when for 1 minute every hour the membranes are cleaned with a flush of feed water and a backflush of permeate. Previously ultrafiltrated water which has been collected during service is pumped in a reverse direction through the membranes into the centre of the fibre and then to drain. The backflush procedure is fully automatic, being carried out by the PLC controller and automatic motorised control valves.

In addition to the automatic backwashing, periodic chemical cleaning is required to maintain the capacity and water quality. See Cleaning Cycle section

Flow Process and Hydraulic Controls

The following notes should be read in conjunction with the process drawing in the Drawing Section and the valve position schedules in Appendix 1.

During service, feed water flows into the plant through the inlet valve and into the inlet of the pump. The flow is through the Feed/CIP pump and into the UF membranes. In the membranes

the flow is in a inside to outside direction before collected at the permeate port. The Permeate then flow out through the permeate valve and off skid.

When the plant is in service a small amount of permeate passes via a flow restrictor and servo float valve to the CIP tank. This permeate is used for backflushing the modules.

When the plant is backflushed the filtered water flows out of the CIP tank through the feed/backwash pump and into the permeate port of the Ultra Filter membranes flowing through the fibres from outside to inside before collecting at the concentrate port and flowing to the drain.

ELECTRICAL CONTROLS

The operation of the unit is carried out through the HMI screen, the layout of the screens is shown in Appendix 7

The other controls on the control panel are:-

Power Isolator

The main power switch/door isolator is on the lower left of the control panel. This isolates the unit from the electrical power supply, as the valves are motorised this will not change their position, which can result in the unit continuing to operate.

Indicator Lights

There are three indicator lamps and one buzzer on the system that are positioned in the control panel:

Colour	Legend	Function
Green	24VDC Circuit	The 24 VDC circuit is ok used for valves
Green	PLC Circuit	The power circuit to the PLC is ok
Green	Instrument Circuit	The 5 VDC circuit is ok used for pressure transducers

E-Stop

If the E-stop button is pressed then the power to the CIP and intermediate pump are cut and the valves are moved to the standby position. The HMI will display an alarm, the E-Stop circuit will only come back into service once the E-Stop reset button has been pressed.

PLC Reset

If the PLC Reset button is pressed for 3 seconds then the unit plc will reset all alarms and functions.

ALARMS

UF Controller

The alarms on the UF controller –

- High Inlet Pressure
- CIP/Feed Pump Failure
- Differential Pressure exceeded
- E-Stop pressed
- CIP tank low during backwash
- Valve failure

- Chemically enhanced Backwash timeout

For all of these alarms the buzzer will be activated and the volt free contact closed, the contact for the volt free contact is given in The Electrical Connection SChedule

The valves will move to the standby position.

To acknowledge an alarm press the flashing alarm symbol in the top right hand corner and press the ack button in the alarm screen when the particular alarm is highlighted

If a valve alarm has occurred then the the RST button needs to be pressed before the unit will commence operation

INSTALLATION

MECHANICAL AND HYDRAULIC CONNECTIONS

Foundations/Drainage

The system will not require any special foundations, provided that a firm, level area, which is capable of supporting the working weight, is available.

Concentrate water from the UF process must flow to an open drain (or gully via an air break) that is capable of passing the necessary flow. The maximum flow of water to drain depends on site conditions, but may be up to 100% of the normal service feed water flow.

Operating Space

Access will be required to monitor the operating flows, pressures and conductivities. Access will also be needed to carry out adjustments or maintenance on the equipment. It is therefore recommended that a minimum of 500mm clearance be allowed around the base for this purpose.

Incoming Water

The feed water to the system must comply with the following:

(a) Available at all times at a flow equal to the required maximum service flow or greater.
(b) Flooded Suction at the required service flow rate or greater.
(c) Temperature between 5ºC and 40ºC.
(d) Filtered for suspended solids above 50 micron.

Pipework

Pipework to be connected to system should not have an excessive amount of Iron or hardness scale deposit. Piping that is heavily built up with scale or Iron deposits should be replaced.

Make sure that the pipework can be connected to the Ultrafiltration system in such a way as to impose no stresses on the inlet connection, and so that it is properly aligned and supported.

WATER SUPPLY REQUIREMENTS AND REGULATIONS

It is essential that the equipment is connected to a pressurised water supply. If connected to a mains supply the local water supply regulations or byelaws must be adhered to. These cover both plumbing and the prevention of back flow into the mains water supply . If there is any doubt, the local water supplier should be consulted.

ELECTRICAL CONNECTIONS

Electrical installation should be carried out by a competent electrician, and must conform to the appropriate standards of safety. An electrical supply of 380/400 V 3pH 50 Hz is required by the system.

The mains supply connection should be made through a separate 380/400 V 3pH 50 Hz switched supply with three phases and neutral, fused and earthed in accordance with Institute of Electrical Engineers Regulations. Current rating should be as shown above. Motor rated fuses must be used.

A 230 to 24V DC safety isolating transformer is fitted within the control panel to provide power to the low voltage valve and pump control circuits and the PLC controller has an integral 230 to 24V DC transformer built in which is used for the PLC inputs power feed and the PLC display panel power supply.

Building Management System connections

The PLC controller has two integral volt free alarm contacts that can be utilised to connect to a BMS system.

Warning Alarm (Malfunction)
Service/Standby

Terminal numbers for the above functions are shown in the electrical wiring schedule

COMMISSIONING

Ultrafiltration systems should only be commissioned by qualified Elga Process Water commissioning engineers.

No attempt should be made to operate the system until it has been commissioned since serious damage could result.

OPERATION

OPERATING PROCEDURES

The Ultrafiltration system is designed to run and rinse automatically and should not be turned off for more than a day to ensure that the regular flush and backflush cycles are completed correctly.

For the first few days of use, the operating pressures, and feed flows should be monitored every few hours and the system adjusted as the membrane beds down.

Thereafter, the flows, pressures and temperature should be monitored daily at a time when the UF system is producing water.

In general, it is advised that cleaning is carried out when pressure differential increases to no more than 10 psi during service. It is recommended that a Elga Process Water service technician with a thorough understanding of the Ultrafiltration system and their cleaning regimes carries this out. The full details of the operating procedure is given in Appendix 1

START-UP

Ensure the installation has been completed correctly in compliance with Installation and Commissioning Section

Ensure the water supply to the unit is on.

Switch the Electrical supply on

Check the Process Switch is disengaged

Turn the unit on at the door isolator.

NORMAL OPERATION

The Unit should be left to run automatically at all times. Periodic supervision of the plant is essential. Check and record the following data.

- Pre-treatment equipment should be checked for correct operation
- Log sheets should be filled in with the following information:

Daily	Monitor flows and pressures and fill in data sheet.
Weekly	Monitor Fouling Index, check log sheets for developing trends, i.e. increased pressure, reduced quality, etc. Act accordingly.

Examples of data recording sheets can be found in the 'record sheets' section.

SHUTDOWN

If the system needs to be shut down for a short period of time it can simply be turned off by pressing the process stop button on the control panel.

If, however, it is to be shut down for more than one week then the UF system should be cleaned with alkaline detergent UFC13 and filled with preservative. It is recommended that an Elga Process Water service technician with a thorough understanding of Ultrafiltration systems and their cleaning regimes carries this out.

EMERGENCY STOP

The Ultrafiltration unit can be quickly stopped in an emergency by turning the system off at the door isolator on the control panel. However this will not cause the inlet or outlet valves to close, nor change the position of the CIP or backflush valves.

Cleaning Cycle

The periodic manual cleaning cycle is controlled by the PLC.

Manual cleaning can be initiated once the system is in standby and is password protected. The screen will then prompt any further action.

CIP OPERATING PROCEDURE: -

Stage 1 Put the unit in standby mode and call for a chemical clean.
Stage 2 When the buzzer sounds and the display shows 'Close Outlet Valve' then the service valve needs to be closed, once this has been acknowledged then the unit will move to the next stage.
Stage 3 When the buzzer sounds and the display 'Add Chemicals' then the required chemicals need to be added (RU3 to remove hardness, UFC13 to remove organics).
Stage 4 When buzzer sounds and display shows 'CIP complete' then the ph of the water needs to be checked and confirmation given that ok before the service valve can be opened and the unit put back into service.

If it is necessary due to excessive contamination then the RU3 or UFC13 clean can be repeated. If a RU3 clean is not required then this can be skipped by picking the UFC13 clean initially.

The total cleaning sequence is shown below: -

Chemical Clean Sequence				
Step	**Action**	**Display**	**Controlling Function**	**Intervention Required**
1	Filling CIP Tank	Filling CIP Tank 1	High Level Float Switch	
2	Buzzer activated	Close Service Valve	operator	Acknowledgment required
3	Adding Chemicals	Add RU3	Operator	Acknowledgment of addition of chemical
4	Circulating Chemicals	Circulating Chemical	2 minutes	
5	Chemically Cleaning Filter	Cleaning Filter	30 minutes	
6	Draining Tank	Drain CIP Tank 1	Low Level Switch plus 1 minute	
7	Mains Flushing of Filter	Flush Membrane	5 minutes	
8	Draining Tank	Drain CIP Tank 2	Low Level Switch plus 1 minute	
9	Filling Tank	Filling CIP Tank 2	High Level Float Switch	
10	Backwashing Filter	Backwash Membrane 1	Low Level Switch	
11	Filling Tank	Filling CIP Tank 3	High Level Float Switch	
12	Backwashing Filter	Backwash Membrane 2	Low Level Switch	
13	Filling Tank	Filling CIP Tank 4	High Level Float Switch	
14	Flush	Membranes Flushing	PH Meter	
15	CIP Complete	CIP Complete	Operator	Acknowledgement of Service Valve opened

FLUSH

A Flush of the system can be instigated. This allows feed water to flow across and through the membrane down the permeate line to the CIP tank and then the drain.

FEED/BACKWASH PUMP

The supply to the unit can be either pressurised (min 2 Barg max 10 Barg) or flooded suction. If it is pressurised then the feed/backwash pump will have to have it's operation inhibited in the "Inhibit Pump Pressure Alarms Screen" this will limit the pump to be only used in internal operations and the inlet pressure to drive the water in Service operations. If it is in a flooded suction application then the "Inhibit Feed Pump Operation" has to be live and the pump will work in internal and service modes.

ROUTINE MAINTENANCE

In addition to the daily and weekly monitoring, the following tasks should be scheduled as part of the routine maintenance programme.

Monthly	Inspect system for leaks and tighten fittings where necessary.
Three monthly*	Replace inlet filter cartridges.
Annually*	Check function of control system. Calibrate Instruments.

***** To be carried out by Elga Process Water Engineer.

RECOMMENDED CONSUMABLES

Part No	Description	Quantity
ELGA 22694	ELGALITE UFC13 12 x 250 gm	1 Box
ELGA 22693	ELGALITE RU3 12 x 500 gm	1 Box
TBA	Cintropur NW650 25 micron bag filter	1 pack of 5

TROUBLE-SHOOTING

The following table is intended as an overall guide to trouble-shooting procedures.

Fault	Check	Action
Filtrate output low	• Pressure differential during service, Pressure gauges UF Module Feed Pressure and UF Module Back Pressure	If high run cleaning cycle
	• Inlet Pressure during service, Pressure Gauge Feed Water Pressure	If below 2 bar in service increase inlet pressure
Unit does not power up	• Check Electrical Supply and MCB's	
CIP Tank not Filling	• Float Valve allows water to flow during filtration	Flush through Float Valve
High Inlet Pressure	• Check Membrane Differential Pressure • Check Permeate line clear	Clean Membranes Clear Line
CIP Pump Fault	• Check Pump overload	Reset Overload and replace as required
Intermediate Pump Fault	• Check Pump overload	Reset Overload and replace as required
E-stop Presses	• E-Stop Pressed	Release E-Stop and press E-Stop reset
CIP tank low during Backwash	• CIP tank inlet valve	Replace or clean
Valve Failure	• Reset	Monitor valve in question and contact Elga
Chemically Enhanced Backwash Exceeded	• PH meter	Re-run Chemically enhanced backwash and contact elga

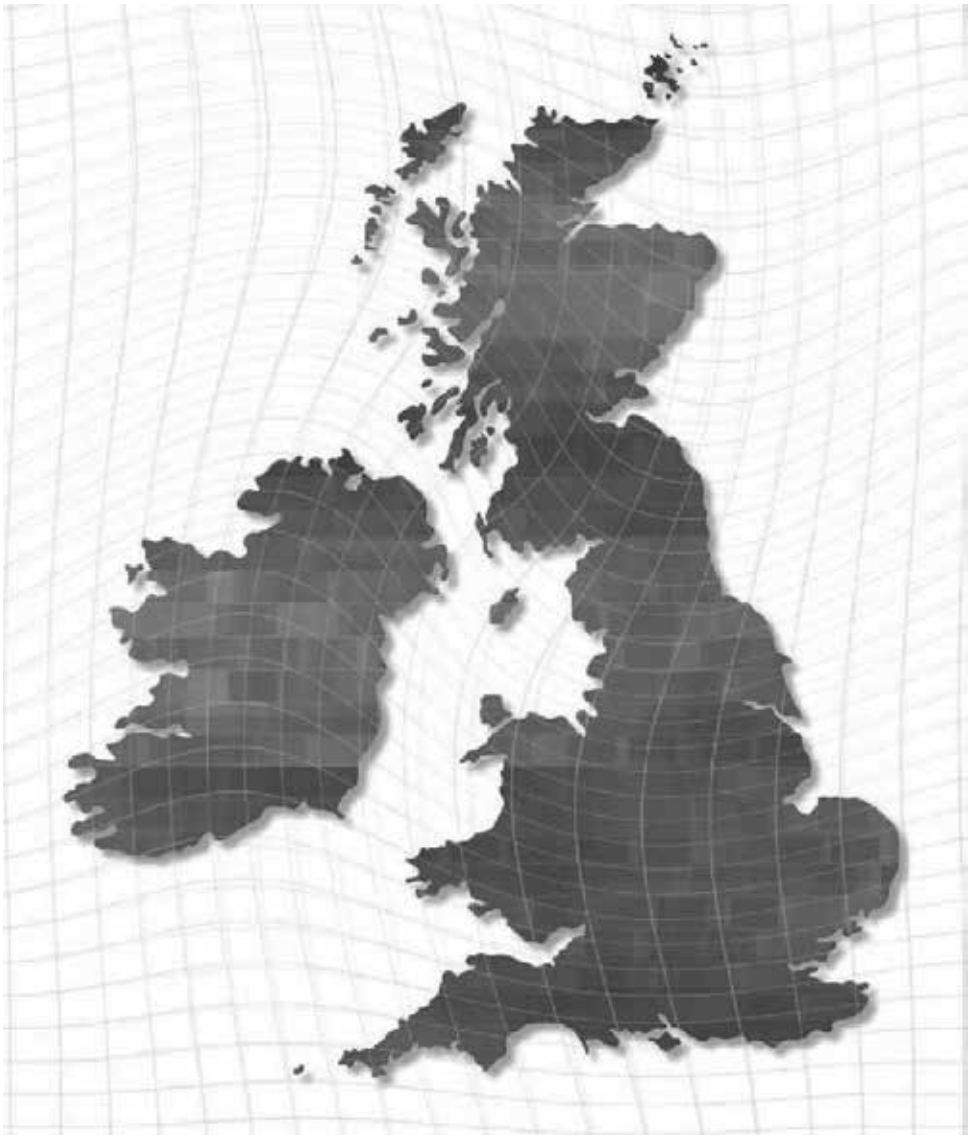
ELGA PROCESS WATER - Service

At Elga Process Water Service we work in partnership with you to ensure uninterrupted, optimal operation of your water and wastewater equipment, processes services and outsourcing requirements. Our unique blend of skills and expertise and the knowledge gathered from more than 70 years of industry experience enables us to provide a wide range of services from media exchange to 24-hour round the clock rapid response emergency service.

Our total Service capabilities include:

- A wide range of service contracts including response sensitive, all inclusive and performance qualification contracts
- Unsurpassed provision of service engineers for on site maintenance and equipment rectification
- Regeneration of DI and aqueous cleaning cylinders
- Supply of cleaning chemicals and media
- Hire equipment and cylinders for short-term requirements
- Service projects including equipment refurbishment, media and ion exchange resin re-bedding, extensions and modifications
- Training for operators and maintenance staff
- Analytical services
- Disinfection services

OUR SERVICE COVERS THE COUNTRY



For all Service requirements contact:

ELGA PROCESS WATER

Telephone: 01355 588000
Fax: 01355 588001
Website: www.elga.co.uk

GLOSSARY OF TERMS

Cleaning in Place (CIP):
Periodic cleaning of the membranes using a detergent or other suitable chemical is required to remove fouling material.

Disinfection:
Periodic disinfection of the membranes using 1% formaldehyde, 1% metabisulphite, 0.05% hydrogen peroxide, or 0.2% peracetic acid solution is required to prevent excessive growth of bacteria in the UF modules and pipework.

Fouling Index (FI) or Silt Density Index (SDI):
A qualitative measure of the particulate and colloidal content of the water.

Membrane:
The permeable material which is used to separate the water from impurities.

Module:
The pressure vessel containing an Ultrafilter element.

Filtrate/Permeate:
The treated water obtained from an Ultrafilter unit, which has passed through the permeable membrane.

Permeate flux:
Permeate flowrate per unit area of membrane per unit of pressure.

Pressure Drop (PD):
Difference between module inlet and outlet pressures.

Pre-treatment:
The process of treating water before it passes through the UF unit such as filtration and chemical dosing.

Feed Water:
Feed water to the water treatment plant from the local water supply.

Recovery:
The ratio of permeate flow to feed water flow x 100%.

Ultrafiltration (UF):
A membrane technique for purifying water.

FOULING INDEX/SILT DENSITY INDEX

The Fouling Index (FI), also known as the Silt Density Index (SDI), is an estimate of the amount of colloidal material present in a water supply. It is based on the rate at which a 0.45 micron membrane filter blocks. To perform an FI test an FI test kit is required (Elga Process Water part no. SSA041).

Operation

- Connect the filter assembly to the sample point, making sure that all fittings are pressure tight and that the filter assembly is held vertically.
- Unscrew and remove the bottom half of the clear filter holder and open the sample valve. Allow the water to run to waste for several minutes to clear the line of any debris and entrapped air.
- Turn off the water using the filter holder On/Off valve and place a filter disc by means of the forceps in the lower half of the holder. Check that the grooves of the filter support plates are facing the filter.
- Open the On/Off valves so that the water drips through the unit in order to completely wet the filter surface, and slowly screw on the bottom half of the housing with one finger over the outlet of the filter housing. This helps remove any air trapped in the filter housing.
- When the air has been expelled, tighten the filter holder.
  It is important that the filter holder assembly is not over tightened, as this may crack the top threaded section. The top of the assembly should be held whenever tightening or undoing the unit.
- Open the On/Off valve fully and adjust the pressure-reducing valve so that a reading of 2 bar is obtained.
- Once the pressure has been set, turn off the On/Off valve.
- Discard the filter used for setting up the apparatus and replace with a new filter as described above.
- Simultaneously turn the On/Off valve on, start the clock and measure the time to collect 100 ml of water using a stopwatch. This initial time, ti, is very critical, and practice will be required to co-ordinate the starting of the stopwatch with the collection of the 100 ml samples.
- The water is kept flowing through the filter and after 5, 10 and 15 minutes, measure the time required to collect further 100 ml samples. Check that the pressure gauge is reading a constant 2 bar; it may be necessary to adjust the pressure reducing valve during the test to maintain a constant 2 bar.

In areas of high fouling index it may be necessary to collect 100ml samples at 1 minute intervals; refer to section headed 'High Index Waters'.

- Included in the test results should be the feed water temperatures as this may have some bearing on the Fouling Index value, especially the, ti value.

Calculation of Results

Formula

% Blockage	=	100 [1 - ti/tf]
FI	=	SDI = % Blockage/TF
FI	=	Fouling Index (dimensionless)
SDI	=	Silt Density Index (dimensionless)
ti	=	Time in seconds for the collection of the initial 100 ml.
tf	=	Time in seconds for the collection of 100 ml at TF, the time relating to 75-80% blockage of the filter disc.
TF	=	Total time, in minutes, of the test.

The aim of the test is to select the time at which the filter disc is 75-80% blocked.

Therefore the ratio of the initial time, ti, divided by tf must be between 0.2-0.25.

Therefore ti/tf = 0.2-0.25 corresponds to 80-75% Blockage.
Example - Low Fouling Index Water

Total Time (minutes)	**100 ml Sample Time** (seconds)
0	6
5	11
10	20
15	28

ti/tf = 6/28 = 0.21

This value is between 0.2 and 0.25 and therefore the fouling index is:

$$FI = \frac{(1 - 0.21) \times 100}{15} = 5.3$$

High Index Waters

For these waters, it will be impossible to obtain even a 5 minutes reading and still have a ti/tf ratio between 0.2 - 0.25.

Repeat the test, measuring the 100 ml sample collections at 1 minute intervals instead of 5 minute intervals until the desired 75-80% plug of the filter has been achieved.

Example - High Fouling Index Water

Total Time (minutes)	**100 ml Sample Time** (seconds)
0	8
1	14
2	27
3	35
4	57
5	83

Because the ti/tf must lie between 0.2 and 0.25 then the 3 minutes value is the time to use

ti/tf = 8/35 = 0.228

$$FI = \frac{(1 - 0.228) \times 100}{3} = 25.7$$

SAMPLE POINTS

There are 3 sample ports on the UF unit, for locations see the Schematic Drawing on Page 36.

SAMPLING METHOD

1. Open Valve and allow full flow out of the valve for 2 minutes
2. Do not touch valve as this can dislodge contaminates from the internal components
3. Open Sterile container and place under stream of water and fill to appropiate level
4. Cap Container
5. Turn valve off

DRAWINGS

See attached documents

Appendix 1 Operating Procedure

The UF plant works on a 1 hour cycle including a 1 minute backwash cycle.

A manually actuated chemical enhanced backwash is required periodically to maintain the performance of the plant.

The standard operating procedure is:-

Filtrate	57 minutes
Backwash	3 minute

Valve Positioning

Mode	MV 01	MV 02	MV 03	MV 04	MV 05	MV 06	MV 07	MV 08	MV 09	MV 10	MV 11	MV 12	MV 13	MV 14	MV 15	MV 16	MV 17	MV 18	P 01
Standby	CL	CL	CL	B	B-C	CL	CL	CL	B	B-C	CL	CL	CL	B	B-C	CL	CL	CL	OFF
Service	CL	CL	OP	B-C	B-C	CL	CL	CL	B-C	B-C	CL	CL	CL	B-C	B-C	CL	CL	CL	ON
Backwash M1&2	CL	OP	CL	B	A-B	CL	OP	CL	B	B-C	CL	CL	CL	B	B-C	CL	CL	CL	ON
Backwash M3&4	CL	OP	CL	B	B-C	CL	CL	CL	B	A-B	CL	OP	CL	B	B-C	CL	CL	CL	ON
Backwash M5&6	CL	OP	CL	B	B-C	CL	CL	CL	B	B-C	CL	CL	CL	B	A-B	CL	OP	CL	ON
Chem. Backwash	CL	OP	CL	B	A-B	CL	OP	CL	B	A-B	CL	OP	CL	B	A-B	CL	OP	CL	ON
Permeate Flush	CL	OP	CL	B-C	B	OP	CL	CL	B-C	B	OP	CL	CL	B-C	B	OP	CL	CL	ON
Circulating Chemicals	CL	OP	CL	A-B	B	CL	CL	CL	A-B	B	CL	CL	CL	A-B	B	CL	CL	CL	ON

Clean Membranes	CL	OP	CL	B-C	B	OP	CL	OP	B-C	B	OP	CL	OP	B-C	B	OP	CL	OP	ON
Flush Membranes	OP	CL	OP	B-C	B	OP	CL	OP	B-C	B	OP	CL	OP	B-C	B	OP	CL	OP	ON
Drain Tank	OP	CL	CL	B	B	CL	CL	CL	B	B	CL	CL	CL	B	B	CL	CL	CL	ON
Fill Tank	CL	CL	OP	B-C	B	OP	CL	CL	B-C	B	OP	CL	CL	B-C	B	OP	CL	CL	ON

Appendix 2

SAFETY DATA ON THE USE OF ELGALITE RU3

Physical Properties	
Melting Properties (Degrees C)	153
Boiling Point (Degrees C)	---
Decomposition Temperature (Degrees C)	---
PH (g/l water)	Approximately 2.6 at 10g/l
Solubility (water)	Good
Odour	Nil
Physical Form (20 degrees C)	Cystalline
Vapour Pressure (20 Degrees C)	---
Bulk Density	970 kg/Cubic Meter
Storage and Handling	
Special precautions for Storage and Handling	Store away from alkalis and handle with care
Incompatible Substances	Alkalis
Hazardous Decomposition Products	---
Hazardous Reactions	Do not mix with Alkalis
Preventive Measures	Protective Clothing
Preventive Measures	Avoid breathing dust of powder- use particle mask
Technical Protection Measures	None Required
Measures after Spillage	Sweep up carefully and wash away
Disposal	Must not be disposed of to drain without neutralization with alkalis to acceptable pH
Fire and Expolsion Hazard	
Flash Point	Non-flammable

Ignition Temperature	---
Extinguishing Media	---
Special Fire Precautions	---
Special Fire and Explosion Hazard	---

Toxicity

No experimental data available. Non toxic at low concentrations

Emergency and First aid Procedures

For Skin contact, copiously wash with water

For eyes, irrigate for 15 minutes and seek medical aid immediately

If swallowed, drink plenty of water with milk and seek medical aid immediately

Special Information

Keep out of reach of children

In case of contact with eyes, rinse immediately with plenty of water and seek medical advise

Immediately take off all contaminated clothing

Wear suitable gloves

Wear eye/face protection

OWING TO OUR POLICY OF CONTINUING DEVELOPMENT, WE RESERVE THE RIGHT TO CHANGE ANY INFORMATION GIVEN ON THIS DATA PAGE

INSTRUCTIONS FOR THE USE OF ELGALITE RU3

Applications

Elgalite RU3 is a powder cleaner based on organic acids formulated to remove iron and mineral scale.

Elgalite RU3 is a general purpose acidic cleaner suitable for reverse osmosis and ultrafiltration membrane capable of tolerating low pH.

Elgalite RU3 is usually used as a pre-rinse prior to an alkaline detergent clean on ultrafiltration membranes.

Usuage

For routine applications Elgalite RU3 is used at a rate of 1.0% in aqueous solution. Under conditions of heavy fouling, with certain membranes, concentrations of 2.0 % may be used.

Notes on Use of Elgalite RU3

See also the section entitled ‘Chemical Cleaning’ in the Ultrafiltration manual.

Use permeate water for chemical make up and recirculation. Normally pre-treated feed water should be used for displacing chemical solutions after cleaning.

Elgalite RU3 should be thoroughly dissolved in the cleaning tank prior to re-circulation. If necessary, a fresh batch of cleaning solution should be made up if the first batch becomes excessively dirty after recirculation.

Cleaning solution should be recircultaed for 30 minutes to 2 hours depending on the condition of the membranes.

Rinsing should be carried out until permeate is acceptable for the product water application.

Additional Notes for Reverse Osmosis

Concentrate should be initially directed to drain during the cleaning process to remove gross contamination from the system. When the concentrate stream clears of gross contamination the plant should be connected for recircultaion.

Appendix 3.

SAFETY DATA ON THE USE OF ELGALITE UFC 13

Physical Properties	
Melting Properties (Degrees C)	60
Boiling Point (Degrees C)	100
Decomposition Temperature (Degrees C)	100
PH (g/l water)	12 (1.2 % aqueous solution)
Solubility (water)	Good
Odour	Slight Chlorine
Physical Form (20 degrees C)	Powder
Vapour Pressure (20 Degrees C)	---
Bulk Density	950 kg/Cubic Meter (approximately)
Available Chlorine	Approximately 240 mg/l (1.2 % aqueous solution)

Storage and Handling

Special precautions for Storage and Handling	Store away from acids and handle with care
Incompatible Substances	Acids
Hazardous Decomposition Products	Chlorine gas liberated on contact with acids
Hazardous Reactions	Do not mix with Acids
Preventive Measures	Protective Clothing
Preventive Measures	Avoid breathing dust of powder- use particle mask
Technical Protection Measures	None Required
Measures after Spillage	Sweep up carefully and wash away

Fire and Explosion Hazard

Flash Point	Non-flammable
Ignition Temperature	---
Extinguishing Media	---
Special Fire Precautions	---
Special Fire and Explosion Hazard	---

Toxicity

No experimental data available.

Caution: Contaions a hazardous ingrediant caustic soda (18%)

Caution: Product is corrosive to skin and tissue. Prolonged contact under wet conditions can irritate the eyes and mucous membranes.

Emergency and First aid Procedures

For Skin contact, copiously wash with water and seek medical aid (caustic burn)

For eyes, irrigate for 15 minutes and seek medical aid immediately

If swallowed, drink plenty of water with lemon juice (not milk) and seek medical aid immediately

Special Information

Causes severe burns**.**

Keep out of reach of children

In case of contact with eyes, rinse immediately with plenty of water and seek medical advise

Immediately take off all contaminated clothing

Wear suitable gloves

In case of insufficient ventilation, wear suitable respiratory equipment.

Wear eye/face protection

Owing to the chlorine content, Elgalite UFC 13 should never be used on reverse osmosis membranes.

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INSTRUCTIONS FOR THE USE OF ELGALITE UFC 13

Applications

Elgalite UFC 13 is a chlorinated , alkaline powder detergent based on a combination of organic and inorganic sequestering agents and chlorine.

Elgalite UFC 13 is recommended for cleaning and disinfecting ultrafiltration membranes and is effective in removing organic and inorganic colloids, biological materials and silica.

Elgalite UFC 13 exhibits very good cleaning , dispersing and soil suspension capabilities combined with the excellent disinfection properties of chlorine.

Elgalite UFC 13 is therefore a versitle cleaning agent suitable for a wide variety of foulants encountered in the ultrafiltration systems.

Usuage

For routine applications Elgalite UFC 13 is used at a rate of 1.2% in aqueous solution.

Notes on Use of Elgalite UFC 13

See also the section entitled ‘Chemical Cleaning’ in the manual.

Elgalite UFC 13 is a two component detergent supplied as two separate sachets contained within a bag. Both sachets should be dissolved in the cleaning tank water to obtain the desired detergent composition.

Use permeate water for chemical make up and recirculation. Normally pre-treated feed water should be used for displacing chemical solutions after cleaning.

Elgalite RU3 should be thoroughly dissolved in the cleaning tank prior to re-circulation. If necessary, a fresh batch of cleaning solution should be made up if the first batch becomes excessively dirty after recirculation.

Cleaning solution should be recircultaed for 30 minutes to 2 hours depending on the condition of the membranes.

Rinsing should be carried out until the levels of detergent and chlorine in the permeate are acceptable for the product water application.

Appendix 4

MONITORING UF PERFORMANCE

Routine monitoring of the UF is advisable to maintain good water quality and also protect the membranes. It is therefore recommended that a performance log is filled in at least once per day and the corrected flux calculated on a regular basis.

Corrected Flux

To compensate for varying temperature and pressures, a parameter called the corredted flux should be calculated. This value can be plotted against time to show how the performance of the pilot UF varies.

The value of the corrected flux is a relationship between the permeate flow, module inlet and outlet pressure and the membrane area. Ideally this value would remain constant with time although statistical fluctuations will be expected. A large varaiation in corrected flux over a period of time indicates that the pilot UF is not functioning correctly. This could be caused by the membranes becoming fouled, for example.

The corrected flux is calculated from the equation

$$C = \frac{QP}{TCF \times MA \times DP} \quad \text{Litres/m}^2\text{.h.b}$$

Where QP = Permeate Flowrate-bar

TCF = Temperature correction factor

A = Membrane Area m2 (45 m^2 per membrane)

P = Pressure drop across the membrane (ie P2 minus P3)

Appendix 5

VALVE TYPE

UF/HYDRA/1/2

3 Port 24 VDC 2” Safi with feedback

MV 4, 5, 9,10 , 14, 15

2 Port 24 VDC 2” Safi with feedback

MV 1, 6, 7, 8, 11, 12, 13, 16, 17, 18

2 Port Pneumatic 3” Safi with feedback

MV 2 & 3

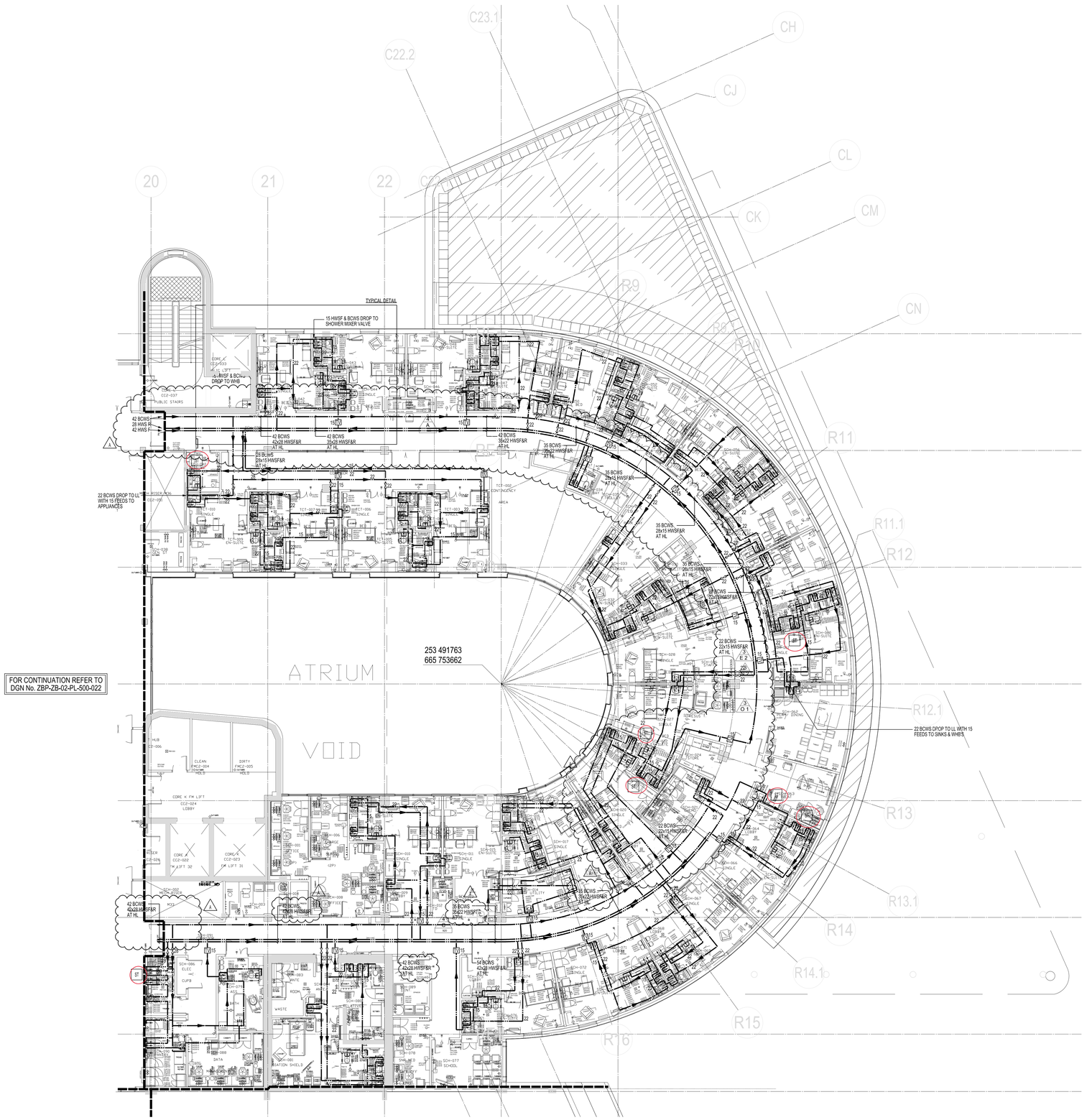
Appendix 6

Membrane Details

Type	Hydraunautics HydraCap 60
Construction	Multi-bore Hollow Fibre
Membrane material	PESM
Active Membrane Area	45 m2
Module Shell Material	PVC-U
End Caps Material	PE
Burst Pressure of Multi-bore fibre	5 Bar
Cleaning and Disinfectant Chemicals	
Free Chlorine max	200 ppm
Hydrogen peroxide max	500 ppm

Appendix 7
HMI SCREENS

See Attached document



Notes:
- This drawing is copyright.
- Do not scale dimensions from this drawing.
- All discrepancies on this drawing are to be reported to the architect.
- Do not modify any element of this drawing.
- Use drawing only for purpose(s) issued.

No	Design Risk Register

This Drawing corresponds with Architects and Structural Drawings
Architects electronic issue dated as below
Compiled from the following reference files;

X-NA-XX-02-PL-251-WIP-SecondFloorPlan_22	dated 12/07/12
X-NA-SZ-02-PL-252-WIP-NSGH_ZA_ZB_ZC_16	dated 09/05/12
X-NA-SZ-02-PL-252-WIP-NSGH_ZD_ZE_ZG_ZH_20	dated 09/08/12
X-NA-SZ-02-PL-252-WIP-NSGH_ZE_11	dated 09/08/12
X-NA-SZ-02-PL-252-WIP-NSGH_ZF_ZK_Z J_16	dated 25/07/12
X-NA-SZ-02-PL-400-WIP-NCH_ZA_ZB_ZC_17	dated 09/05/12
X-NA-SZ-02-PL-400-WIP-NSGH_ZD_ZE_ZG_ZH_22	dated 09/08/12
X-NA-SZ-02-PL-400-WIP-NSGH_ZE_16	dated 09/08/12
X-NA-SZ-02-PL-400-WIP-NSGH_ZF_ZK_Z J_21	dated 25/07/12
NA-XX-02-PL-S72-010 rev 11	dated 28/07/11

and Structural Engineers drawing;

X-WSP-SZ-02-PL-260-WIP-STRUCTURAL_32	dated 27/07/12
X-WSP-SZ-XX-PL-U00-WIP-GRID_00	dated 04/04/11
X-WSP-SZ-02-PL-220-WIP-SLAB_39	dated 27/07/12

Architects to be informed of all discrepancies in dimensions
Contractor to check all dimensions on site
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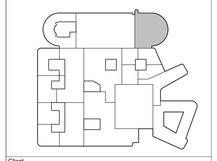
NOTES

1. FOR SYMBOLOGY REFER TO ZBP DRG No. ZBP-XX-XX-DT-595-001
2. THIS DRAWING TO BE READ IN CONJUNCTION WITH ALL CONTRACT DOCUMENTATION
3. REFER TO LATEST ARCHITECTURAL AND STRUCTURAL DRAWINGS AND RELEVANT CONSTRUCTION DETAILS.
4. HOT WATER DRAW OFF TEMPERATURES TO FITTINGS SHALL BE CONTROLLED BY POINT OF USE THERMOSTATIC MIXING VALVES (TMV). WATER TEMPERATURES SHALL BE CONTROLLED TO TEMPERATURES AS INDICATED IN THE SPECIFICATION. FITTINGS THAT DO NOT HAVE A TMV FITTED ARE INDICATED AS (60) IE 60°C. WHERE HOT WATER TEMPERATURES ARE NOT REGULATED, A PERMANENT NOTICE SHALL BE AFFIXED ADJACENT TO HOT TAP STATING "CAUTION VERY HOT WATER".
5. ALL HOT WATER PIPE ROUTES SHALL INCORPORATE PROVISION TO ACCOMMODATE THERMAL EXPANSION. THE SUB CONTRACTOR SHALL EMPLOY A SPECIALIST TO ADVISE SUCH PROVISION BASED ON THE ACTUAL INSTALLATION
6. DOMESTIC SERVICES PIPEWORK IS TO BE ARRANGED TO RUN LEVEL AND AS FAR AS POSSIBLE. VENT VIA THE MAIN RISERS. WHERE THIS IS NOT POSSIBLE, MANUAL AIR VALVES SHALL BE PROVIDED.
7. PIPED SERVICES ABOVE SOLID CEILINGS TO HAVE MINIMUM NUMBER OF JOINTS AND PREFERRABLY NO JOINTS AT ALL.
8. WHERE PIPEWORK PASSES THROUGH FIRE OR SOUND RATED WALLS OR STRUCTURE, THE HOLE THROUGH WHICH THE PIPES PASS SHALL BE MADE GOOD TO EQUAL THE RATING OF THE WALL/STRUCTURE.
9. FOR PIPEWORK AND VALVE ARRANGEMENTS TO SANITARY FITTINGS REFER TO DRAWINGS ZBP-XX-XX-DT-581-006 AND 007.
10. THERMOSTATIC BALANCING VALVES ON 15mm HWS RETURN PIPEWORK SHALL REGULATE TO A MINIMUM OF 0.02 l/sec. ALL OTHER COMMISSIONING SETS SHALL REGULATE TO THE FLOW INDICATED
11. FINAL CONNECTION SIZES HWS & CWS:- SINGLE (EXCEPT BATH) - 15mm.
12. THE MAXIMUM LENGTH FOR THE HWS FLOW DEAD LEG TO ANY FITTING SHALL NOT EXCEED - 3.0 METRES
13. EVERY INDIVIDUAL FITTING SHALL INCLUDE A TERMINAL ISOLATING VALVE WITH FLOW RESTRICTOR.
14. DISTRIBUTION PIPEWORK SIZES BASED ON:- LTHW HTG & CHW - UP12 50mm - MANNESMANN MAPRESS. OVER 50 mm - VICTAULIC. DOMESTIC SERVICES – STAINLESS STEEL GAS - HEAVY WEIGHT STEEL WITH SCREWED WELDED JOINTS.
15. ISOLATION VALVES FOR INDIVIDUAL ROOMS ARE SHOWN FOR INFORMATION ONLY. REFER TO ZBP TYPICAL DETAIL DRAWINGS ZBP-XX-XX-DT-581-006 AND 007 FOR APPLIANCE VALVING ARRANGEMENTS.
16. FINAL LOCATIONS OF SENTINEL TAPS TO BE IDENTIFIED BY THE CONTRACTOR.

LEGEND

TV — THERMOSTATIC VALVE SET

Rev	Date	Revision Notes	Drn	Chk
A	17.08.12	ISSUED FOR CONSTRUCTION T3 REVISION TO RISER / PIPE ROUTES ANTI LIGATURE NOTE ADDED REVISED AS INDICATED	JJ	PE
02	13.07.12	ISSUED FOR TENDER T1 REVIEW	JJ	PE
01	13/08/10	ISSUED FOR INFORMATION	MDB	PE



Client: NHS Greater Glasgow and Clyde

Contractor: Brookfield MULTIPLEX / BM

ZBP — Zisman Bowyer & Partners LLP Consulting Engineers www.zbp.co.uk

Project: NEW SOUTH GLASGOW HOSPITALS (NSGH) PROJECT

Drawing Title: PUBLIC HEALTH SERVICES DOMESTIC & GAS SERVICES LAYOUT SECOND FLOOR NCH SCHIEHALLION WARD

Job No	Drawn	Checked	Approved
2900	JJ	SEB	PE
Status: CONSTRUCTION T3	Date: JAN'11		Scale @ A0: 1:100

Drawing No.

Origin	Zone	Level	Type	Content	Sequential	
ZBP	ZC	02	PL	500	023	A

0 2 4 6 8 10

Chief Nursing Officer Directorate

T:
E: [redacted]

The Scottish Government

Dear Colleague

PROVISION OF SINGLE ROOM ACCOMMODATION AND BED SPACING

Further to the interim guidance issued by David Hastie, then Head of Property and Capital Planning, on 15 December 2006, the work of the Steering Group on single room provision has now been completed. This letter sets out the conclusions reached and introduces updated guidance on the future provision of single room accommodation and bed spacing in new and refurbished projects.

The background to the Steering Group's work is set out in Annex A.

Action

NHS Boards should implement the new guidance in all schemes in excess of delegated limits that have not yet submitted Outline Business Cases. For schemes within delegated limits the guidance should be applied for such projects that have not commenced procurement. The guidance is as follows:

New-build facilities

- For all new-build hospitals or other healthcare facilities which will provide in-patient accommodation there should be a presumption that all patients will be accommodated in single rooms, unless there are clinical reasons for multi-bedded rooms to be available.

Refurbishment of healthcare facilities

- For projects where the refurbishment of major healthcare facilities has been approved it is recognised that each building to be refurbished will present unique problems. However, in developing proposals for substantially refurbishing healthcare facilities NHS Boards should seek to provide the maximum number of single rooms consistent with the approach for new-build, e.g. 100%.

- In developing proposals for single room provision in refurbishments, recognising the constraints posed by existing buildings, it has been decided that the overall level of single room provision should be 50% as an absolute minimum, with due regard to the clinical needs of specific patient groups.

CEL 48 (2008)

11 November 2008

Addresses

For action
Chief Executives NHS Boards
Chief Executive National Services Scotland
Chief Executive Golden Jubilee Hospital

For information
Chief Executives other NHS Special Boards
Director Health Facilities Scotland
Medical Directors
Nursing Directors
Finance Directors

Enquires to:
Mike Baxter
St Andrew's House
Regent Road
Edinburgh EH1 3DG

Tel: 0131-244 5041
Fax: 0131-244 3465

[redacted]

For any HAI related issues **enquiries to:**
Callum Percy
St Andrew's House
Regent Road
Edinburgh EH1 3DG

0131 244 5669

[redacted]

http://www.scotland.gov.uk

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POSITIVE ABOUT DISABLED PEOPLE

Pending the conclusion of the further work set out below schemes will be considered on a case by case basis and NHS Boards should consult with the Capital Investment Group.

Further work

- Further work is required to support clinical decision making on the need for multi-bedded areas for specific patient groups, or clinical specialties where 100% single rooms would be regarded as always appropriate. A Delphi Consultation exercise with the clinical speciality leads designated by the Chief Medical Officer is currently underway, and supporting materials will be produced in the near future. Separate advice on this issue will be issued in due course.

- Health Facilities Scotland will be asked to review and update all relevant technical guidance and also to lead the work on developing a risk matrix tool in conjunction with the Single Room Steering Group and other key stakeholders.

Yours sincerely

[redacted]

Paul Martin

Chief Nursing Officer

INVESTOR IN PEOPLE
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Annex A

Background to the work of the Steering Group

Following a Peer Review of the European Union Health Property Network Report entitled "Hospital Ward Configuration: Determinants Influencing Single Room Provision", a Steering Group was established in March 2006 to take forward the recommendation that further evidence in a Scottish context should be gathered. This Group's membership was drawn from those involved in the Peer Review event who were experts in their subject and who represented a broad range of professional disciplines, both from NHSScotland and Scottish Government Health Department (now Health Directorates). The Steering Group has now reported and its recommendations have been accepted. The report will shortly be available in full at www.scotland.gov.uk/haitaskforce.

This Steering Group had as its remit:

> To consider the evidence supporting the establishment of the future level of single room provision within new-build hospitals and in the refurbishment of major hospital facilities in Scotland.

The Group also considered the related issue of the appropriate space around each bed where these are not located in a single room. For the purpose of the report, a single room was defined as "a room with space for one patient which normally contains, at a minimum, a bed, locker, clinical wash-hand basin and also sanitary facilities comprising a toilet, shower and wash-hand basin". The Group did not consider the requirements for "specialised isolation rooms" with fully engineered ventilation.

Members of the Steering Group recognised that there was a need for information which was specific to Scotland and commissioned a number of reports/studies as follows:

- Literature review
- Public attitude survey
- Nurse staffing report
- Financial impact study

In addition to these reports, the Group also had the benefit of a survey undertaken at the Golden Jubilee National Hospital of patients who had experience of both single room and multi-occupancy room provision. In relation to the financial impact of an increased level of single room provision, the Group had the benefit of the outcome of a study undertaken in Northern Ireland of the financial impact of increasing single room provision from 50% to 100%.

Having identified and evaluated options appropriate in a Scottish context, the Steering Group recognised that not only is it necessary to strike a balance between service quality and the opportunity cost in an environment which is influenced not only by clinical and "building" interest but also by the issue of patient safety and public expectation. It was also recognised as crucial that any conclusions and recommendations made regarding single room provision in future new-build and refurbished in-patient accommodation should be future-proofed and able to accommodate the changing standards expected by patients, given the lifecycle of such facilities which often extend beyond 50 years.

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Recommendations

The Steering Group's recommendations were as follows:

1) For all new-build hospitals or other healthcare facilities which will provide in-patient accommodation there should be a presumption that all patients will be accommodated in single rooms, unless a lower percentage provision for specific patient groups has been justified to and approved by the Scottish Government Health Directorate (SGHD) as part of the Business Case approval process. Those patient groups for which 100% single room provision is considered essential will be agreed with the SGHD's Chief Medical Officer.

2) For those projects which identify a refurbishment as the appropriate option to be developed, the Steering Group recognised that it is extremely difficult for it to establish a definitive proposal as each of the buildings to be refurbished will present unique problems. However, the Steering Group's recommendation was that in developing proposals for refurbishing healthcare facilities which include in-patient accommodation, Health Boards should seek to provide the maximum number of single rooms consistent with the approach recommended for new build healthcare facilities and that the overall level of single room provision within any refurbished accommodation should be 50% as an absolute minimum.

3) For bed spacing, the Group considered that the current advice remains appropriate - namely that having regard to ergonomic criteria, primarily the space required for patient handling and other activities which take place in the immediate vicinity of the bed it is recognised that the minimum bed space should not be less than 3.6 m x 3.7m.

Accordingly when planning any new in-patient accommodation or any major refurbishments of existing accommodation it is recommended that the increased bed space is adopted.

Further work

The Group also recognised a need for further work to be undertaken and has commenced a Delphi Consultation exercise with the clinical speciality leads designated by the SGHD's Chief Medical Officer. This exercise, when completed, should identify those specific patient groups for whom 100% single room provision is essential.

Further the Group recognised that it would be helpful to Boards in developing projects for a Risk Matrix Tool to be developed. It is proposed that this be based on the SCART (Statutory Compliance Assessment Risk Tool) recently developed by Health Facilities Scotland (HFS) for use by all NHS Health Boards.

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CAPITA SYMONDS

NEW SOUTH GLASGOW HOSPITAL

ADULT AND CHILDREN'S HOSPITAL AND THE ENERGY CENTRE

NEC 3 SUPERVISORS REPORT NO. 19

OCTOBER 2012

NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDRENS HOSPITAL AND ENERGY CENTRE

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ADULT AND CHILDRENS HOSPITAL AND ENERGY CENTRE

1.0 EXECUTIVE SUMMARY: ADULT & CHILDRENS HOSPITAL

Visits to the site during October 2012 indicated that the construction and procedures are progressing in a satisfactory manner in accordance with the Employer's Requirements.

Throughout, the standard and quality of the workmanship is generally good and operations are being carried out in an acceptable manner.

Brookfield continues to undertake their Quality Assurance systems on site with inspection and checklist documentation available for the ongoing construction activities. Over the period, we have closely liaised with Brookfield and witnessed both drainage tests and 85 point check to partitions on Level 0. Our witnessing resulted in successful tests. We also have successfully carried out some witnessing of electrical testing in the Energy Centre. Other tests scheduled for the fire sprinkler testing were cancelled on three occasions due to the lack of water pressure. We await confirmation of new test date.

The standard of the work in the exemplar rooms in progress during this period is good. We shall continue to monitor the work planned for the coming month including door frames, screens, sanitary ware, ceiling trims, radiant panels bulkhead for lighting, wall protection and medical hoist. The internal finishes workmanship standards are used as a benchmark for all room completions.

The roof work is continuing on Level 1, 2 and 3 Zones G and D in accordance with the drawings.

Cladding is progressing on the south elevation and courtyards 3, 4 & 5 and the "STO" system is progressing on the south and east elevations.

Energy Centre structural work is largely completed. Various items of plant are still being installed via the north elevation. Structural quality to date appears satisfactory, although some minor snagging still remains outstanding as reported during the last period.

All mini-piling work has now been completed. Further meetings have been held with Brookfield to confirm certain issues associated with this and to confirm the nature of the 'as built' details that will be provided on ZUTEC for both the rotary piles and the mini-piles. Checks will be made to ensure that comprehensive as built records are provided.

Concreting to the main A&C building has again progressed in several areas. This has included 2nd and 3rd floors in Zones D and E, 3rd, 4th and 5th floors in Zone H, roof level in Zone A, and ground floor slabs in Zones D, E and H. Quality throughout has generally been good. Workmanship to the small 20mm step in floor slabs at all levels in Zones J and E continues to be poor and has not been satisfactorily addressed.

Structural steelwork erection to the atrium walkway has been substantially completed during the period. As noted in the last report quality wise, the main concern is the damage to the fire protection coating (shop applied) on some sections. Brookfield is aware of this and the damaged areas are receiving intumescent coating. Snagging of the structure has also been ongoing during the period. Elsewhere ancillary steelwork around cores and at stairwells has progressed, and in occasional places some minor remedial attention to bolts and cleats is required.

Sub-slab drainage in Zones A, D, E and H has progressed during the period with pressure tests proving satisfactory. Some rodding demonstration remains to be carried out when position of scaffolding permits. Drainage proposals in Zones A and B have also been reviewed during the period.

A few quality issues remain to be addressed from previous reports but these are not considered programme critical at this stage.

The M&E installation is now progressing at pace, with pre-fabricated sections and second and final fix being installed in the A&C areas. Large plant items continue to be installed in the Energy Centre and areas are now being commissioned looking towards partial completion in the coming months. Testing is now commencing in the Energy Centre.

In general terms we are satisfied that the installations continue being installed to the correct standard, and are of a good quality however we have noted again that certain items this month that have raised concern. These have been raised with the Contractor.

Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 49, 50, 51, 52, 537, 54, 55, 56, 57, 58, 59, 60, 61, 62 and 63 were issued.

- Damaged deformed boards due to poor stacking.
- Broken glass gauge to Energy Centre Tank No 1.
- Open ducts/vents.
- Seeking confirmation when damage roof insulation will be replaced.
- Requesting dry film thickness results for factory applied and site applied intumescent coating.
- Requesting method statement for air leakage tests.
- Confirm remedial action to damaged steel framework.
- Seeking confirmation if the attached holes without bolts to steelwork bridge connections reflects the design intent.
- Seeking confirmation when High level SVP in Level 3, Plant Room and Level 1, Zone G. - between CCW-003 and RAF-062 will be sealed.
- Seeking confirmation when pIpework on Level 1, Zone H STW-039 Single Bed, STW-094 Male Staff Change and STW-043 Corridor will be capped.
- Seeking confirmation when clash between spigot and electrical containment will be addressed.

- Seeking confirmation when SVP will be capped in various locations Level 1 Zone H.
- Seeking confirmation when sprinkler system is capped level 1 Zone G between CCW-OO6 and void.
- Seeking confirmation when Knauf boards will be fitted in accordance with NBS K10.

Supervisor's Notification of Defects (CI 42.2) No 11,12,13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 and 26 were issued.

- Sprinkler heads in plant room obstructed by fire rated ductwork in plant room.
- Moterised damper inaccessible due to duct in plant room.
- Restricted access to ductwork access hatch in corridor adjacent to Zone H near Stair F.
- Ductwork obstructed by modular frame Zone H.
- Part OF Stud, Level 2 Zone D cut away.
- Fixing to cladding visible.
- Seeking confirmation when cabling in various locations on level 2 is supported properly.
- Seeking confirmation when the damper in Level 3 Pant Room is sealed properly.
- Seeking confirmation when the ductwork in various locations on Level 2 which is uncapped or falling off will be addressed.
- Seeking confirmation when the dead legs which exceed 3m in various locations on Level 1 and 2 will be addressed.
- Seeking confirmation when smoke detection heads in various locations on Level 0 Zone G will be capped.
- Seeking confirmation when the smoke detection heads in various locations on Level 1 Zone G and H will be capped.
- Seeking confirmation when the Air Handling Units exposed in Level 2, Plantroom are adequate protection.
- Seeking confirmation when the restricted access to ductwork is addressed.
- Pipework bracket inadequately fixed.
- Rodding eye partially covered by partition.

We continue to be assisted by the site teams and the NHS Project Team who produce an internal weekly report which is of assist to us in resolving various construction, mechanical, electrical, and quality issues. We continue to close out our Supervisor's Notifications and Defects when we have received satisfactory responses.

2.0 DESIGN COMPLIANCE CHECK

The drawing and specification review is complete. Previous reviews have been conducted, with comments marked on drawings and returned to Brookfield.

3.0 PROCEDURES REVIEW

3.1 Contractor's QA Procedures

Brookfield and their subcontractors have continued with their QA and checking and inspection procedures during the period. We are in discussion and liaison with Brookfield's Quality Manager on QA matters and we undertake regular reviews of their QA documentation.

The standard of the work in the exemplar rooms in progress during this period is good. We shall continue to monitor the work planned for the coming month including door frames, screens, sanitary ware, ceiling trims, radiant panels bulkhead for lighting, wall protection and medical hoist. The internal finishes workmanship standards are used as a benchmark for all room completions.

Workmanship overall is of a good standard throughout.

Below is a plan showing the partition opened up for inspection on Level 0 and part of the 85 point check list. We witnessed an 85 point check to the partitions between rooms AAW-338 and AAW-335. The partition was generally constructed in accordance with the drawings and specification. However there were two failures and they were: -1. Screw breaking the paper. 2. Mastic not applied to abutment stud. 3. Are items not applicable. These were remedied and a further inspection was carried out.

The next page shows an extract from the 85 point check list. The first column shows that the items have been constructed in accordance with the specification and the second identifies the failures.

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19	Two beads of mastic between fireboard and soffit.	✓			Lift section if not visible (no deviation)
20	Correct fixings use for head track.	✓			Check against detail (no deviation)
21	Correct fixing centres used.	✓			Measure @ least 10 fixings (no deviation from detail)
22	Picture frame bead of mastic at junction of fireboards/soffit both sid	✓			Check both sides (no deviation)
23	Correct board used for infills in ribdeck.			✓	Check against detail (no deviation)
24	Correct number of boards used for infills.			✓	Check against detail (no deviation)
25	Correct insulation use in infills.			✓	Check against detail (no deviation)
26	Small holes in ribdeck filled with Rockwool.			✓	Visual check use torch (no deviation)
27	Bead of mastic around infill to ribdeck.			✓	Visual check use torch (no deviation)
28	Infill boards overlap fireboard by 7mm.			✓	Measure @ least 3 rib deck (no deviation)
29	Correct type of stud used, eg: C stud, I stud.	✓		✓	Check against detail (no deviation)
30	Correct gauge of stud.	✓		✓	Check against detail (no deviation)
31	Studs cut to correct length for deflection.	✓			Stud length = + 0 and - 5mm
32	Studs at correct centres (300-400-600mm)	✓			Measure top middle bottom (no deviation)
33	Doorway built to correct specification for weight of door.	✓			Check against detail (width -0 +5mm height -0 +10mm)
34	Leg of door head 250mm minimum.	✓			Measure both legs (no deviation)
35	Door head mitred.			✓	Visual check (no deviation)
36	Floor track returns up stud 300mm.			✓	Measure both legs (no deviation)
37	Correct number of screw in door head.	✓			Check against detail (no deviation)
38	Timber inserted in door stud to correct			✓	Visual check (no deviation)
39	Timber in head of double door.	✓			Visual check (no deviation)
40	Door stud cloaked in head track.	✓			Visual check (no deviation)
41	Screws at correct centres in door stud.			✓	Measure both legs (no deviation)
42	Doorfscreen formed in right location.	✓			Check against drawing (no deviation)
43	Doorfscreen formed to correct size.	✓			Check against drawing (width -0 +5mm height -0 +10mm)
44	Doorfscreen formed to correct height.	✓			Check against drawing (-0 +10 mm)
45	Screen cill at right height.	✓			Check against drawing (no deviation)
46	Mastic applied to abutment studs.		✓		Lift section if not visible (no deviation)
47	Correct fixings to abutment studs.	✓			Visual check (no deviation)
48	Fixings at correct centres to abutment studs.	✓			Measure all fixings to abutment (no deviation)
49	Flat plate fitted at deflection head.	✓			Check full length visual (no deviation)
50	Flat plate at correct distance from headtrack.	✓			Check against detail (if 15mm deflection then top of flat plate 15mm from bottom of headtrack no deviation)
51	Flat plate screwed to all studs.	✓			Visual check (no deviation)
52	Bead of mastic at junction of floor/track.	✓			Visual check (no deviation)
53	Correct type of board.	✓			Check against detail & back of board (can only be replaced with minimum performace equal or better)
54	Correct thickness of board.	✓			Visual against detail (no deviation)
55	Correct number of layers.	✓			Visual against detail (no deviation)
56	Screws fixed no more than 50mm from corners of boards.	✓			Measure top to bottom (no deviation)
57	Screws fixed at Maximum 300mm centres.	✓			Visual plus measure on any that look over (no deviation)
58	Screws arcund door openings maximum 200mm centres.	✓			Measure complete door/opening (no deviation)
59	Screws arcund glazed screens maximum 200mm centres.	✓			Measure complete door/opening (no deviation)
60	Screws to external corners at 200mm centres.			✓	Measure top to bottom (no deviation)
61	Screws not breaking paper.		✓		Visual check maximum deviation 10% of screws breaking paper (1.2 x 2.7 board = 39 screws 10% = 4 screws)
62	Screws not proud of board.	✓			Visual check (no deviation)
63	Flat plate at cross joint of outer layer of board.	✓			Lift section if not visible (no deviation)
64	Boards not too short at deflect on head.	✓			Use pre cut guage or tape - 5mm
65	Boards not too long at deflection head.	✓			Use pre cut guage or tape + 0mm
66	Boards screwed to flat plate at deflection head.	✓			Visual check (no deviation)
67	Screws to flat plates at correct centres.	✓			
68	Boards to abutments cut the right length.			✓	Use pre cut gauge check both sides
69	Joints to double layer staggered vertically.	✓			Lift section if not visible
70	Joints to double layer staggered horizontally.	✓			Lift section if not visible
71	Abutment details built correctly.			✓	Check against detail
72	All required studs for 2nd fix fixed in place.			✓	Visual check of pick up studs

We requested Brookfield to provide us with their Air Test Procedures and Programme. They have confirmed that there is no programme in place yet. However Building Sciences a UKAS accredited testing laboratory for testing in accordance with CIBSE TM23 and BS EN 13829 2001 are already on board and have been carrying out interim site inspections to check workmanship etc.

Brookfield has issued drawings to Building Sciences to mark up zonal areas / sample areas for testing. When this exercise is complete, these will be sent to the Board for approval / agreement.

A programme to carry out air tightness testing will then be developed. These will normally be arranged to be carried out in areas that are as complete as possible. The testing will also be arranged in conjunction with Mercury.

Once the marked up drawings are received back, Brookfield will be able to develop a preliminary programme which will be issued to Capita Symonds. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 22).

We have asked Brookfield to provide a method statement for the air leakage tests. Methodology will be provided by Building Sciences along with the Marked up areas for Board approval all as Communication No 22. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 55).

3.2 Early Warnings

Currently nothing to report.

3.3 Board Equipment Installation, Testing and Commissioning

Currently nothing to report.

3.4 Non Conformance Reports

We are aware of a number of NCR's raised and are being kept up to date as to their status.

4.0 CONSTRUCTION REVIEW

4.1 Visits to the Works

Site inspections were carried out by the NEC3 Supervisors on the 1st , 2nd , 3rd, 4 th, 5th, 8th, 9th, 10th, 11th, 12th, 15th, 16th, 17th, 18th, 19th, 22nd, 23rd, 24th, 25th, 26 th, 29th, 30th, and 31st October 2012.

4.2 Elements of the Works available for inspection

- Energy Centre – steelwork and cladding. Local blockwork at ground, 1st and 2nd floor levels.

- Main building – Cores A, B, C, D, E, F, G, K and L internally, Zones A, B, D, E, G and H ground floor slabs, Zones E and F basement area, ground floor suspended slabs, 1st and 2nd floor slabs. Zone H 1st to 5th floor slabs. Zones A and J 1st and 2nd floor slabs, 3rd floor Zones D and E.
- Zones A, B, D, E, G and H below slab drainage.
- External Drainage – specific sections of installation where access is possible.
- Tunnels between ACH and Labs, and Cores C to F.
- Structural steelwork to Atrium (prior to erection).
- Structural steelwork to roof at Zones D and G.
- Dual carriageway to Renfrew Road, and carriageway from Hardgate Road.
- SFS.
- Internal Partitions.
- M&E modular units.
- Roofing.
- Cladding.
- Windows.
- Sto system.

4.3 Observations from October 2012 Inspections

The visual inspections of the work carried out to date indicate that the works are generally being carried out to a satisfactory standard. We continue to be assisted by the site teams and the NHS Project Team in resolving various construction, mechanical, electrical, and quality issues. We continue to close out our Supervisor's Notification and Defects when we have received satisfactory responses. Listed below are observations still to be closed and those raised following site visits in October 2012.

4.3.1 Structural

The minipiling exercise has now been completed – full details and piling records will be included in Zutec on completion and after receipt of all tests and associated details.

Quality on all concrete works has generally appeared good but the following points remain outstanding from previous reports:-

- Finish to ground floor in Zone F and 1st floor in Zone J (as last report)
- 20mm level change detail in 1st, 2nd and 3rd floor slabs at Zones E and J has been poorly formed and remedial action is required. This situation has persisted and has not been fully addressed.
- Cracks to the soffit of the suspended ground floor slab between Cores A, B, C and D being kept under review.
- Spalling to a couple of parapet walls at the top of Core G.

We have requested Brookfield to provide details of proposed remedial action to ensure that the 1st floor slab at Zone E complies with the construction drawings and specifications. Brookfield has confirmed that they have been in dialogue with Dunnes and the works are currently being altered and once completed and checked they confirmed that they will invited Capita Symonds to inspect. We are still not satisfied with the response and would still wish to see details of proposed remedial action as requested. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 26).

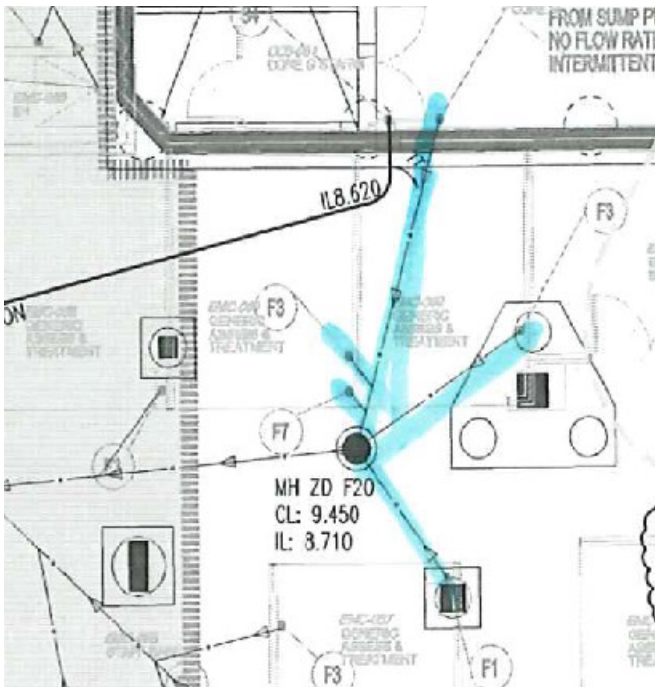
We have asked Brookfield to confirm if the attached holes without bolts to the steelwork bridge connections reflects the design intent. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 57).

4.3.2 Energy Centre

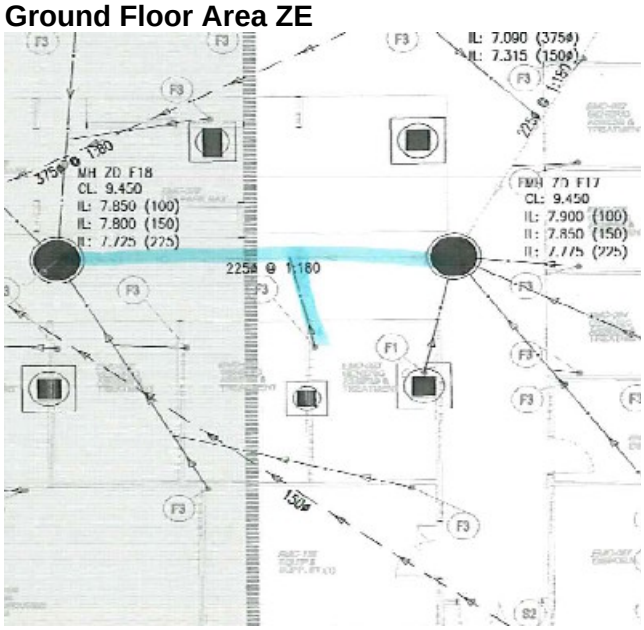
We noted that there was a broken glass gauge in the Energy Centre Tank number 1. Brookfield reported that they are aware of this item and is No 14 on their sheet EC.00.005; Page 1 of the Outstanding Works document. This will be mutually reviewed on completion of works. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 50 is closed out.

4.3.3 Drainage

Below slab drainage installation has continued during the period. Drain pressure tests have been carried out on all newly laid sections in ZE. Test records are kept by Brookfield as part of their QA procedures and some tests were independently witnessed by the NEC3 Supervisor team.



Ground Floor Area ZE



Ground Floor Area ZE

4.3.4 Dual Carriageway to Renfrew Road. (A&C)

Sections of the existing tarmac surfacing on the western carriageway just north of the Energy Centre are showing local signs of breaking up with some rutting apparent. This is unexpected for the length of time that the tarmac has been down and the amount of traffic usage, albeit this has been fairly heavy at times. Brookfield is aware of this and are monitoring with their subcontractor. Remedial work will be carried out at the appropriate time before the wearing course is applied. No change from last period.

4.3.5 Pipework.

Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is progressing at pace and in general is being installed to a good standard. It was noted however that there are still some open ends being left on the pipework, although to a lesser degree than previously reported. The contractor should be reminded that these need to be sealed, to prevent the ingress of moisture and subsequent corrosion that may develop.

We have identified locations where the dead legs on hot water pipe runs are excessive and greater than the specified distance of 3m. We are working with the Contractor to review and identify all areas and to ensure this is not repeated in the future installations.

We noted that Pipework was not capped on Level 2, Gridlines E1-F & 2.1-2.3, Level 2, Plantroom, Gridlines J-I1 & 1-1.1, Level 2, THE-208 Workstation 6x Persons and Level 1, Corridor, Gridlines G1-G & 4-5.1. Brookfield has confirmed that all ends capped off including facing module. MRI Quench pipe has been returned into the opening in the wall and this end is capped off. The other issues raised is work in progress, consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 59 is closed out

There are SVP's uncapped on Level 1, Zone H STW-039 Single Bed, STW-094 Male Staff Change and STW-043 Corridor. Brookfield has intimated it is not common practice to seal SVP / RWP coming through the soffit. They will be capped off if going down through the slab to prevent blockages but not from the soffit upwards as there cannot be ingress from this direction. They acknowledge that these were capped off when this item was initially raised but as noted above, this is not common practice. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 61).

We noted that sprinkler pipework was uncapped on Level 1, Zone G between CCW-006 and Void. Brookfield has confirmed the pipe is now capped. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 62 is closed out.

Before


After

4.3.6 Ventilation

The installation of ventilation ductwork in the A&C hospital is progressing well, and has been installed to a good standard. It appears that any open ends are being sealed but we have noted some exceptions and these have been highlighted to the contractor during our weekly site inspections. The level of damage occurring during the delivery process is much reduced from that previously reported, however the contractor should be reminded that care should be taken to avoid such damage occurring.

During an inspection on site we noted that there are sections of ductwork uncapped or not covered properly. We asked Brookfield to confirm when these have been capped/covered. Brookfield has confirmed that the ductwork in Plantroom 31 Level 3 is now capped off properly. They have also informed us that the pipe running through the fire stoppping is a cable way and not a duct and therefore this is why is it not capped. Work shown on the third photograph was in progress and is now complete.

Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 38 is closed out.

We asked Brookfield to confirm remedial action to damaged steel framework shown below. Brookfield intimated that the damage shown was caused by plant working on the ground floor drainage, the section of steel damaged is sacrificial and will be removed as partitions get installed around the riser. This steelwork is designed to protect the services until the partitions are installed. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 56 is closed out.

During our visit to site we noted the following items which required to be temporarily sealed/covered. Consequently we raised Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 51 with Brookfield. (See photos below) Brookfield has addressed the issues raised and provided photographic evidence. Capita are assisting Brookfield to identify one other location.

4.3.7 Insulation

The thermal insulation installation to the pre-fabricated sections of pipework is being completed off site, before delivery.

4.3.8 Pressure testing

Pressure testing of the modular pipework sections on a zone by zone or area by area basis is to be programmed through the commissioning meetings.

We await further information from Brookfield on their programme and methodology.

4.3.9 Medical Gases

Brookfield has confirmed that the redundant medical gas pipework has been removed and all sleeves through walls have also been capped. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 44 is closed out.

4.3.10 Energy Centre

The installation for the standby generators is progressing to completion, and the installation is of good standard. Generator on site testing is due to commence with load banks to be installed outside the Energy Centre.

We have witnessed various tests on the HV switchgear and this is now connected and awaiting to be energised.

The second batch of generators has been delivered and positioned on site.

We have raised a concern with the Contractor regarding the control of the first phase of the generator installation and await their response.

4.3.11 Trunking

Cable trunking is being installed as part of the offsite fabricated sections that are being installed in the A&C hospital and in general the installation is of a good standard.

We noted that Vertical trunking riser on Level 3 Plantroom is not covered providing passage to the floor below. Brookfield confirmed that the opening was previously boarded over but was removed for the formation of the upstand. This is being reviewed and is filled in. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 37).

There is a clash between duct spigot and electrical containment. Brookfield to confirm that this is a recorded snag and will be rectified by the ductwork installer MJ Vent. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 60 is closed out.

4.3.12 Cable Trays

Cable trays are being installed as part of the offsite fabricated sections that are being installed in the A&C hospital and in general the installation is of a good standard.

4.3.13 Cabling

Modular wiring looms are now being installed as part of the offsite fabricated assemblies and carefully tied up for protection and installation is of a good standard.

4.3.14 Conduit

Solid conduit installations are well progressed in the areas being fitted out and are of a good standard.

4.3.15 Void Detection

We asked Brookfield to confirm when the removal of dust caps from smoke detector heads has been replaced. Removal of caps at this stage of the contract may lead to the contamination of the detector heads. Brookfield has confirmed dust caps or polythene covers to all smoke detectors are to be fitted and that this is in progress. Brookfield also confirmed that Mercury is carrying out tool box talks to all operatives. Photographs of completed areas to be issued. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 40). See photo below

4.3.16 Intake Sub Station

Brookfield has confirmed that they are still pulling cables into the Intake Substation for the Energy Centre and Adults & Children's.

The main front door to the sub-station is jamming in the frame and is exceedingly difficult to open without excess force on the door handle. Brookfield to confirm when this issue has been addressed.

There are also damaged batteries from the switchgear which are still lying in the corridor and require to be correctly disposed off. Brookfield confirmed they would contact SPEN to find out when they are to be removed (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 30 & 45).

4.3.17 Partitions

There were a number of impact damaged partitions on Levels 1 and 2 and we shall continue to monitor these prior to and during final side sheeting.

A joint inspection of the replacement boards previously affected by water was carried out. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 17 is closed out.

During October rainwater entered the building through the floor joint between ZD and ZE and ZG and ZH causing water damage to a number of partially constructed partitions. It is Brookfields intention to have the affected boards replaced. We shall continue to monitor this.

During an inspection on site we noted that rainwater had damage many of the plasterboard partitions.

We noted that Pipe (MPGS) penetrations through plasterboard have not been cored to an acceptable industry standard. Insulation was not in place within 600mm bay where coiled cable drops installed. We asked Brookfield to confirm insulation will be installed and advise QA procedure for ensuring compliant installation installed before second side boarding.

Brookfield has confirmed the following:

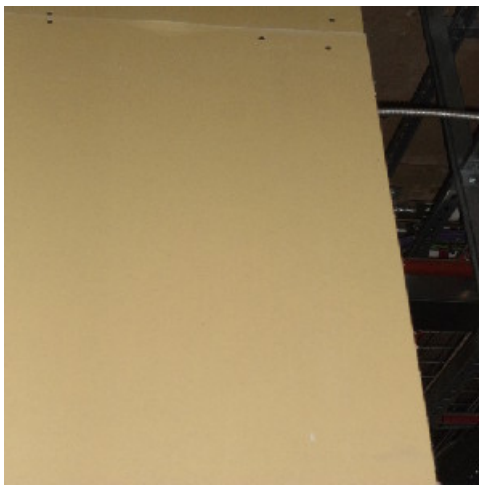
- Damage to all partitions and plasterboard repaired/replaced at 2nd fix stage, BMCE inspect all walls prior to, and after 2nd side boarding.
- ITP's are undertaken at each stage of partition construction and offered to BMCE for inspection to ensure compliance.
- Operatives would ensure insulation is installed prior to wall closure where removed by other trades. Remedial action would be to open wall from stud to stud and reinstate sticky pins and insulation.
- Astins undertake random 85 point checks (QITP check) on closed partitions, this entails reopening off the partition to ensure conformance to specification.

Brookfield has also sent a copy of the Supervisor's Communication to Mercury in relation to the pipe penetrations.

Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 47 is closed out.

We noted that plasterboard has become deformed due to poor stacking and the edges/corners are damaged. We have asked Brookfield to ensure boards are stacked properly to prevent boards being discarded. Brookfield confirmed that every effort is made to ensure the labourers store materials correctly, in this instance Astins will cut the boards into usable patress sizes and reuse at fire/acoustic stopping stage of works. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 49 is closed out.

We noted that some boards have not been fixed in accordance with BS and NBS K10 Specification on horizontal and edge joints. This was at area THE-349 Exit Bay. Ensure screw fixings are 300mm centres, reduced to 200mm at external angles. Brookfield has confirmed that the boards have been fitted to the appropriate centres and provided photographic eveidence below Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 63 is closed out.



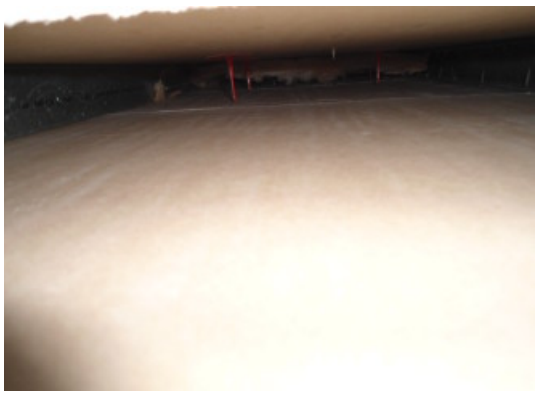
Before

Before

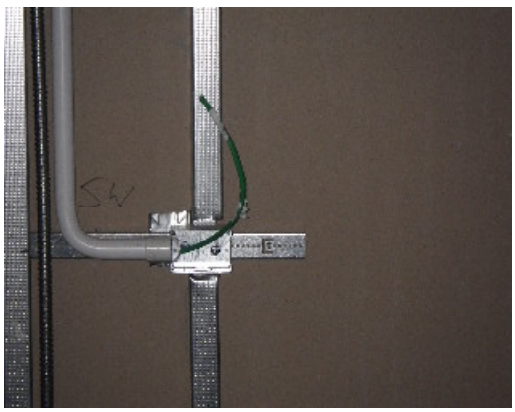
After

After

We noted that there was insulation missing from the upper sections of the boarded partitions in THE-202 General Theatre and THE-200 PREP. There was insulation also missing approx 2m in length of the boarded out partition. Confirm when the boards have been removed and the insulation has been fitted prior to boarding out the lower section to allow us to re-inspect the partition. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 64). See photos below.



A partition stud had been cut and a back box fitted. This was brought to Brookfields attention and they resolved the problem without delay by fitting an intermediate stud. (See photos below)



Before After

4.3.18 Roofs

Roofwork is continuing in Zone G and D on all levels and is being carried out in accordance with the drawings and specifications. A roof integrity test has been carried out to a substantial area of the roof on Level 4 and we await the test results.

We made a number of observations during a site inspection and these were as follows:

- Current specification we have retrieved from Aconex for Liquid Applied Waterproof Roof Coatings is NA-SP-J31 Rev0 date of issue 21/06/2010. We asked for confirmation of the current specification.
- We have asked Brookfield to confirm that the type of waterproof coating that has been applied is the "Permaquik 6100 Monolithic Membrane Roofing System" by Radmat Building Products Ltd as BBA Certificate No 97/3336. Confirm that the waterproof coating has been applied in accordance with manufacturer's recommended installation instructions and comply with the specification.

- We asked if any representatives from Radmat been on site to assess the installation process - to determine that the substrate is acceptable and thereafter to ensure that the application of PermaQuik 6100 has been carried out correctly and in compliance with Radmat's recommendations
- We asked Brookfield to confirm that a 35 year Radmat Gold Warrant will be provided as Specification NA-SP-J31.
- Confirm insulation board and filter layer comply with Specification NA-SP-J31.
- Provide roof integrity test results for Zone D Level 3.

We discussed the issues with Martin McGurk of Radmat and John O'Kane of Prater on the 10th October. Martin McGurk explained that the important issue is always in maintaining the continuum of the insulation at the corner joint. He intimated that this can be achieved in a number of ways and is not limited to the generic illustration in the Radmat catalogue. He confirmed that the method Prater had used in this instance is acceptable.

It was further explained that taking the vertical insulation board to the top of the waterproofing layer allows the vertical board to be trapped and held in place by the depth and pressure of the horizontal insulation layer. This method is commonly used where there is no further retraining method of the vertical board.

In the position shown the vertical insulation is sitting on the top face of the horizontal insulation. This is acceptable as the vertical layer is retained in place using

- A mechanical clip situated at the top of the insulation slab under the coping panel.
- The cobble layer between the paving slab edge and the face of the insulation.
- Adhesive strips applied between the insulation and the Alutrix backing of the upstand.

We were referred to Prater drawings 113-XX-XX-DT-240-007 and 113-XX-XX-DT-240-024 which illustrate that both of the configurations mentioned above are incorporated on the project. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 52 is closed out.

There are damaged insulation boards adjacent to the hoist access and a few isolated boards elsewhere on the roof. We asked Brookfield to confirm when these are replaced and provide photographic evidence of the replacement boards. Brookfield had a meeting with Martin McGurk from Radmat on site on the 10-10-12 and also took on board the question of compression and U value performance of the insulation when depressed under load.

After the inspection a number of issues were raised by Capita in relation to the roof insulation. The discussion included areas where insulation boards were damaged and Martin McGurk confirmed that some boards were replaced during his

inspection due to damage. The final area discussed was that next to the hoist where the waterproofing was incomplete, we made the point that the damage to insulation board edges was expected and the boards were in fact sacrificial and primarily there as a protective measure for the waterproofing below. They needed to be lifted to allow the jointing and subsequent testing of the hot melt and would subsequently be replaced with new. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 53 is closed out but we will continue to monitor the work.

During a site visit we noted that there were High level SVP,s not sealed in Level 3, Plant room. Therer was also rain water pipework uncapped on Level 1, Zone G. We have asked Brookfield to confirm when these will be sealed. Brookfield has intimated that if sealing is being queried regarding the sealing of SVP's or RWP's i.e. between pipe and slab. This is work in progress – sequential works ongoing to ensure building is watertight / firestopped. However, if by sealing, it is meant 'capping' off of pipework – then it is not common practice to seal SVP / RWP coming through the soffit. They will be capped off if going down through the slab to prevent blockages but not from the soffit upwards as there cannot be ingress from this direction. We acknowledge that these were capped off when this item was initially raised but as noted above, this is not common practice. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 58).

4.3.19 Cladding

Cladding is underway on the south elevation of Zones G & D and internal courtyards in accordance with the drawings and specifications.

We noted that there was an incorrect fixing to the cladding in Courtyard 4. Brookfield has confirmed that this fixing was a temporary measure at the time to allow the panel to be held in place and has now been rectified. Consequently Supervisor 's Communication General Matters / Other Instructions (CI 13.1) No 35 is closed.

4.3.20 Windows

Windows are progressing on the external elevations and courtyards in accordance with the specifications.

4.3.21 Basment Walls Core C

We inspected the Concrete finish to the Basement Walls Core C with Brookfield and Currie and Brown and found the painted concrete acceptable. We did highlight to Brookfield that the interface of the wall/ceiling to cover up visible gaps.

4.3.21 Water Prevention into Building

Water ingress as a result of rain penetration through walls and soffits were evident. We have asked Brookfield to advise on proposals for preventing rain penetration and QA procedure for remedials to water damaged finished/stored work elements.

(See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 46).

4.3.22 Fire protection

We asked Brookfield to provide dry film thickness results for the atrium steel in support of the fire proof certification. These must be for both the factory applied intumescent coating and the coating being applied on site. Brookfield has confirmed that they have been in communication with JD Pierce their sub contractor on the Steelwork and have received the following information;-

- Intumescent paint logs for various components.
- Steel Certs
- Welding certs

Brookfield confirmed that they will reviewed these and will follow up with a further response. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 54).

4.4 Defects from October 2012 Inspections.

Brookfield has confirmed that the original access hatches which have been labelled as out of use and new access hatches opened up. Consequently Supervisor's Notification of Defect (CI 42.2) No 03 is closed out.

During an inspection on site we noted on the first floor but more specifically within zone ZG corridor CCW115 void detection has been located in close proximity and between ventilation ducts. We believe that this does not comply with the requirements of BS5839. Brookfield has confirmed that with reference to area 1-525 & 1-528 they have carried out a site survey and agreed to the provision of additional detection as follows:

Three additional detectors required in area 1-525.
One additional detector in area 1-528.l

The photo below shows the new void detection consequently Supervisor's Notification of Defect (CI 42.2) No 04 is closed out.

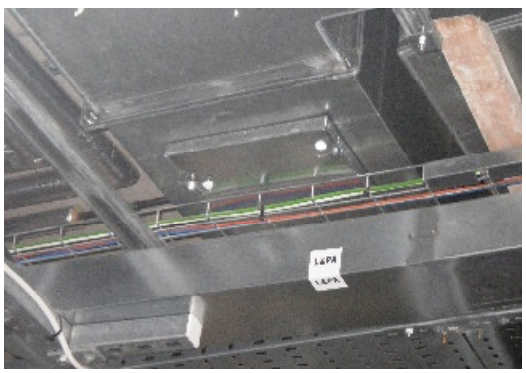
We have asked Brookfield to confirm proposals to correct the misaligned bolts at the half landing in Core G between Level 3 and Level 4. Brookfield has confirmed that they have spoken to WSP about this cleat and viewed it with them. They are looking for a new extended cleat with 4no new anchors and the existing one removed. Consequently Supervisor's Notification of Defect (CI 42.2) No 07 is closed out.

Duct access is blocked Level 2 Zone D corridor adjacent Zone E. We have asked Brookfield to confirm their solution to allow full access to the duct. (Supervisor's Notification of Defect (CI 42.2) No 08).

We have raised a Defect Notification for a Steel angle plate which is too short on Level 3 Zone G. We await a response from Brookfield. (See Supervisor's Notification of Defect (CI 42.2) No 09).

Bolts missing from angle plates in the Energy Centre. (See Supervisor's Notification of Defect (CI 42.2) No 10).

Duct access hatch blocked by chilled water pipework at ground floor area around DB cupboard AAW190. Confirm when this has been addressed.



Sprinkler head at H.L. in plant room obstructed by fire rated ductwork in plant room. Brookfield has advised us that there is a second level / layer of sprinkler pipework to be installed in the plant room. Consequently this is not a defect. This will not be fitted until a later date when other services are completed in the area. Supervisor's Notification of Defect (CI 42.2) No 11 is closed out.

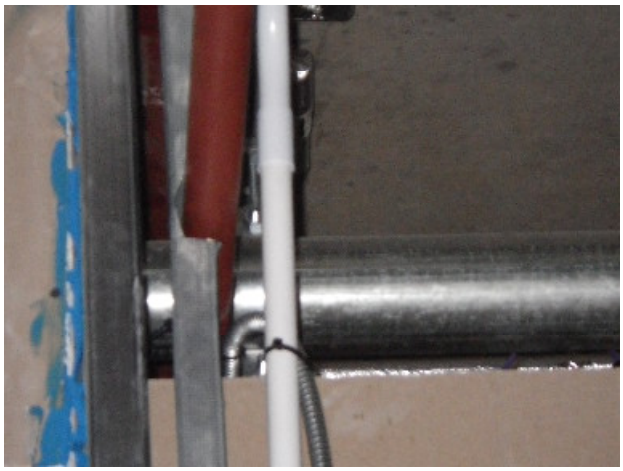
Motorised damper inaccessible due to adjacent duct in Plant Room. Brookfield is investigating this and will report. (See Supervisor's Notification of Defect (CI 42.2) No 12).

Restricted access to ductwork access hatch in corridor adjacent to Zone H near Stair Core F. Brookfield has intimated that the hatch is not restricted and access can readily be gained. We shall revisit this and report back with our findings. (See Supervisor's Notification of Defect (CI 42.2) No 13).

Ductwork obstructed by modular frame Zone H. Brookfield is investigating this and will report (See Supervisor's Notification of Defect (CI 42.2) No 14).

Part of the stud in Level 2 Zone D to the partition in room THE-173 has been cut out. This was not in compliance with Knaufs specification and would have affected the performance of the partition. Brookfield wrote to both Mercury and Astins to ensure that this does not happen again. They also confirmed that this would be discussed at the morning meetings between the sub -contractors and floor mangers. We carried out a joint inspection with Brookfield and confirm that the cut out stud was removed. Consequently Supervisor's Notification of Defect (CI 42.2) No 15 is closed out.

There were two other areas on the ground floor which we brought to Brookfield's attention and these have been resolved.



Stud cut.

Cut stud removed and new stud fitted.

One of the fixings to the cladding is visible beneath the capping pieces and the cladding is indented. We have asked Brookfield to confirm when this defect has been addressed. See Supervisor's Notification of Defect (CI 42.2) No 16).

During our inspection visit to site we noted that cabling was not supported on Level 2, THE-123 Riser, THE-165 Prep, THE-151 and THE-180. Consequently we have raised a Supervisors Notification of Defect (Cl 42.2) No 17. Brookfield confirmed that cables to be supported by half hitching the coil back up to the supporting partition. See photos below.

Before

After

Damper in the duct on Level 3, Plant room is not sealed correctly. We have asked Brookfield to confirm when this has been addressed. Brookfield are investigating this and will report. See Supervisor's Notification of Defect (CI 42.2) No 18).

The Ductwork is not capped and Level 2, Gridlines E1-F & 2.1-2.3 and Level 2, THE-350 Ultra Clean Theatre 8. Level 1, Zone G CCW-047 Bed Bay Vent Protection loose. Brookfield has confirmed that all ductwork identified has been covered. See photos below. Supervisor's Notification of Defect (CI 42.2) No 19 is closed out.

Before

Before

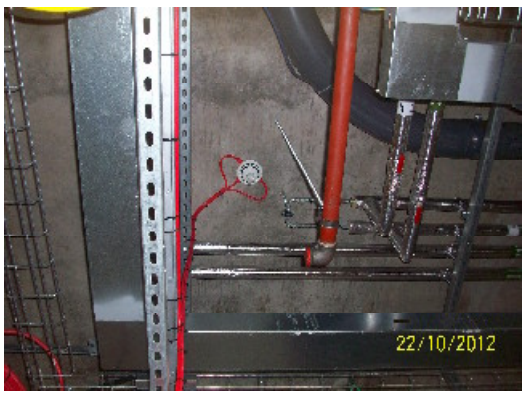
After

After

We noted a dead leg which exceeded 3m on Level 2, THE-126 Dirty UT and Level 1, Zone D CCW-201 Staff Lounge. Consequently we have raised Supervisor's Notification of Defect (CI 42.2) No 20 and have asked Brookfield to confirm when this is addressed.

There are smoke detection Heads uncapped in numerous locations on Level 0 Zone G. Consequently we have raised Supervisor's Notification of Defect (CI 42.2) No 21. See response to Supervisor's Communication No 40

There are smoke detection Heads uncapped in numerous locations on Level 1 Zones D, G and H. Consequently we have raised Supervisor's Notification of Defect (CI 42.2) No 22. See response to Supervisor's Communication No 40



The Air Handling Units is exposed. We have asked Brookfield to confirm when adequate protection has been provided. Brookfield has confirmed that the Air Handling Units has been inspected and ductwork has been connected to units. This is work in progress, however, they should have been re-covered once works were completed. The units have know been protected. Awaiting photos. (See Supervisor's Notification of Defect (CI 42.2) No 23).

Before

Before

After

After

There is restricted access to a duct hatch due to an SVP vent Level 1, Zone E Corridor space adjacent to RCF-xxx IT HUB. We have asked Brookfield to confirm when the access is unrestricted. See Supervisor's Notification of Defect (CI 42.2) No 24).

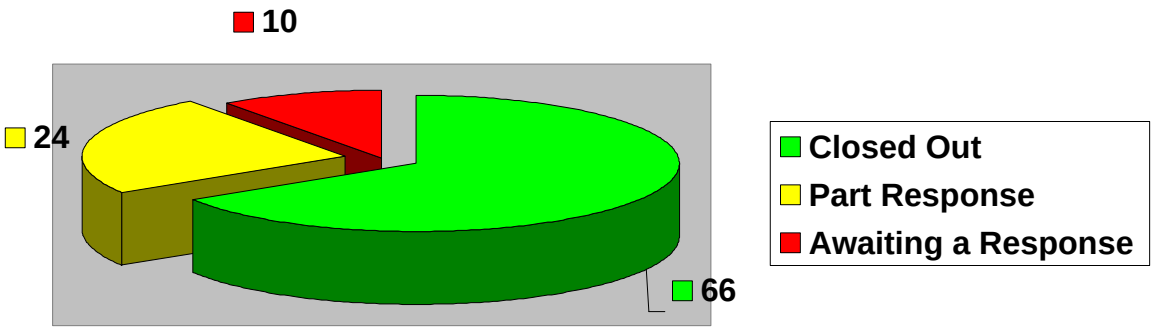
Pipework brackets are inadequately fixed on Level 1, Zone D CCW-201 Staff Lounge. Consequently we have raised Supervisor's Notification of Defect (CI 42.2) No 25).

We noted that the partition wall partly covers a rodding eye on Level 0 Room EMC-124 Office (4P). We have asked Brookfield to confirm measures to address this issue. See Supervisor's Notification of Defect (CI 42.2) No 26 and photo below.

NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDRENS HOSPITAL AND ENERGY CENTRE

SUPERVISOR'S REPORT NO. 19 **OCTOBER 2012**

5.0 INFORMATION REQUIRED



NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDRENS HOSPITAL AND ENERGY CENTRE

SUPERVISOR'S REPORT NO. 19 **OCTOBER 2012**

Item No.	Description	Date Requested	Comment	
Items 1 to 21 have been closed out				
22	Brookfield to provide us with their Air Test Procedures and Programme.	03/07/12	Response received.	
23	Confirm if this is an adequate vehicular turning circle for an oil tanker, refrigerated articulated vehicle and a Liebherr LTM 1250-61 mobile crane to gain access and egress around the building.	19/07/12	Closed out.	
24	Confirm how and when the defects to the fire protected steelwork will be addressed	23/07/12	Closed out.	
25	Please provide details of proposed measures to ensure compliance with drawings and specifications.	23/07/12	Closed out.	
26	Provide details of proposed remedial action to ensure that the 1st floor slab at Zone E complies with the construction drawings and specifications.	26/07/12	Response received.	
27	Ensure screw fixings are 300mm centres, reduced to 200mm at external angles in accordance with BS and NBS K10. Confirm that plates are in place between sheets where double sheeted and will be located in all horizontal joints.	26/07/12	Closed out.	
28	Confirm open drainage on Levels 1 & 2 is sealed.	01/07/12	Closed out.	
29	Confirm if there are any design plans to introduce additional stiffening to 1500nn high partitions.	29/08/12	Closed out.	
30	Confirm when cabling is complete, water pumped out and batteries removed.	10/08/12	Response received.	
31	No timber in partition lintels.	29/08/12	Closed out.	
32	Advise proposed remedial action link reinforcement from pile caps Zone D.	29/08/12	Closed out.	
33	Ductwork was not capped on Level 1 Vent Plant Room. Confirm when this is done	07/09/12	Closed out.	
34	Locations throughout have drainage pipework which is uncapped Confirm when this has been addressed.	07/09/12	Closed	
35	Confirm when incorrect fixing has been rectified to Courtyard 4 cladding.	07/09/12	Closed out	
36	Insulation missing from the upper section of the boarded partition. Confirm when insulation has been fitted prior to boarding the lower section.	07/09/12	Closed out.	
37	Vertical trunking riser Level 3, Plantroom is not covered providing passage to the floor below. Confirm when this has been addressed.	11/09/12	Response received.	
38	There are sections of ductwork uncapped or not covered properly in the locations listed above. Confirm when these have been capped/covered.	11/09/12	Closed out.	
39	Part of the stud to the 60min partition in room CCU-012 has been cut out. This is not in compliance with Knaufs specification	12/09/12	Closed out.	
40	Confirm when removal dust caps from smoke detector heads have been replaced	12/09/12	Response received.	
41	Duct access hatch blocked by chilled water pipework at ground floor area around DB cupboard AAW190. Confirm when this has been addressed.	12/09/12	Closed out.	
42	Confirm when vent control is protected on Level 3 Zone D.	13/09/12	Closed out.	
43	Cables were hanging unsupported. Confirm when addressed	13/09/12	Closed out.	
44	Confirm when the redundant medical gases on Level 1 will be removed.	13/09/12	Closed out.	
45	See Supervisor's Communication No 30.	18/09/12	Response received.	
46	Advise on proposals for preventing rain penetration	20/09/12	Open	
47	Confirm remedial action to partitions Level 2 Theatres.	20/09/12	Closed out.	
48	Confirm remedial to various roofing observations.	20/09/12	Open	

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49	Damaged and deformed boards caused by poor stacking	27/09/12	Closed out.	
50	Broken glass gauge to Energy Centre Tank number 1.	15/10/12	Closed out.	
51	Confirm when ducts/vents are temporarily sealed/covered.	03/10/12	Response received.	
52	Insulated board fixed to the internal face of the south facing parapet wall on the level 3 roof rests on the horizontal insulation. Confirm if acceptable to Radmat.	10/10/12	Closed out.	
53	Confirm when damaged roof insulation will be replaced.	10/10/12	Closed out.	
54	Provide dry film thickness results for factory applied intumescent and remedial repairs on site.	12/10/12	Response received.	
55	Provide air method statement for air leakage tests.	12/10/12	Open	
56	Confirm remedial action to damaged steel framework.	15/10/12	Closed out.	
57	Please confirm if the attached holes without bolts to the steelwork bridge connections reflects the design intent.	16/10/12	Open	
58	Level 3, Plant room. High level SVP not sealed Level 1, Zone G. - Between CCW-003 and RAF-062	16/10/12	Response received.	
59	Confirm when popework on Level 1, Zone H STW-039 Single Bed, STW-094 Male Staff Change and STW-043 Corridor will be capped.	23/10/12	Closed out	
60	Confirm when clash between spigot and electrical containment will be addressed.	23/10/12	Closed out.	
61	Confirm when SVP not wil be capped various locations Lwvwl 1 Zone H.	23/10/12	Response received.	
62	Confirm when sprinkler system is capped level 1 Zone G	23/10/12	Closed out.	
63	Kanuf boards not fitted as per BS and NBS K10 in level 2 THE-340 Exit Bay	23/10/12	Closed out.	

6.0 SUPERVISORS TESTS AND INSPECTIONS

Tests not required	N/A
Tests required but not tested	Req
Tests required which has passed tests	Pass

Tests				
Ref	**Title**	**To be Notified by**	**Status**	**Test Date**
01-11	Various tests undertaken from the 9/07/2012 to the 10/07/2012			
12	Drain rodding test – sub-slab drainage Zone D.	Brookfield	Pass	18/09/2012
13	Below drainage air tests	Brookfield	Pass	09/10/2012
14	Energy Centre A side Electrical Test	Brookfield	Pass	30.10.12

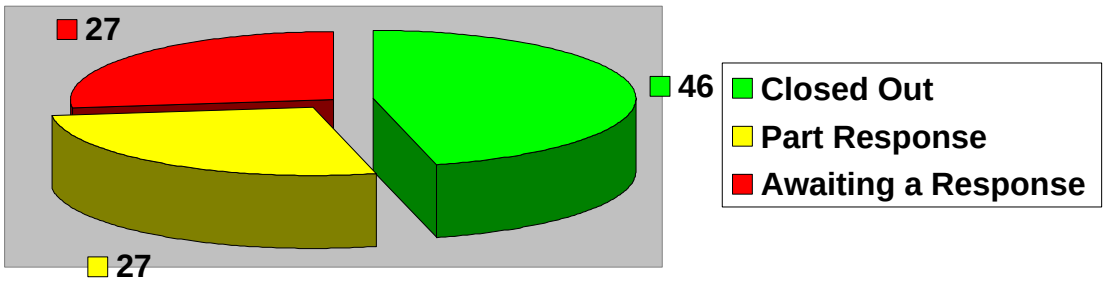
Inspection not required	N/A
Inspection required	Req
Inspection complete	Pass

Inspections				
Ref	**Title**	**To be Notified by**	**Status**	**Inspection Date**
1	85 Point check to partitions room AAW-338	Brookfield	Pass	24/10/2012

NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDRENS HOSPITAL AND ENERGY CENTRE

SUPERVISOR'S REPORT NO. 19 **OCTOBER 2012**

7.0 DEFECTS NOTIFICATIONS ISSUED



NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDRENS HOSPITAL AND ENERGY CENTRE

SUPERVISOR'S REPORT NO. 19 **OCTOBER 2012**

Item No.	Description	Date Requested	Comment	
01	We are concerned about the level of damage to the ductwork and the subsequent amount of time re-working it on site to effect repairs. Confirm action to prevent further damage and provide evidence that the existing damage has been repaired.	22.03.12	Closed	
02	Some piles were reported as out with positional tolerance.	02.05.12	Closed	
03	Access to ductwork insufficient. Confirm remedial measures.	30.07.12	Open	
04	Void detection located in close proximity and between ventilation ducts.	31.07.12	Closed	
05	Void detection not fitted between smoke /fire barriers.	31.07.12	Closed	
06	DHW dead-legs appear to be excessive.	31.07.12	Closed	
07	Misaligned bolts.	23.08.12	Closed	
08	Confirm action to allow full access to duct. Level 2 Zone D corridor adjacent Zone E.	13.09.12	Closed	
09	Steel angle too short	27.09.12	Open	
10	Bolt missing from angle plate..	27.09.12	Open	
11	Sprinkler head at H.L. in plant room obstructed by fire rated ductwork in plant room.	02.10.12	Closed	
12	Motorised damper inaccessible due to adjacent duct in Plant Room.	02.10.12	Response received.	
13	Restricted access to ductwork access hatch in corridor adjacent to Zone H near Stair Core F	02.10.12	Response received.	
14	Ductwork obstructed by modular frame Zone H.	02.10.12	Response received.	
15	Part of stud, Level 2 Zone D cut away.	10.10.12	Closed	
16	Fixing to cladding visible. Confirm when this will be addressed	18.10.12	Open	
17	Confirm when cabling in various locations on level 2 are supported properly.	23.10.12	Closed	
18	Confirm when damper in duct is sealed properly in Level 3 Pant Room.	23.10.12	Response received	
19	Ductwork uncapped or falling off. Confirm when addressed. Various locations Level 2.	23.10.12	Closed	
20	Dead legs exceed 3m in various locations on Level 1 and 2. Confirm when this will be addressed	23.10.12	Response received.	
21	Confirm smoke detection heads in various locations on Level 0 Zone G will be capped.	23.10.12	Response received.	
22	Confirm when smoke detection heads in various locations on Level 1 Zone G and H will be capped.	23.10.12	Response received.	
23	Air Handling Units exposed in Level 2, Plantroom. Confirm when adequate protection has been provided.	23.10.12	Open	
24	Confirm when restricted access to ductwork is addressed.	23.10.12	Open	
25	Pipework brackets inadequately fixed	23.10.12	Open	
26	Partition wall partly covers rodding eye. Please confirm measures to address this issue	30.10.12	Open	

NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND ENERGY CENTRE

SUPERVISOR'S REPORT NO. 19 **OCTOBER 2012**

John Redmond
Capita Symonds
Technical Advisory Services

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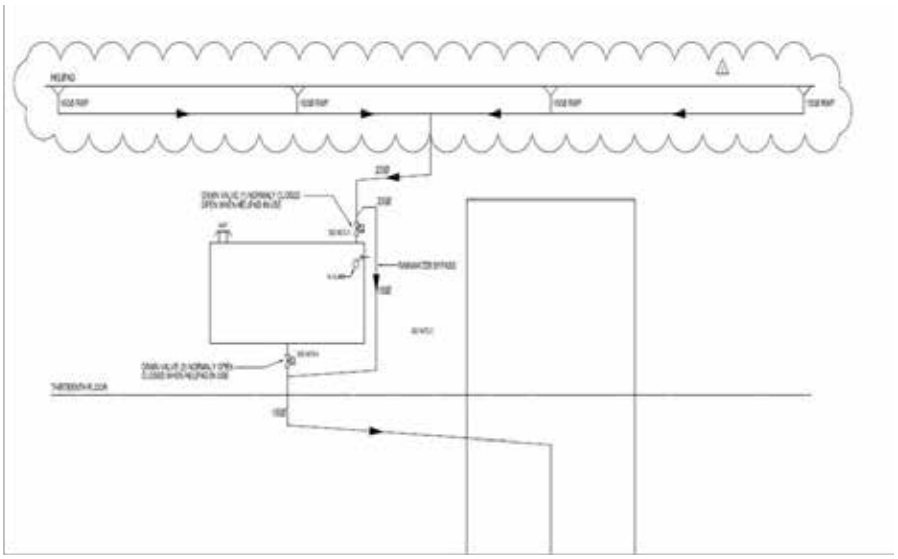
	Signed	Date
Originated by	John Redmond	31st October 2012
Completed by	Dave Ramsay	31st October 2012

SOILS & WASTE AND RAINWATER SYSTEM DESCRIPTION

1. Rainwater

The rainwater system comprises of Blucher pipe connected to the rain water outlets set into the roof. The rainwater is piped to the ground floor and connects to the underground rainwater system. There is access doors located at 1200mm above each floor slab on each down pipe for access in the event of any blockages.



- Rainwater installed using “Blucher Pipework”
- Blucher floor gullies and RWO’s
- Labelled “Rainwater”
- Helipad Holding Tank

2. Soils, Vents and Waste

The soils and waste (S&W) system stacks have been installed in Ensign cast iron pipework for diameters greater than 2". Pipework 2" and below is installed in terrain PVC. All vent pipework has been installed in terrain plastic. The S&W system takes waste from all wash hand basins, water closets and sinks to the ground floor where it connects to the underground foul waste system. The waste from the domestic wash hand basins and WC's is installed using Terrain PVC pipe and fittings. Rodding eyes are installed at each WC and WHB and at 1200mm above the floor level on all vertical drops.

Where these systems pass through the floors or fire walls there are fire collars fitted to prevent the spread of fire. The fire collars expand and seal the openings when they reach a certain temperature.

- Drainage installed using Cast Iron pipe 4" and above
- Less than 4" using plastic
- All vents in Plastic
- Rodding Eyes at 1.2m above floor – every floor & behind all IPS's
- Labelled "Drain", "Vent", "Radioactive"

3. Basement Drainage and SUMP Pumps

The basement S&W feeds into a sump pump located in Pump room FMB-024. From this sump pump the S&W is pumped back into the ground floor and underground foul waste system.

There are several other permanent sump pumps within the basement; these provide pumped drainage for the following:

- Water filtration backwash
- Emergency overflows for the CWS Tanks.
- Emergency overflows for the sprinkler system tanks.
- Emergency overflows for the renal concentrate storage tanks.
- Emergency drainage for Core G lift sump.

There are also several emergency sump pits located throughout the basement corridors, these have I.Vs, non-return valves and quick release couplings to allow a temporary sump to be installed. Details on these can be found on the record drawings and manufacturers literature.

4. Helipad Drainage

The helipad drainage has been installed in Ensign cast iron pipework complete with a rain water holding tank located on level 13 - roof. There are 2-port control valves (1) on the inlet to the tank and (2) on the outlet from the tank and a tank by-pass arrangement. These valves are manually controlled each time a helicopter comes in to land so that in the event of an incident any fuel spillages can be collected and disposed of in an appropriate manner.

4.1. Normal operation

During normal operation 2-port valve no 1 on the inlet to the tank is closed and 2-port valve no 2 is open. Rainwater is diverted through the by-pass and no rainwater enters the tank.

4.2. Helicopter Approach

When a helicopter is approaching the helipad the 2-port valve positions are moved manually by the ground crew. Valve 2 is closed and valve 1 is open. Rainwater is collected in the holding tank.

4.3. In Event of Fire

The valve positions remain in position as above and all fuel, fire-fighting foam and rainwater is collected in the holding tank until it can be removed in a controlled manner.

4.4. Normal Helicopter Departure

The valve positions are returned to normal operating conditions and the rainwater is released into the underground rainwater system via an underground petrol interceptor

For record drawing information please refer to the following drawings:

- **P(52)** series drawings for details on the pipe work distribution on the floors
- **PP** series drawings for details on the pipe work distribution in the plant rooms

LEGEND

FA	--	FROM ABOVE
FLL	--	FROM LOW LEVEL
TB	--	TO BELOW
TA	--	TO ABOVE

REFERENCE DRAWINGS:

1. Architectural
   - X-NA-XX-02-PL-251-WIP-SECONDFLOORPLAN_31
   - X-NA-SZ-02-PL-253-WIP-NSGH_ZA_ZB_ZC_21
   - X-NA-SZ-02-PL-400-WIP-NSGH_ZA_ZB_ZC_23

AS BUILT DRAWING

Rev	Date	Revision Notes	Chk	App
Z1	10.06.14	As-Built	GMD	ROD

Contractor

Brookfield MULTIPLEX BM

MERCURY ENGINEERING
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Finnieston Buisiness Park
Minerva Way
Glasgow G3 8AU
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Project

NEW SOUTH GLASGOW HOSPITALS
(NSGH) PROJECT

Drawing Title

Second Floor Plan NCH
Schiehallion Ward
As-Built Above Ground Drainage &
Rainwater Layout

Job No	Drawn	Checked	Approved
GB1.0008	RF	G.McD	R.O'D
Status		Date	Scale@A0
AS-BUILT		10.06.14	1:50

Drawing No

Origin	Zone	Level	Type	Content	Sequential	Rev
ME	ZC	02	PL	581	508	Z1

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A48235836

Welcome to NSGH

Domestic Water Services Systems

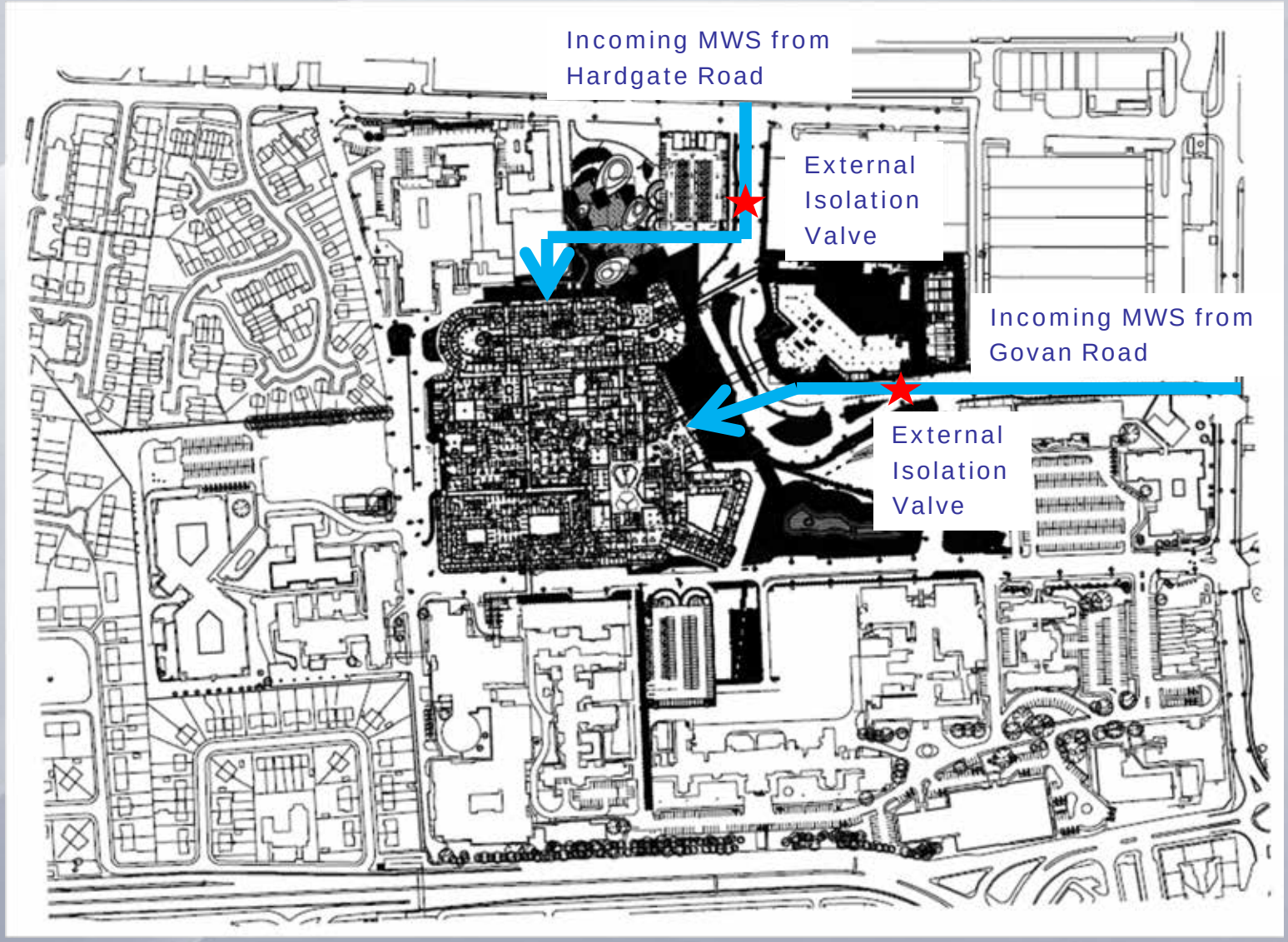
24th Nov 2014 ….9:00-12:30

Ciaran Kellegher

NSGH – Domestic Water Systems

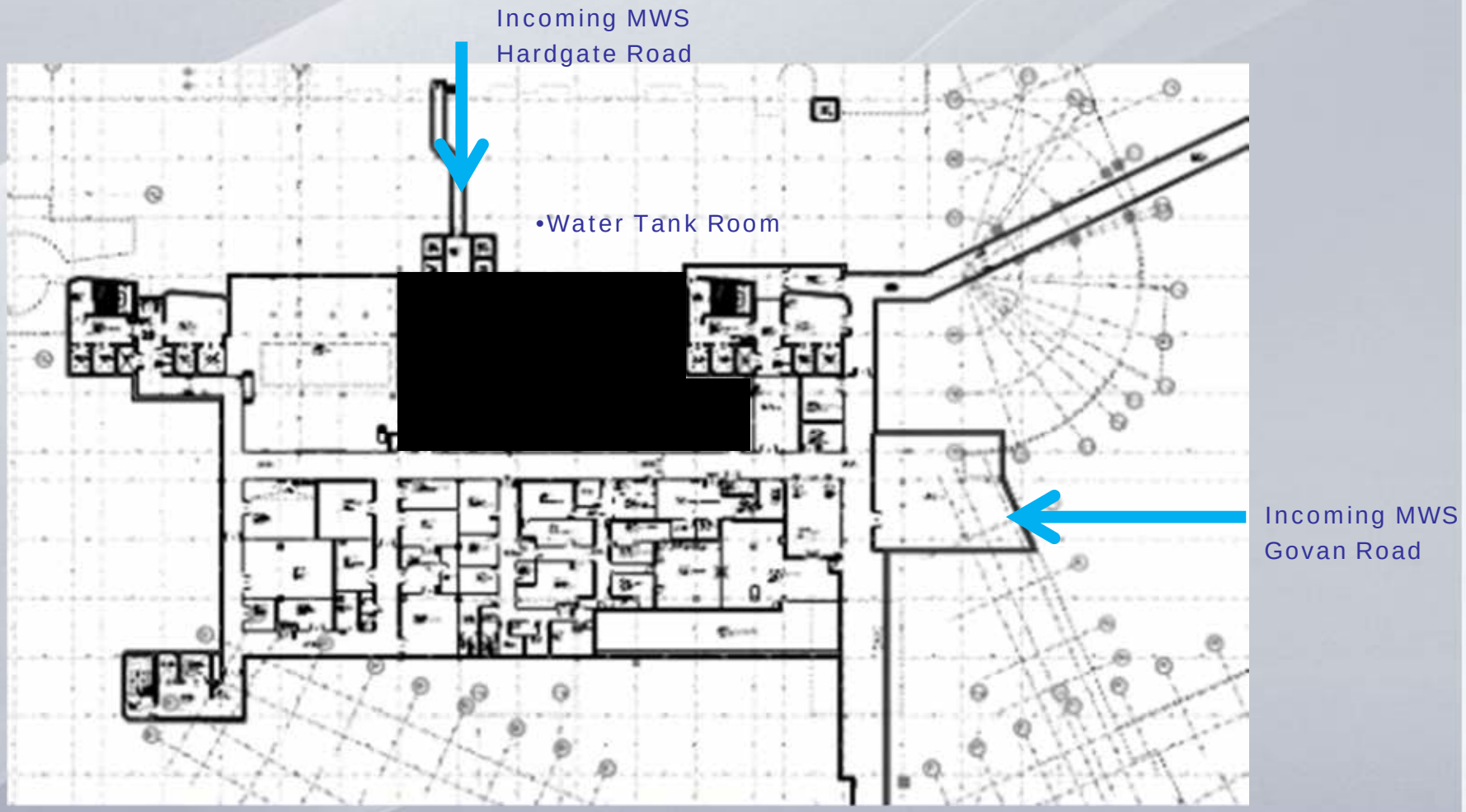
- 1. System Description & Orientation
  - a) Basement tank room
  - b) Distribution routes
  - c) Calorifier skids locations and areas served
- 2. Key Components
  - a) Cold water Storage tanks
  - b) Float valves
  - c) Booster set
  - d) Filtration Plant
  - e) Calorifier Skids
  - f) Hot water return pumps
  - g) Thermal balancing valves
  - h) Pressure reducing valves
  - I) Water Meters
  - J) Dump Valves
  - K) Sentinel Points
- 3. Operation and Maintenance of system equipment
  - a) Cold Water Storage Tanks
  - b) Booster sets
  - c) Filtration plant
  - d) Calorifier Skids

NSGH – Domestic Water Systems

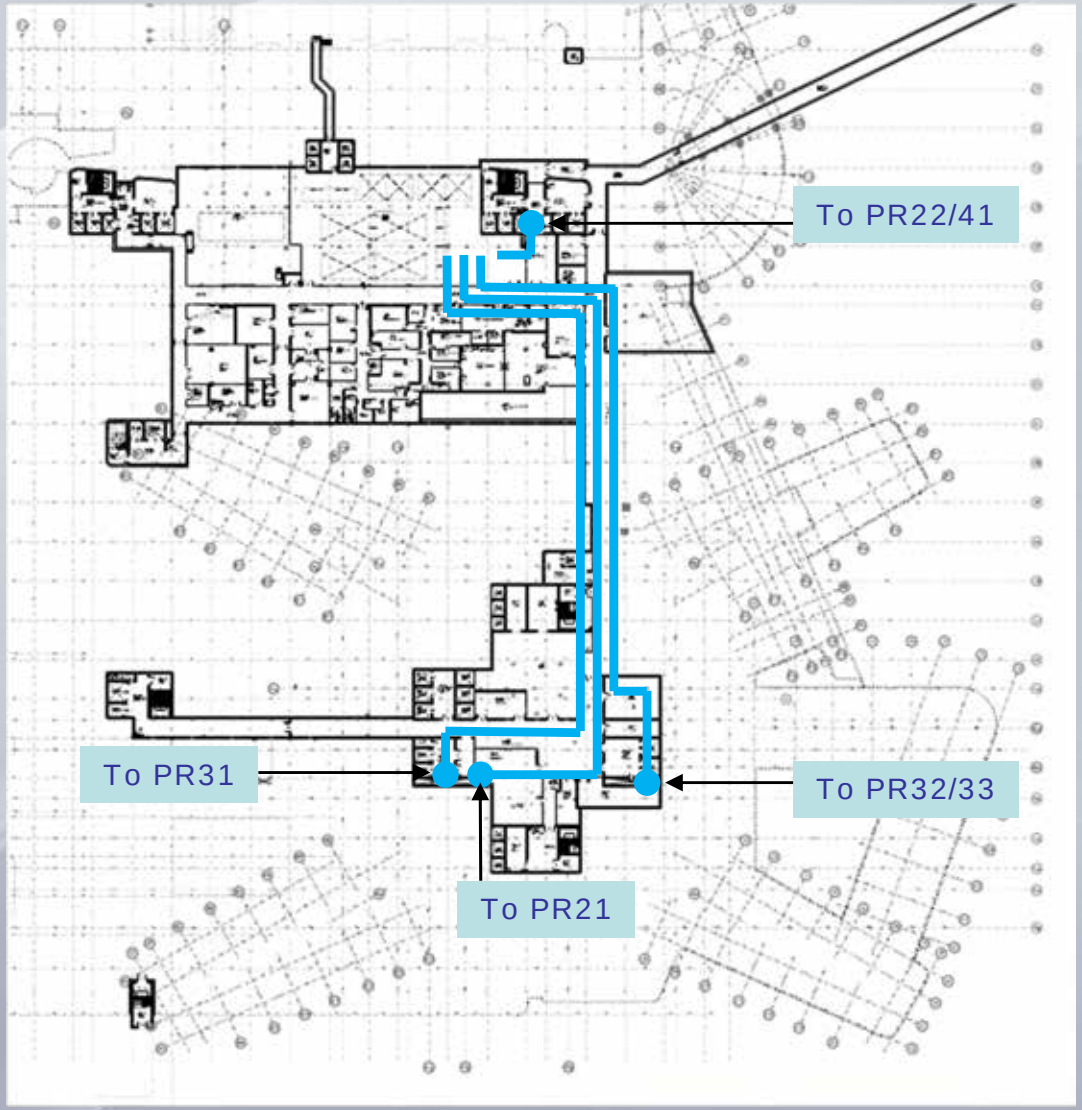


Site Plan

NSGH – Basement Water Tank Room

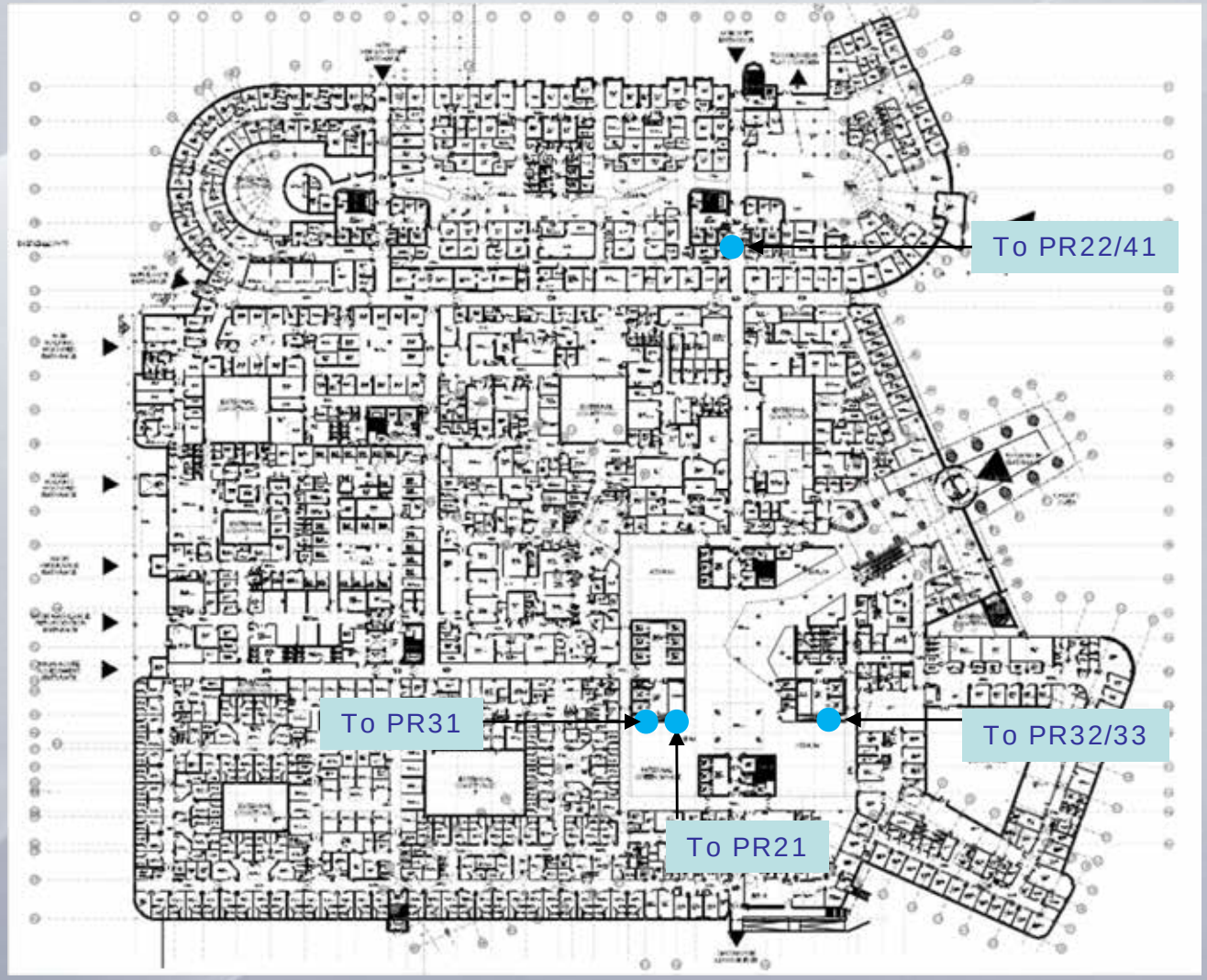


NSGH – Mains Water Distribution Routes



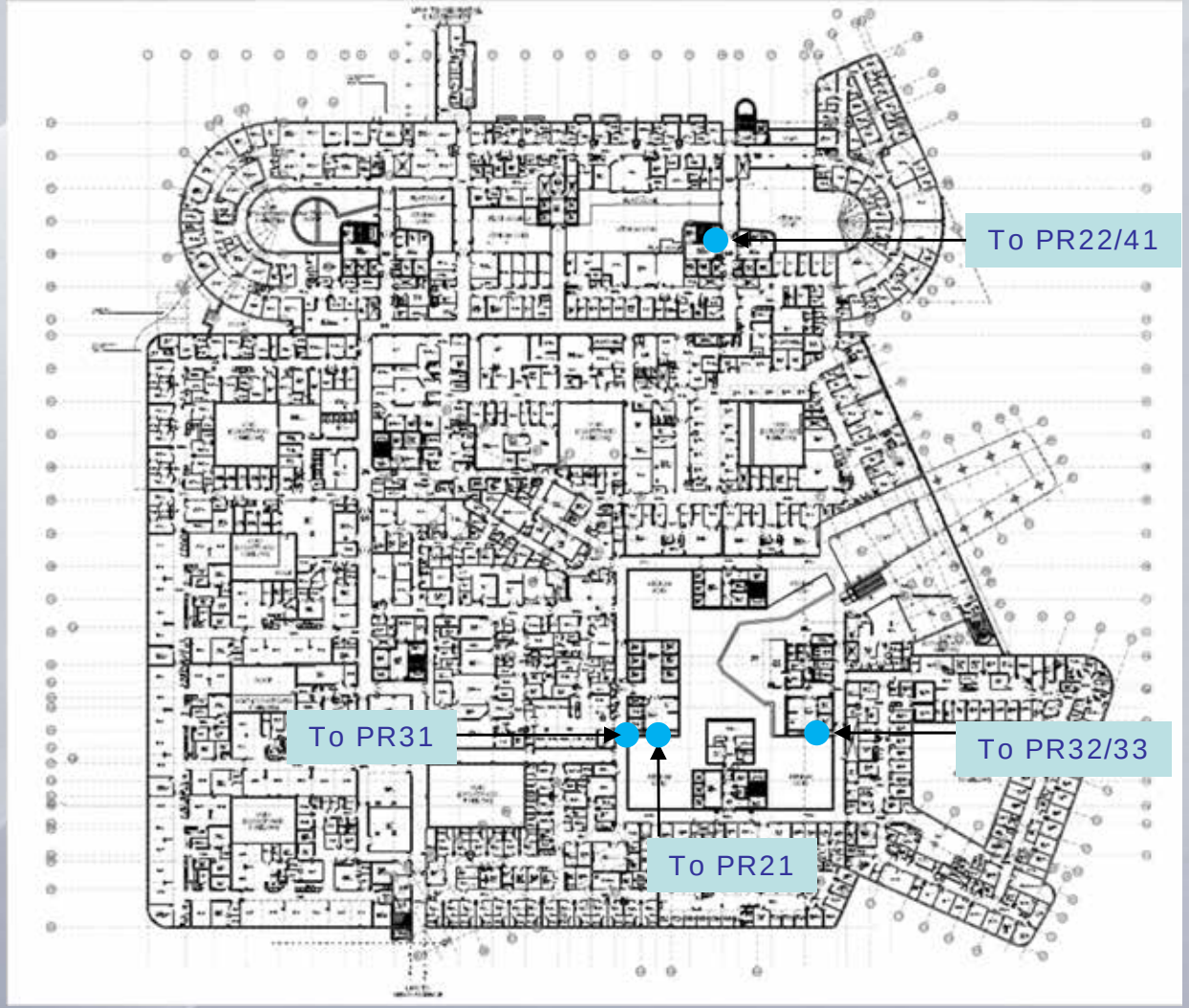
Basement Floor

NSGH – Mains Water Distribution Routes



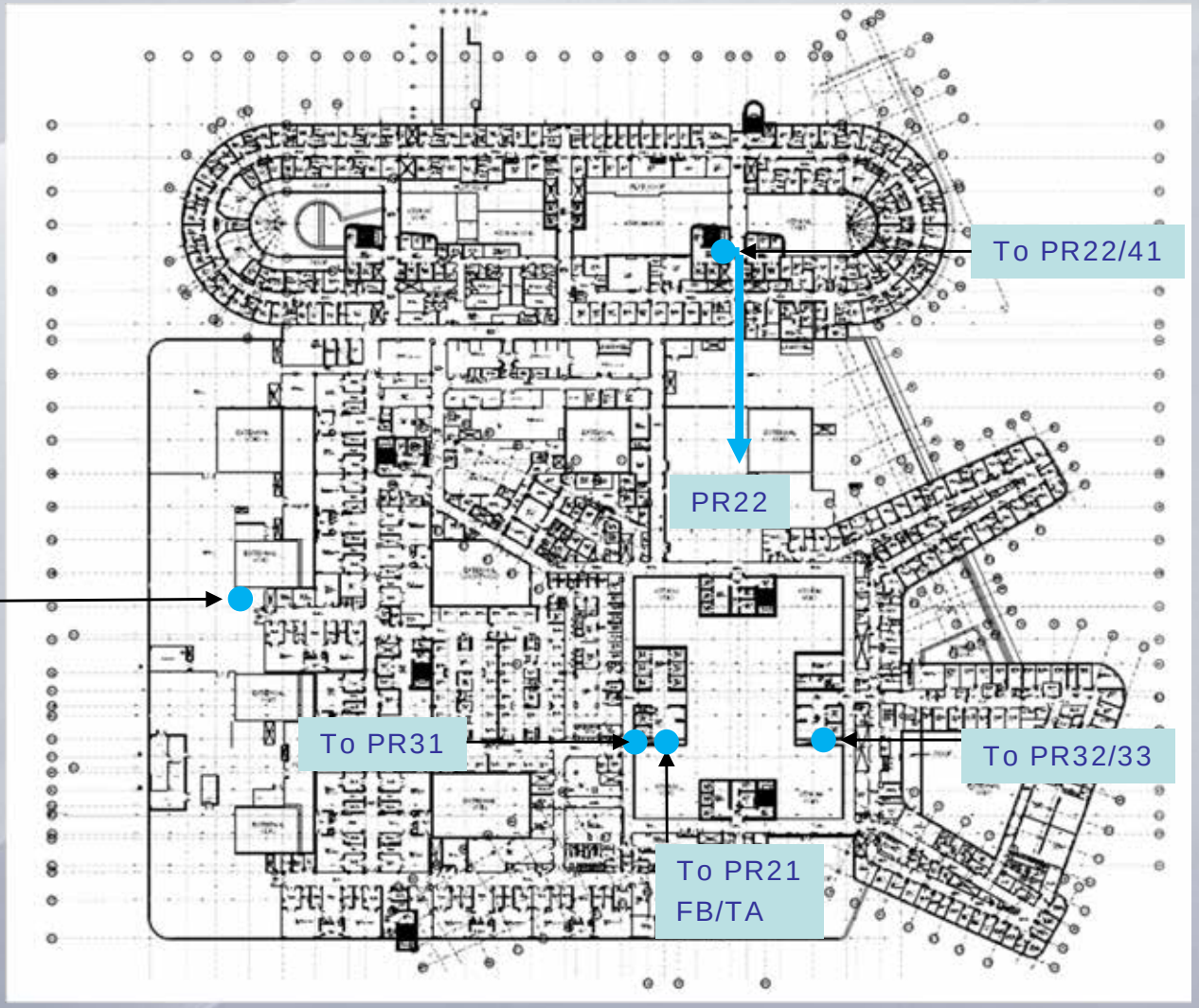
Ground Floor

NSGH – Mains Water Distribution Routes



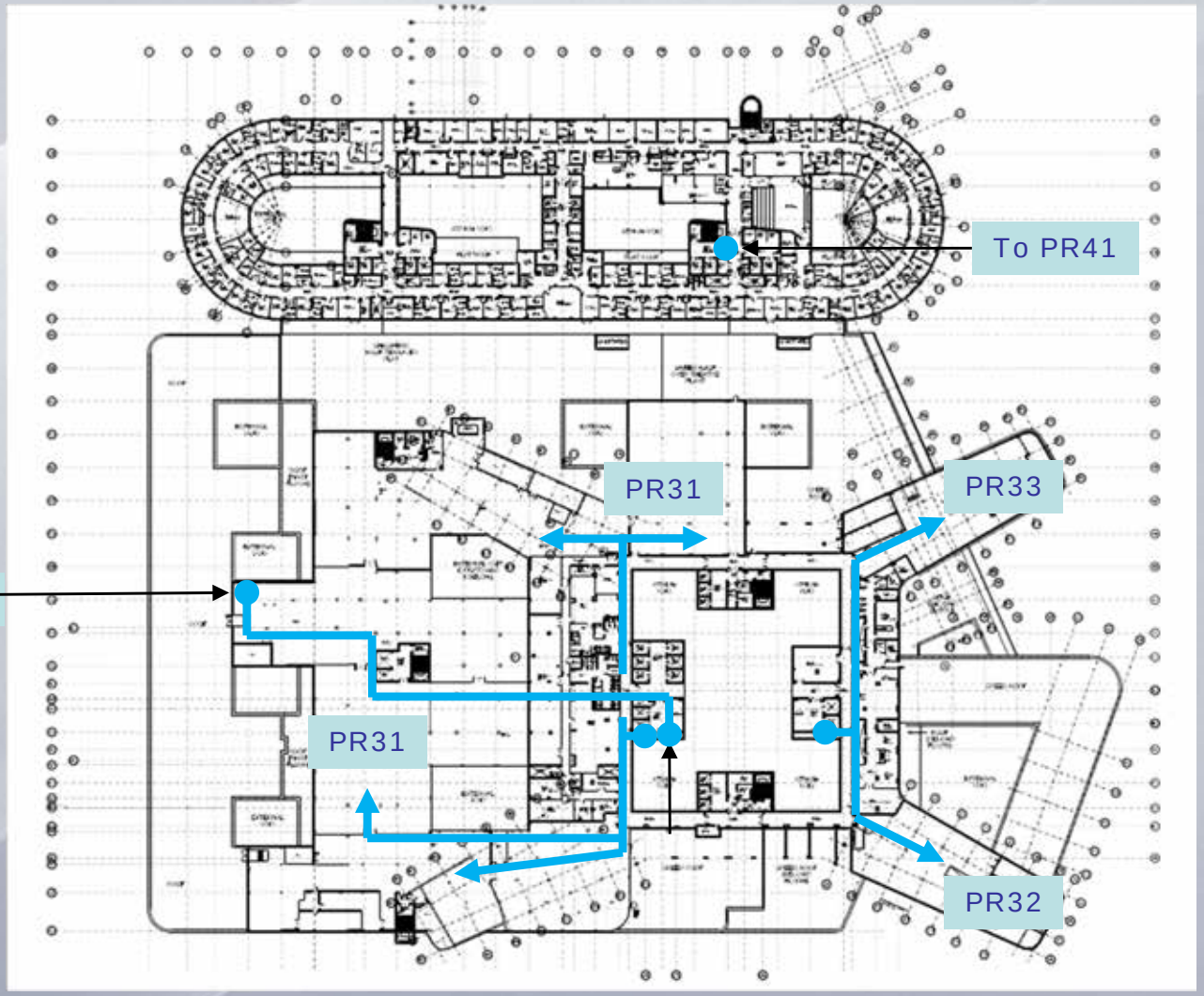
First Floor

NSGH – Mains Water Distribution Routes



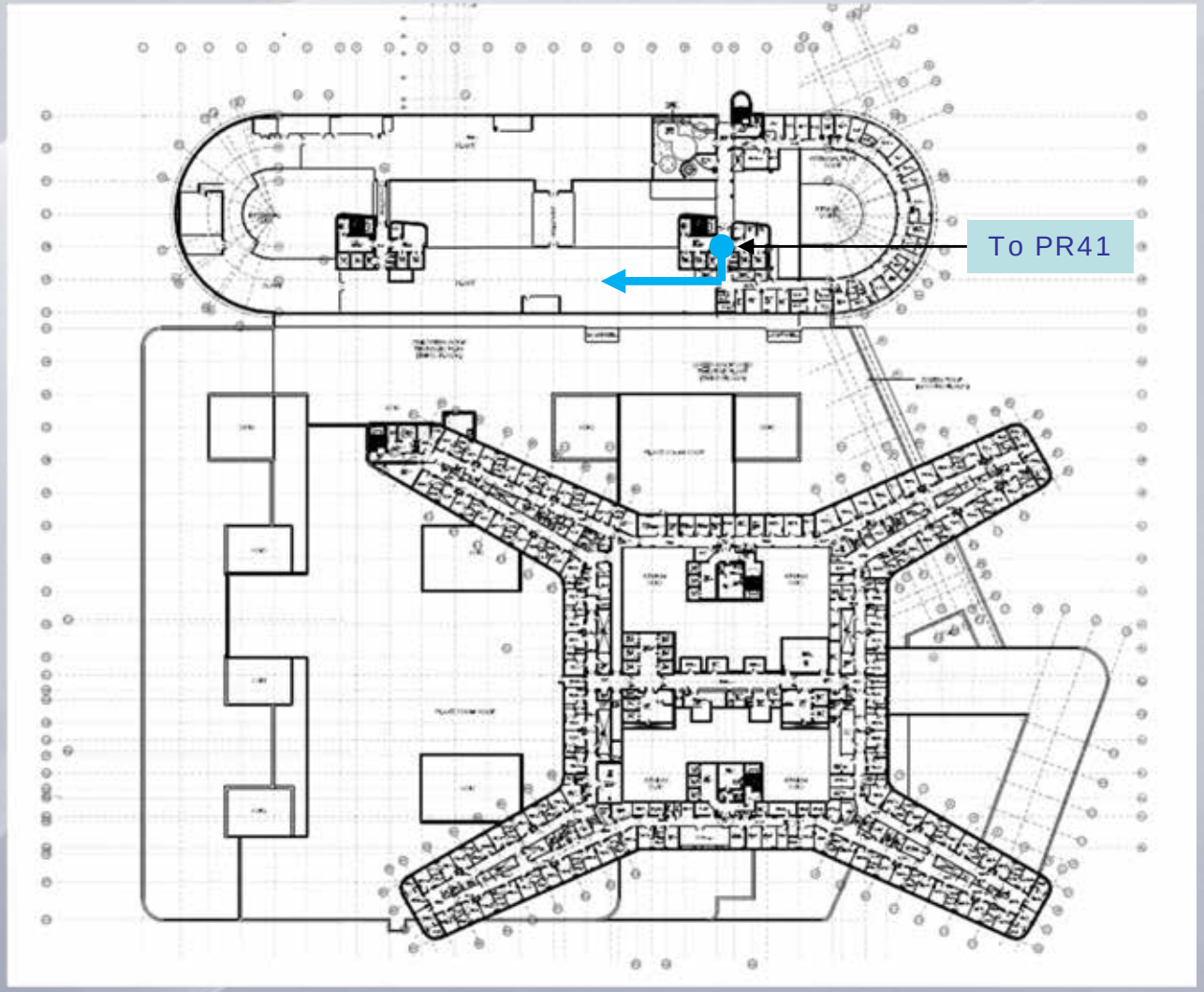
Second Floor

NSGH – Mains Water Distribution Routes



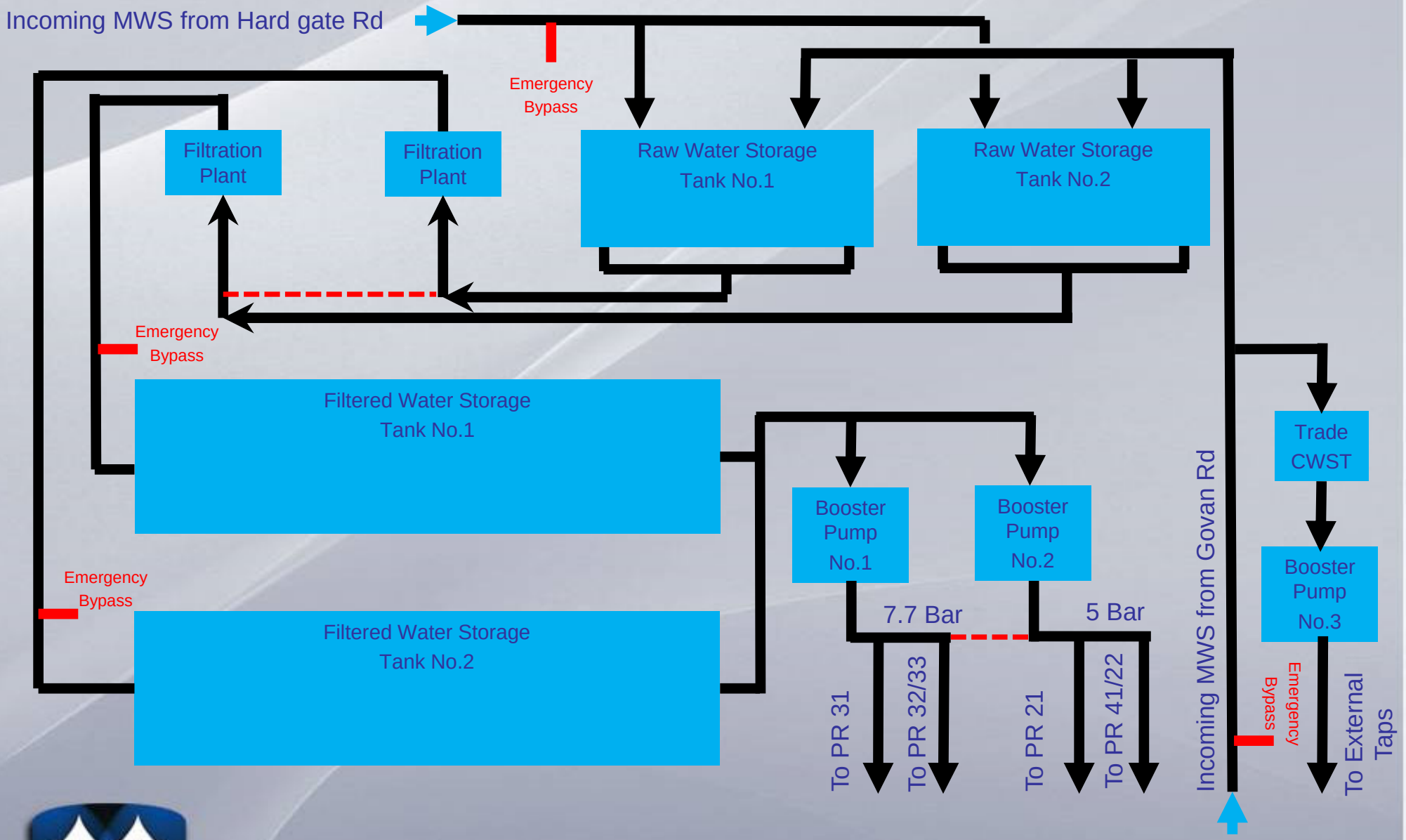
Third Floor

NSGH – Mains Water Distribution Routes

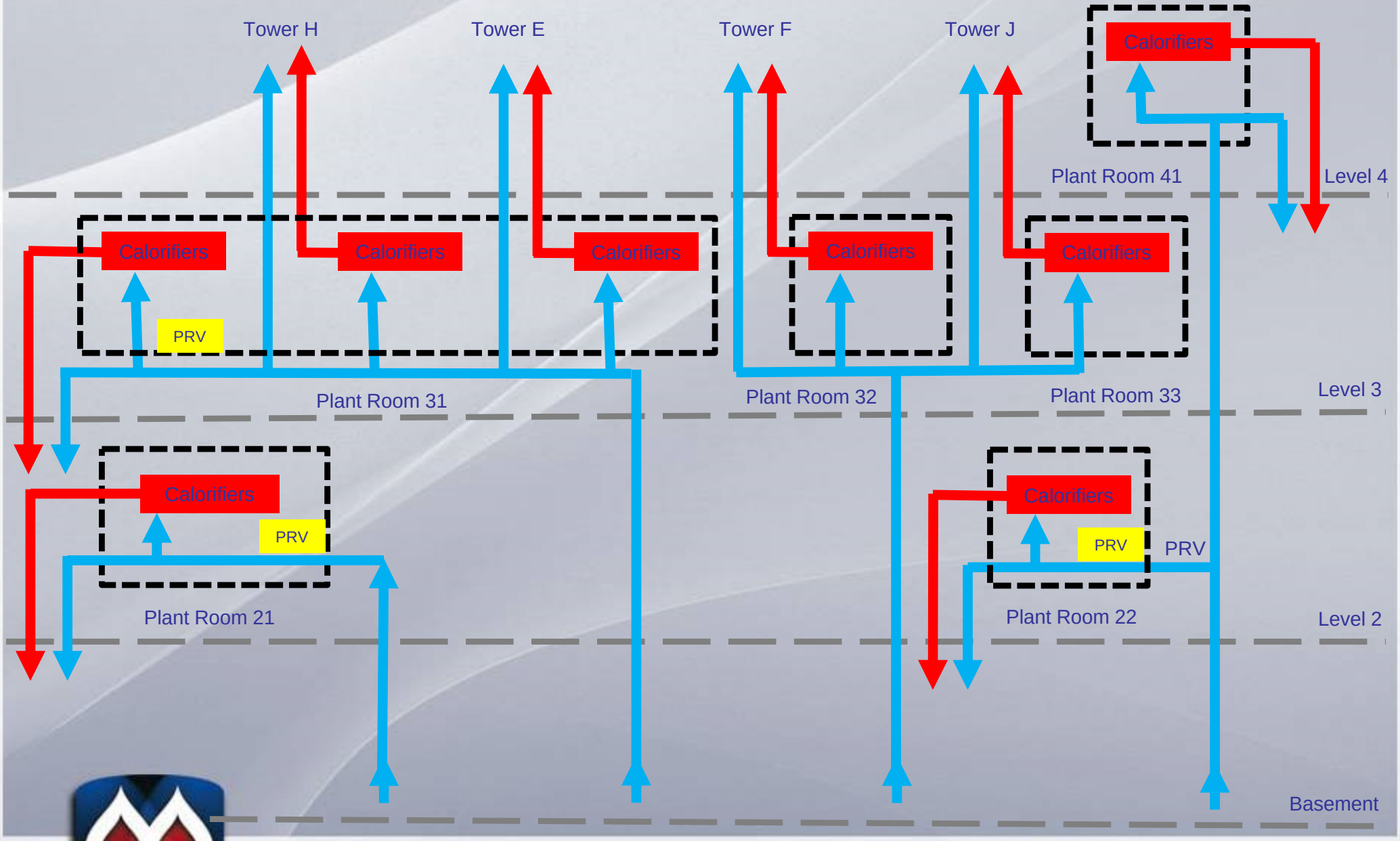


Fourth Floor

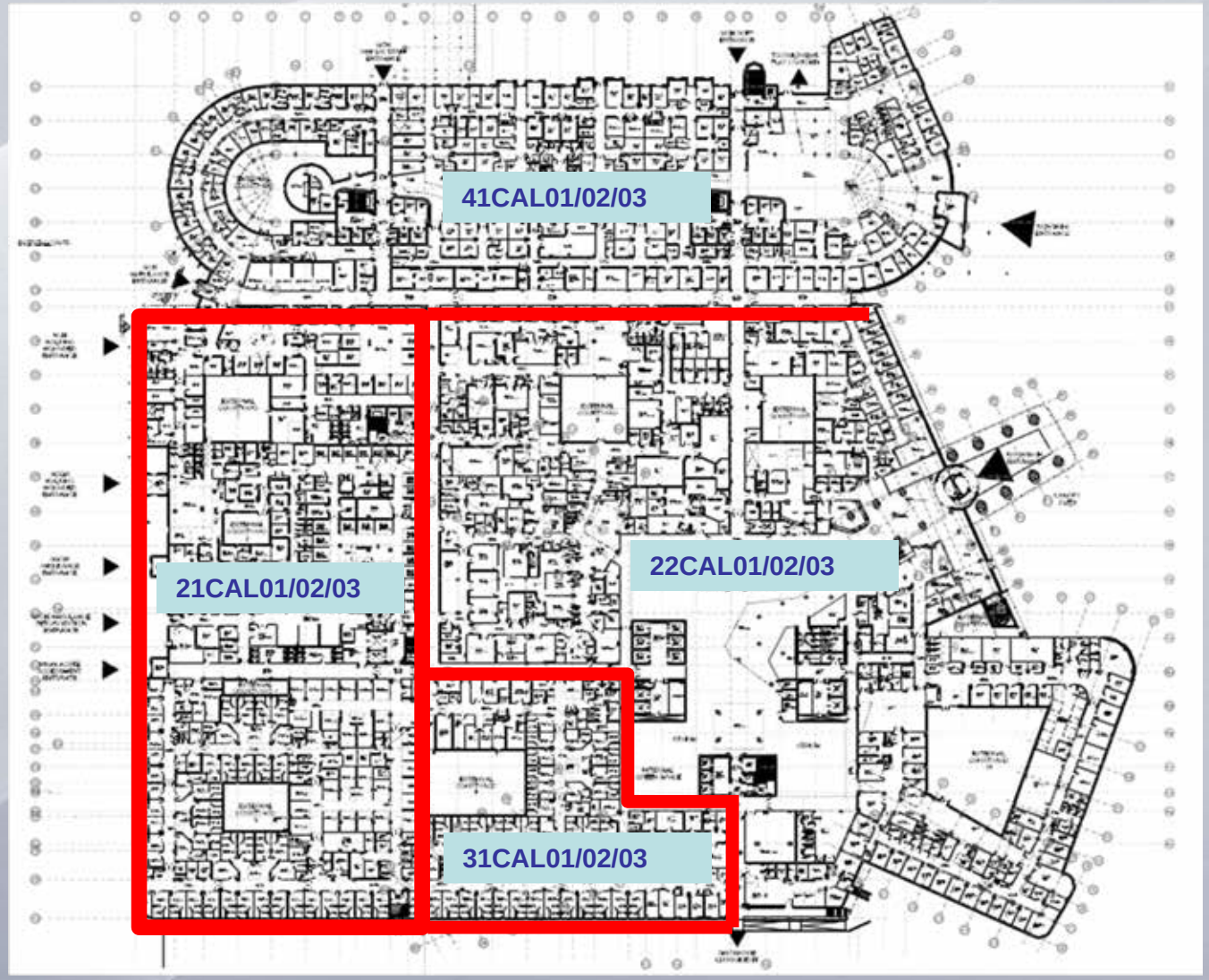
NSGH - Domestic Water System



NSGH - Domestic Water System

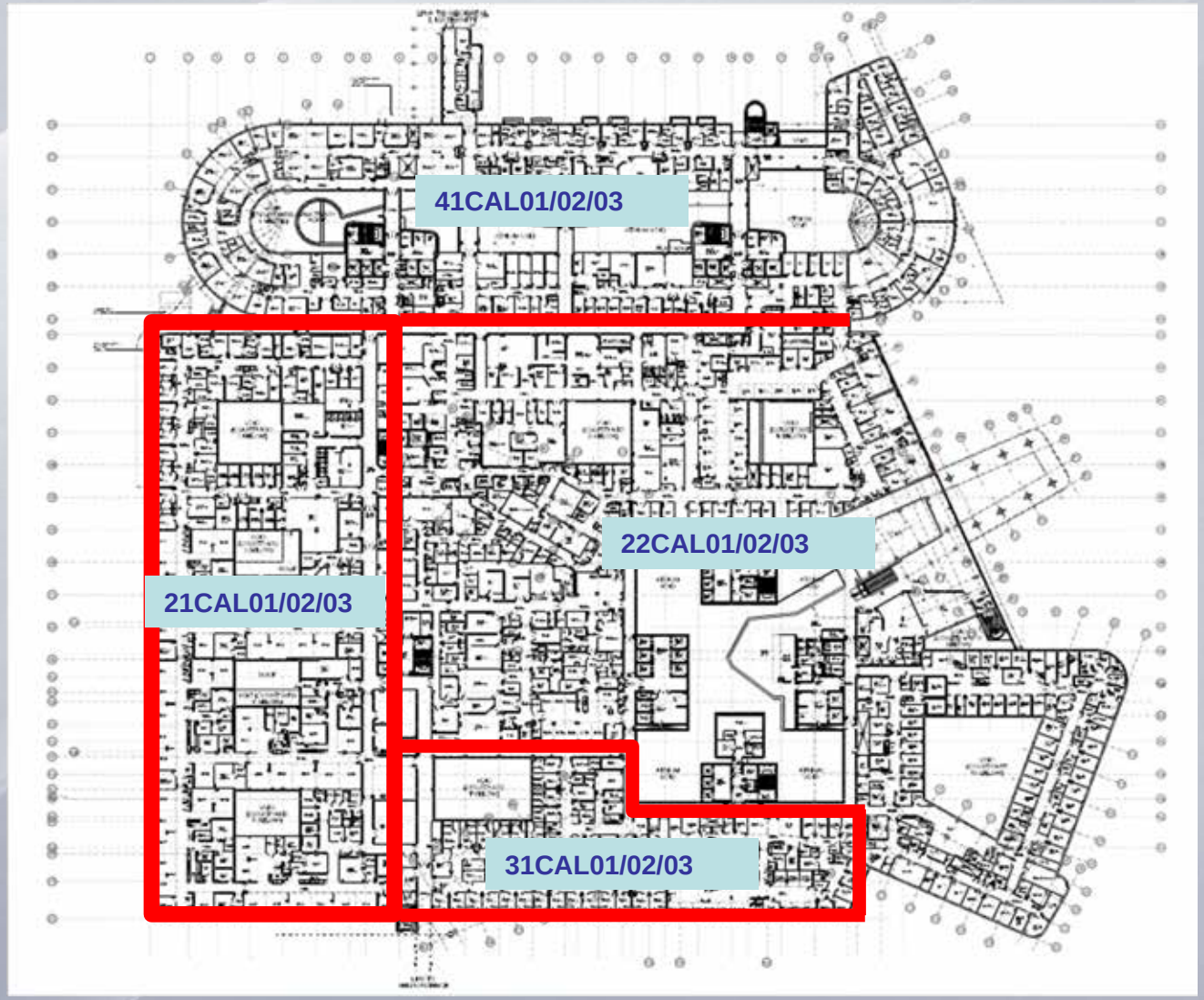


NSGH - Domestic Water System



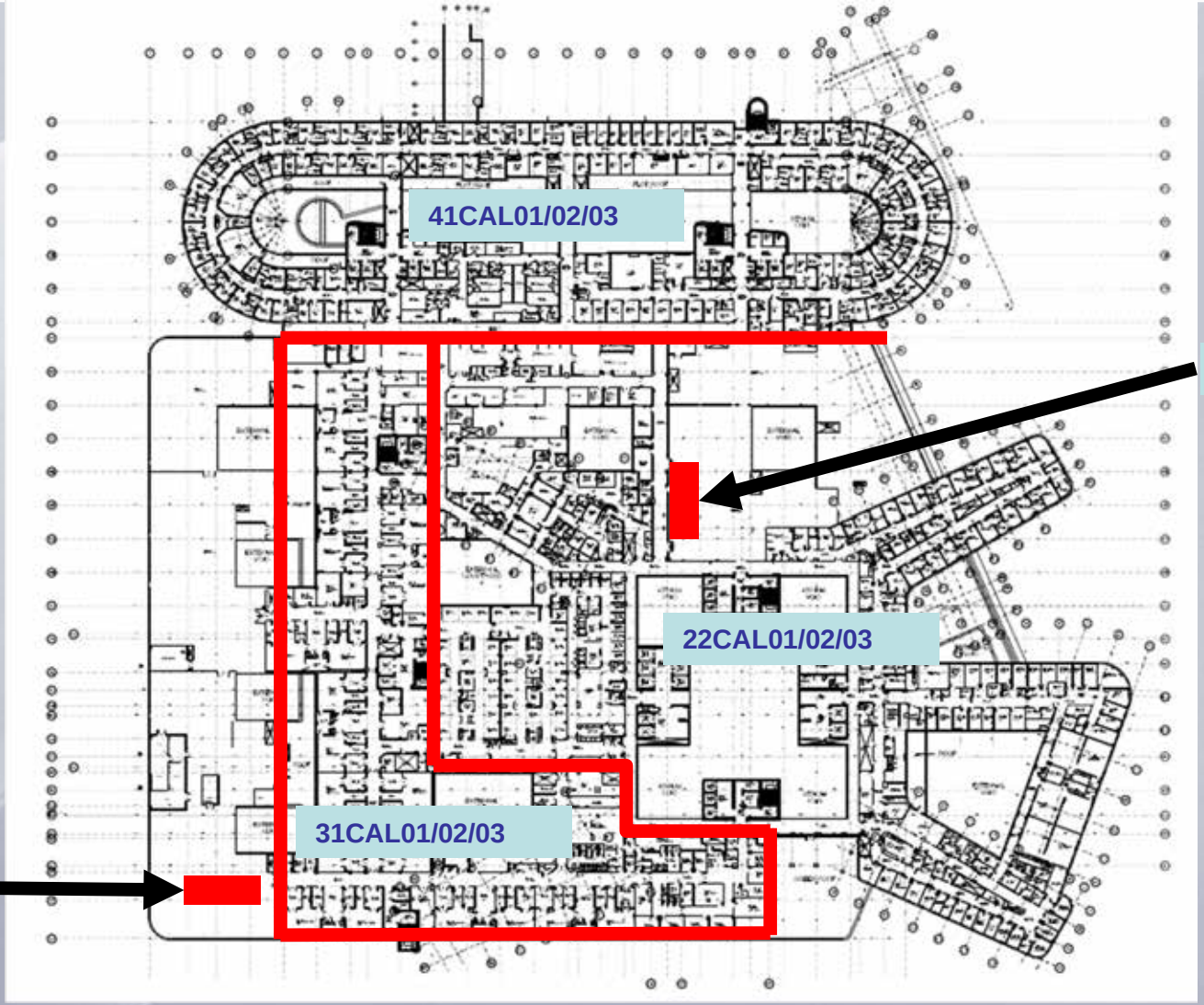
Ground Floor

NSGH - Domestic Water System



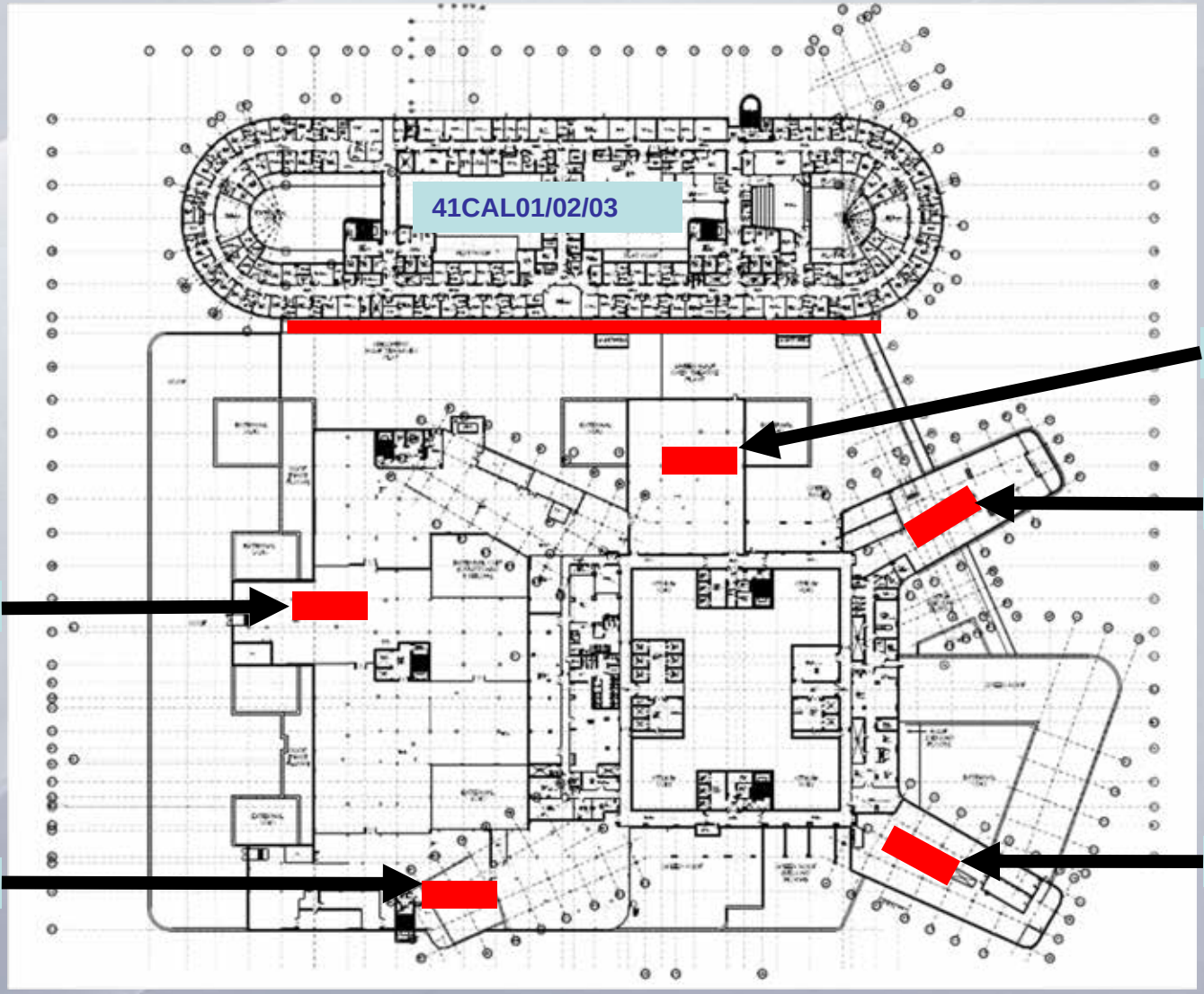
First Floor

NSGH - Domestic Water System



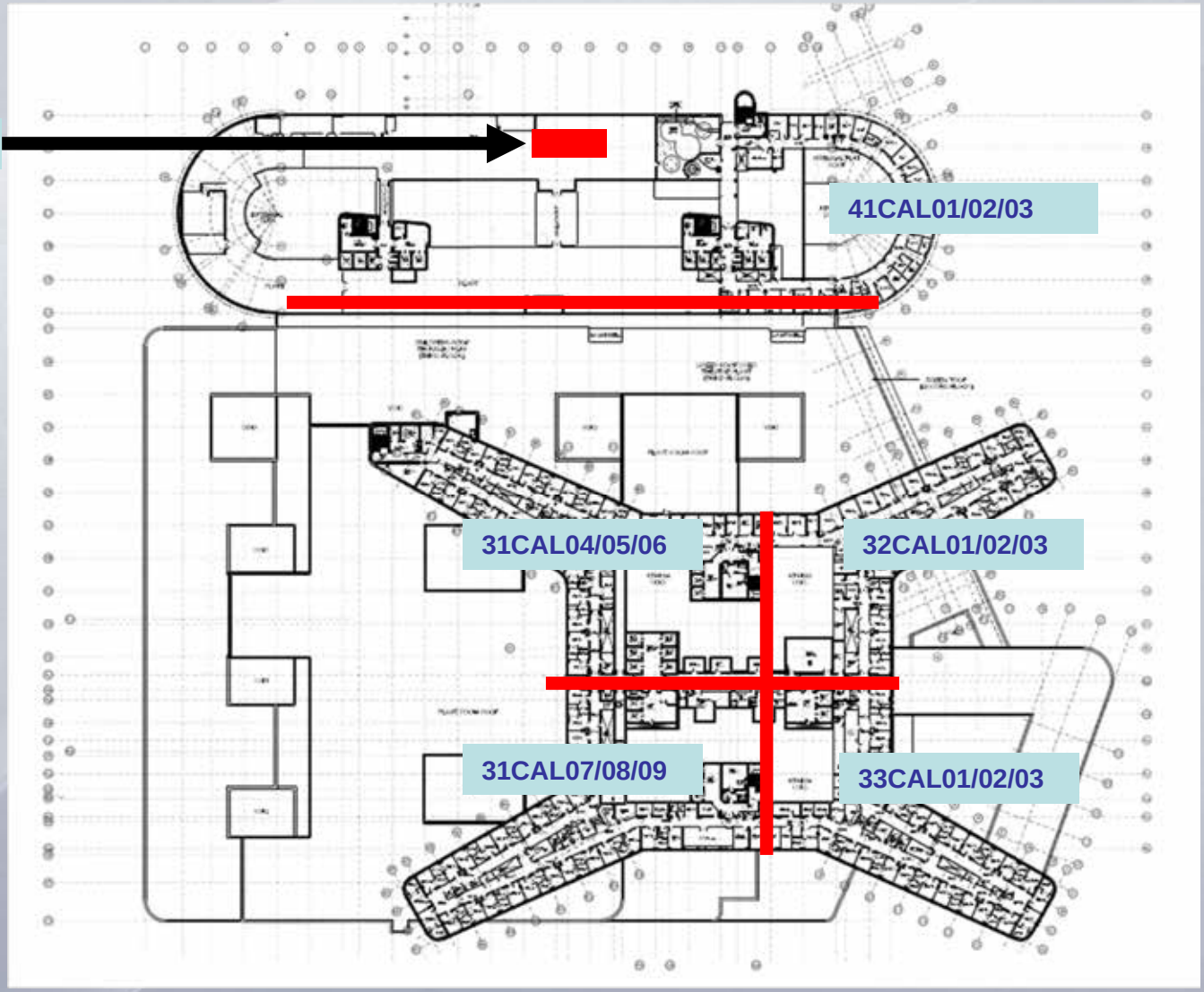
Second Floor

NSGH - Domestic Water System



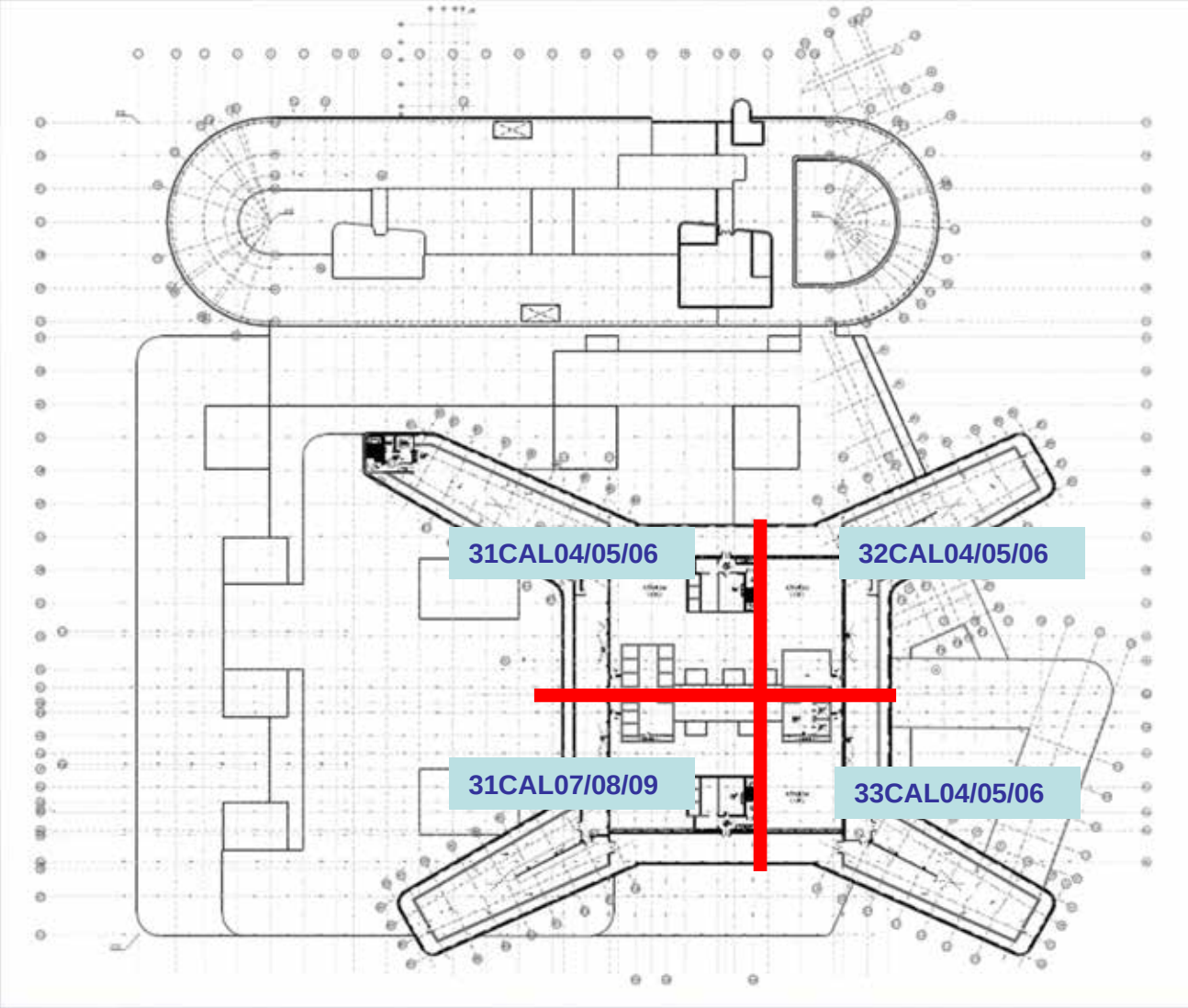
Third Floor

NSGH - Domestic Water System



Fourth Floor

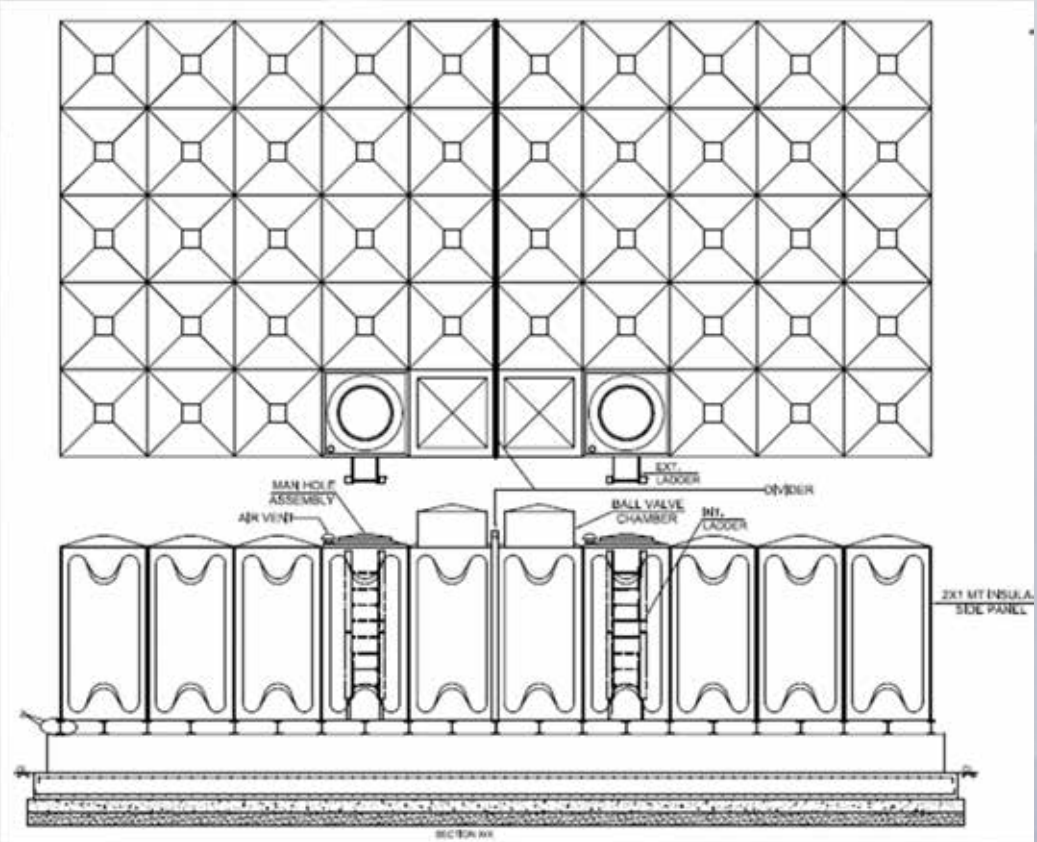
NSGH - Domestic Water System



Fifth - Eleventh Floor

NSGH - Domestic Water System

A) Cold Water Storage Tanks

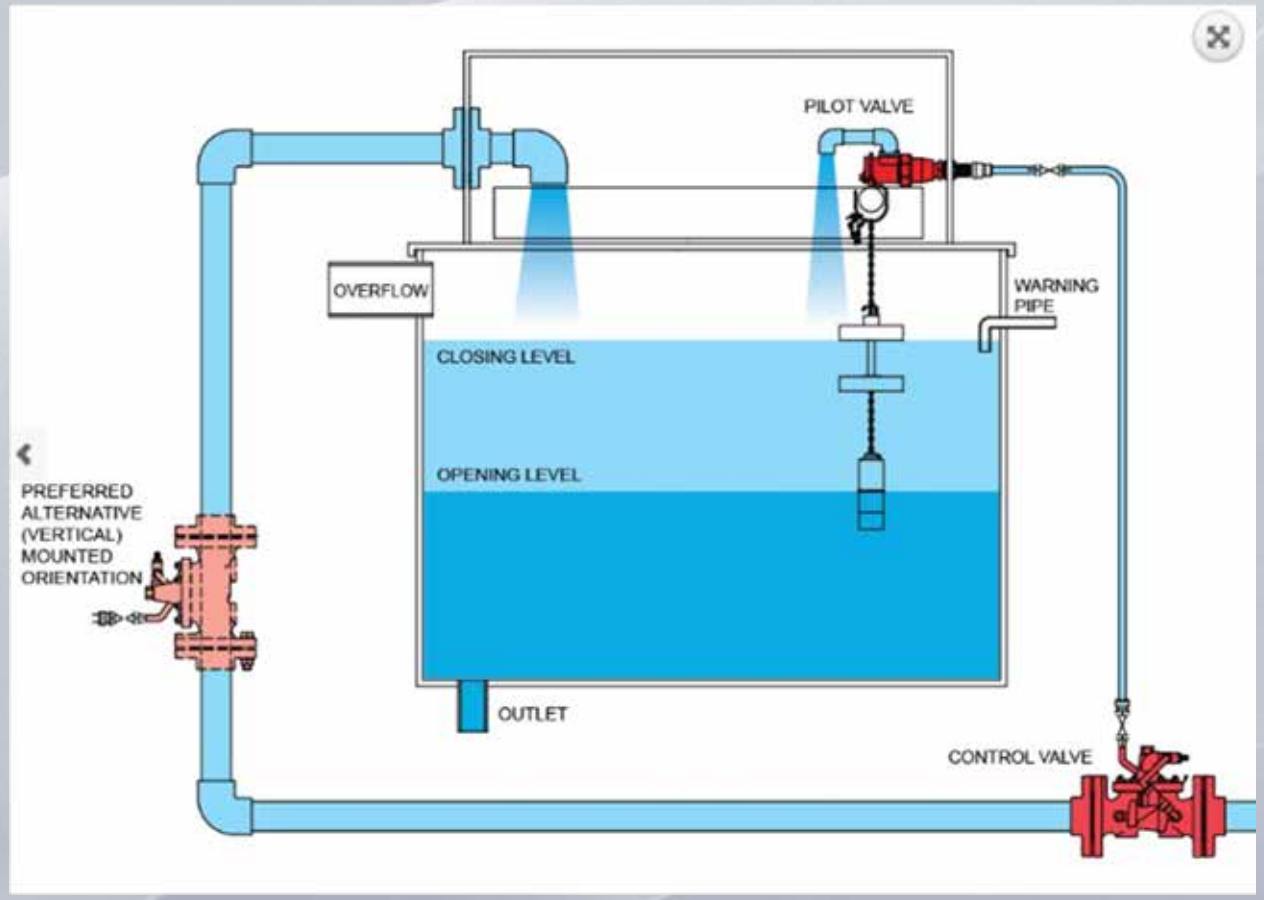


- 2No Raw water tanks
  - 10m long x 5m wide x 2m High
  - 100,000 Litres Nominal Capacity
- 2no Filtered water tanks
  - 27.5long x 5m wide x 2m high
  - 275,000 Litres Nominal Capacity
- 1no Trade Water Tank
  - 2m long x 2m long x 1m high
  - 4000 litres Nominal Capacity

- Raised Float valve chamber
- Access Manway
- Internal & External Ladders
- Overflow pipe
- Warning pipe
- High & low level sensors
- Temperature Sensors

NSGH - Domestic Water System

B) Keraflow KP Type Float Valves



•Typical Installation

•Control Valve

•Pilot Valve

NSGH - Domestic Water System

C) Cold Water Booster Sets

Dual Pressure set points
5.5 bar & 7.7 Bar

Automatic Pump cycling

Individual isolation

Stainless steel manifolds

Full automatic control c/w 3 colour backlit monitor
- Green – operation
- Red – Fault
- Orange – Fault acknowledged

1no serves PR21, PR22 & PR41

1no serves PR31,PR32 & PR33

NSGH - Domestic Water System

D) Filtration Plant

Capillary ultrafiltration module (HYRDAcap60)

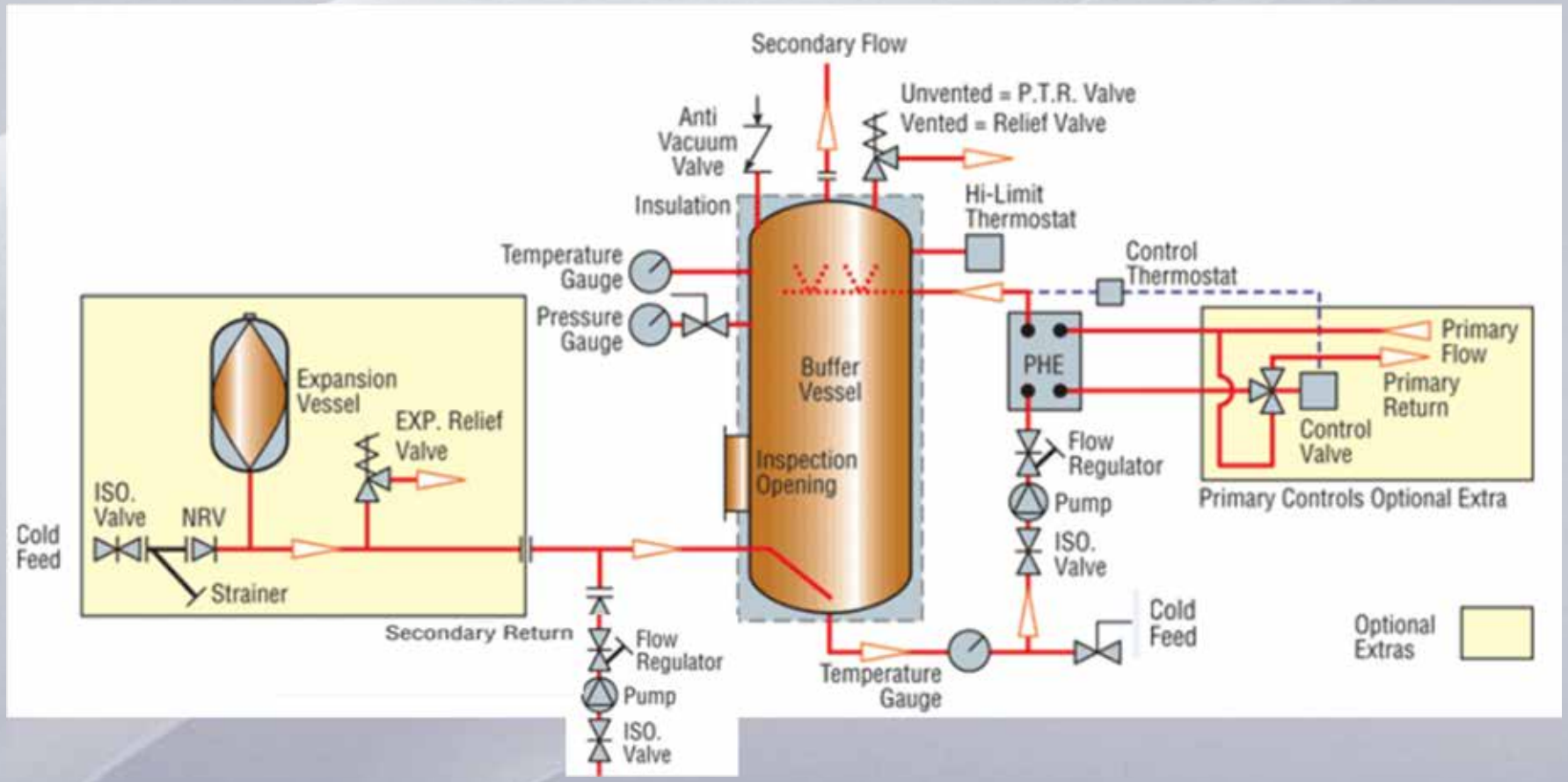
Flowrate 2.7 – 6.8 m3/s

Water backwash

Inside to outside flow

NSGH - Domestic Water System

E) Calorifier Skids



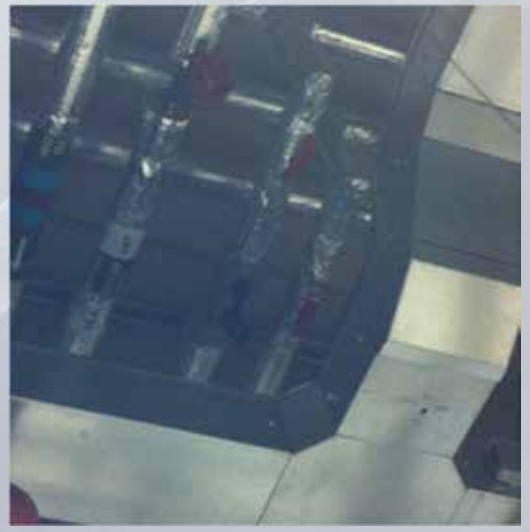
F) Hot Water Return Pumps

WILO MHIE

NSGH - Domestic Water System

G) Thermal Balancing Valves

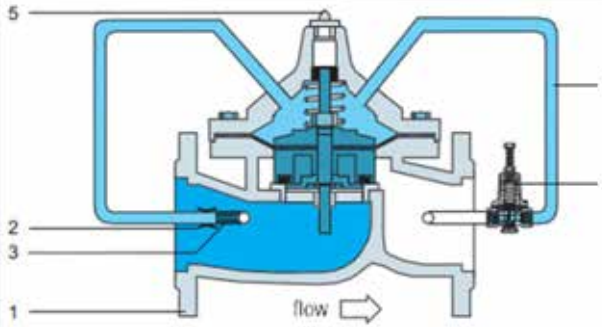
Multi-Therm
Figure 141 or Figure 143



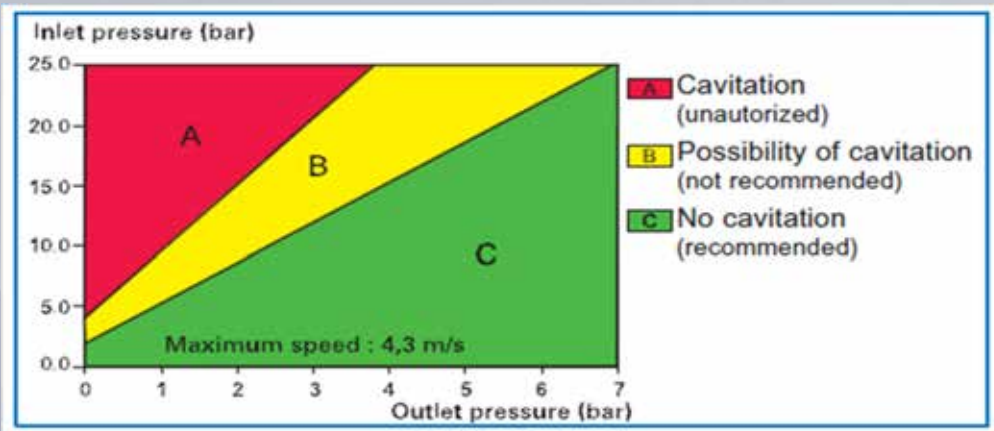
Multi-Fix
Figure 150 or Figure 151

H) Pressure Reducing Valves

WATTS PR500



No.	name
1	Body/Main valve
2	Fixed orifice
3	Flow strainer
4	Pilot valve
5	Air vent
6	Flexible tubing



Example: 15 bar upstream, 1 bar downstream = cavitation, unauthorized
10 bar upstream, 4 bar downstream = no cavitation, authorized

NSGH - Domestic Water System

I) Water Meters

Woltmann pulsed meters

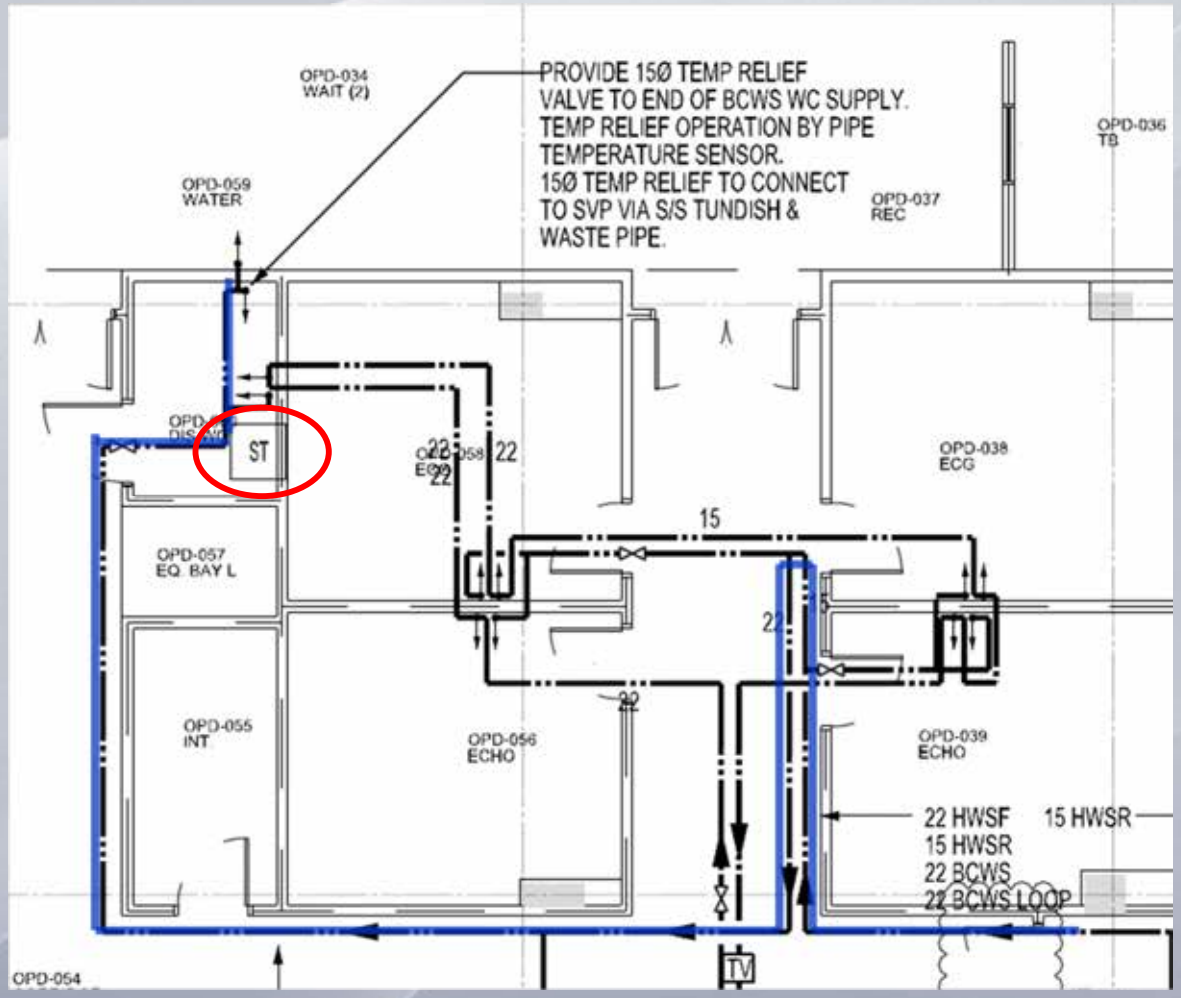
Linked back to BMS Front end

Installed on

a. Incoming Mains
b. Water supply to each Plant room
c. Cold feed to each bank of Calorifiers
d. Kitchen/Restaurant Supplies
e. Retail units supplies
f. Renal plant supplies

NSGH - Domestic Water System

J) Dump Valves



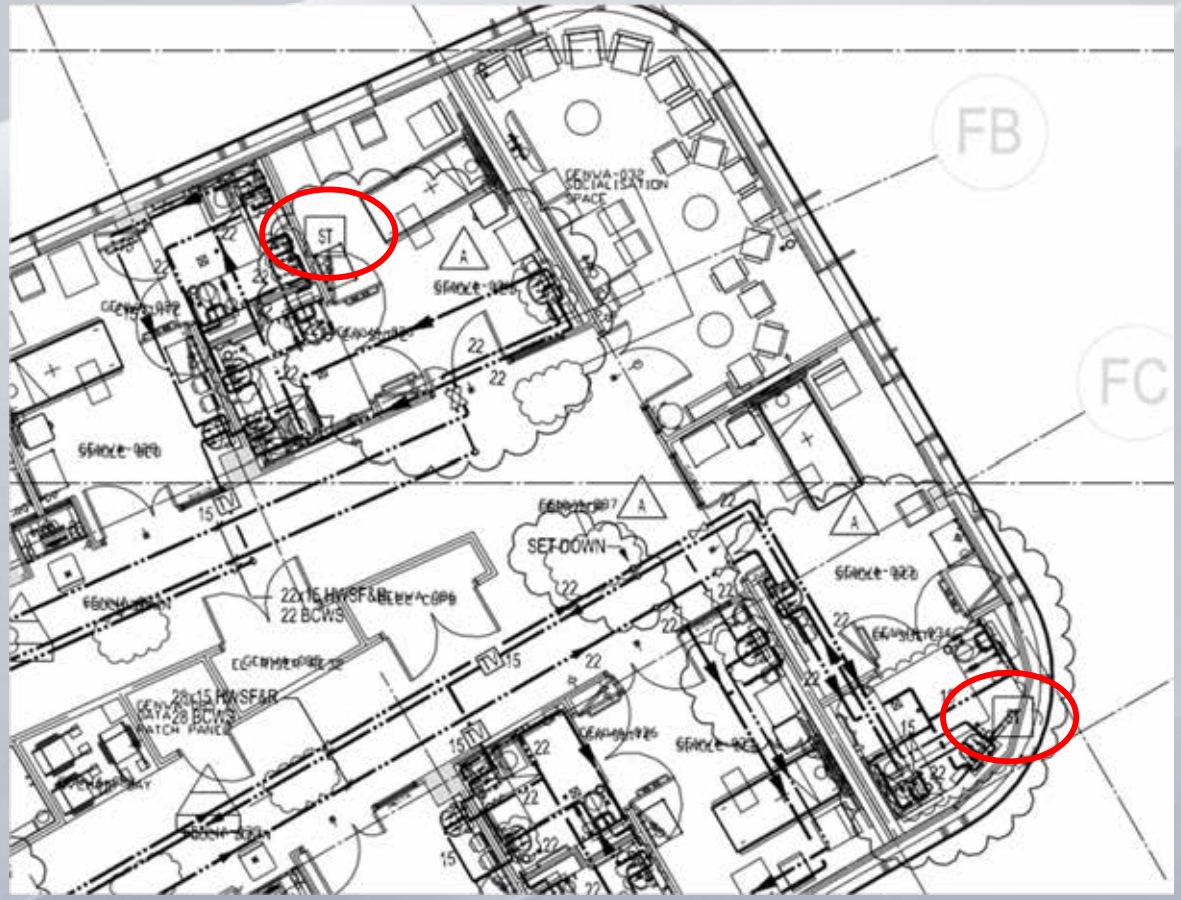
Dump valves installed at end of BCWS

Temperature controlled

Design – typically end of line at high use areas

NSGH - Domestic Water System

K) Sentinal Points



Indicated on drawings as ST

Labelled on site at tap

PR41 - DOMESTIC WATER SYSTEM DESCRIPTION

1. Overview

There are 2 No. incoming mains water supplies serving the Adults and children's hospital building. These enter the building in the basement manifold room and basement tank room and run into the tank room to serve 2no Raw water storage tanks. These incoming mains both have double check valves, water meters, 2 port isolation valves and keraflow float valves all located within the tank room.

The water meters are linked to the BMS system and allow the user to cross reference the quantity of water used against the quantity indicated on the external meter. This will highlight if there are any leaks on the external water main (see schematic included in 2 below). The 2 port valves allow the alternative use of each incoming main every 7 hours

From the raw water storage tanks the water is then filtered through the filtration plant before being stored in the potable bulk cold water storage tanks. All cold water storage tanks are 2 compartment tanks and are piped in such a way as to allow tank maintenance without disrupting the water supply to the building. Float switches within the tanks give the filtration plant the enable and stop signals based on the water level within the tanks. These levels can be adjusted to suit the water demand so that an optimal turnover of water can be achieved.

The filtered water is then pumped to serve the building via 2 no booster sets. Each booster set is set to a different set point pressure depending on which plant room it serves. (see below). Each booster set has 2no set points which will allow either serve the building in the event of failure.

There are 5 water storage tanks in the building:

- 2 No. 100,000 Litre Raw water storage break tanks
- 2 No. 275,000 Litre Potable bulk cold water storage tanks
- 1 No. 2,800 Litre Trade water storage tank

There are 2 No water booster sets in the building:

- BS01 – Feeding Plantroom 31, 32 & 33 - 7.3 Bar
- BS02 – Feeding Plantroom 21, 22 & 41 – 5.1 Bar

2. System Description

Plant room 41 is served from booster set BS02 at 5.1 Bar. The boosted water is pumped directly from the basement to PR41. The line serving Plant room 41 is metered in the basement.

From the plant room the BCWS is distributed to each riser and the bank of calorifiers. 41CAL01, 41CAL02 & 41CAL03. The water in the calorifiers is heated via a plate heat exchanger (feed from the MTHW circuit) on each calorifier skid. Each calorifier skid consists of a storage cylinder, shunt/de-strat pump, plate heat exchanger, expansion vessel and associated pressure, temperature and vacuum safety valves.

The BCWS and HWS F&R are then distributed together allowing for equal pressures at the outlets between the hot and cold water. The hot water is circulated to the outlet and back to the calorifiers by a hot water return pump so that temperature is maintained throughout the system. There are Kemper thermostatic balancing valves installed on the system in line with the design to ensure hot water is available within 2 minutes at every outlet.

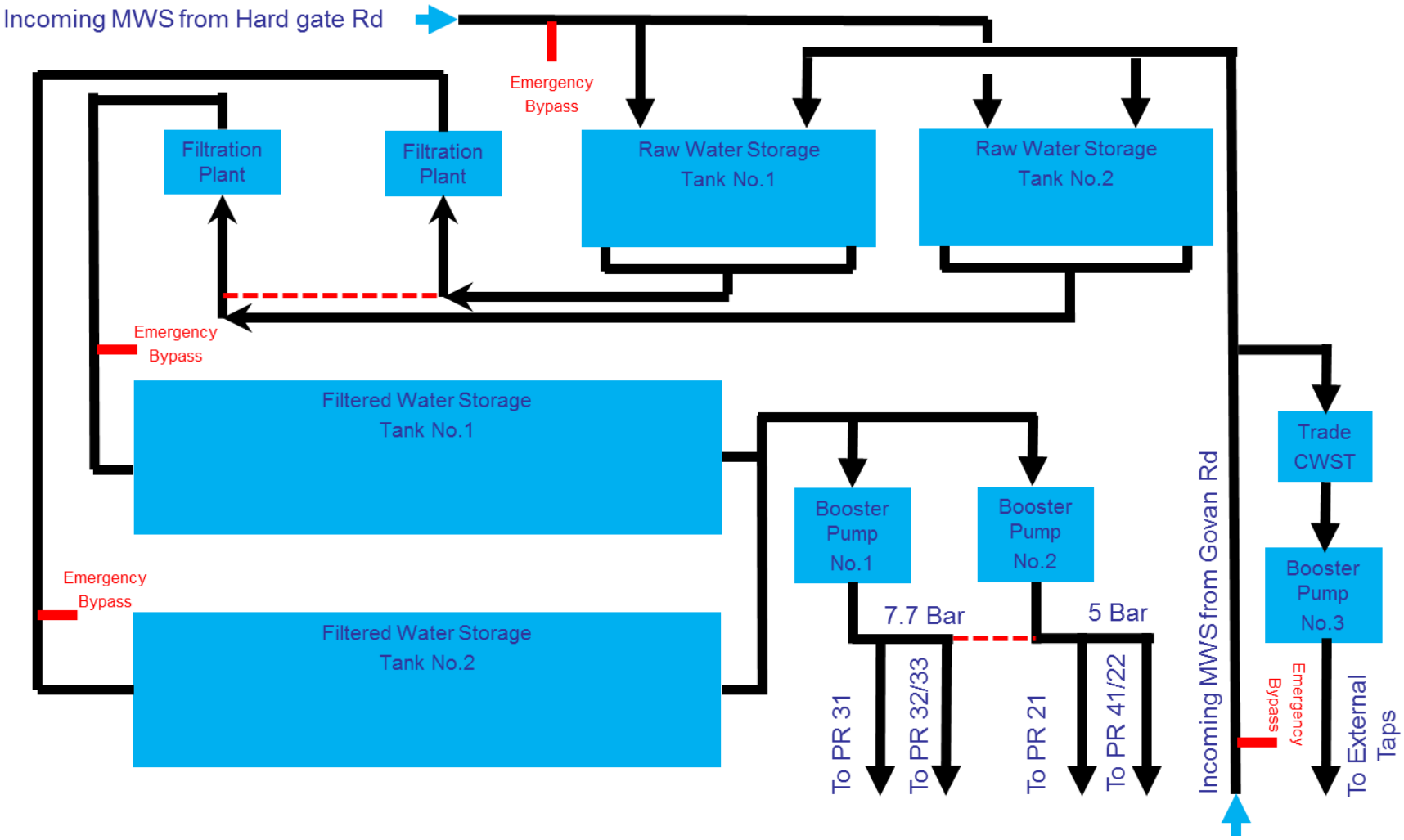
The cold feed to the calorifiers is also metered. The meter is located at the calorifier skids.

The design philosophy is that the distribution pipe work is laid out in such a way that areas of high use are at the end of lines. This ensures good turn-over of water within the system. Where this cannot be achieved temperature operated dump valves are installed.

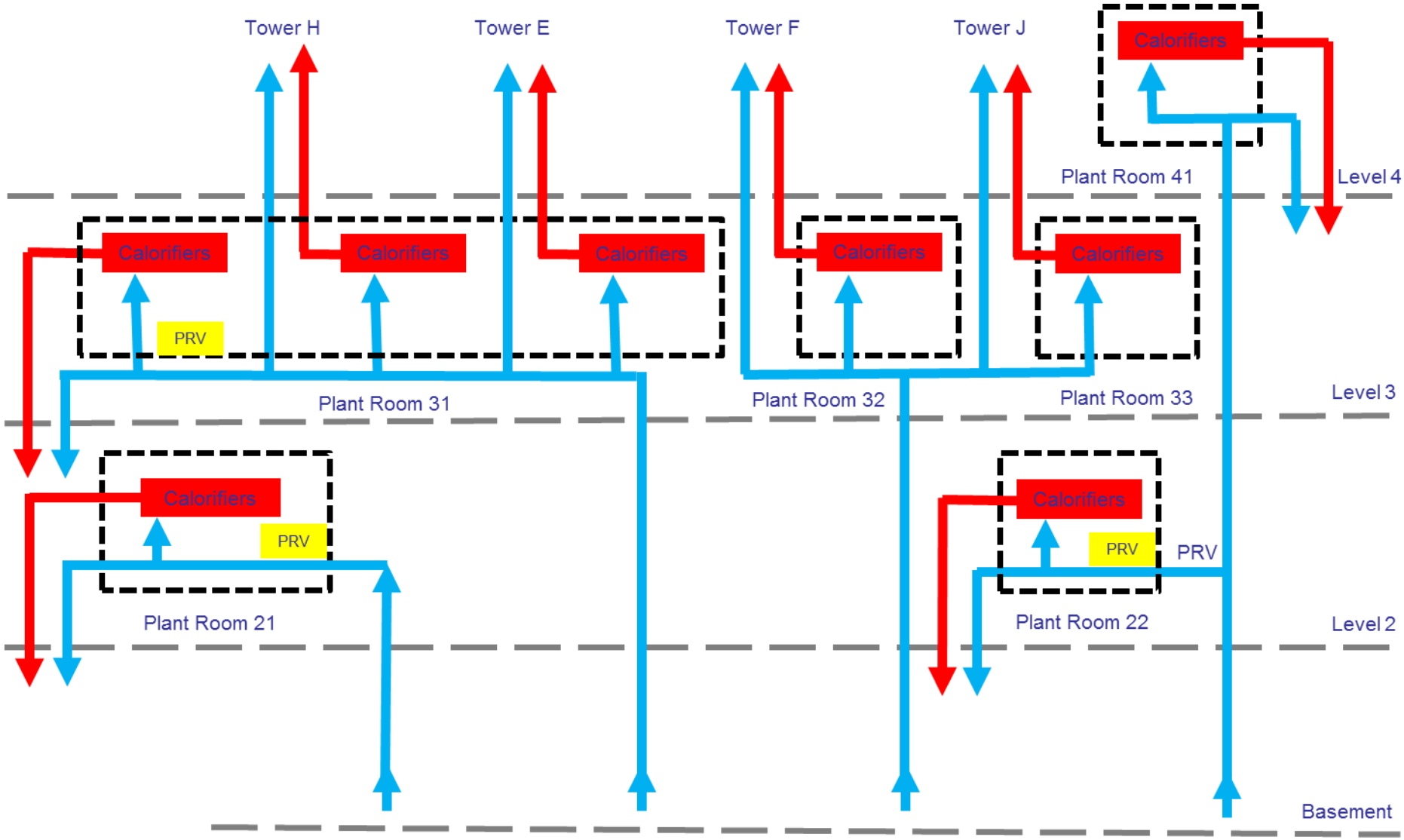
For record drawing information please refer to the ***500*** series drawings for details on the pipe work distribution on the floors and plant rooms.

For the distribution of the domestic water systems in relation to plant rooms please see “schedule of risers” document.

3. Overview of Domestic Water System (A&C Tank Room)



4. Schematic of DWS Area Served by Plantroom



HORNE

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Horne OPTITHERM Thermostatic Bib Tap

Type TBT02

INSTALLATION, COMMISSIONING, OPERATING AND MAINTENANCE INSTRUCTIONS

APPROVAL

The Horne OPTITHERM Thermostatic Bib Tap has been independently tested as a Type 3 TMV by WRc-NSF and approved to the requirements of *NHS Model Engineering Specifications D08: Thermostatic mixing valves (Healthcare premises),* to the following designations.

APPLICATION	DESIGNATION	HOT & COLD WATER PRESSURES	WATER TEMPERATURES
WASHBASIN	HP-WE	1 to 5 BAR (Hot and cold pressures do not need to be equal)	HOT: 52°C - 65°C COLD: 5°C - 20°C
		Static Pressure Max. 10 Bar	Differential between mixed and supply temperatures: Min. 11°C

Table 1

If the Horne OPTITHERM Thermostatic Bib Tap is operated outwith these conditions it cannot be guaranteed to operate as a Type 3 TMV.

The Horne OPTITHERM Thermostatic Bib Tap is supplied with WRAS approved integral single check valves (spring-loaded, resilient trim in-line check valve cartridge with plastic guide and stem) located in each of the hot and cold water supply inlets.

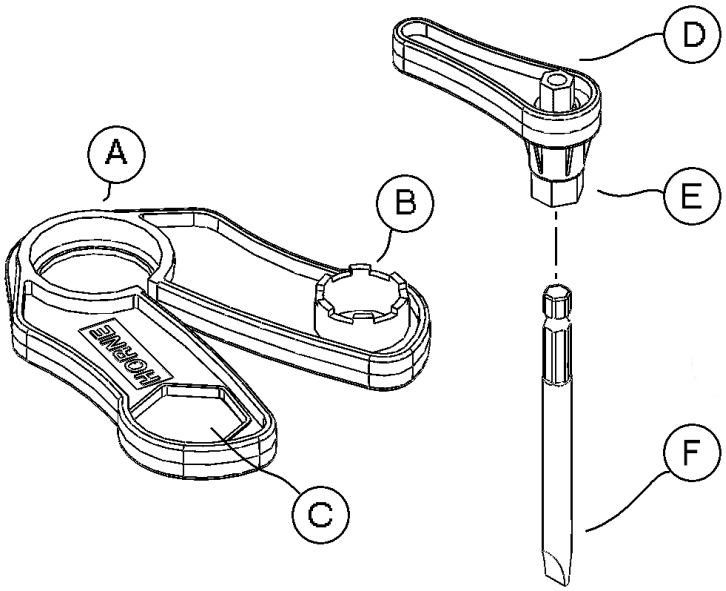
The Horne OPTITHERM Thermostatic Bib Tap is a tap containing a thermostatic mixing valve (TMV). All comments made herein regarding TMVs apply equally to thermostatic taps.

ACCESSORIES:

MULTI-TOOL:

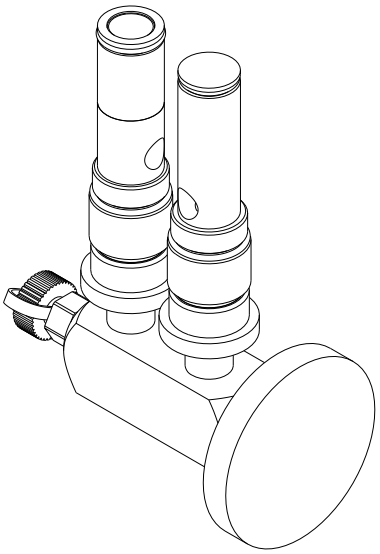
Optitherm Multi Tool (Part No. 5459) & Screwdriver bit (Part No. 5632). Available as part of full toolkit (part no. 5491).

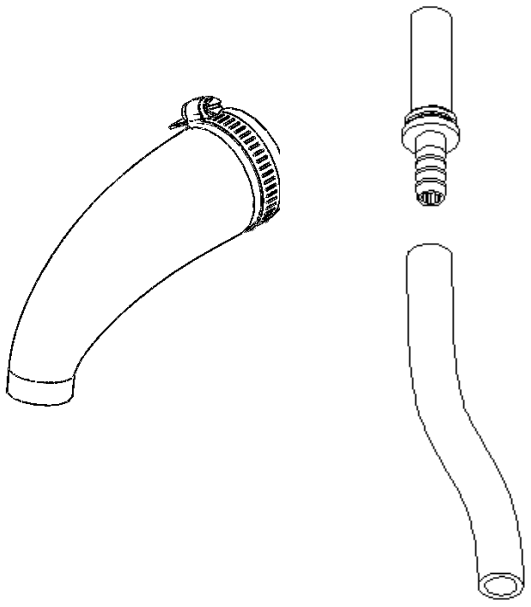
A	Endcap Gripper
B	Outlet Fitting Tool
C	26mm Ring Spanner
D	8mm Hex Key
E	12mm Hex Key
F	Screwdriver Bit



THERMAL DISINFECTION ADAPTOR:

As part of Water Quality Compliance Kit – Part no. 6006. See Section 2.4 & 4.2





FLUSHING ADAPTORS.

Part nos. 5684 (left), & 5492 (right).
The Parts on the right are also contained in Water Quality Compliance Kit, part no.6006.

Table of Contents

[1] INSTALLATION

The Horne OPTITHERM Thermostatic Bib Tap must be installed in accordance with the Water Supply (Water Fittings) Regulations 1999.

1.1 NOTE ON O-RING FITTING

Before fitting o-rings care should be taken that they, and the grooves/bores into which they fit are…

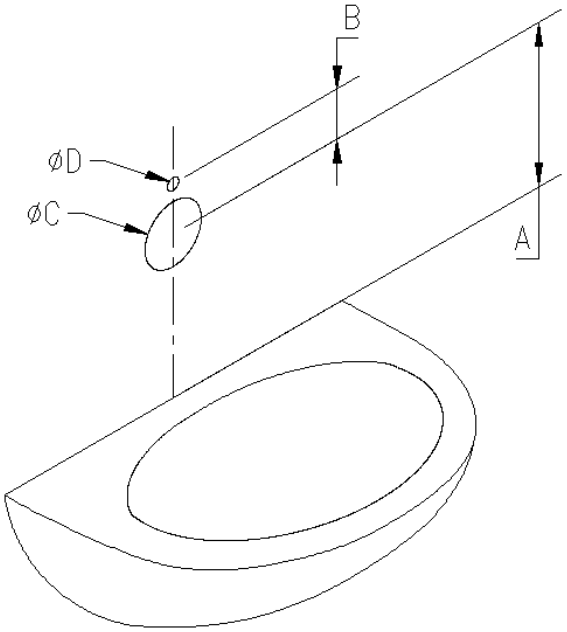
- ◊ Clean
- ◊ Free from damage (nicks, tears, etc.)
- ◊ Lubricated lightly with water or a WRAS approved silicone oil.

Failure to do this may result in leaks and considerable damage.

1.2 FITTING

The Horne OPTITHERM Thermostatic Bib Tap is intended for installation on a vertical panel above a surgical basin or bath with no tap holes.

1.2.1 Before installation, 2 holes must be bored in the panel in the configuration shown in the diagram.



A	150mm to 300mm depending on vessels to be filled. Less than 150mm will impede access for servicing. Recommended height 225mm
B	34mm
C	48mm (min 47mm, max 50mm)
D	6mm
Panel thickness	30mm maximum

Diagram 1

► Open out the last (fold out) page of this instruction booklet to see the installation diagrams ►

1.2.2 Install the spigot (5) to the panel. Ensure that the chrome bezel (7) is located around the spigot first, and that the locating pin in the bezel engages in the small hole bored previously in the panel. The bezel should be retained between the spigot and the panel. Tighten to the panel using the 1½ BSP bulkhead nut (8) supplied. Put this nut on tightly. If it works loose the tap will not be secure and the nut may be difficult to tighten later, after the panel has been fixed.

1.2.3 Attach the 10mm compression couplings (22), or optional flexible hoses (9) to the spigot with the Hot Water Supply connected to the inlet port nearest the lever with the red endcap (i.e. the left hand side as one faces the basin), and the Cold Water Supply connected to the inlet port nearest the lever with the blue endcap (i.e. the right hand side as one faces the basin). The note in 1.1 regarding o-ring fitting should be especially heeded here, as any leaks in the hose o-rings may go undetected for some time and cause considerable damage. Torque couplings or hoses to 5Nm.

1.2.4 At this stage, the screw (6) can be used to attach an electrical earth, if required.

1.2.5 Connect the couplings (or flexible hoses) to the water supply behind the panel, close the ball valves (13,14) in the spigot and test for leaks. Once this part of the installation is confirmed to be watertight, and the hot and cold supplies are confirmed to be the right way around (see section 2.2), all further work on the Horne OPTITHERM Thermostatic Bib Tap can be done with the panel in place.

1.2.6 If applicable, attach the required extension piece (4) to the spigot using the 4 no. M5 screws (2) and washers (3) supplied. Ensure that the interconnect nozzles (1) are located correctly with their o-rings between the spigot (5) and the extension piece (4). See note in 1.1 regarding o-ring fitting.

1.2.7 Offer the main tap body up to the spigot. Locate firmly over the spigot and tighten the retaining screw (15) from below. In order to get a good fit of the tap onto the spigot it is helpful to push the tap against the spigot and slightly upwards as the retaining screw is tightened – this ensures that there is no gap between the spigot and the tap body. Torque the retaining screw to 5Nm (if a torque wrench is not available, tightening fairly tightly with the 4mm hex key supplied should be adequate for this purpose).

1.2.8 Do not open the tap yet. Commence with the flushing procedure as detailed in 1.3 below.

1.3 FLUSHING OF PIPEWORK (METHOD 1)

Pipework must be flushed in accordance with Water Fittings Regulations 1999, schedule 2 G13.1 before connecting the Horne OPTITHERM Thermostatic Bib Tap.

> The most common cause for complaint regarding the performance of any TMV/thermostatic tap is traced to dirt or debris in the TMV or check valves.

1.3.1 DO NOT OPEN either tap lever before flushing the hot and cold water pipework.

1.3.2 A flushing kit (Horne part no: 5492, or as part of the Water Quality Complance Kit, part no. 6006) is available to provide means of flushing the pipework.

1.3.3 Unscrew the main bottom cover (16) using a strap wrench.

1.3.4 Remove a strainer/check-valve cartridge (20,21) using a 12mm hex key or Horne tool no. 23-5459.

1.3.5 Using an 8mm hex key or Horne tool 23-5459, screw the flushing adaptor (22) into the space occupied by one of the strainer/check valve cartridges (20,21).

1.3.6 Ensure that the hose is securely attached to the flushing adaptor and that the open end of the hose is also secure - the hot water could scald badly if the hose 'whips' unexpectedly.

1.3.7 Open the ball valve (13,14) using a flat bladed screwdriver from under the spigot, and allow the water to flow at full bore into the sink until the water flows absolutely clean.

1.3.8 Repeat on the other side so that both hot and cold supplies to the tap are flushed.

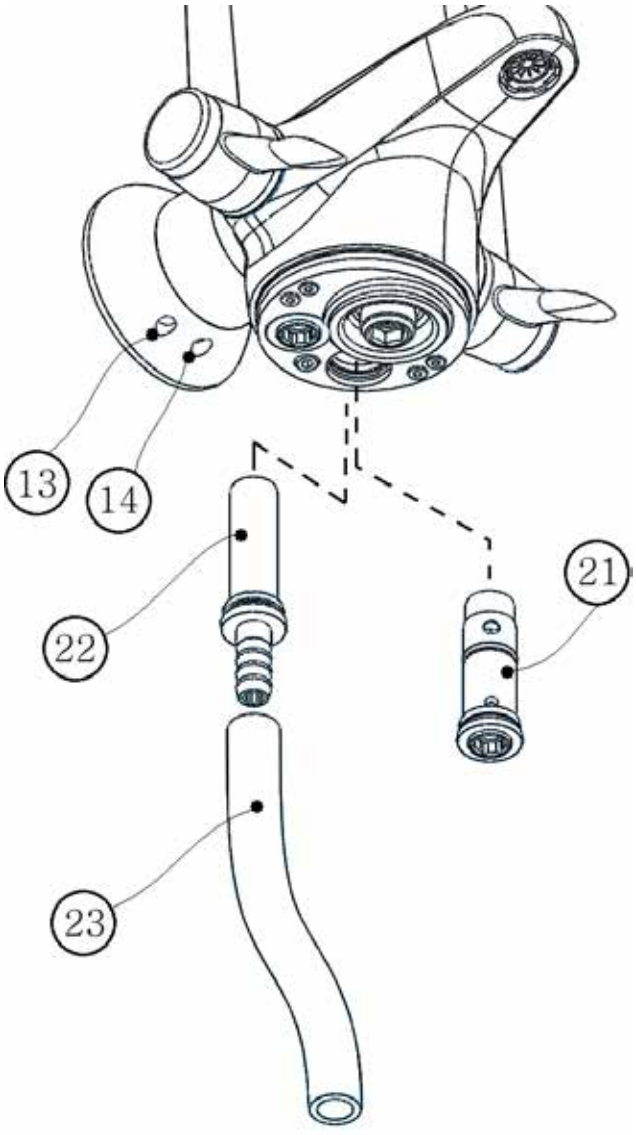
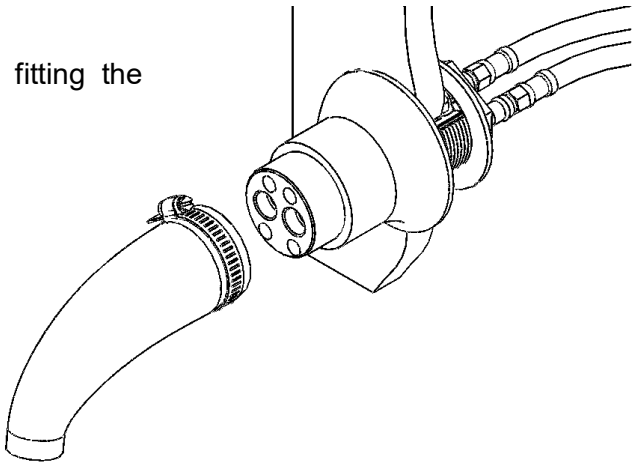


Diagram 2

Key to diagram above				
13	Hot isolating valve		14	Cold isolating valve
21	Strainer/check-valve cartridge		22	Flushing adaptor
23	Flushing hose			

1.4 FLUSHING OF PIPEWORK (METHOD 2)

Alternatively the pipework can be flushed before fitting the Optitherm to the spigot using Horne part no.5684.



1.4.1 Connect adapter to spigot with jubilee clip around the large end.

1.4.2 Tighten the jubilee clip.

1.4.3 Open the valves from under the spigot and allow water to flow at full bore into the basin until the water runs absolutely clean.

[2] COMMISSIONING

The commissioning process comprises sections 2.1 to 2.7 below. The tap cannot be considered commissioned until these processes are all carried out.

Note that it is NOT possible to commission the Horne OPTITHERM Thermostatic Bib Tap before the hot water service (boiler) has been commissioned.

2.1 FLUSHING

Before commissioning the Horne OPTITHERM Thermostatic Bib Tap, it is imperative that flushing of the pipework has been carried out in accordance with section 1.3 or 1.4.

2.2 TEMPERATURE CHECK (COLD WATER)

2.2.1 Open the cold water isolating valve (14) and lever (12), allow the water to run for a while and ensure that cold water flows from the spout (if hot water comes out, then the supplies are connected the wrong way around). Ensure that the tap is run for long enough to draw off any deadleg to be absolutely sure. Getting this right will save frustration later.

2.2.2 To check the temperature of the incoming cold water, open the blue/cold lever (12) only, and measure the temperature after 30 seconds. This should be within the range on table 1, page 1.

2.2.3 If hot water comes out of the spout when the blue lever is turned, the inlet hoses will have to be reversed behind the panel. This necessitates removal of the spigot (section 1.1 describes fitting of the spigot).

2.3 TEMPERATURE CHECK (HOT WATER)

2.3.1 To check the temperature of the incoming hot water, follow the procedure in section 4.3 for removal of the strainer/check valve cartridge on the hot side only (see also diagram in section 1.3)

2.3.2 Screw the flushing adaptor (22: diagram 2) into the space which was occupied by the hot strainer/check valve cartridge (20).

2.3.3 Ensure that the hose (23) is securely attached to the flushing adaptor. Take care that the open end of the hose is also secure and pointing down the drain as the hot water could scald badly.

2.3.4 Carefully open the hot ball valve (13) from under the spigot and measure the temperature of water that flows out from the tube after 30 seconds; it should be within the range on table 1, page 1.

2.3.5 Re-fit the strainer check-valve cartridge (20) and the bottom cover (16).

2.4 THERMAL DISINFECTION

2.4.1 Following the hot water temperature check it is recommended that thermal disinfection be carried out using the Water Quality Compliance Kit (part no.6006) as part of the commissioning procedure. Instructions for the thermal disinfection procedure are supplied with this kit

2.5 TEMPERATURE CHECK (MIXED WATER)

2.5.1 Check that hot and cold water supplies are at or near to their designated temperatures and pressures (see sections 2.2 & 2.3 and Table 1 on Page 1 for details).

2.5.2 Open the red (safe hot) lever only and allow water to run through the TMV.

2.5.3 Measure the temperature at the spout. This is the temperature of the mixed water. Ensure that the mixed water temperature is set appropriately. For healthcare applications, basin taps should always be set to 41°C.

If necessary, make minor adjustments to the temperature setting as described in Section 2.6 below.

N.B. For TMV3 applications the mixed water at the terminal fitting should never be set to exceed 41°C.

2.6 MIXED WATER TEMPERATURE ADJUSTMENT

2.6.1 The Horne OPTITHERM Thermostatic Bib Tap is approximately set at the factory to check for correct function. However temperature must be checked and adjusted on site to ensure correct installation. For healthcare applications, basin taps should always be set to 41°C.

For other applications, where applicable, the range of temperature adjustment is 35 – 44°C.

2.6.2 It should be noted that the Horne OPTITHERM Thermostatic Bib Tap requires a temperature differential of at least 11°C to work correctly (ie. the mixed water temperature must be at least 11°C lower than the hot water temperature and 11°C higher than the cold water temperature).

To alter the temperature setting, carry out the following procedure.

2.6.3 Unscrew the main bottom cover (16) using a strap wrench.

2.6.4 Check that hot and cold water supplies are within the designated temperature and pressure ranges (see sections 2.2 & 2.3)

2.6.5 Open the red/safe-hot lever (11) and allow water to flow until the mixed water temperature has stabilised. Make sure that the dead leg from the Hot Water Supply to the Horne OPTITHERM Thermostatic Bib Tap has fully cleared.

2.6.6 Using a 4mm hex key, turn the adjusting screw (19) clockwise as viewed from below † to reduce the mixed water temperature or anti-clockwise to increase it. Adjustments of not more than half a turn at a time should be made. The temperature at the outlet should be measured and allowed to stabilise after each adjustment.

† Note screwing the adjusting screw inwards towards the cartridge will reduce the set temperature. Screwing it outwards away from the cartridge will increase the set temperature. The screw has a conventional right-hand thread.

After making an adjustment, close the red/safe-hot lever (11) for ten seconds then re-open it and measure the mixed water temperature again. If a further adjustment is required, repeat the procedure.

2.7 COLD WATER FAILURE TEST

2.7.1 Close the cold water isolating valve (14) and, after 6 seconds, measure the mixed water temperature. The flow of mixed water should immediately stop and then a drip or trickle may or may not be seen. The temperature, measured after 6 seconds, of any water coming from the tap

should not be more than 3°C above the mixed water set temperature measured in 2.4.1 above. If no water comes out this is also acceptable.

2.7.2 If the Horne OPTITHERM Thermostatic Bib Tap performs satisfactorily, open the cold water isolating valve (14) – the Horne OPTITHERM has passed the cold water failure test.

2.7.3 However, if the water coming from the tap is at a temperature of more than 3°C above the mixed water temperature setting, then the Horne OPTITHERM is not shutting off the hot water supply properly. The cartridge is likely to be contaminated with dirt or damaged. Replace the cartridge according to section 4.5.

Note that the Horne OPTITHERM may, in some circumstances, fail the cold water failure test if the hot supply temperature is not 11°C above the set mixed water temperature. The hot water temperature can be checked as outlined in section 2.3 above..

[3] OPERATION

Operation of the Horne OPTITHERM Thermostatic Bib Tap is the same as that of a conventional tap. Open the red lever to draw hot water at a safe and comfortable temperature (controlled by the thermostatic mechanism). Open the blue lever to draw fresh, cold water. The user may notice a slight pulsing of the water stream if both levers are opened. This is normal and is not a cause for concern. Note that it is not normally necessary to open both levers simultaneously as the water supplied from the hot lever is at a safe and constant temperature.

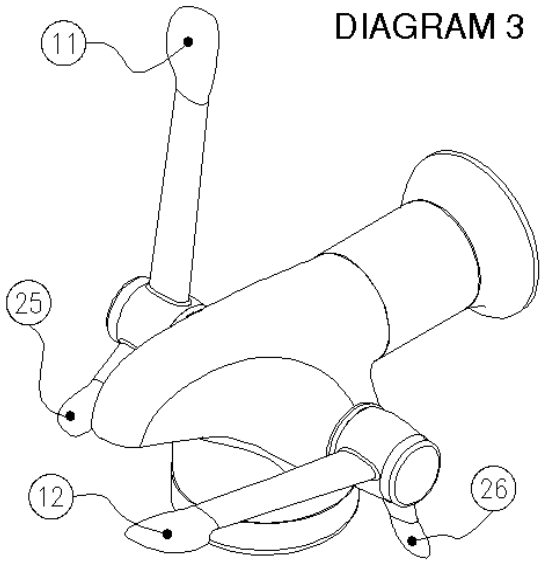
3.1 DUAL LEVER VERSION

The dual levers on the Horne OPTITHERM Thermostatic Bib Tap are a unique feature to prevent the spread of infection.

The intended mode of operation is that the user should open (turn-on) the tap using a thumb to push the short lever (25,26) backwards and downwards.

After washing, the long lever (11,12) should be returned to the original position with an elbow, thus avoiding re-contamination by touching the short lever again.

DIAGRAM 3



Key to diagram above				
11	Long lever (safe-hot)		12	Long lever (cold)
25	Short lever (safe-hot)		26	Short lever (cold)

3.2 SHORT LEVER VERSION

The short levers are pulled forwards to open (turn-on). And pushed backwards to stop the water flow.

3.3 LEVER CLUTCH

The Horne OPTITHERM is fitted with clutches on the levers to prevent lever breakage in the event of a lever being forced either accidentally or intentionally. Hence if the tap lever is found to be at an unexpected angle, simply push the lever in the opposite direction, beyond the normal 'stop'. One or two clunks should restore the lever to its correct position.

3.4 POTABLE WATER SUPPLY

When cold water is drawn (via the blue lever) from the Horne OPTITHERM Thermostatic Bib Tap the water completely bypasses the thermostatic mechanism. Hence, if the cold water supply to the Horne OPTITHERM Thermostatic Bib Tap is potable, so is the water drawn via the cold lever. NB: care should be taken to run the tap for at least 20 seconds before drawing water for drinking. This will ensure satisfactory purging of the spout.

[4] MAINTENANCE

Maintenance of all TMVs and thermostatic taps is essential. If a TMV does not operate properly, there is a risk of someone being scalded. The frequency of maintenance depends upon the condition of the water passing through the TMV. The remarks in 4.1.3 regarding in-service testing apply equally to maintenance. Generally, the thermostatic cartridge should be replaced after three years. The strainer/check-valve cartridges and ceramic disc cartridges should be replaced as necessary.

4.1 IN-SERVICE TESTING

4.1.1 Periodic testing should be carried out to check whether or not any deterioration has occurred in the performance of the Horne OPTITHERM Thermostatic Bib Tap.

4.1.2 A COLD WATER FAILURE TEST should be carried out as described in paragraph 2.7 above. If the water coming from the tap is at a temperature of more than 3°C above the mixed water temperature setting then the Horne OPTITHERM Thermostatic Bib Tap is due for maintenance.

NOTE: A TMV in need of maintenance can be undetectable in normal use and only become apparent when a disruption occurs in the hot or cold water supply pressures or temperatures.

4.1.3 The frequency of in-service testing depends upon the condition of the water passing through the tap. In-service testing must be carried out more frequently in hard water areas than in soft water areas. As a general guide, in-service testing should be carried out at least every twelve months and, where the water is hard, the interval may be less than six months. Experience of local conditions and the in-service testing record will dictate the frequency of in-service testing.

4.2 FLUSHING AND THERMAL DISINFECTION

4.2.1 Horne recommends periodic thermal disinfection in conjunction with high velocity flushing, using the Water Quality Compliance Kit (part no.6006). See paragraphs 1.3 and 1.4. The periodicity of this maintenance should be determined in conjunction with the current best practice.

4.3 CLEANING AND REPLACEMENT OF STRAINERS

4.3.1 Close the isolating valves (13,14) at the back underneath the tap spigot; open the levers and allow the residual water to drain.

4.3.2 Unscrew the main bottom cover (16) using a strap wrench.

4.3.3 Remove the strainer/check-valve cartridges (20,21) using a 12mm hex key or Horne special tool (part no. 23-5459).

4.3.4 The strainer can be removed from the top of the cartridge and cleaned or replaced as necessary.

4.4 TESTING AND REPLACEMENT OF CHECK VALVES

4.4.1 Close the isolating valves (13,14) at the back underneath the tap spigot; open the levers and allow the residual water to drain.

4.4.2 Unscrew the main bottom cover (16) using a strap wrench.

4.4.3 Remove a strainer/check-valve cartridge (20,21)

Remove the strainer basket from the top. Inspect the white plastic check valve for signs of obvious damage. Carefully insert a probe (pen or similar) down the strainer hole to ensure that the check valve element can move freely. It should spring back into the closed position when released. It should also be possible to blow through the cartridge from the top to the bottom, but not the other way around. If the check-valve is not in good condition, the whole strainer/check-valve cartridge should be replaced.

4.5 REPLACEMENT OF THERMOSTATIC CARTRIDGE

4.5.1 Close the isolating valves (13,14) at the back underneath the tap spigot; open the levers and allow the residual water to drain.

4.5.2 Unscrew the main bottom cover (16) using a strap wrench

4.5.3 To remove the thermostatic cartridge, first remove the thermostatic cover (18) using a 12mm hex key or Horne tool no. 5459. The thermostatic cartridge (17) can then be removed in one of 2 ways.

- ◊ Screw the Horne cartridge removal tool (part no. 5458) into the cartridge from underneath. This can then be pulled downwards to remove the thermostatic cartridge.
- ◊ Use a 4mm hex key to turn the adjusting screw (19) clockwise and remove it from the thermostatic cover (the adjusting screw has the same thread on it as the cartridge remover no.5458). This can be used to screw into the cartridge and remove it. Ensure that the adjusting screw o-ring is in good condition; clean; free from debris and lightly lubricated with water or WRAS approved silicone oil before re-assembly (see 1.1).

4.5.4 The new cartridge can be inserted into the tap body from below. If the o-rings are dry, they should be lubricated with some water or WRAS approved silicone oil.

4.5.5 Screw in the new thermostatic cover, again lubricating the o-ring if necessary.

4.5.6 Be sure to adjust the temperature and perform a cold-water failure test after replacing the cartridge. These processes are detailed in sections 2.4.1; 2.6 & 2.7.

4.6 REPLACEMENT OF CERAMIC DISC CARTRIDGES

4.6.1 The ceramic disc cartridges are reliable and expected to give a very long life provided that the strainers are maintained in a clean condition. If replacement is necessary a kit should be purchased from Horne for this purpose (part no. 5489). The kit will comprise…

- ◊ Endcap removal tool – (part no. 23-5459)
- ◊ Pair of ceramic disc cartridges (27) – (part nos. 44-5406 & 44-5407)
- ◊ Pair of torque control members (31) – (part no. 23-5410)
- ◊ 2 no. o-rings (32) (part no. 42-3452)
- ◊ 4 no. o-rings (33) (part no. 42-5416)
- ◊ 2 no. M4 screw (35) (part no. 41-5414)

4.6.2 Unscrew and remove the aluminium endcap using the special Horne tool (no. 5459)

4.6.3 Unscrew and remove the screw and washer (34,35). 2.5mm hex key needed.

4.6.4 Pull the lever outwards to remove

4.6.5 Remove the spline adaptor and torque control member (30,31). These may come out as one piece.

4.6.6 Unscrew the actuator sleeve (28), using a 26mm ring spanner or Horne tool no. 5459.

4.6.7 Using a 17mm spanner, unscrew the ceramic disc cartridge (27). This will be tight.

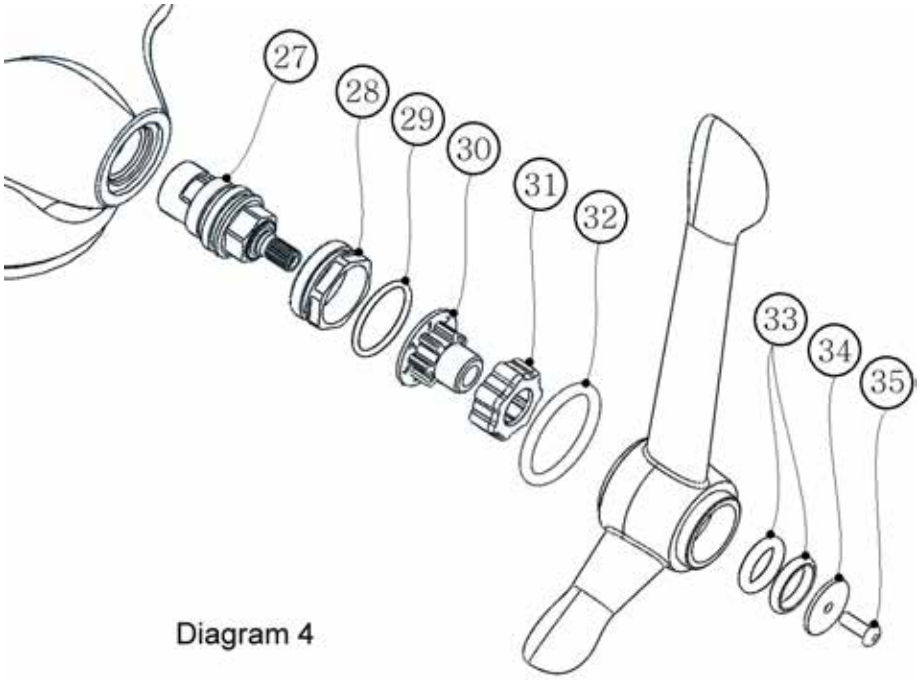


Diagram 4

4.6.8 Fit the replacement cartridge and tighten well. Note that the two cartridges are left and right handed. The cartridge with the small nicks around the 17mm spanner hex is for the left (hot) side of the tap. If the o-ring around the cartridge is dry, lubricate it with a little water or WRAS approved silicone oil.

4.6.9 Fit the new actuator sleeve and o-ring. If using a spanner for this take care not to over-tighten it as the thread is plastic - only light torque is needed. Horne tool no. 5459 can be used.

4.6.10 Remove the old torque control member (31) from the spline adaptor, and push-fit the new one. Lubricate this with a little (silicone) oil around the outside before final assembly.

4.6.11 Fit this assembly over the ceramic disc cartridge spline. Note that the spline has 20 teeth and the torque control member has 7 lobes. This allows 140 possible orientations of the lever. The correct orientation will have a lobe as near as possible to the vertical position (with the ceramic discs closed). It may be beneficial to experiment with orientations to ensure that the two levers end up aligned neatly with each other.

4.6.12 Re-fit the levers, replacing o-rings if necessary. The large o-ring goes on the in-board side and the two small ones go immediately under the penny washer on the out-board side.

4.6.13 Refit the washer and M4 screw tightly. Then fit the endcap (red on the left, blue on the right). Use the tool no. 5459 to tighten the endcap. This will prevent unauthorized removal.

4.7 REMOVAL OF TAP FROM SPIGOT FOR WORKSHOP MAINTENANCE

If desired the tap body can be removed from the spigot for off-site maintenance. Furthermore, a substitute tap body can be fitted while the original tap is being maintained. The process for this is as follows.

4.7.1 Close the isolating valves (13,14) at the back underneath the tap spigot; open the levers and allow the residual water to drain.

4.7.2 Unscrew the main bottom cover (16) using a strap wrench.

4.7.3 Loosen the tap retaining screw (15) until the head is flush or slightly proud of the bottom of the tap body.

4.7.4 Pull the tap away from the panel horizontally until it is free of the spigot. Pay careful attention not to drop it as it is rather heavy and may cause damage.

4.7.5 Rotate the tap to allow the residual water to pour out into the sink.

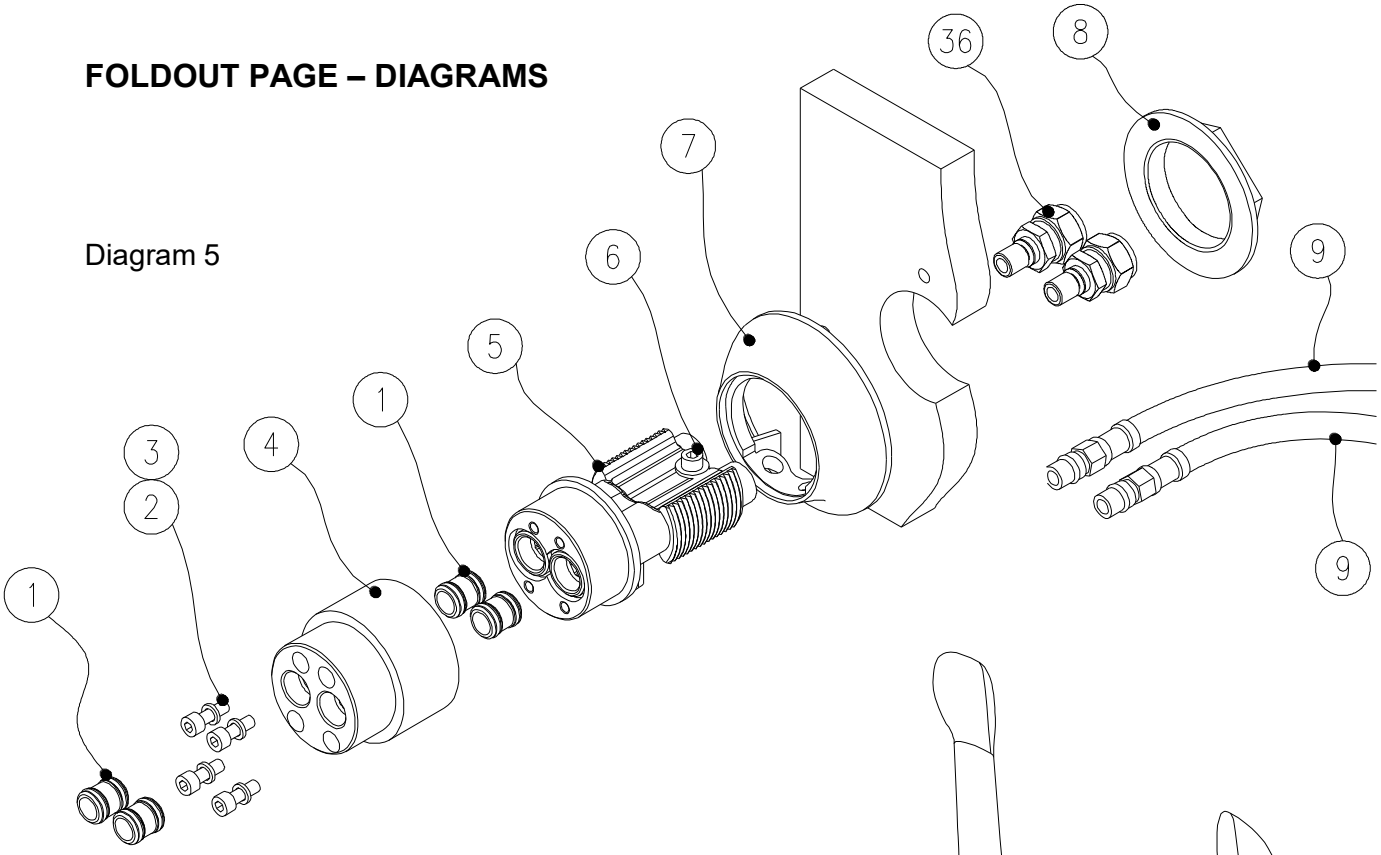
4.7.6 If a replacement tap body is to be fitted, follow the procedure in 1.2.7. The commissioning procedures in 2.4.1; 2.6 & 2.7 should be followed for the new tap body.

Key to Diagram on Page 10	
27	Ceramic Disc Cartridge
28	Actuator Sleeve
29	Act. Sleeve O-Ring
30	Spline Adaptor
31	Torque Control Member
32	O-Ring
33	O-Ring
34	Washer
35	M4 Screw

Key to Diagram on Page 12				
1	Interconnect Nozzles		2	M4 Screws
3	Fibre Washers		4	Extension Piece
5	Spigot		6	Earth Screw & Washer
7	Bezel		8	Bulkhead Nut
9	Optional Inlet Hose		10	---
11	Long Lever Hot		12	Long Lever Cold
13	Hot Isolating Valve		14	Cold Isolating Valve
15	Tap Retaining Screw		16	Main Bottom Cover
17	Thermostatic Cartridge		18	Thermostatic Cover
19	Adjusting Screw		20	Strainer/Check-valve (H)
21	Strainer/Check-Valve (C)		36	10mm comp. coupling

FOLDOUT PAGE – DIAGRAMS

Diagram 5



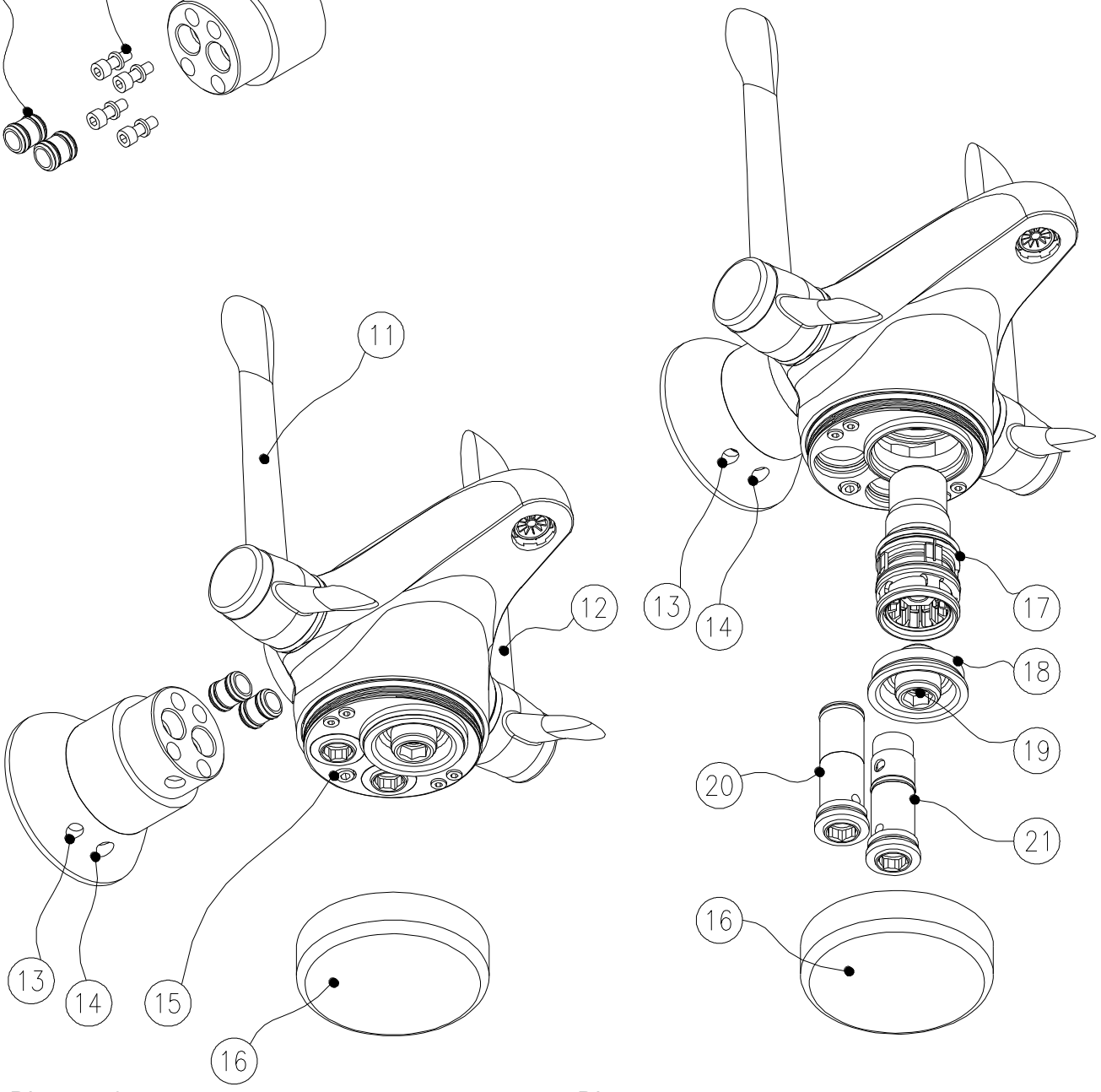


Diagram 6

Diagram 7

[5] FAULT FINDING CHART

SYMPTOM	POSSIBLE CAUSE	ACTION	REFER TO SECTION
Mixed water temperature too high	Temperature setting too high. Temperature has been set when hot water supply temperature was too low	Re-adjust temperature setting ensuring hot water supply is at correct temperature.	2.4.1, 2.6
	Hot water supply has migrated into cold water supply	Inspect/replace cold check-valve assembly (21)	4.4
	Thermostat Element has failed. This can be checked by carrying out a hot or cold water failure test.	Replace Thermostatic cartridge (17) and cover assembly (18)	2.7 & 4.5
Mixed water temperature too low	Temperature Setting too low	Re-adjust temperature setting	2.4.1, 2.6
	Hot water supply temperature has fallen.	Check hot water supply temperature.	2.3
	Cold water has migrated into hot supply	Inspect/replace hot check-valve assembly (20)	4.4
	Cold valve face requires cleaning	Remove thermostatic cover (18) and clean up valve face	4.5
Mixed water flow rate too low.	Partly blocked strainers	Clean strainers	4.3
	Unusually high pressure drop in supply pipework	Check all valves are full open. Check Pressurisation unit. Check mains supply	-
	Extra Demand added to system	Check pipe sizing	-
Mixed water temp does not respond to adjusting screw	Thermostatic cartridge is seized	Replace Thermostatic cartridge (17) and cover assembly (18)	4.5
	Hot and cold inlets reversed	Reverse inlet connections (9,10). Connect hose from hot supply to inlet nearest red endcap	2.2
	Hot water supply temperature is too low	Check hot water supply	-

5.1 FAULT FINDING CHART – CONTINUED…

Mixed water temp changes and is not steady	Thermostatic cartridge is seized	Replace Thermostatic cartridge (17) and cover assembly (18)	4.5
	Thermostat element has failed. (This can be checked by carrying out a hot or cold water failure test)	Replace Thermostatic cartridge (17) and cover assembly (18)	2.7, 4.5
Water at outlet runs full hot or full cold	Hot and cold inlets are reversed	Reverse inlet connections (9,10). Connect hose from hot supply to inlet nearest red endcap	2.2
Valve continues to pass cold water when hot supply is isolated	Cold valve face is contaminated with debris	Remove loose debris from between Thermostatic cartridge (17) and cover assembly (18). Or replace (17) and (18) if no loose debris is found.	4.5
Valve continues to pass hot water when cold supply is isolated.	Element has failed, or Slide-Valve seal is damaged, or Fouling at hot valve seat	Replace Thermostatic cartridge (17) and cover assembly (18)	4.5
	If water flowing is more than 11°C above required mixed water temperature then valve may not have been commissioned with an adequate hot water supply temperature; or the set temperature may be too high. NB If this is the case the valve may not offer scald protection	Re-commission the valve, closely following the guidance in Section 2.	2.2 thru' 2.7
	If water flowing is less than 11°C above required mixed water temperature then the hot water supply temperature may not be sufficient to cause thermal shut-off. (N.B. this is possible with combi boilers).	Repeat test with hot water temperature at least 11°C above required mixed water temp.	2.3, 2.7
Water flow pulses when both levers are opened at once	This can happen when cold water pressure is low relative to the hot water pressure. Note that it is not normally necessary to open both levers simultaneously as the water supplied from the hot lever is at a safe and constant temperature.	This is not a fault condition and is normal	-
Tap does not shut-off when levers are in the closed position	Possible contamination on interconnect nozzle (1) o-rings.	Remove o-rings, clean and re-assemble	-

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Contour 21

Contour 21
what works and why

An informative guide to commercial bathroom solutions for all sectors

Armitage Shanks

Contour 21
A solution for every sector

Contour 21 sanitary ware and fittings are designed to meet the rigorous demands of today's commercial installations. Tailored to the individual needs of each construction sector, Contour 21 blends striking aesthetics with enhanced durability and combines improved water efficiency with regulatory compliance.

Schools

Hospitals

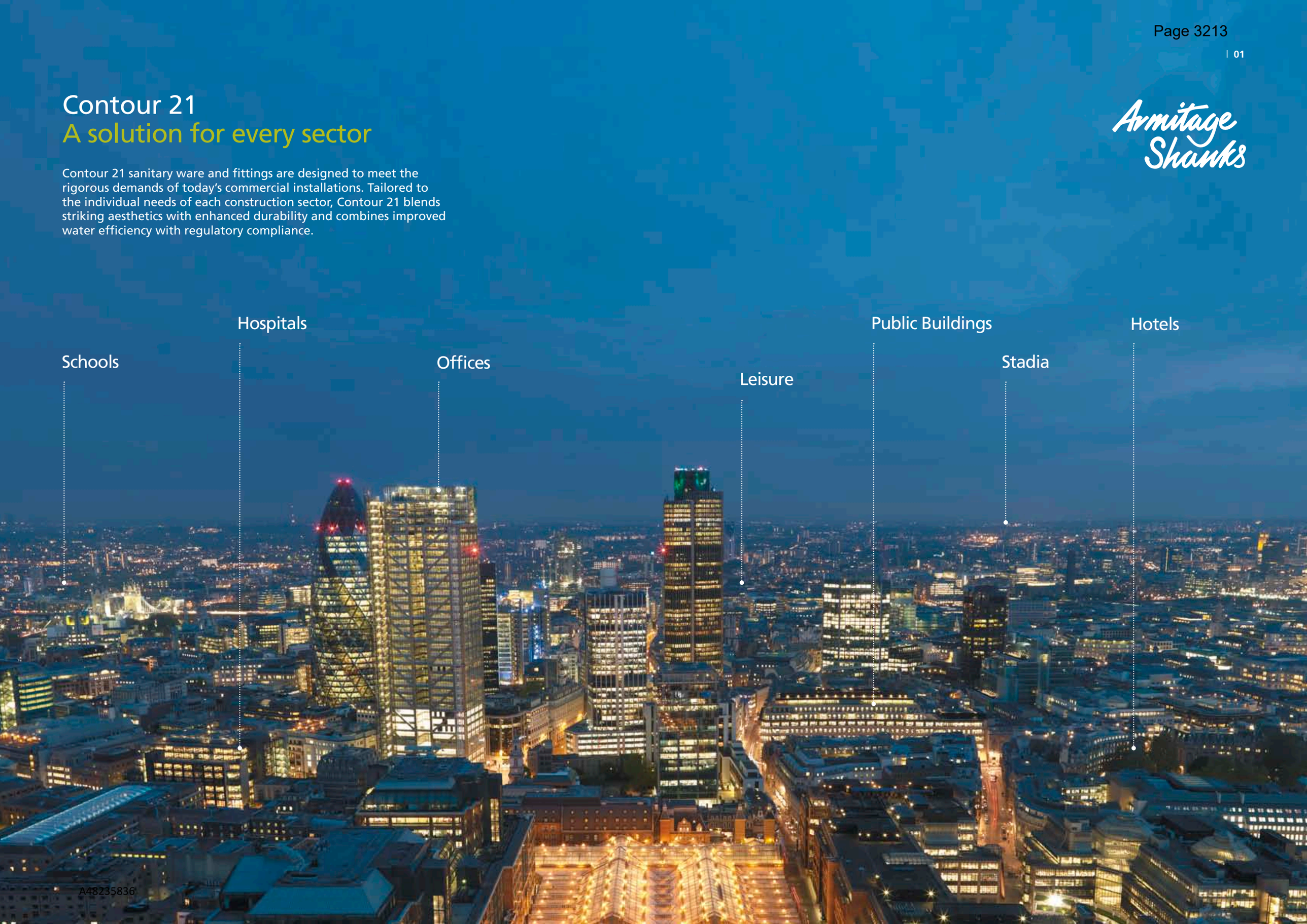
Offices

Leisure

Public Buildings

Stadia

Hotels



Contour 21
Every bathroom, every building, everywhere

Each type of building places a unique demand on the products and facilities within it. Contour 21 meets the performance and regulatory needs of every different sector, these are just a few of them.

Schools

Research has proven the common sense belief that clean, safe and functioning school toilets promote improved behaviour. Creating toilets pupils value, and can use when required, has a positive influence on their health, willingness to learn and attendance.

Armitage Shanks, the primary sponsor of the "Bog Standard" campaign for school toilet improvement, has been a key supplier to schools since 1910. School specific Contour 21 products have been designed in line with recent government guidelines to cope with heavy duty use and minimise water wastage.

Hospitals

The specification of sanitary ware and fittings for healthcare use can be a critical decision. For over 50 years Armitage Shanks has specialised in developing products that meet the complex functional requirements of hospital environments and the demands of government legislation.

Healthcare specific Contour 21 WC's and basins share modern ultra-hygienic designs which are fully compliant with the Department of Health's Health Technical Memorandum 64, while Markwik 21 mixers have been developed in line with the requirements of HFN30, HTM04 and HTM64.

Offices

Forward thinking businesses, concerned with helping their staff perform at optimum levels, realise their washrooms make a significant statement about the company's, and management's, attitude towards the people who work for it. While different organisations require different approaches, the fundamental specification factors are common; fitness for purpose, water economy, return on investment, equal access for all, easy cleaning and the effective use of space.

Contour 21's extensive product collection features hard-wearing water efficient products suitable for the smallest offices and the largest corporate headquarters.

Leisure

The scope of buildings designed to cater for the growth in leisure activities is vast; from the small town museum, to the regional music arena, from the local golf course's clubhouse to the newest shopping centre or mega mall. Whatever size the building, the necessity to design durable, aesthetically pleasing, easy to maintain washrooms is just as important.

Water management is particularly significant in entertainment or shopping facilities and Contour 21's water efficient products can help reduce water wastage and utility bills.

Part M

The Disability Discrimination Act 2004 requires that commercial and public buildings are suitable for use by disabled people. The Act defines disability as long term physical or mental disabilities, and short term conditions, such as pregnancy. The washroom requirements necessary for compliance with this Act are described in Part M of the Building Regulations.

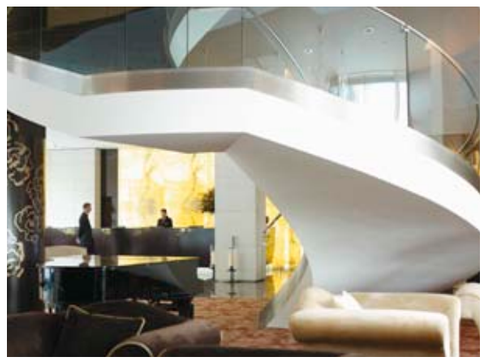
Armitage Shanks has developed Contour 21 Part M products in consultation with national disabled groups. These products meet the requirements of Part M and are suitable for an extensive range of applications.

Cardiff Millennium Stadium

Stadia

Over 1.3 million people visit Cardiff's Millennium Stadium annually. The UK's first fully retractable roof encloses almost 75,000 spectators for each major rugby or football game. Providing washroom facilities for the fans is the foundation of each successful event. While every venue may not share the prestige of the Millennium Stadium, functional, attractive and cost effective washroom design is just as important for local facilities.

Contour 21 is designed to cope with the demands of constant use in such heavy duty applications while minimising water wastage.



Hotels

Today's guest demands a lot from their room's en-suite; they expect to be impressed, they hope to be intrigued and they want to have nothing like it at home. For the hotelier however, there are concerns beyond simple aesthetics. They must balance style with ease of cleaning, performance with durability and ergonomics with water saving, particularly in public washrooms.

Achieving this may sometimes mean compromise, but with Contour 21 that is never necessary. Water efficiency, reliable performance, regulatory compliance and low maintenance are designed into every timeless Contour 21 piece.

Contour 21
Designed for the future

Commercial washrooms are subject to more stringent legislation, more inconsiderate use, harsher cleaning regimes and a tougher cost/benefit analysis than their domestic counterparts. Contour 21 has been designed specifically to meet these challenges.

Water Efficiency

Most commercial buildings, according to the Environment Agency, can reduce water consumption by around 50%. The Building Research Establishment's Environmental Assessment Method (BREEAM), sets the standard for best practice in sustainable design and is a useful measure of a building's level of achievement. When combined with the DEFRA backed Water Technology List, a collection of products that will make a positive impact on water saving, it will help to optimise the water efficiency of any project. Water saving is fundamental to the Contour 21 collection:

- Contour 21 dual flush WC's can flush on as little as 4.5/3 litres of water, a saving of up to 45%.
- Sensorflow 21's electronic washroom water management solution ensures water is only used when required.
- Contour 21 mixers are supplied with regulators to reduce their flow down to 5lt/pm at 3 bar.
- Contour 21 mixers include CLICK technology with "half" and "full" flow rate stops.
- Contour 21 non-concussive taps automatically stop water flow after a preset time, potentially saving 15%.

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Hygiene

Cleanliness and hygiene are the primary concern of public washroom users, many will even employ personal rituals aimed at avoiding physical contact with surfaces. They will use all their senses to judge hygiene; aroma, lighting, texture and colour all play a part. A washroom's physical layout and size can also be a factor as the last available WC or urinal "that no one else wants" is often perceived as below standard, or unclean. Contour 21 products can help to optimise the hygiene performance of a washroom:

- Contour 21 sanitary ware's smooth external contours eradicate dirt traps.
- Contour 21 sanitary ware's internal design minimises cavities that can harbour bacteria.
- Contour 21 and Sanura 21 hygenIQ urinal's anti-splash fin reduces urine splash back by up to 90%.
- Contour 21 WC's rimless pans eliminate a traditional bacteria haven.
- Contour 21 wall hung WC pans encourage faster more effective floor cleaning.
- Contour 21 back outlet basins are designed for "in wall" traps, making cleaning easier.
- Markwik 21 mixers can be easily disinfected, stopping the growth of bacteria such as legionella.

Durability

Commercial washrooms inevitably endure higher levels of use and receive rougher treatment than their domestic counterparts. Their durability will therefore be vital in delivering a cost effective design and specifying hard wearing, low maintenance products will help reduce full life costs. Rigorous daily cleaning regimes can degrade the finishes of products not designed for commercial environments. Commercial grade durability is built-in to the Contour 21 collection:

- Contour 21 sanitary ware is finished in high performance glaze for long term performance and colour retention.
- Contour 21 mixers use special seals to prevent commercial cleaning products entering the mixer body and damaging the cartridge.
- Contour 21 mixers and fittings are guaranteed for 5 years.
- Contour 21's anti-slip coating for baths and showers is guaranteed for 10 years.
- Contour 21 ceramic products have a lifetime guarantee.

Maintenance

Minimising the down-time of a commercial bathroom or washroom is critical to its success. An "out of order" sign will at best annoy the user, and at worst cost the owner money. Choosing sanitary ware that is designed for low maintenance, and also ease of maintenance, will help to keep a facility fully operational. Sometimes even the toughest products fail and the on-going availability of spare parts must also be considered when preparing a scheme. Contour 21 products are quick and easy to maintain and deliver long term performance:

- Contour 21 products are manufactured and guaranteed by the market leader in commercial sanitary ware.
- Contour 21 products are supported by a comprehensive, and long term, replacement parts service.
- Contour 21 sanitary ware's clean, organic design makes cleaning faster and more effective.
- Markwik 21 panel mounted mixers can be serviced from the front, without removing wall panels.

Sustainability

Sustainability is now seen as an area of competitive advantage in the commercial arena and choosing long lasting and environmentally responsible products is increasingly important. Armitage Shanks is committed to minimising the impact of its manufacturing processes on the environment. Over the last decade we have invested in cleaner, more energy efficient plant and introduced many sustainable practices:

- In 1998 less than 10% of the clay effluent we produced during vitreous china casting was re-used. Today over 80% of it is recycled for use in the production of floor tiles and bricks.
- In 2006 a new glaze Ultra Filtration System was installed at our Rugeley facility. As a result the glaze waste we send to landfill has reduced by 900 tonnes/ year and discharge fallen by 12,000m3/year.
- In 2000 producing 1kg of sanitary product created 1.36kg of CO2. By improving the energy efficiency of our manufacturing processes we have reduced that to 1.15kg of CO2/kg of product.

Contour 21
Multiple choices for multiple applications

For almost every sector of the commercial washroom market there is a Contour 21 product that has been designed to meet its needs. Because every piece has been developed with the performance, durability and regulatory demands of the broader commercial market in mind, many Contour 21 products can be used across several different market sectors. This flexibility allows the specifier to mix and match styles to create unique bathrooms over a broad spectrum of applications.

Contour 21
New products, new possibilities, new options

Established Armitage Shanks' products and exceptional new designs have joined the Contour 21 family, creating an extended sanitary ware solution for every commercial sector.

Contemporary styling defines the new members of the Contour 21 range. Redesigned Profile, Planet and Orbit basins, and a new Contour 21 under-mount basin, give a designer feel to offices and high-end leisure facilities.

The elegant new Portman 21 pedestal basin, when combined with the new close-coupled Contour 21 WC, offers the perfect product solution where domestic products are required in a commercial application. Even the humble urinal has been reimagined and improved, thanks to the anti-splash fin of the hygenIQ Contour 21 urinal.

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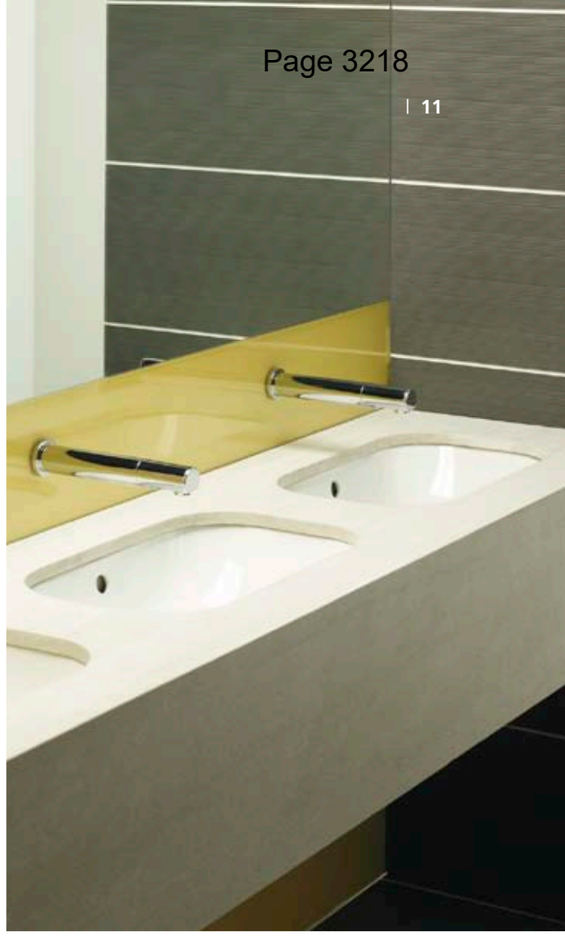
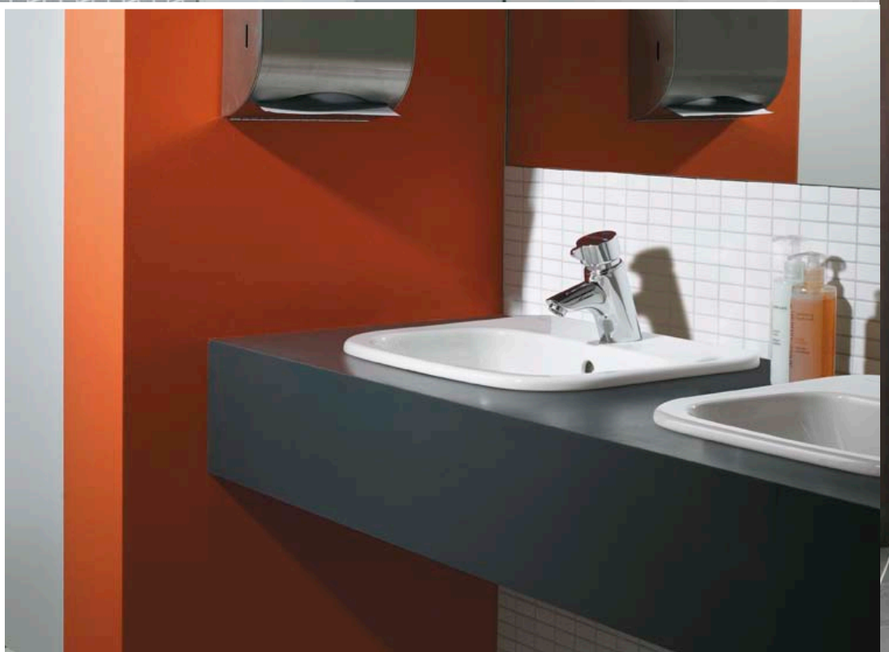
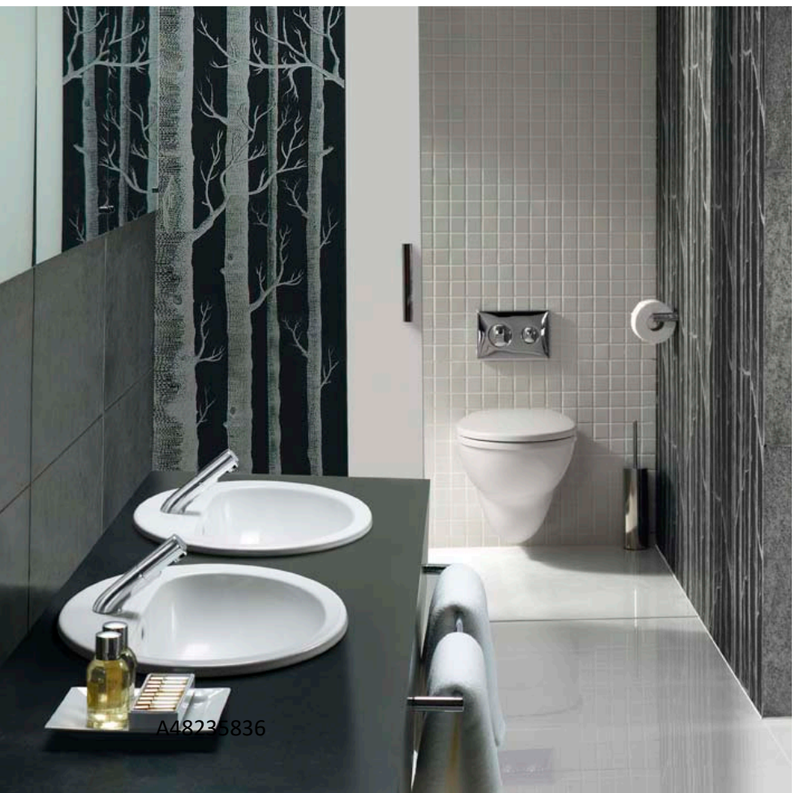


The additions to the Contour 21 family mean it can now serve an even wider range of sectors. While sharing the same durability and functionality, these new products have a "softer" commercial look suitable for installations where aesthetics are as important as performance.





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At the heart of every additional product is Contour 21's dedication to meeting the needs of the specifier. Despite looks that make these "designer commercial" products at home in a 4 Star hotel en-suite and executive washrooms, each one has been specially chosen for their ruggedness and fitness for purpose. From the smallest bathroom to the largest public facility, the extended Contour 21 collection has a choice of designs to satisfy the most demanding client.

Contour 21
Form and function perfectly combined

With durability and performance as its foundation, Contour 21's timeless and elegant aesthetics lift it beyond the constraints of normal commercial products. The "where, what and why" of the collections' key pieces are highlighted in the following pages.

Contour 21
Washbasins

Contour 21
37cm hand rinse basin (S212201)

- One centre tap hole
- No overflow or chain hole

See Contour 21 Price Guide for complete range of products and codes

Contour 21
37cm handrinse basin with right hand taphole (S247401) *Above*
37cm handrinse basin with left hand taphole (S247301) *Left*

- Right or left hand tap hole option
- No overflow or chain hole
- Part M compliant

See Contour 21 Price Guide for complete range of products and codes

Contour 21
60cm basin (S215501)

- Back outlet
- No tap holes, overflow or chain hole
- Concealed trap (not included)
- Suitable for use with ducts or panel systems
- Meets HTM64 requirements for clinical basins
- 50cm version also available

See Contour 21 Price Guide for complete range of products and codes

Contour 21
60cm accessible basin (S216801)

- One centre tap hole
- Improved design provides easier access for wheelchair users
- Side bars allow user to pull wheelchair up to basin
- Broad rim provides elbow support
- 55cm version also available

See Contour 21 Price Guide for complete range of products and codes

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Portman 21
40cm basin (S231401)

- Right, left or one central tap hole option
- Two tap hole option or no tap hole option
- With or without overflow or chain hole
- Compact modern design for general washroom use
- Basin with no overflow meets HTM64 requirements for non clinical use

See Contour 21 Price Guide for complete range of products and codes

Portman 21
55cm basin with semi-pedestal (S247801)
50cm basin with semi-pedestal (S248201) *Not shown*

- New from Armitage Shanks
- One, two or three tap hole option
- With overflow
- With or without chain hole
- Wall hung semi-pedestal
- Ideal for applications requiring a domestic look

See Contour 21 Price Guide for complete range of products and codes

Portman 21
50cm basin (S225401)

- Right, left or one central tap hole option
- Two tap hole option or no tap hole option
- With or without overflow or chain hole
- Midsize design for general washroom use
- Basin with no overflow meets HTM64 requirements for non clinical use

See Contour 21 Price Guide for complete range of products and codes

Portman 21
50cm basin with full pedestal (S248201)

- New from Armitage Shanks
- One, two or three tap hole option
- With overflow
- With or without chain hole
- Full height pedestal
- Ideal for applications requiring a domestic look

See Contour 21 Price Guide for complete range of products and codes

Portman 21
60cm basin (S225601)

- Right, left or one central tap hole option
- Two tap hole option or no tap hole option
- With or without overflow or chain hole
- Contemporary design for general washroom use
- Basin with no overflow meets HTM64 requirements for non clinical use

See Contour 21 Price Guide for complete range of products and codes

Portman 21
55cm basin with full pedestal (S247801)

- New from Armitage Shanks
- One, two or three tap hole option
- With overflow
- With or without chain hole
- Full height pedestal
- Ideal for applications requiring a domestic look

See Contour 21 Price Guide for complete range of products and codes

Profile 21
50cm semi-countertop basin (S249401)

- New to Armitage Shanks
- One central tap hole or two tap hole option
- With overflow
- No chain hole
- Stylish rectangular design will suit school, hotel or office projects

See Contour 21 Price Guide for complete range of products and codes

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Planet 21
50cm countertop basin (S248401)

- New from Armitage Shanks
- One central tap hole or two tap hole option
- With overflow
- No chain hole
- Stylish rectangular design will suit school, hotel or office project

See Contour 21 Price Guide for complete range of products and codes

Orbit 21
55cm countertop basin (S248601)

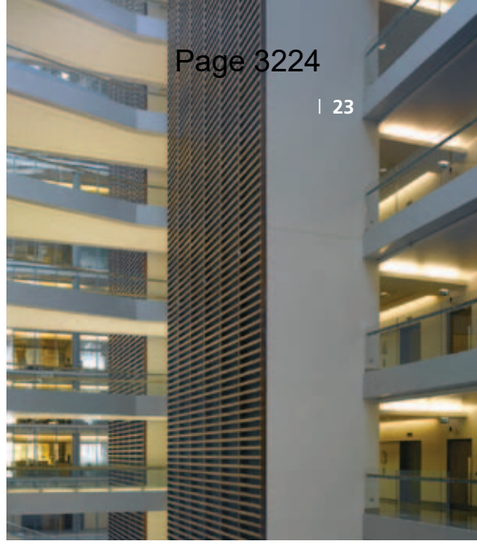
- New from Armitage Shanks
- One, two or three tap hole option
- With overflow
- No chain hole
- Oval design saves counter space when used in rows

See Contour 21 Price Guide for complete range of products and codes

Contour 21
50cm under countertop basin (S249601)

- New from Armitage Shanks
- Use with countertop or wall mounted taps, mixers and spouts
- With overflow
- No chain hole
- Simple contemporary design mounts under the counter

See Contour 21 Price Guide for complete range of products and codes



Airside
80cm washroom basin (S242801)

- One tap hole or no tap hole option
- No overflow or chain hole
- Incorporates shelf for personal belongings and washing kit

See Contour 21 Price Guide for complete range of products and codes

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Leadenhall
55cm washroom basin (S205801)

- No tap holes
- No overflow or chain hole
- Back outlet suitable for concealed trap
- Striking tapered profile, starkly upmarket design

See Contour 21 Price Guide for complete range of products and codes

Cherwell
42cm under countertop basin (S257001)

- Use with countertop or wall mounted taps, mixers and spouts
- No chain hole
- Simple and pure large hemispherical bowl
- Glazed or unglazed options

See Contour 21 Price Guide for complete range of products and codes

Marlow
56cm under countertop basin (S256001)

- Use with countertop or wall mounted taps, mixers and spouts
- No chain hole
- Graceful elliptical bowl for any modern washroom
- 48cm version also available

See Contour 21 Price Guide for complete range of products and codes

Contour 21
WC's

Contour 21
75cm projection back-to-wall WC (S305301)
70cm projection back-to-wall WC (S305501) *Not shown*

- Rimless pan
- 46cm raised height for easier wheelchair transfer
- Compliant with Part M requirements
- Available with 4.5 single flush or 4.5/3 dual flush

See Contour 21 Price Guide for complete range of products and codes

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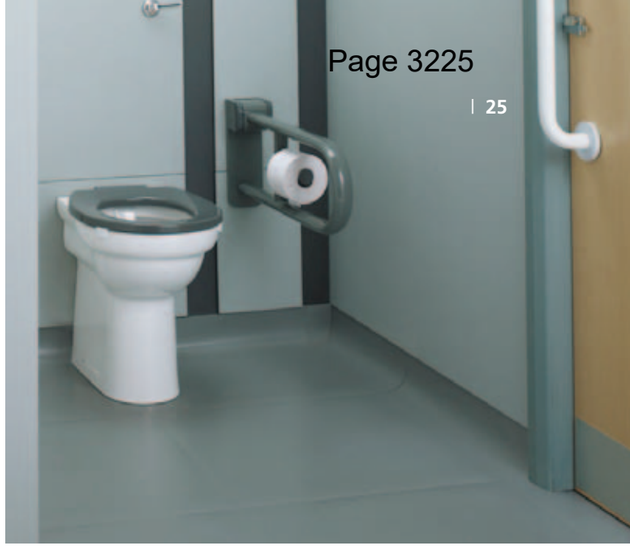

Contour 21
Standard height rimless back-to-wall WC (S305601)

- Rimless pan
- Standard 41cm height for general use
- Standard projection
- Available with 4.5 single flush or 4.5/3 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
46cm raised height rimless back-to-wall WC (S305701)

- Rimless pan
- 46cm raised height for easier wheelchair transfer
- Standard projection
- Compliant with Part M and HTM64 requirements
- Available with 4.5 single flush or 4.5/3 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
46cm raised height closed coupled WC (S305401)

- Rimless pan
- 46cm raised height for easier wheelchair transfer
- 75cm extended projection
- Compliant with Part M requirements
- Spatula lever for easy flushing
- 4.5 syphon flush with delay fill

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Rimless wall hung WC (S307601)

- Rimless pan
- Standard projection
- Compliant with Part M and HTM64 requirements
- Available with 4.5 single flush or 4.5/3 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Rimless wall hung WC (S307701)

- Rimless pan
- 70cm extended projection
- Compliant with HTM64 requirements
- Available with 4.5 single flush or 4.5/3 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Rimless wall hung WC (S307801)

- Rimless pan
- 75cm extended projection
- Compliant with Part M requirements
- Available with 4.5 single flush or 4.5/3 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Schools 305mm back-to-wall WC (S304601)
Schools 355mm back-to-wall WC (S304701) *Not shown*

- Lowered height for use by young children
- Can also be used as a back-to-wall WC
- Available with 4/2.6 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Schools 305mm close coupled WC (S304601)

- Lowered height for use by young children
- Can also be used as a back-to-wall WC
- Available with 4/2.6 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Schools 355mm close coupled WC (S304701)

- Lowered height for use by older children
- Can also be used as a back-to-wall WC
- Available with 4/2.6 dual flush

See Contour 21 Price Guide for complete range of products and codes

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Contour 21
Back-to-wall WC (S309501)

- New from Armitage Shanks
- Suitable for residential/domestic installations
- Available with 6/4 or 4/2.6 dual flush

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Close coupled WC (S309201)

- New from Armitage Shanks
- Suitable for residential/domestic installations
- Available with 6/4 or 4/2.6 dual flush

See Contour 21 Price Guide for complete range of products and codes

Wentworth
Close coupled WC pan (S316201)

- New from Armitage Shanks
- Standard height for general use
- Standard projection
- 6 litre syphon flush with side lever

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Brassware

Contour 21
Dual control thermostatic shower mixer (A4127AA)

- Twin lever control
- Wall mounted
- Suitable for concealed supply pipes

See Contour 21 Price Guide for complete range of products and codes

A48235836

Contour 21
Single lever thermostatic bath mixer (A4135AA)

- Sequential control
- Closed fist use, suitable for Part M applications
- Wall mounted
- Suitable for concealed supply pipes
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Thermostatic basin mixer (A4131AA)

- Single lever operation
- Closed fist use, suitable for Part M applications
- Suitable for concealed supply pipes
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Thermostic basin mixer (A4169AA)

- Single lever operation
- Closed fist use, suitable for Part M applications
- Suitable for concealed supply pipes
- Copper trails
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Dual control exposed thermostatic bath/shower mixer (A4128AA)

- Twin lever control
- Wall mounted
- Thermal disinfection facility
- Suitable for concealed supply pipes

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Single lever built-in thermostatic shower mixer (A4129AA)

- Sequential control
- Built-in design, suitable for concealed supply pipes
- Safety temperature stop
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Single lever exposed thermostatic shower mixer (A4130AA)

- Sequential control
- Exposed design, suitable for concealed supply pipes
- Safety temperature stop
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
15cm wall mounted tubular spout (A4180AA)
23cm wall mounted tubular spout (A4183AA) *Shown above*

- Ultra hygienic no-touch operation
- Separate sensor, proximity activated
- Requires pre-mixed water
- Auto flow shut off when sensor obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

A48235836

Sensorflow 21
23cm wall mounted compact tubular spout (A4849AA)
15cm wall mounted compact tubular spout (A4846AA) *Not shown*

- Ultra hygienic no-touch operation
- Built-in sensor, proximity activated
- Requires pre-mixed water
- Auto flow shut off when sensor obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Small basin spout (A4664AA)

- Ultra hygienic no-touch operation
- Reduced overall height
- Built-in sensor, proximity activated
- Requires pre-mixed water
- Auto flow shut off when sensor obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Basin spout (A4171AA)

- Ultra hygienic no-touch operation
- Built in sensor, proximity activated
- Requires pre-mixed water
- Auto flow shut off when sensor is obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

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Sensorflow 21
Deck mounted compact basin spout (A4851AA)

- Ultra hygienic no-touch operation
- Built-in sensor, proximity activated
- Requires pre-mixed water
- Auto flow shut off when sensor obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Electronic WC flush control, panel mounted (S359967)

- Proximity activated urinal flushing
- For rimmed and rimless urinal bowls
- Mains water or tank fed water
- Auto flow shut off when sensor obstructed
- Conceal cistern included
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Basin spout (A4176AA)

- Built in sensor, proximity flow activated
- Single lever manual temperature control
- Requires pre-mixed water
- Auto flow shut off when sensor is obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Electronic WC flush control, surface mounted (A4669AA)

- Proximity activated urinal flushing
- For rimmed and rimless urinal bowls
- Mains water or tank fed water
- Auto flow shut off when sensor obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
15cm wall mounted cast spout (A4178AA)

- Ultra hygienic no-touch operation
- Built in sensor, proximity activated
- Requires pre-mixed water
- Auto flow shut off when sensor is obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Shower sensor and solenoid (A4185AA)

- Ultra hygienic no-touch operation
- Proximity flow activated
- Requires pre-mixed water
- Auto flow shut off when sensor obstructed
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Piccolo 21
Basin pillar mixers (B9142AA)

- New from Armitage Shanks
- Anti vandal outlets
- Ceramic cartridge for accurate flow control and drip free operation
- 5lt/min laminar flow regulator
- Hard wearing easy to see hot and cold temperature indicators

See Contour 21 Price Guide for complete range of products and codes

Piccolo 21
Single lever basin mixer with pop up waste (B9135AA)

- New from Armitage Shanks
- CLICK water saving cartridge
- Fitted with 5 l/min airated flow regulator
- Flow straightener option to increase flow rate at lower pressures
- Ceramic cartridge for accurate flow control and drip free operation
- Top fix fitting
- Temperature limit stop option

See Contour 21 Price Guide for complete range of products and codes

Piccolo 21
One hole bath mixer (B9138AA)

- New from Armitage Shanks
- Ceramic cartridge for accurate flow control and drip free operation
- Temperature limit stop option
- Designed for use on low or high pressure systems

See Contour 21 Price Guide for complete range of products and codes

Piccolo 21
One hole bath/shower mixer (B9139AA)

- New from Armitage Shanks
- Ceramic cartridge for accurate flow control and drip free operation
- Temperature limit stop
- Shower handset, hose and adjustable wall fixing bracket
- Designed for use on low or high pressure systems

See Contour 21 Price Guide for complete range of products and codes

Piccolo 21
Two hole bath mixer (B9140AA)

- New from Armitage Shanks
- Ceramic cartridge for accurate flow control and drip free operation
- Designed for use on low or high pressure systems

See Contour 21 Price Guide for complete range of products and codes

Piccolo 21
Two hole thermostatic bath shower mixer (A4989AA)
Two hole bath/shower mixer (B9141AA) *Not shown*

- New from Armitage Shanks
- Ceramic cartridge for accurate flow control and drip free operation
- Designed for use on low or high pressure systems
- Shower handset, hose and adjustable wall fixing bracket
- Eco button limiting flow to 50% with manual override
- Built in thermostat with cool safe to touch body
- 40°C safety stop with override facility adjustable to 43°C, 46°C or 48°C

See Contour 21 Price Guide for complete range of products and codes

Avon 21
Self closing basin pillar taps (B8267AA)

- Anti vandal design
- No pop-up waste
- Dual indices
- Self closing shut off for water economy
- Closed fist use, suitable for Part M applications

See Contour 21 Price Guide for complete range of products and codes

Avon 21
Self closing exposed thermostatic shower valve (B8264AA)

- Anti vandal design
- Suitable for fixed/overhead shower head
- Mixed water outlet on top
- Self closing shut off for water economy

See Contour 21 Price Guide for complete range of products and codes

Avon 21
Self closing built-in thermostatic shower valve (B8265AA)

- Anti vandal design
- Suitable for concealed supply pipework
- Self closing shut off for water economy

See Contour 21 Price Guide for complete range of products and codes

Avon 21
Self closing basin mixer (B8263AA)

- Anti vandal design
- No pop-up waste
- Self closing shut off for water economy
- Closed fist use, suitable for Part M applications

See Contour 21 Price Guide for complete range of products and codes

A48235836

Markwik 21
Wall mounted thermostatic basin/sink mixer (A4553AA)

- For use in medical and healthcare applications
- Long single lever sequential operation
- Built in sterilisation system
- Designed in line with HTM64, HTM04 and HFN30
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Markwik 21
Single lever thermostatic basin/sink mixer (A4803AA)

- For use in medical and healthcare applications
- Long single lever sequential operation
- Insulated cool to the touch twin pillar body
- Designed in line with HTM64, HTM04 and HFN30
- Revised design eliminates swan-neck water pocket
- Easy retrofit for replacing old non-compliant fittings

See Contour 21 Price Guide for complete range of products and codes

Markwik 21
Wall mounted thermostatic basin/sink mixer (A4554AA)

- For use in medical and healthcare applications
- Ultra hygienic proximity sensor flow start and stop
- Built in sterilisation system
- Designed in line with HTM64, HTM04 and HFN30
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes

Markwik 21
Sterilising kit for thermostatic mixers (S8293NU)

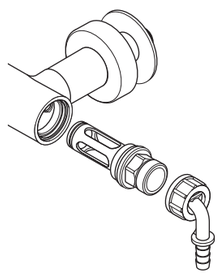
- For use with Markwik thermostatic healthcare mixers
- Easy sterilisation of healthcare mixers
- Front fixing, no need to remove fitting

See Contour 21 Price Guide for complete range of products and codes

Markwik 21
Wall mounted thermostatic basin/sink mixer (A4555AA)

- For use in medical and healthcare applications
- Ultra hygienic proximity sensor flow start and timer controlled stop
- Built in sterilisation system
- Designed in line with HTM64, HTM04 and HFN30
- TMV 3 approved

See Contour 21 Price Guide for complete range of products and codes



Markwik 21
Purging kit for Markwik Insulate products (A4556AA)
Purging kit (S8214AA) *Not Shown*

- For use with healthcare thermostatic mixers
- Flushes debris after installation
- Purging cartridge replaces maintenance cartridge
- Mixer can be flushed without affecting thermostat

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Urinals

A48235836

Page 3235

Contour 21
hygenIQ urinal (S611901)

- Improved hygiene performance
- Unique anti-splash cast fin, rimless bowl
- Splash back reduced by up to 90%
- 67cm overall height
- Concealed trap

See Contour 21 Price Guide for complete range of products and codes

Sanura 21
hygenIQ urinal (S611701)

- Improved hygiene performance
- Unique anti-splash cast fin, rimless bowl
- Splash back reduced by up to 90%
- 40cm overall height
- 50cm version also available
- Exposed trap

See Contour 21 Price Guide for complete range of products and codes

Sensorflow 21
Urinal sensor panel mounted (A4854AA)
Urinal sensor surface mounted (A4856AA)

- Proximity activated urinal flushing
- For rimmed and rimless urinal bowls
- Mains water or tank fed water
- Mains or battery power

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Part M

A48235836

Page 3236

Sensorflow 21
Wall hung WC Doc M pack (S6987AA right hand)
(S6986AA left hand) *Not shown*

- State of the art Part M compliance
- Hygienic sensor operated basin mixer
- Hygienic sensor operated WC flush
- Extended projection WC for easier wheelchair access
- Chrome grab rails and hinged support arm
- White seat with stability retainers

See Contour 21 Price Guide for complete range of products and codes

Contour 21
Close coupled WC Doc M pack (S6967AC right hand)
(S6966AC left hand) *Not shown*

- Part M compliant, LANTAC approved
- TMV 3 approved thermostatic sequential mixer
- Right or left hand tap hole basin option
- Raised height WC for easier wheelchair access
- White, blue or stainless steel grab rails and hinged support arm
- White, blue or grey seat with stability retainers

See Contour 21 Price Guide for complete range of products and codes

Part M Solutions
What works and why

- Armitage Shanks' informative guide to Part M washrooms
- Overview of section 10.3 of Part M4 of the Building Regulations
- Scale of provision required by BS6465 and section 5.7 of Part M3
- 10 approved Part M bathroom and washroom layouts
- 10 Armitage Shanks Part M packs

See our Part M Solutions brochure for
complete range of products and codes

Contour 21
Part M Grab Rails

White

Blue

Stainless Steel

Grey

Charcoal

Contour 21
Fixed grab rails

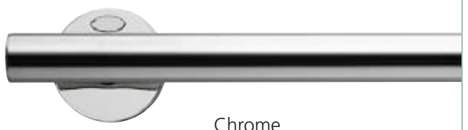
Available in white, grey, blue, charcoal, stainless steel or chrome to provide contrast with their background for visually impaired users. Each rail is made of 33mm diameter polyester coated aluminium (with the exception of the stainless steel and chrome rails), has concealed fixings for improved hygiene and security and is capable of supporting 200kg.

Contour 21
Hinged support arm

A robust support that folds up and out of the way, simplifying transfer from wheelchair to WC. Slip resistant contact surfaces enhance safety and promote confidence in the user. The hinged support arm can support 200kg when fixed using best practice.

See Contour 21 Price Guide for complete range of products and codes

Stainless Steel



Chrome

A48235836

Guarantee

lifetime
All ceramic products

5 years
on taps and mixers, toilet seats and cistern fittings

Our confidence in the quality and reliability of our product allows us to offer outstanding extended guarantees on all our products – where the product fails within 5/25 years/lifetime we offer a free replacement or replacement part (or nearest equivalent). So when your washroom has been satisfactorily installed and is working well, please ensure you register your guarantee.

This guarantee is transferable – it applies to the product not the purchaser provided the guarantee registration is passed on to the new owner.

Liability is limited to individual products and the guarantee does not cover the consequential loss or damage or installation costs. This guarantee does not affect your statutory rights. Products must be installed, used and cared for in line with our fixing instructions and local water regulations, and room must be adequately ventilated.

Parts (e.g. flushvalves) are guaranteed for five years and will be replaced if found to be faulty. The guarantee does not cover general wear and tear.

Applies to UK and Republic of Ireland only.

You can register for guarantees on a bathroom bought on your behalf by a plumber or builder.

Colours printed in this book are as near as possible to the manufactured range of Armitage Shanks quality bathrooms. For accurate comparisons of colours, see actual ware on display at Armitage Shanks retailers. Our policy is one of continuous improvement and we reserve the right to change specification and design at any time without notice.

Products can be subject to tolerances due to manufacturing processes.

the essential specifiers series

If you would like to request the Hospital, Brassware, Part M, School, Office, Contour 21, Hotel or Trade Price List brochures from our 'Essential Specifiers Series',

call 0800 590311

For further information on any of our products;

please call
0870 122 8822

or visit
www.thebluebook.co.uk

The bluebook has long been the most comprehensive guide to bathroom and washroom products. Now the bluebook DVD provides an interactive version allowing you to navigate through more than 1250 pages of detailed drawings and specifications instantly. Once installed on your hard drive blue bookcan be automatically updated with the latest product information every time you go online.

A division of Ideal Standard (UK) Ltd.

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P1453 01/11

additional resources
Further information about the Disability Discrimination Act is available from the following organisations.

Department for Work & Pensions
www.dwp.gov.uk

Disability Rights Commission
www.drc-gb.org

Direct Gov
www.direct.gov.uk

technical helpline
0870 122 8822

Armitage Shanks

HORNE®

Product datasheet: T108A2L

INCLUSIVE DESIGN TSV1 SHOWER PANEL
Includes integral Type 3 Approved thermostatic shower valve pre-plumbed within a white epoxy-polyester powder-coated aluminium panel with lever hand controls, single function handset, flexible hose and riser rail.

FEATURES & BENEFITS

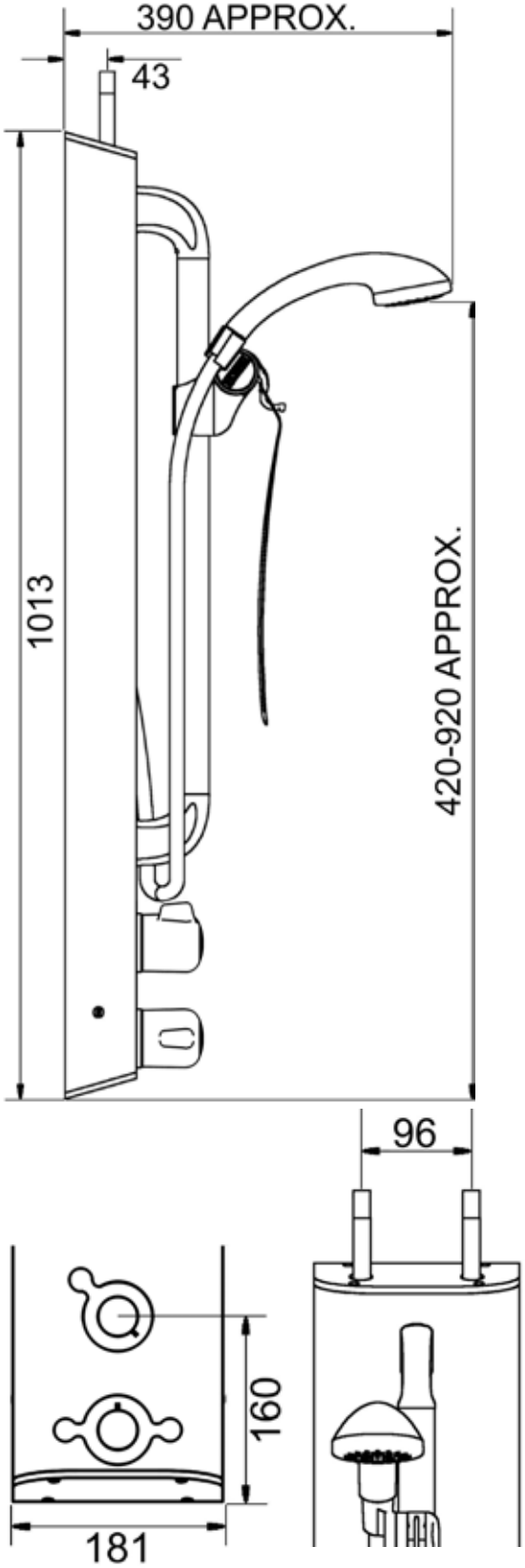
- Durable, anodised and powder-coated (RAL 9010, LRV=84) panel and robust fittings ensure long lifespan
- Integral healthcare-approved shower valve with BS 8300 compliant lever controls
- Robust riser rail with inclusive design handset holder
- Single function handset with 1.25m easy-clean and anti-kink hose with PVC liner
- Integral 8 L/min flow regulator for water and energy conservation
- Low level integral servicing valves for ease of maintenance and performance testing
- Fast and easy installation, for new or retrofit applications
- Pressure tested assembly, to 16 bar
- Optional accessories:
  - Pipe cover kit, same profile as panel
  - 2 metre hose, part number SA-108B

The TSV1-3 thermostatic shower valve is Type 3 and UK Water Regulation 4 Approved.

HORNE®

Product datasheet: T108A2L

Dimensions in mm Original Drawing Ref: 10367



The **T108A2L** shower panel is pre-plumbed with an integral dual control Type 3 approved thermostatic mixing valve, which features:

- Low level isolating servicing valves
- Integral fine mesh strainers provide essential protection to internal mechanism of the valve and ancillary fittings
- Angle pattern inlets enable easy access to the strainers
- Integral check valves prevent cross migration of water supplies
- Flushing facility to allow water supplies to be flushed clean during commissioning

Operating Conditions (Type 3 TMV):

- Range of temperature adjustment up to pre-set maximum, usually 41°C at the showerhead
- Range of hot water supply temperature: 55 — 65°C
- Maximum static pressure: 10 bar
- Minimum differential between hot water temp. and mixed water temp.: 5°C
- Range of maintained water supply pressures: 0.2—5 bar

Unequal pressures are usually acceptable if gravity-pressure supplies one of the inlets: minimum 0.2 Bar. When both supplies are pumped, pressures should be nominally balanced.

HORNE ENGINEERING LTD, P O BOX 7, Rankine Street, Johnstone, PA5 8BD.
Tel: +44 (0)1505 321455 Fax: +44 (0)1505 336287
Email: sales@horne.co.uk web: www.horne.co.uk

Certificate No. FM 1224

HORNE ENGINEERING Ltd reserve the right to alter design and specifications without notice.

NEW SOUTH GLASGOW HOSPITALS

Y40 PERFORMANCE SPECIFICATION FOR BUILDING MANAGEMENT SYSTEM AND AUTOMATIC CONTROLS

VOLUME 1
GENERAL REQUIREMENTS

Ref: ZBP-XX-XX-SP-660-401

Status: T3 for Construction

Rev: F

Date: March 2014

WALLACE WHITTLE is a trading name of TUV SUD Ltd
TUV SUD Ltd is a TÜV SÜD Group Company

Specification Check / Revision Sheet

Project	**New South Glasgow Hospitals**	Project Number	**2900**
Service (s)	**Mechanical**	Ref	**ZBP-XX-XX-SP-660-401**
Performance Specification Title	**Building management system and automatic controls Volume 1 – General requirements**	Date	**May 2010**
Prepared By	**SP**	Checked By	**AP**

Revision Ref.	Date of Revision	Page N$^{o(s).}$	Revision Details	Checked By
01	June 10		Initial issue for comment	AP
02	Nov 2011	-	Issued T1 Tender Review. Minor revisions in general text.	AP
A	Jan 2012	7 to 13, 15 to 17, 19, 22, 32 & 41	Amended as indicated in accordance with team comments. Issued for T3 Construction	SP
B	Oct 2012	-	Updated at completion of detailed design	SP
C	Nov 2012	-	Clause numbering added Clauses 11.6, 11.13 and Y41-915 amended	SP
D	June 2013	11, 12, 15, 16, 17, 21	Updated following RDD Review	SP
E	January 2014	12, 13, 14, 16	Amendments as indicated following team comments	SP
F	March 2104	-	Amended as indicated in accordance with RDD process	SP

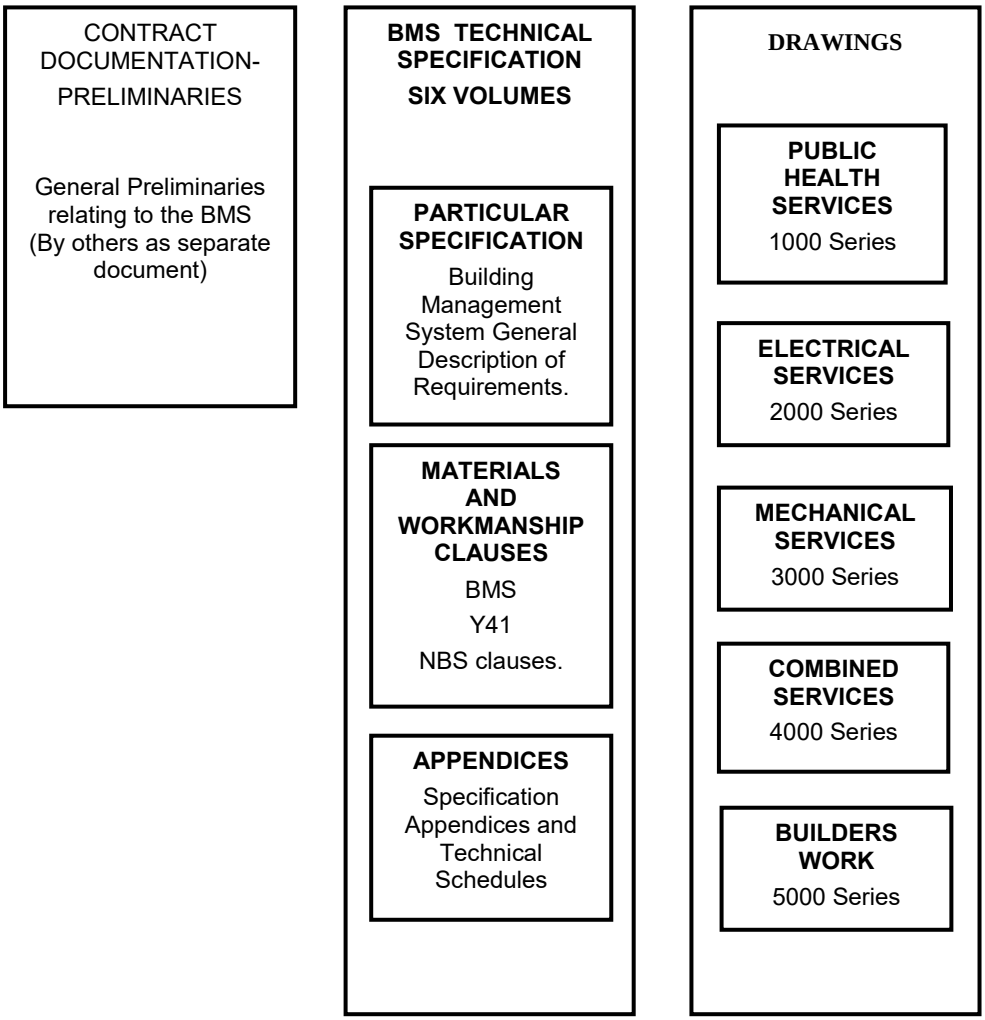
TUV SUD WALLACE WHITTLE
RDD COMMENT/RESPONSES

Document Revision Reviewed	**B**
RDD COMMENTS	**RESPONSE**
Front page - Development of the BMS/Controls will be managed via BMS specification clarification log	Noted
6.0 p.8 –to be developed via log process	Noted part of FDS review process
10.0 p.11 – This will be a replicated head end @ new location in labs bldg	Clause 11.1 amended to suit
10.0 p.11 para 9 – refer to log	Noted part of FDS review process
10.0 p.11 para 14 – refer to log for definition of manual control	Noted part of FDS review process
P.13 * - Link to utility monitoring – refer to logs	Noted part of FDS review process
11.0 p.14 – Boston to allocate space in rack for future retained estates server	Text amended
11.0 p.15 development required re metering (logs)	Noted part of FDS review process
11.0 p.15 – see previous note re space for retained estate server	Text amended
11.0 p.15 – storage requirements to be developed (logs)	Noted part of FDS review process
11.0 p.16 – to be reviewed via logs	Noted part of FDS review process
11.0 p.16 (AMT) – likely to be limited to fiscal meters with remainder handled on integrated ERM	Text amended as part of FDS process
11.0 p.17 – does this include positional feedback	No
11.0 p.18 – further development required via logs & Schnieder	Noted part of FDS review process
11.010.3 p.18 – has this been decided?	Text amended
11.0 p.19 – to be reviewed with Board FM team	Noted part of FDS review process
11.0 p.20 – scope to be developed & agreed	Noted part of FDS review process
11.0 p.20 (drawings) – metering strategy, meter tree, graphic proposals, controls strategy	Text amended
11.0 p.22 – review ???? supported by UPS	All plant disabled under power failure and reinstated in accordance with generator load management
Y41 445A – PC specification to be agreed with NHSGGC, HI & T	Noted part of FDS review process
Y41 915 – refer to BREEAM –MAN01	Text amended

Y40 BUILDING MANAGEMENT SYSTEM

SPECIFICATION VOLUME INDEX

OVERALL FRAMEWORK OF TENDER DOCUMENTATION
BUILDING MANAGEMENT SYSTEM TECHNICAL SPECIFICATION



Y40 VOLUME 1 – GENERAL REQUIREMENTS

CONTENTS

MATERIALS AND WORKMANSHIP CLAUSES

APPENDICES

1.0 GENERAL INTRODUCTION

1.1 Purpose of Document

This Specification is based on the NBS suite of specifications.

The development of the design, manufacture, supply, installation, wiring, setting to work and commissioning of the works described in this document shall be undertaken by the Specialist Sub-Contractor and is referred to in this document as “the Specialist”.

To carry out the development of the design, the Specialist shall obtain the necessary supporting documentation including that listed in Appendix A.

This specification relates to the Building Management System (BMS) serving the Adult and Children’s’ Hospitals and the adjacent Laboratory. The BMS serving the Laboratory/FM Building is covered by separate specifications, but the two parts of the project will ultimately form a single integrated system.

This specification shall be read in conjunction with all other mechanical and electrical engineering services specifications and the architectural drawings.

1.2 Description of Project

The two hospitals providing Adult and Children healthcare are located on the existing Southern General Hospital site and provide some 1400 beds plus associated treatment and diagnostic departments, and support facilities.

The hospitals are accommodated in a 12 storey building comprising a four storey podium and 8 storey tower rising out of the podium.

A basement houses FM support facilities and a tunnel link from the laboratory/FM building.

Plantrooms are generally located at roof level at levels 2, 3, 4 and 12, and house ventilation plant, main heating and cooling stations, and HWS generation, electrical substations and other key plant.

The building is generally constructed from reinforced concrete.

A central energy centre to the north of the hospital and laboratory/FM buildings houses heating, cooling, CHP, standby generation and fuel storage.

Main services emanate from the energy centre to serve the hospital building and laboratory/FM building, with future capacity to serve the retained estate on the remainder of the site.

2.0 EXISTING SITE AND SERVICES

Not applicable

3.0 SCOPE

The scope of work covered by this Performance Specification shall include the following:-

- Building Management System and Automatic Controls
- Power and control wiring to plant and control devices
- All containment within plantrooms necessary for the BMS and operation of plant
- Conduits in or on walls outside plantrooms (secondary containment)
- Local cable containment from main distribution boards to plant items
- Setting to work and commissioning

The following is specifically excluded from the scope of this performance specification:-

- BMS system within Laboratory/FM Building
- Host data/IT network (specified elsewhere)

4.0 PERFORMANCE SPECIFIED SYSTEMS

The BMS is a performance specified system and this specification outlines the requirements to be met by the system.

5.0 SPECIFIC EXCLUSIONS

The following is specifically excluded from the scope of this Performance Specification:-

- Power wiring feeds to main distribution boards
- Main trunking and tray runs outside plantrooms (primary arterial containment)
- The BMS shall reside on the FM data network. IT network sockets shall be provided by others in plant areas to the Specialist's requirements

6.0 INTERFACES AND DEMARCATIONS

The BMS shall be provided as a complete working system serving the Adult and Children's Hospitals and the Laboratory/FM. Allowance shall be made for future extension to other parts of the hospital site.

The BMS supplier shall provide information to other parties for mains power supplies and fire alarm system interfaces, etc.

The BMS shall be integrated with a host Internet Protocol network which will support communication, interaction, data transfer and data retrieval from and between the various engineering systems in the building. The Building Management System shall be fully integrated with this network and shall provide control over the engineering plant and facilities to enable the management of maintenance and energy usage. The BMS shall be connected to the host network via gateways.

The BMS will be provided with Graphical User Interface points which will permit the interrogation of all systems integrated with the host Internet Protocol network down to component level. It is not intended that the BMS will control the system but rather will monitor component status and provide fault alarm indication at the Graphical User Interfacessss.

7.0 APPLICABLE STANDARDS

All elements of the works shall be in accordance with the requirements of current legislation, regulations and industry standards unless otherwise stated.

The Building Management System shall accord with all appropriate Hospital Technical Memoranda, Codes of Practice and relevant British and European Standards listed in all Scottish Health Technical Memoranda and Appendix A.

8.0 DESIGN CRITERIA

External Design Conditions

Winter	-	-6°C sat
Summer	-	26.2°C db 18.5°C wb
For operating theatre plant	-	30°C db 20°C wb
Sizing for refrigeration plant		30°C

8.1 Internal Design Conditions

The internal design criteria for each space including temperature and humidity, ventilation rates, lighting level, noise levels, etc are given on the environmental sheet of the Activity Data Base (ADB) information for each room.

The specialist shall set the automatic control systems to achieve the environmental requirements for each space as defined therein.

8.2 System Operating Conditions

Incoming gas pressure:

200mbar at medium pressure
21mbar at low pressure

Incoming water pressure:

0.7bar minimum

MTHW heating at energy centre:

Flow Temperature: 105°C
Return Temperature: 75°C

LTHW CT heating:

Flow Temperature: 80°C
Return Temperature: 65°C

LTHW VT heating:

Flow Temperature: 75°C
Return Temperature: 70°C

LTHW LVT heating:

Flow Temperature: 60°C
Return Temperature: 50°C

Primary Chilled Water Flow Temperature at energy centre	-	6°C
Primary Chilled Water Return Temperature at energy centre	-	14°C
Secondary Chilled Water Flow Temperature at hospital	-	8°C
Secondary Chilled Water Return Temperature at hospital	-	13°C
Chilled Beam Flow Temperature	-	15°C
Chilled Beam Return Temperature	-	18°C

8.3 Electricity Supply Characteristics

LV power characteristics: 400 / 230 V, 3 phase, 50 Hz. 230 V, 1 phase, 50 Hz.

8.4 Energy and Carbon Target

The project has stringent energy and carbon targets and *the BMS* shall be selected and commissioned to achieve optimum performance.

Energy target: 40GJ/100m^3

Carbon emissions target: 80kg/m^2

9.0 LIAISON

The Specialist Sub-Contractor shall include for liaison with:-

Health and Safety Professionals. As well as the Health and Safety requirements of this specification, the Specialist Sub-Contractor shall include for close liaison with Health and

Safety professionals including the Hospital's Health and Safety Advisors and the CDM Co-ordinator and shall comply with the CDM Regulations and all Health and Safety regulations.

The Contractor. The Specialist Sub-Contractor shall liaise with the Contractor through whom all communications must flow. Drawings and other documentation will be available via the Contractor. The Specialist Sub-Contractor shall include for liaison with members of the Contractor's team with an interest in the planning and administration of the Building Management System.

Other Specialist Sub-Contractors. The Specialist Sub-Contractor shall liaise with other specialist sub-contractors as necessary to ensure that all interfaces between the Building Management System and other systems are allowed for. This shall include but not be limited to:-

- Fire Alarm and Detection specialist
- Security systems specialist
- IT Specialist
- Electrical Network Management System (ENMS) specialist

The Hospital. The Specialist Sub-Contractor shall include for liaison in conjunction with the Contractor with members of the Hospital's team with an interest in the planning and administration of the Building Management System.

The Architect. The Specialist Sub-Contractor shall include for review of the Architect's reflected ceiling plans and wall elevations and shall liaise as necessary with the Architect to assist with the production of these drawings. The Specialist Sub-Contractor shall ensure that the reflected ceiling plans and wall elevations show all control devices and equipment in the correct positions.

The Fire and Risk Engineer. The Specialist Sub-Contractor shall follow the recommendations of the Fire and Risk Engineer in the production of the drawings.

The Mechanical Services Contractor. The Specialist Sub-Contractor shall liaise with the Mechanical Services Contractor to obtain/provide details of:-

- Motor power requirements and characteristics
- Valve/coil pressure drops and limitations

The Electrical Services Contractor. The Specialist Sub-Contractor shall liaise with the Electrical Services Contractor to provide details of:-

- BMS power supply requirements
- Cable tray requirements

Building Control. The Specialist Sub-Contractor shall liaise, with and adhere to, the requirements of the Building Control Officer.

Any other member of the Project and Trust teams concerned with the planning and administration of the project.

10.0 BMS OVERVIEW

The computer-based system shall provide Direct Digital Control (DDC) to control, monitor and provide historic data logs for the relevant equipment and processes. The BMS shall utilise a network of standalone DDC controllers associated with each equipment/plant system. Controllers shall communicate using an open communication protocol in accordance with ISO 16484-5 and CEN TC247 at management and automation levels. Use of open protocols shall also allow the integration of plant manufacturer's bespoke controllers/control strategies where applicable.

~~The BMS shall interface with the existing system(s) within the Estates department and where possible allowing access to view all parameters within the system. This is envisaged to be in the form of a 'proprietary mimicking' package with the existing Trend head end.~~

The Specialist shall allow for an additional P.C front end for administration and programming.

The Graphical User Interface shall connect to network controllers via the Engineering Network.

The Graphical User Interface shall be covered by the 1hr UPS back up for the Engineering Network server. This is a standalone UPS provided by the Specialist.

The BMS front end shall access real time data from the BMS network and have password security and allow users to view and edit all BMS values via user friendly colour graphic displays as well as receive alarms and logged data.

Network controllers shall be located in major plantrooms and key riser locations and connect to a field network of DDC controllers associated with each equipment/plant system.

Each network node shall function as a router and the mesh network shall have a proactive discovery function to constantly search for and remember optimal linkages, providing a diverse routing capability.

The Specialist shall provide a wireless network graphical commissioning and maintenance tool, where network display screens graphically present the mesh network, all the devices in it and their connectivity levels.

The DDC controllers shall also communicate on a 'peer to peer' network level with frequency inverters to allow full bi-directional data transfer to eliminate BMS point duplication and provide more efficient performance, monitoring, alarming and metering.

The BMS shall include the facility to monitor intelligent utilities meters via an industry standard protocol interface (e.g. Bacnet or Modbus), whereby consumption metering information shall be available on the BMS.

The BMS shall generate escalating alarm screens when plant is run under manual control.

Integrated systems information shall be presented in a layered presentation format using standard layouts, symbols and colour schemes agreed with the client. The minimum level of functionality required for the integrated systems is shown in the table below:-

Integrated System	Indication	Graphic Interaction
Fire Detection and Alarm	Addressable fire zone status (normal, alarm, fault). Fire panel fault.	Monitor progress of fire over split screens with alarm history and ongoing mapped events, Isolate, silence, evacuate, test
Smoke Damper Control System	Damper open/closed/fault status. Fully automated complete with reset facility.	View status and alarms.
Smoke clearance systems	System inputs and operating status, alarms.	Monitoring.
Fire Control Interface Points	Fireman's override switch status.	Monitoring
Chillers (including MRI Chillers)	Operating status and efficiency, energy consumption, alarms, temperatures, flow switches etc.	Monitoring
Boilers and Pumping Equipment	Operating status and efficiency, energy consumption, alarms, temperatures, flow switches etc.	Monitoring
Boiler House	Presentation schedule.	
Helipad Fire-fighting Systems	Status (normal, alarm, fault). Fire panel fault.	View status and alarms.
Generators	Operating conditions, alarms Power Output.	Monitoring, link to plant reinstatement and load shedding. Part of ENMS. Critical items to be monitored by BMS
Meters	Metered data.	Monitoring, link to Utilities Management software.
Inverters	Operating status Motor current consumption, power consumption, speed and frequency. Manual override.	Scheduling, speed control, changeover with flying start and link to Utilities Management software.
HV/LV Switchgear	ACB status/tripped Bus Coupler status Power consumption Load profile information Logged data ASCO switch status Fault and alarm conditions UPS/IPS and battery status. Presentation schedule, HV & LV switch gear.	Part of ENMS system which are monitored by BMS.
Intruder Alarm	Common alarm panel fault.	Monitoring.
Nurse Call	System fault per department.	Monitoring.
Medical Gas Alarms	Main plant alarm and fault.	Monitoring.
Sprinklers	System status, alarms and faults	Monitoring.
Gas Fire Extinguishing System	Operating status, alarms and faults	Monitoring.
IPS	Operating Status Alarm/Fault	Monitoring.
Integrated System	Indication	Graphic Interaction
UPS	Operating Status On Battery/Fault	System status monitoring.

LZC Systems (CHP & PV)	Operating status power consumption energy provided	System monitoring.
RO Water	Operating Status Power and water consumption fault	Active mimic of each system front end, monitoring.
Water filtration plant	Operating Status Power and water consumption fault	Active mimic of each system front end, monitoring.
Surgeons Panels	Mimic of panel Indications. Clocks, lighting, IPS/UPS, mains power, generator power, UCV/HVAC status, temperature, humidity, air sampling, medical gas alarms and AGS system indicators.	Active mimic of each surgeon's panel.
Energy Centre Fuel System Leak Detection	Leak detection in fuel tank bunds within energy centre.	Monitoring.
Automated Material Transfer Systems (AGV)	System fault/alarm.	Monitoring.
Pneumatic transfer systems	System zone healthy - fault.	Monitoring.
Lifts	System fault.	Monitoring.
Escalators	System fault.	Monitoring.
ICT Server Rooms	Temperature, plant status, leak detection alarms.	Monitoring.
ICT Hub Rooms	Temperature, plant status, leak detection alarms.	Monitoring.
Decontamination services system	System Monitoring.	Monitoring and recording common fault.
Decontamination tracking system	System Monitoring.	Monitoring and recording common fault.

The integrated control platform shall reflect all system interactions within the graphical environment to display the relevant information on the same graphical display to provide a user friendly and intuitive format together with clear instructions where required.

11.0 BMS EQUIPMENT AND FACILITIES

The BMS equipment shall generally consist of the following: -

- Graphical User Interface Work Station
- Server (sufficient space shall be allowed in the rack for future 'retained estate' servers to the requirements advised by the Board.
- Data Storage
- Portable User Interfaces (Laptops, PDA's, portable keypads etc.)
- Engineering network
- Network Controllers
- DDC Controllers housed in distributed control enclosures
- Motorised Control Valves and Damper Actuators
- Sensors, Switches and other field mounted control & monitoring devices

11.1 Graphical User Interface Work Station

GUIWS PCs shall be provided in the following locations:-

FM Office
Labaratory/FM building
A further PC to be located in agreement with the Board.

The local plant PCs shall only display graphics and plant data relevant to that plant area.

The Graphical User Interface Work Station (GUIWS) shall provide the following facilities:

- Alarm annunciation, management, logging and reporting
- Plant operating status monitoring, logging and reporting
- Environmental conditions monitoring, logging and reporting
- Scheduling, adjustment and configuration.

Alarms shall be categorised depending on their criticality and at least ~~5~~ 3 categories shall be available, with user defined routing and annunciation options for each alarm. Highly critical alarms shall be routed to a 24hour manned position and the BMS shall have the facility to send alarms via SMS text message, email or to portable PDA.

A reports generation facility shall be provided whereby reports may be generated automatically at a scheduled time or triggered by an event. The reporting function shall also allow custom, user-defined report generation.

The BMS shall log energy consumption via the connected utility meters throughout the hospital.

The BMS shall have the facility to export energy data to third party software to demonstrate the energy performance of the building in accordance with stipulated requirements.

Dynamic flow diagrams shall provide an interactive interface and shall be supplied displaying the following features:-

- Each and every connected point, status conditions (running/stopped etc.), analogue values with engineering parameters (ºC, %RH, l/s etc.). Output positions (% open, speed, etc.).
- Monitored values set points etc., shall all be displayed with the use of colour to differentiate between different types of displayed values and different plant status.
- All calculated parameters as dictated by the controls specification (average, highest, lowest etc.)
- Selected optimiser switching times (start, stop)
- Adjustable set points and overrides
- Current sequences in operation
- Energy/efficiency calculations
- Alarm conditions, shown highlighted
- Click boxes to gain text, panels, pre-configured graphs and other displays
- To select pre-configured control actions
- In addition, a general site plan together with building and floor plans to be allowed for each level including roof void, plant areas etc.
- Generally, colour displays shall be supplied on the basis of one per plant, with main and cross indexing/paths to allow movement between the displays in a logical manner. An exit to the head/index page shall be available from each display.

- The correct performance of the displays shall form part of the plant commissioning procedures.
- The displayed values must be constantly refreshed while the graphic flow diagram remains on the screen.
- The Specialist shall include for creating all the graphics for the plant systems and sub-systems within the buildings as defined by the drawings and associated documentation.
- An engineer's utility allowing new displays to be created and changes made to those formatted shall be supplied. The use of this programme shall be considered for ease of use and its operation shall be incorporated in the training process.
- The ability to print screen information at any moment in time, including graphic flow diagram and numeric values, shall be provided.

All graphics shall be agreed in principle with the *Client and Contractor* prior to the production of graphics pages.

The GUIWS shall incorporate full graphics drawing and editing facilities to allow new graphics and changes to the structure of the graphics to be configured by the operator.

Links shall be provided from graphics to the electronic O&M manuals and associated asset register to assist fault finding and ordering of replacement components.

11.2 Server

The server, which is already provided under the lab/FM phase of the project, shall be sized to store and run all necessary proprietary software associated with the connected systems, all necessary software to run the network, data storage for all associated systems, including, energy usage logs, plant usage logs, etc.

11.3 Storage

The storage shall be sized to accommodate copies of all necessary proprietary software associated with the operation of the BMS and all interface systems together with all input data to allow access of system archive information for a period of ~~24 calendar months~~ 53 weeks on a rolling basis. The storage shall be industry standard raid configuration with resilience and automatic redundancy.

Long term storage will be dealt with under the Client's IT system.

Archive information shall include where applicable: energy usage logs, water usage logs, plant usage logs, plant alarm logs, zone temperature logs, zone humidity trend logs, access control databases, etc.

11.4 Portable User Interfaces

In addition to the main graphical user interfaces the following portable devices shall be provided, one laptop and eight PDA's allowing system interrogation from any of the distributed controllers. All graphics shall be dynamic, forming part of a layered structure, which are consistent and provide a logical and intuitive navigation facility of the building's systems and show the following as a minimum: -

- HVAC plant temperatures, set points and status conditions.
- Ventilation System status

- Valve and damper control signal positions.
- Fire Safety System status
- Electrical System status
- Filter status
- Metered data (via ERM system)
- Building plans
- Integrated systems information and facilities as previously described.

Local interrogation and adjustment shall be carried out by portable user interfaces. Wireless connection shall be provided in the main plantroom areas or otherwise via data connection at the local DDC controller or controls enclosure. Local adjustment and overrides shall be notified and logged at the GUIWS. The BMS shall be designed generally to prevent unauthorized tampering and cases of manual override causing excess energy consumption.

11.5 Network Controllers

Network controllers shall be as described in the overview above and shall be located at key locations throughout the hospital.

11.6 DDC Controllers in Distributed Control Enclosures

DDC controllers shall carry out the control and monitoring of plant and equipment as well as local metering and logging functions. The controllers shall be housed in control enclosures in a distributed configuration to suit the staged delivery and the offsite fabrication and testing of the plant systems served. This shall comprise for example one enclosure per AHU and so on.

Each enclosure shall have a panel live and common fault indication lamps and local reset pushbutton. DDC Controllers (with the exception of terminal control and monitoring only) shall incorporate ~~three position~~ manual override switches to allow selection of On, Off or Auto for each motor drive. These switches shall form an integral part of the controller and provide software feedback to the BMS.

11.7 Automatic Monitoring and Targeting (AMT)

This is part of the ERM system.

The ERM system shall be capable of exporting data to the Board's AMT system which is presently located within the site Clock Tower. The BMS software script shall be provided to ensure that all energy usage figures required for the AMT shall be available for use in the system.

11.8 Power Autonomy and Emergency System Monitoring

The BMS monitors all equipment and it is imperative that the information gathered is retained and is available in the event of loss of mains power.

All outstations, communications and network equipment shall be equipped with battery or UPS backup to provide 30 minute autonomy. This is provided by the Specialist as part of the BMS installation.

The main GUIWS and its associated accessories, screens, and printer shall be equipped with a UPS backup to provide 30 minute autonomy. This is provided by the Specialist as part of the BMS installation.

The Specialist shall configure all elements of the system to allow monitoring of the emergency systems during all failure scenarios and this facility shall be demonstrated during the system Integration Testing.

The Specialist shall carry out any modifications highlighted during the IST to ensure that the installed system provides full emergency system monitoring.

11.9 BMS System Control Strategies

The general design principal for this project is to provide local decentralized control panels to be purpose designed and integral with the ‘stand-alone’ plant and equipment. Generally, each major power consumer, e.g. Pumps, Fans etc. shall be supplied with their dedicated ‘intelligent’ inverter drive motors, to be used as the means of control and for direct interrogation of status, fault levels and energy consumption. These drives shall be powered by cables fed directly from section boards located in the respective plant rooms. All information abstracted from the invertors and other controllers shall be accessible via the BMS.

11.10 Interactive Support and Utilities Management

11.10.1 Condition Based Monitoring

The BMS shall be capable of being linked to a condition based monitoring package capable of the following: -

- 24 hour alarm analysis
- Repeated alarm analysis
- Analysis of duration from alarm acknowledgement to clearance
- Analysis of unacknowledged alarm duration
- Hardware point alarm analysis
- Analysis of an alarm failure pattern
- Analysis of control loop performance and usage
- Analysis of optimiser performance at occupancy time
- Analysis of terminal & BMS start-up and shut down times
- Analysis of user access to BMS
- Analysis of modified points and manual overrides on a per user basis
- Sensor calibration and avoidance of drift

The system shall automatically produce reports on the system performance in a user friendly, easily understood colour graphical format.

The site shall be capable of being linked to permanently manned 24/7 remote support centre.

11.10.2 Interactive Utilities Management

The system shall be capable of exporting information to a smart utilities management software, which has real time links to the utilities provider's billing system and can provide comparative analysis and profiling to check tariffs and charging with BMS metered data.

Any invoice discrepancies can be highlighted and recovered by the client.

Profile analysis functions can identify any abnormalities in energy consumption and report and alarm accordingly. Profiling can be carried out by department and areas and by system as well as on a whole building basis.

Links to plant operating logs and alarms can be provided to assist investigation.

Load shaping reports can be provided by department and areas, identifying peak demands, CO2 and carbon consumption.

11.10.3 Engineering Network

The network shall comprise a series of hubs, provided to suit the building layout and wiring topology generally located in plant areas, linked to a core switch and server located in the ~~FM Office~~ main server rooms.

Each hub shall comprise a switch which shall communicate with local field devices via Category 6A copper cable infrastructure and shall communicate with other hubs and the server via multi pair single mode blown fibres. The Specialist shall provide a fully functioning network, which shall operate entirely on its own or shall seamlessly form part of the wider hospital network if so required. In any case the network shall be fully equipped to enable access from a remote PC via the hospital IT network and via the World Wide Web in accordance with the client's own IT policy.

11.10.4 Alarm Management

Alarms generated by any outstation shall be processed by a main operator's terminal to sort into at least 12 types. Each type may have any combination of the following parameters:-

- Alarm general/critical, outstation group, point label, location
- Transmission destinations with operator time schedule
- Store associated plant parameters on initiation
- Select print action
- Select audible alarm
- Log to alarm file
- Password level for acknowledgement

Alarm Inhibition

When an alarm condition is displayed it shall be independent of any other possible alarm or cause that may initiate a string of further alarms, e.g. boiler lock-out shall not initiate flow and return water temperature alarms and space temperature alarms.

Where such circumstances occur, the software shall inhibit any such sequential alarms. The Specialist shall co-ordinate such sequences in his detailed design and submit details sufficient to demonstrate compliance with requirements. The initial alarm of such a chain

shall indicate on the GUIWS which other alarm points are covered in the particular sequence. The programme shall inhibit dialogue alarms for a period of time after start-up of associated plant to prevent spurious alarms.

The programme shall also inhibit alarms when the associated plant is switched off by the BMS.

The programme shall inhibit alarms during the start-up of each plant item. This delay time period shall be for a maximum of 10 minutes to enable the building service installation to reach a stable condition.

Critical Alarm

Urgent Operator action required. Sounds an audible alarm in the FM Office, which can be manually muted. Is indicated on the GUIWS as a message with the associated graphics schematic and recorded on the printer. GUIWS display is not eliminated until alarm acknowledged.

These alarms shall include, but not be limited to, the following:-

- Chiller failure
- Cooling systems pressurisation low/high pressure
- Boiler failure
- Heating systems pressurisation low/high pressure
- All air handling plant fans, unless provided with stand-by fans or motors
- All supply fans, unless provided with stand-by fans or motors
- All extract fans, unless provided with stand-by motors
- All pumps, unless provided with stand-by motors
- All electrical monitoring points
- All safety circuit monitoring points

Refer to the relevant Descriptions of Operation in subsequent specification volumes for further details.

11.11 Building Log Book

The Specialist shall provide a simple overview of the BMS system for inclusion in the Building Log Book to meet the requirements of the Scottish Building Regulations Non Domestic Technical Handbook.

The Specialist shall liaise with the Contractor, who is preparing the overall document, to provide the documentation in a compatible format.

11.12 Site User Training

The Specialist shall supply the following training for the FM engineering staff:-

General Engineering Staff

Off-site prior to handover; non-specific system structure, components and applications. Operation of user terminals, keyboards, use of displays, overrides, passwords.

On-site; specific system structure, outstations locations, control strategy overviews. Operation of user terminals, adjustments, trend graphs and alarm handling. Other networked components.

Engineers & Selected Staff

Off-site prior to handover; complete training courses at the Manufacturer's works, instruction in the following; all as above but also including configuration of outstation and user terminals, software, Windows/DOS file structures, password and engineering utilities, fault-finding, tuning and maintenance.

On-site, while the Board's Estate engineers shall attend the acceptance demonstrations, the Specialist shall instruct him in the specific application of the system, the structure and the control strategies adopted to meet the specification.

11.13 Drawings

As part of the development of the design the Specialist shall prepare general arrangement drawings of the Building Management and Automatic Controls Systems based on the Architect's base drawings and coordinated with other services and building elements. These drawings shall be drawn in Autocad (.dwg) with the model files drawn at 1:1 scale. One hard copy of each level together with a CD with all electronic files (PDF and .dwg) must be returned with the tender return. A proposed drawing list shall be submitted with the tender.

The drawings shall indicate as a minimum:-

- Sensor locations
- Motor Control Centre locations and sizes
- Power supply requirements
- Cable containment requirements
- Metering strategy/meter tree
- Graphics proposals
- Controls strategy

12.0 GENERAL SYSTEM REQUIREMENTS

The description of the operating requirements of each individual system is given in Volumes 2 to 6, which shall be read in conjunction with the contents of this volume.

12.1 Systems Operation

The six volumes that make up this specification shall be read in conjunction with the following:-

Schedules of Equipment
Engineering Systems Schematics
Schedules of Monitoring and Control Functions for each system type
System reference numbers

The number, size and type of wiring required for the automatic controls and the Building Management System shall be installed in accordance with the Specialist's requirements and the relevant electrical specification.

12.2 Smoke Damper System Operation

For details of smoke/fire damper operation refer to Volume 5 Ventilation Systems.

12.3 Power Failure

When a power failure occurs all plant shall be disabled.

All plant is controlled from the BMS under emergency or return of mains normal supply.

As the emergency standby generators are run up enabling signals shall be given to the BMS from the Electrical Network Management System (ENMS) to start/stop the sequence of plant start-up. A number of signals, relating to the capacity steps of generators shall determine which plants are allowed to run to limit the load on the generators. Refer to the Electrical Load Priority Schedule, document reference ZBP-XX-XX-SH-600-250 for details of sequenced starting of plant.

The timing for the starting of plants is to be sequenced in order not to overload the generators. The BMS shall confirm that power is available to the plantroom area before the re-energising sequence is initiated for those particular plants.

In the event that one or more of the generators fails during emergency power operation the ENMS shall signal the BMS to stop the plant generally in the reverse order to the starting sequence.

The information provided above and in the schedule shall be subject to final agreement. Sequence of starting shall be agreed with the client prior to the commissioning stage.

As a general overview the following shall be noted:

- Upon power failure and power restoration either from the mains or emergency standby generators all cooling valves shall be driven closed as soon as power is available until the individual plant is energised by the ENMS sequence. This will avoid hunting of the circulating pumps until a stable operating condition is achieved.
- Whilst the plants may receive an enable signal from the ENMS the restart procedure associated with safety controls, etc may extend the actual restart period. The BMS shall take cognisance of this when ramping up the plants and, for instance, hold fan inverters at a low speed to limit power draw.
- No ventilation plants shall be enabled by the BMS until the boiler plant is energised and operating at a stable condition. As the CHP will be disabled under standby generator conditions it may be necessary for additional boilers to be brought up to operating temperature to match the heating load.
- The two IT Server Rooms cooling supplies have a high priority. It is proposed that the primary chilled water mains will act as a thermal store until the first chiller can be enabled. This will require at least one ‘A’ and one ‘B’ primary circulation pump to be enabled at a very early point in the restart sequence. All major cooling plate exchanger valves elsewhere on the primary cooling system to be driven closed so that maximum capacity is available for IT cooling.
- Under emergency standby generator conditions the absorption chiller, dry air coolers and associated pumping equipment shall be disabled as this only operates in association with the CHP system.
- In the event of standby generator failure and the need to shed one or more of the chillers all secondary chilled water pumps shall be stopped immediately to remove

load from the system. Once the status of the emergency standby generator system has been established, chillers and secondary pumps will revert back to normal sequence control of the ENMS to suit the generator capacity available.

12.4 Individual User/Occupant Controls

Where individual room control of temperature is provided the user shall have the ability to adjust the temperature by a maximum of 2^{o}C around the set-point as set at the central supervisor. The set-point adjuster shall not indicate temperature but simply have +/- and direction arrow.

12.5 Control Valve Selection

Where MTHW, LTHW and chilled water systems utilise variable volume control systems they shall have differential pressure control valves (DPV) installed as indicated on the drawings, and supplied and installed by the Mechanical Contractor.

The purpose of the DPV is to automatically compensate for the rise in differential pressure across the circuit that it services, as the circuit flow rate falls under the dictate of the 2-port control valve(s), and vice versa.

DPVs used in conjunction with motorised control valves and TRVs will be arranged to maintain a constant differential pressure across the circuit.

The Specialist shall, in conjunction with the Mechanical Contractor, liaise with the DPV supplier to ensure the correct motorised control valve selections are made.

Similarly, the Specialist shall also liaise with the pump supplier, to ensure that the pump speed control system is totally compatible between the 3 elements, i.e. DPV, motorised/thermostatic valves and pump characteristic and control.

It shall be noted that the minimum pressure drop across combination of control valve and coil to be 25kPa to suit operation of Differential Pressure Control Valve. The maximum operating pressure of the control valve, coil and interconnecting pipework/accessories shall also be reviewed against the selection of the DPV.

The air handling plant in many instances has a design reserve capacity of 25% included for future flexibility. In order to avoid poor control operation from oversizing of control valves the valves for these plants shall be selected at the current design operating capacity. The Schedule of Air Handling Units identifies the flow rate that the control valve shall be selected to under this initial installation. Pipework connecting the control valve shall have the future capacity included.

12.6 Links to Laboratory Building, Energy Centre and Site Retained Estate

The BMS systems in the Laboratory and Energy Centre shall be fully integrated into the Adult and Children's' Hospital system with a fully open interface at the FM Office Front End PC.

Links shall be provided to the existing site BMS to give a common alarm only as it is unlikely that the systems will be compatible. The Specialist shall investigate the operation of the existing system(s) and prepare a report to include identifying whether exchange of real time data can take place between the systems.

12.7 Meters

The BMS shall be linked to the various system meters and equipment drives to log and indicate energy usage throughout the Hospital and Energy Centre buildings. Refer to Volume 6 of the specification for further details.

The metering graphics shall be set up in parent-child configuration to map energy use from department layouts through building sectors to whole buildings and energy centre.

12.8 System Descriptions, Primary Measurement and Control Schedules

The descriptions and schedules that follow in Volumes 2 to 6 constitute the makeup of key points for the BMS monitoring and control, and where applicable must be used in conjunction with the relevant drawings and the detailed general description of operation of the Mechanical, Electrical and Public Health services.

12.9 Key to Item Identification Letters

AFS	Air Flow Switch
AHU	Air Handling Unit
BO	Boiler/Burner
CAL	Calorifier
CH	Chiller
CT	Constant Temperature
CV	Control Valve
DATD	Direct Acting Thermostat Device
DPS	Differential Pressure Switch
EF	Extract Fan
FS	Flow Switch
FTS	Flue Temperature Sensor
HS	Humidity Sensor
HU	Humidifier
HX	Heat Exchanger
LS	Level Switch
M	Meter (All Services)
MDA	Motorised Damper Actuator
MV	Motorised Valve
PIR	Passive Infra Red (Detector)
PR	Pressurisation Unit
PU	Pump
SDP	Pressure Detector
SF	Supply Air Fan
TA	Tank
TS	Temperature Sensor
VT	Variable Temperature

12.10 Wiring Requirements for Mechanical Services

The Specialist shall supply and install the power wiring from the primary plantroom HVAC boards, provided by others, to the local secondary panel, provided by the Specialist, then onto individual items of plant.

The minimum cable size for power supplies shall be 2.5mm^2

The incoming sub-mains and the primary plantroom HVAC board shall be carried out by the Electrical Services Contractor.

The Specialist shall co-ordinate the plant power wiring with all other trades within the plantrooms.

Y41 BUILDING MONITORING AND MANAGEMENT SYSTEMS

GENERAL

110 ELECTRICITY METERING For Hospital and Energy Centre.
- Number and location of meters: Refer to electrical services schematic diagrams and BMS Specification - Volume 6.
- Monitoring period: Submit proposals.
- Reporting: Submit design proposals.

120 FUEL METERING For Hospital and Energy Centre.
- Fuel: Gas & Oil.
- Number and location of meters: Refer to mechanical services schematic diagrams and BMS Specification - Volume 6.
- Monitoring period: Submit proposals.
- Reporting: Submit design proposals.

130 WATER METERING For Hospital and Energy Centre.
- Number and location of meters: Refer to public health services schematic diagrams and BMS specification - Volume 6.
- Monitoring period: Submit proposals.
- Reporting: Submit design proposals.

130A HEAT METERING For Hospital and Energy Centre.
- Number and location of meters: Refer to mechanical services schematic diagrams and BMS specification - Volume 6.
- Monitoring period: Submit proposals.
- Reporting: Submit design proposals.

SYSTEM PERFORMANCE

210 DESIGN
- Design: Complete the design of the building monitoring and management system.
- Standards:
  - Communications network: To BS EN 50174-1.
  - Communications protocol: To BS EN ISO 16484-5.
  - Documentation of plant/ application specific functions: To BS EN ISO 16484-3.
- Proposals: Submit drawings, technical information, calculations and manufacturers' literature.

PRODUCTS

310 ENCLOSURE Integral plant control panels or standalone Motor Control Centres
- Manufacturer: Contractor's choice.
  - Product reference: Contractor's choice.
- Standard: To BS EN 62208.
- Ingress protection to BS EN 60529: IP54.
- Mechanical protection to BS EN 62262: IK05.

- Finish: Manufacturer's standard.
  - Colour: Manufacturer's standard.
- Method of fixing: Contractor's choice.
- Incoming cabling access: Top entry.
- Outgoing cabling access: Top entry.
- Locking mechanism: Cylinder locks with a standard key type.
- Identification of cable terminations: Label with circuit reference, with push-on plastics markers.
- Internal wiring: Segregate power and signal cabling. Contain within slotted trunking.
  - Wiring capacity (maximum): 45% full by volume.
- Accessories: None.

440 FIELD CONTROLLERS Located in Motor Control Centres or integral plant enclosures

- Standard: To BSRIA AG 9/2001.
- Manufacturer: Submit proposals.
  - Product reference: Contractor's choice.
- Integral enclosure:
  - Ingress protection to BS EN 60529: IP54.
- Mounting: Suitable for DIN rail mounting.
- Network communications options: BACnet MS/TP.
- Port arrangement: Manufacturer's standard.
- Controller inputs, sensors and devices: Submit proposals.
- Controller outputs, actuators and switching devices: Submit proposals.
- Internal power backup:
  - Type: Submit proposals.
  - Battery functions: Submit proposals.
- User interfaces: Access password protected programmable LCD with back light and membrane keypad.
- Accessories: None.

445A DESKTOP PC Locations as required by the client

- Manufacturer: Contractor's choice.
  - Product reference: Contractor's choice.
- Processor:
  - Clock speed (CPU): Contractor's choice.
  - Clock speed (front side bus): Contractor's choice.
  - L2 cache size: Contractor's choice.
- Operating system: Contractor's choice.
- RAM: Contractor's choice.
- Hard drive: Contractor's choice.
- Optical drive: Contractor's choice.
- Graphics card:
  - Memory: Contractor's choice.
  - Resolution: Contractor's choice.
- Network card Contractor's choice.
- I/O ports: Contractor's choice.

450 KEYBOARDS User interface

- Standard: To BS EN ISO 9241-4, -400 or -410.
- Type: USB.
- Manufacturer: Contractor's choice.

- Product reference: Contractor's choice.
- Features: QWERTY with full upper/ lower case ASCII key-set and numeric keys.

460 MONITORS User interface
- Standard: To BS EN ISO 13406-2.
- Type: LCD.
- Manufacturer: Contractor's choice.
  - Product reference: Contractor's choice.
- Size (nominal diagonal): Submit proposals.
- Resolution: 1680 x 1050.
- Response time: 5 ms.
- Display Screen: Anti-glare coated.
- Interfaces: One VGA 15 pin HD D-Sub (HD-15)
- Display positions: Adjustable height, swivel, and tilt.
- Additional features: None

510 PRINTERS User interface
- Type: Submit proposals.
- Manufacturer: Contractor's choice.
  - Product reference: Contractor's choice.

EXECUTION

620 INSTALLATION OF BUILDING MONITORING AND MANAGEMENT SYSTEMS
- General: Install in accordance with BSRIA AG 9/2001.

625 INSTALLATION OF FIELD CONTROLLERS
- Clearance (minimum):
  - Front access: 1000 mm in front of field controller.
  - Mounting height: 1000 mm from finished floor level.
- Fixing equipment: Fix on DIN rail mounted within enclosure.

627 INSTALLATION OF CABLES
- Timing: Do not start internal cabling until building enclosure provides permanently dry conditions.
- Cables: Install in one uninterrupted run.
- Arrangement: Position vertically and horizontally in line with equipment served, and parallel with building lines. Provide drip loop to prevent water entering equipment.
- Orientation: Dress cables flat, free from twists, kinks and strain.
- Cable pulling: Do not overstress.
  - Installation method: Submit proposals.
- Jointing: At equipment and terminal fittings only.
- Cables routes generally: To follow arterial containments routes as indicated on drawings.
- Cables from other systems: Segregate and cross at right angles.
  - Distance from steam and low temperature hot water systems running parallel: 500 mm minimum.
- Terminations: Support cable within 150 mm of termination.
- Balanced twisted-pair cabling:
  - Maximum untwist at terminations: 12 mm.

630 INSTALLATION OF SENSORS

- General: Install in accordance with Building Controls Group (BCG) Control sensor installation.

COMPLETION

910 INSPECTION AND TESTING
- Standard: To BS 7671.
- Notice before commencing tests (minimum): Submit proposals.
- Certificates: Submit.
  - Number of copies: Submit proposals.
- Test equipment identity: Record on test certificates.
- Certificates of calibration: Submit for each test instrument.
- Control panel test certificates: Submit.
  - Number of copies: Submit proposals.

915 COMMISSIONING
- General: Commission in accordance with BSRIA AG9/2001 and BCIA System start up and commissioning guide. Achieve the requirement to obtain BREEAM Credits (Man 1).

920 SPARES
- Spare fuses: Mount within each control panel.
  - Number: Submit proposals.
- Spare devices: Supply.
  - Number: Submit proposals.
- Spare lamps: Mount within control panel.
  - Number: Submit proposals.

925 KEYS
- Field controller enclosure door keys: Supply.
  - Number: 3 of each type used.

930 DOCUMENTATION
- Operation and maintenance instructions: Submit.
- Record drawings: Submit.

Electrical Installations

All electrical services associated with the BMS shall be installed in accordance with the Common Electrical Clauses Specification, reference ZBP-XX-XX-SP-532-247.

APPENDIX A

SUPPORTING DOCUMENTATION

In order to carry out the design, the Sub-Contractor shall require access at least to the documentation listed below.

The following information is, or shall be, available from the Contractor:-

1. Standard General Conditions and Preliminary Clauses
2. Wallace Whittle specification and drawings for Building Management System in Laboratory/FM building
3. WSP: Hospital Fire Strategy Report.
4. Nightingale Associates: Fire Strategy Drawings
5. Nightingale Associates: Building Plans
6. Nightingale Associates: Building Sections
7. Nightingale Associates: Wall Elevations
8. ZBP: Schematic diagrams (Refer to individual system descriptions).
9. *ZBP: Services general arrangement layouts*
10. *ZBP: Environmental Strategy Drawings (526 series)*
11. ZBP: Mechanical Systems Specifications.
12. ZBP: Fire Detection and Alarm systems.
13. ZBP: Common Electrical Clauses (ZBP-XX-XX-SP-532-247)
14. ZBP: Fire Fighting Installations Performance Specification (Sprinklers).
15. Schindler: (Lift supplier): Details of Lifts.

Drawings for other specialist systems shall be developed by other Sub-Contractors during the detailed design period and shall be made available by the Contractor when complete.

CAPITA SYMONDS

NEW SOUTH GLASGOW HOSPITAL

ADULT AND CHILDREN'S HOSPITAL AND THE ENERGY CENTRE

NEC 3 SUPERVISORS REPORT NO. 26

MAY 2013

NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND ENERGY CENTRE

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NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND ENERGY CENTRE

SUPERVISOR'S REPORT NO. 26 MAY 2013

1.0 EXECUTIVE SUMMARY: ADULT & CHILDREN'S HOSPITAL

Visits to the site during May 2013 indicated that the construction and procedures are progressing in a satisfactory manner in accordance with the Employer's Requirements.

Throughout, the standard and quality of the workmanship is generally good and operations are being carried out in an acceptable manner.

Together with Brookfield we carried out quality and compliance inspections on Level 1 Area 1-525, 1-528 and 1-526. The areas inspected were to a good standard and the defects captured by Brookfield were generally of a minor nature. We did however identify a number of defects which Brookfield recorded on to their IDMS system. These included defective opening and closing turn handles which operate the internal blinds in area1-528. We raised a Defect for this to cover the entire site. Following a meeting with Brookfield and the Manufacturer it was agreed that the operational problems would be addressed during June.

Brookfield continues to undertake their Quality Assurance systems on site with inspection and checklist documentation available for the ongoing construction activities. Over the period, we have closely liaised with Brookfield and witnessed 85 point check to the partition on Level 0 Area 529, Level 1 Area 537, Level 2 area 522b and the Children's Hospital Level 3 Area 506.

A partition checked on Level 0 had a few failures which were rectified. Brookfield and Astins also opened additional partitions in two other rooms and these had no failures.

An 85 point check was carried out to a partition formed on Level 1 Area 537. The first floor inspection to the partition between room OPD1-084 and OPD1-182 identified a number of major failures including gaps in the insulation. Insulation was also dislodged, missing, had insufficient fixings and fixings too close to the edge of the boards. As a result of this inspection two additional areas were opened up in rooms OPD1-077 and OPD1-101. In both locations insulation was missing and dislodged. Brookfield instructed Astins to open up additional partitions in the area, record and photograph these and carry out any necessary work. This was carried out and remedial measures taken to ensure that the partitions complied with the specification.

A partition checked on Level 2 area 522b and the Children's Hospital Level 3 Area 506 had no failures.

We witnessed below ground drainage tests in Zone F Pour 4/5 and Zone C Pour 3 and Zone C Pour 3. There were no issues resulting from these tests.

Civil and structural works continue to be to a generally high quality standard.

In respect of the piling records on ZUTEC, replacement of the current construction drawings by 'as built' drawings is still awaited.

Piling has commenced in the car park area and from a quality perspective appears to be progressing satisfactorily.

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All floors to the Atrium Bridge have now been cast and deflection checks to date have been further examined in respect of datum issues. A final report is still awaited from Brookfield in respect to this. Meanwhile the steelwork subcontractor has been carrying out remedial work to the intumescent paintwork and side cladding installation has commenced. An independent testing organisation is carrying out checks on this paintwork and their report/certificate is awaited. This is now of more significance as damage to intumescent paintwork was noticed during the period, as well as cracks in the paintwork at some web/flange locations.

Concrete slab work to the ACH has again continued apace during the period. Floor slabs are essentially completed on the 12th floor on both the SE and SW arms (Zones G and D). Work is now at the 11th floor on the NE and NW arms (Zones J and F respectively). On the Children's Hospital section the final floor slabs have been completed in Zone C. All of the work generally appears to be of good quality throughout. Ground floor slab pouring is now also substantially completed. Sub-slab final drainage tests in Zones C and F were carried out successfully.

Steelwork erection has continued to the roof of the Children's Hospital in Zones A and B. Communications have been raised with Brookfield and are listed on the following page.

Steelwork erection has also commenced on the roof of the SE arm (Zone G). Some sections of galvanised steelwork were delivered well out of shape and straightness tolerance and were being returned to the subcontractor for appropriate attention.

External blockwork has continued in Zones D and G on the south and east faces, and from a structural perspective generally appears to be satisfactory.

We have carried out general inspections of the M&E installations during the period and have conducted witness testing of HV Electrical systems and pipework water sample testing in the main A&C Hospital. The general standard of workmanship is good and the installations subject to test appear to be performing to the correct standard.

The sample AHU21 in plant room PR21 was inspected and comments provided for action by Mercury. It was agreed that this unit will form the standard for all other AHU's, therefore any issues are to be fully closed out to ensure quality installation.

The M&E installation quality is remaining at a good standard and we are satisfied that these are being installed to a compliant standard. It should however be noted that there may be some instances where AHU's may not necessarily meet SHTM 03-01 and have asked clarifi9cation on these points.

The M&E installations are progressing on all levels up to Level 8 and range from first fix module installation to almost completed areas.

The installations in the Energy Centre are well advanced with the advanced A-side systems commissioned and handed over. Commissioning programmes for the B Side have been presented and significant commissioning will be taking place from June to December 2013.

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We are continuing to work with Brookfield during our inspections highlighting any items that have raised concern. Items identified in this manner are generally being addressed by the site team in advance of any defect notice being raised.

With respect to the potential access issues to high level sprinkler heads raised in Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 75. Brookfield is reviewing potential access issues, in an effort to find a solution but this has not been presented for review.

In general terms we are satisfied that the installations continue to be installed to a compliant standard, and are of a good quality. However we have noted that certain items this month that have raised concern. These have been raised with the Contractor as follows:-

Supervisor's Communication General Matters / Other Instructions No 114, 115, 116, 117, 118, 119, 120, 121, 122, 123 and 124 were issued in May.

- Seeking an explanation of the rational and design philosophy and proposals to achieve 25% spare capacity.
- Requested evidence that all Atrium steelwork fire protection steelwork has been protected in accordance with the specifications. Also to include for areas hidden behind cladding panels and provide dry film thickness results.
- Seeking assurances that ground floor storm drainage has sufficient access panels to comply with Building Standards/Building Control requirements. Seeking confirmation that the 50mm above ground waste drainage connecting to 100mm is also compliant.
- Seeking confirmation that the lack of concrete foundations below 2 sets of 'goal post' elements will be addressed with no impact on the room/space requirements.
- Poorly positioned concrete bases below 3 other columns.
- Requesting proposals to address paint damage to steelwork.
- Seeking floor flatness and levelness tolerances for the Atrium Bridge.
- Seeking design philosophy in relation to the air handling unit/compliance with DW144.
- Seeking confirmation that the CDM Coordinator has considered trip hazard from low level pipes.
- Seeking confirm when remedial measures have been completed in relation to the damaged duct.

Supervisor's Notification of Defects (42.2) No 50, 51, 52, 53, 54, 55 and 56 were issued during May.

- Seeking confirmation of remedial measures to address screw fixings puncturing lead panels.
- Screw fixings not in accordance with NBS specifications.
- Seeking confirmation that remedial works were carried out to damaged roof membrane.
- Seeking confirmation of measures to address blocked access hatches.
- Seeking confirmation of measures to address internal blinds which are difficult to open/close.

- Seeking dry film thickness results and confirmation of remedial measures to damaged intumescent paint.
- Seeking confirmation of measures to address blocked access hatch.

We continue to be assisted by the site teams and the NHS Project Team who produce an internal weekly report which assists us in resolving various construction, mechanical, electrical and quality issues. We continue to close out our Supervisor's Notifications and Defects when we have received satisfactory responses.

2.0 DESIGN COMPLIANCE CHECK

Currently nothing to report.

3.0 PROCEDURES REVIEW

3.1 Contractor's QA Procedures

Brookfield and their subcontractors have continued with their QA and checking and inspection procedures during this period. We are in discussion and liaison with Brookfield's Quality Manager on QA matters and we undertake regular reviews of their QA documentation.

Together with Brookfield we carried out quality and compliance inspections on Level 1 Area 1-525, 1-528 and 1-526. The areas inspected were to a good standard and the defects captured by Brookfield were generally of a minor nature. We did however identify a number of defects which Brookfield recorded on to their IDMS system. These included defective opening and closing turn handles to the internal blinds in area1-528. We raised a Communication for this to cover the entire site.

We had concerns that the insulation removed and disturbed at high level was not being managed through the QA system. Following discussions with Brookfield they have confirmed that they will review the sign off check sheets to ensure that insulation is included as a hold point of the high level installation. We are still awaiting confirmation that they have reviewed their QA documentation.

As a result of inspections on site we have brought to Brookfield's attention a few snags and these have been loaded onto their IDMS system to be resolved as part of their snagging rectification process.

An 85 point check was carried out to a partition formed on Level 0 Area 529. The ground floor inspection in room AAW-116 identified a number of major failures including gaps in the insulation, insulation dislodged, insufficient fixings and fixings too close to the edge of the boards. As a result of this inspection two more 85 point checks were carried out in rooms AAW-123 and room AAW-133. There were no major problems found in these rooms and the insulation was intact. However there was a doubt about the need for back plates on the first skin.

An 85 point check was carried out to a partition formed on Level 1 Area 537. The first floor inspection to the partition between room OPD1-084 and OPD1-182 identified a number of major failures including gaps in the insulation, insulation dislodged, missing insulation insufficient fixings and fixings too close to the edge of the boards. As a result of this inspection two additional areas were opened up in rooms OPD1-077 and OPD1-101. In both locations insulation was missing and dislodged. See photographs below showing the faults found.

Room OPD1-101. Patress not fixed behind board and insulation missing.

Room OPD1-077. Insulation missing Gaps between insulation at low level.

Insulation missing behind pattress

Insulation set aside either side of conduit drops.

Insulation short.

As a result of this inspection two additional areas were opened up in rooms OPD1-077 and OPD1-101. In both locations insulation was missing and dislodged. Brookfield instructed Astins to open up additional partitions in the area, record and photograph these and carry out any necessary work. This was carried out and remedial measures taken to ensure that the partitions complied with the specification

An 85 point check was carried out to a partition lead lined one side and boarded the other between room THE 125 and room THE 128 in area 522b Level **2. QA checks**

had been carried out prior to the partition being completed and remedial action taken. No faults were found.

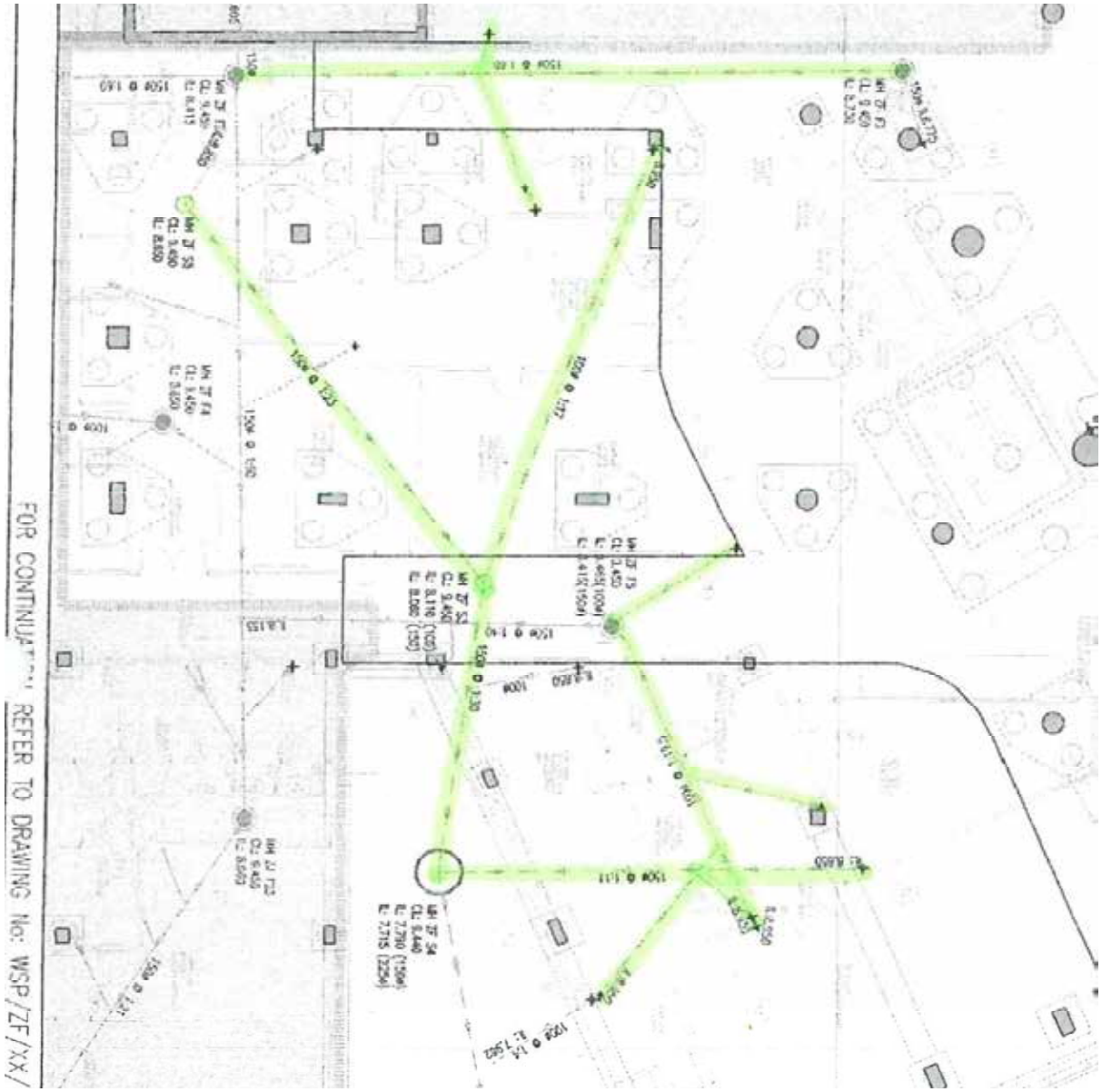
A partition checked in the Children's Hospital Level 3 Area 3-xxx had no failures.

We reviewed Brookfield's NCR Tracker and noted the issues raised by the Package Managers. We will continue to review the NCR's especially those issues in relation to the quality of the blockwork and pointing on the south and east elevations. We are also monitoring the issue in relation to water between the glass of the Structal Panels.

We raised a couple of issues with Brookfield concerning missing putty pads in level 1-510 and potential flanking issues in relation to the construction of partitions on Levels 2 and 3. These two issues have been raised as NCR's by Brookfield.

We witnessed below ground drainage tests in Zone F Pour 4/5 and Zone C Pour 3 and Zone C Pour 3. There were no issues resulting from these tests.

The next page shows an area of below ground drainage witnessed.



Zone F Pour 4/5 Final Air Test

INSPECTION OF PERMAQUIK DEPTH

Contract name: NSGH	Contract No: 1204	Drawing No:240-180 (REV C)
CONTRACTOR: PRATER LTD	SUBCONTRACTOR: JIMMY HAND	PRATER
Name of roof/ wall system: Permaquik hotmelt		

REFERENCE (see attached drawing)	DEPTH	CORRECT DEPTH	DATE	CHECKED BY	AREA OF INSPECTION
1	7mm	7-10mm	13/3/13	FRANKY MARTIN	Level 2 Zone J
2	7mm	7-10mm	13/3/13	FRANKY MARTIN	Level 2 Zone J
3	10mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
4	9mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
5	8mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
6	8mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
7	10mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
8	9mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
9	7mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
10	8mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
11	8mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
12	8mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J
13	8mm	7-10mm	13/3/13	FRANKY MARTIN	Level 3 Zone J

The above is a depth check for the roof Zone H.

3.3 Board Equipment Installation, Testing and Commissioning

Currently nothing to report.

3.4 Non Conformance Reports

We reviewed Brookfield's NCR Tracker and noted the issues raised by the Package Managers. We will continue to review the NCR's especially those issues in relation to the quality of the blockwork and pointing on the south and east elevations. We are also monitoring the issue in relation to water between the glass of the Structal Panels and potential flanking issues in the Children's Hospital Levels 2 and 3.

4.0 CONSTRUCTION REVIEW

4.1 Visits to the Works

Site inspections were carried out by the NEC3 Supervisors on the 1st, 2nd, 3rd, 6th, 7th, 8th, 9th, 10th, 13th, 14th, 15th, 16th, 17th, 20th, 21st, 22nd, 23rd, 24th , 27th , 28th , 29th ,30th and 31st May 2013.

4.2 Elements of the Works available for inspection

- Energy Centre – structurally complete. Civil works around.
- Main building – Cores A, B, C, D, E, F, G, K and L internally, Zones A, B, C, D, E, F, G and H ground floor slabs, Zones E and F basement area, ground floor suspended slabs, 1st to 9th floor slabs throughout the main hospital, to floor 12 Zones D and G, and to floor 10 Zones F and J. Zones A, B, D and G roof area.

- Zones C and F below slab drainage.
- External Drainage – specific sections of installation where access is possible.
- Tunnels between ACH and Labs, and Cores C to F.
- Structural steelwork to Atrium (limited due to access).
- Structural steelwork to roof at Zones A, B, D and G.
- Dual carriageway to Renfrew Road, turning area in front of the main entrance, and carriageway from Hardgate Road.
- Internal Partitions.
- M&E modular units.
- Roofing.
- Cladding.
- Windows.
- Sto system.
- Brickwork Courtyard 5 and south east elevation.
- Brickwork/blockwork south east elevations.
- Basement blockwork.
- Cap park piling mat area.

4.3 Observations from May 2013 Inspections

The visual inspections of the work carried out to date indicate that the works are generally being carried out to a satisfactory standard. We continue to be assisted by the site teams and the NHS Project Team in resolving various construction, mechanical, electrical, and quality issues. We continue to close out our Supervisor's Notification and Defects when we have received satisfactory responses. Listed below are observations closed out, still to be closed and those raised following site visits in May 2013.

4.3.1 Structural

In respect of the piling records on ZUTEC the current construction drawings are still to be replaced by 'as built' drawings. Piling to the new car park has commenced and from a quality perspective appears to be progressing satisfactorily to date.

Quality on all concrete works has generally appeared good but the following points remain outstanding from previous reports and we continue to monitor these:-

- Finish to ground floor in Zone F and 1st floor in Zone J.
- 20mm level change detail in all floor slabs at Zones E and J – remedial work on these areas is in progress.
- Cracks to the soffit of the suspended ground floor slab between Cores A, B, C and D being kept under review.
- Spalling to a couple of parapet walls at the top of Core G.

At the Atrium Bridge deflection checks have been further examined in respect of some datum issues. Brookfield report is awaited in relation to proposed methodology for completion of floor finishes and fenestration in relation to levels. Remedial work to the intumescent paintwork has progressed. A report/certificate is awaited from the Independent Tester. However, during the period, damaged areas to some of this

paintwork have been observed as well as some cracks in the web/flange zone of some steel sections. External cladding erection has commenced.

Steelwork to the roof of the Children's Hospital section (Zones A, B and C) has progressed and while generally satisfactory 3 areas have been raised in communications with Brookfield. concrete bases missing from 2 sets of steel 'goal posts', 3 columns not sitting on concrete foundations fully, and damaged paintwork. In the Children's Zone A atrium, at 1st floor level, steel angle fixings to the concrete core wall remain in need of remedial attention. The concrete deck above has now been cast.

Steelwork erection has also commenced on the roof of the SE arm (Zone G). Some sections of galvanised steelwork were delivered well out of shape and straightness tolerance and were being returned to the subcontractor for appropriate attention.

Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 57 has been physically addressed and a formal response received from Brookfield. Consequently this communication is now closed out.

Concrete slab work to the ACH has continued apace during the period. Slab work is essentially completed to level 12 on the SE and SW arms (Zones D and G) and is progressing on the 11th floor on the NE and NW arms (Zones J and F respectively). On the Children's Hospital concrete work is now substantially completed. Ground floor slabs in the ACH are now also substantially completed. All of the work generally appears to be of good quality throughout. Sub-slab drainage tests in Zones C and F have proved satisfactory.

Blockwork has continued in the basement areas and workmanship appears of good quality to date. External blockwork has continued in Zones D and G on the south and east external faces of the building with structural quality appearing satisfactory.

We have brought to Brookfield attention the fixings of the steel angle to the wall at the 1st floor suspended composite deck in the atrium area of Zone A of the Children's hospital. We have asked them to confirm they are in accordance with the

Specification and relevant current codes of practice and standards. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 111. We would note that this has not been addressed for at least 8 weeks and the concrete deck above has now been cast.

Three internal columns in the Children's Hospital Zone B Roof Steelwork do not align with the concrete bases (by approximately 150mm). We asked Brookfield to confirm that the proposed extension to the concrete bases is of sufficient structural integrity as the existing face of the base. The base is not scabbled and there is no connecting reinforcement into the existing base. Brookfield confirmed that the steelwork is in the correct location, there is however a discrepancy between the WSP and JDP drawings, and unfortunately the plinths were cast to the WSP drawing. They are currently pursuing a solution via the designer to complete the concrete works. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 117.

Two internal RHS columns in the Children's Hospital Zone B appear to be held up by adjoining steelwork. This may be work in progress, but we asked Brookfield to confirm the final detailing. Brookfield has informed us that the final detail is a connection to concrete. The concrete works and subsequent bolting up will be undertaken prior to the installation of any cladding. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 118.

Several areas of steelwork in the Children's Hospital Zone B have significant paint damage. Brookfield has confirmed that the painter will return to site (when the liner sheet is in place to offer sufficient protection) to carry out the remedial painterwork. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 119.

4.3.2 Energy Centre

Steelwork snagging appears to have been addressed, but much tidying up remains outstanding in the eastern half of the building. Externally, quality of the concrete hardstanding to the north of the building appears good.

4.3.3 Drainage

We witnessed below ground drainage tests in Zone F Pour 4/5 and Zone C Pour 3 and Zone C Pour 3. There were no issues resulting from these tests.

4.3.4 Dual Carriageway to Renfrew Road. (A&C)

The defects previously identified will be reviewed nearer to completion when they will be effectively rectified.

4.3.5 Pipework.

Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is progressing and in general is being installed to a good standard. Some systems are undergoing chemical cleaN prior to testing. We have witnessed water tests for the chilled beam chilled water and heating pipework and results were acceptable.

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We are continuing to monitor all pipework installations to identify possible dead legs. The quality checking by Brookfield would appear to be identifying these before our inspections.

We have asked Brookfield to confirm the flow of water from the sprinkler head highlighted is not restricted by the adjacent section of unistrut. Brookfield has confirmed that the sprinkler head deflector appears to be under the unistrut and that the Sprinkler contractor will check this when they are installing the under services protection. If the head is shielded by the unistrut, they will turn the head pendant. Still awaiting photograph showing completed work. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 74.

During our inspections in Plant Room 21, we noted that all AHU condensate discharges are routed to gullies via low level unprotected plastic pipework. This is a potential trip hazard. We have asked Brookfield to confirm that the CDM Coordinator has considered this problem and has asked if there are any measures to address this. There is also the risk of the pipes being broken. Refer to SHTM03-01 clause

4.25. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 122).

LTHW pumps are mounted on inertia bases however, there are no pump flexes. Vibration will transmit through pipework as a result. Possible longer term leakage/ damage through pipework joints. Please confirm if this has been considered and if there any measures are proposed to address this. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 123.

4.3.6 Ventilation

The installation of ventilation ductwork in the A&C hospital is progressing well, and has been installed to a good standard. It appears that any open ends are being sealed but we have noted some exceptions and these have been highlighted to the contractor during our weekly site inspections.

An inspection was carried out in Plant Room PR21 for the AHU21 to allow this unit to set the standard for all other AHU's. A number of items were also reviewed external to the unit which will require rectification.

The comments recorded for items external to the unit were as follows and we intend to raise Communications for the following observations;

- Unistrut supports for ductwork and pipework do not have lateral restraint to prevent damage and potential collapse.
- Supply ductwork at high level near louvre is not sealed and there was evidence of gaps between duct sections which will give rise to leakage.
- We will ask if chain restraints to access hatches particularly at high level is required, to prevent covers falling from height when maintenance/ inspection is being carried out.
- Location of hatch at rear of AHU into vertical face of duct section impedes access.

We raised the following comments with Brookfield on internal AHU components during our site inspections and we await their response.

- Please confirm design criteria for AHU in relation to the following concern over location of fan discharge in relation to coil face, approx 1m between components for following reasons;
- Please confirm that the fan discharge velocity will not exceed face velocity of the coil immediately in front of the discharge
- Please confirm that location of fan discharge is offset and will provide uniform velocity across face of coil. Please confirm Coil 'off coil' conditions.
- Please confirm if this is a heating or cooling coil as this will affect parameters for face velocity and potentially cause condensate carry over if cooling coil. HTM recommendations for coil face velocities are maximum of 2m/s as SHTM clause 3.47
- Please confirm if blast plate is required after fan discharge to improve uneven velocities and air turbulence onto coil face, as per SHTM clause 4.51
- If blast plate is fitted, please confirm overall fan static pressure is still adequate for system resistance and resulting SFP's will meet assumed energy model requirements
- Please confirm borosilicate glass traps are installed to condensate drip trays. Refer to SHTM clauses 4.20 to 4.24
- Please confirm that only one motor is belted as this will cause unnecessary wear on second motor, refer to SHTM clause 4.60. Please confirm if fan control is by inverter and method of control/ switching.
- Please confirm that internal components/ surfaces are of stainless steel construction.
- Please confirm grade of filtration.
- Please confirm that the thermal wheels are fitted with purge feature.
- Please confirm that a moisture eliminator is installed downstream of the cooling coil.
- Please confirm that the AHU is compliant with SHTM03-01, or state any agreed derogation.
- Extract section fan door construction when opened, has sharp edge above head height. Please confirm what will be installed to prevent injury when carrying out maintenance.
- Final fin combing to be carried for all coils out prior to testing/ commissioning.
- Please provide pressure test certificates carried out at manufacturer's works.
- Please review generally cables crushed/ bent within some inspection chambers and MCC enclosure.

Some of the above items have now been rectified, however, we are concerned that there may be instances where the AHU does not comply with SHTM 03-01. It is important that all issues are closed out to allow this AHU to set the standard across the development.

The electrical containment appeared to be restricting access to duct access hatch adjacent to riser THE-2127. Brookfield has confirmed that the Hatch has been repositioned as shown in photograph. The sprinkler flexi is temporarily tied off, the final position of the flexi will be clear of the new hatch. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 73 is closed out.

We noted that there was restricted access to ductwork in the corridor near Atrium Void Core C. Brookfield confirmed that the tray is to be re-routed or access hatch re-positioned. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 110.

We noted that the air handling unit 21AHU16 supply duct transition does not appear to comply with HVAC DW144 clause 11.6 & 11.7 which could result in high pressure loss.

We have asked Brookfield to confirm the design philosophy in relation to this observation and any proposed remedial measures. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 121).

The duct is damage on Level 3 Plant Area at core D. We asked Brookfield to confirm when remedial measures have been completed. Brookfield has confirmed that this duct is already highlighted on the NCR (BMCE-NONC-000176) issued last week with a number of other uncapped sections of ductwork in PR31 and PR22. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 124 is closed out, however we shall continue to monitor this through Brookfield's NCR tracker.

4.3.7 Insulation

The thermal insulation installation to the pre-fabricated sections of pipework is being completed off site, before delivery and completed after installation.

4.3.8 Pressure testing

Pressure testing of the modular pipework sections on a zone by zone or area by area basis is to be programmed through the commissioning meetings.

We await further information from Brookfield on their programme and methodology.

4.3.9 Medical Gases

Medical Gas pipework in being installed in all areas. Testing has successfully been carried out on some sections of the main distribution systems. We have witnessed these tests with the Authorising Engineer. Additional testing is programmed to take place in May.

4.3.10 Energy Centre

The A- side of the Energy Centre has been partially handed over.

We are continuing to monitor the installations in the remaining A Side areas and all B side areas.

Based on the commissioning programme issued by BM there will be more significant testing and commissioning taking place during the coming months in the roll up to handover of the A&B sides in May 2014.

The second batch of generators has been delivered and positioned on site. Test dates for these are programmed for June 2014.

Testing was carried out on the Busbar network linking switchboards 7A to 8A and 7B to 8B. We await feedback from Schneider Switchgear Service regarding the last tests on the continuity of busbars.

There are some defects/snags still to be completed andf Brookfield has confirmed that they will be completed by Friday 21st June 2013.

4.3.11 Trunking

Cable trunking is being installed as part of the offsite fabricated sections that are being installed in the A&C hospital and in general the installation is to a good industry standard.

4.3.12 Cable Trays

Cable trays are being installed as part of the offsite fabricated sections that are being installed in the A&C hospital and in general the installation is to a good industry standard.

We noted that the data cabling installed on cable basket did not appear to have capacity for future expansion.

We asked Brookfield to confirm the rationale and design philosophy and their proposals to achieve 25% spare capacity. Brookfield has provided photos showing approximately capacity in data baskets. The first photo appears to be 100% full, but the second photo shows an actual capacity of 50%. Brookfield has confirmed that this ratio appears constant to all areas checked over all floors. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 114 is closed out.

4.3.13 Cabling

Modular wiring looms are now being installed as part of the offsite fabricated assemblies and carefully tied up for protection and installation is of a good standard.

Void detection appears inadequate and inaccessible due to plasterboard ceiling. The Scotshield updated drawings following the changes by Building Control to the Fire Strategy are awaited. Once these are received by Mercury these will be issued to confirm adequate protection. These are still awaited. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 77.

The junction box appeared to be inaccessible due to the ceiling installation. We asked Brookfield to confirm if this is the case. Brookfield has confirmed that the grille shown adjacent to CCW 061 is in fact not connected to the ductwork system and is just a transfer grille (CVG). It can therefore be used as an access hatch to get to the junction box. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 79 is closed out.

4.3.14 Conduit

Solid conduit installations are well progressed in the areas being fitted out and are to a good industry standard.

4.3.15 Void Detection

There appears to be no void coverage as required within the NHS Firecode. We have asked Brookfield to confirm the void protection philosophy On Level 2, Gridlines I-H & 1.1-2.1. They have confirmed that the detection in the zone area noted above has not commenced yet. The lack of void detection now extends between gridline I & E. Currently air handling units and associated ductwork are installed, with ductwork at high level blanketing almost the entire underside of the ceiling slab.

Brookfield has confirmed that the void detection has been installed in the correct location. The Scotshield updated drawings following the changes by Building Control to the Fire Strategy are awaited. Once these are received by Mercury these will be issued to confirm adequate protection. Drawings still awaited. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 65).

Hoist cabling in CCW 051 is inadequately supported. Brookfield confirmed this has been clipped and a photograph will follow as soon as they get access back into the area. The detail shown will be that for the rest of the hoist cabling. Photograph still awaited. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 78).

There appears to be restrictive space for the void detection. The Scotshield updated drawings following the changes by Building Control to the Fire Strategy are awaited. Once these are received by Mercury these will be issued to confirm adequate protection. Still awaiting drawing. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 90).

We have asked Brookfield to confirm that the void detector above the ductwork in room AAW-381 is providing adequate protection. The Scotshield updated drawings following the changes by Building Control to the Fire Strategy are awaited. Once these are received by Mercury these will be issued to confirm adequate protection. Drawings still awaited. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 93).

We noted that there were no protective covers on the void detectors in rooms CCW-053 EQ BAY L and CCW 066 STATUS LAB on Level 1. We have asked Brookfield to confirm when the covers will been fitted to prevent dust infiltration. We have also asked them to confirm if there are any other void detectors that need to be covered that are not visible and to confirm to us when these been covered. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 112).

4.3.16 Intake Sub Station

Brookfield has confirmed that the final cables will be pulled through over the next few weeks. Last of the cables are being pulled in the Substation, the pits will be cleared and apertures sealed by mid June 2013. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 30 & 45).

4.3.17 Partitions

During an inspection on site we noted that screws had not been fitted at 200mm centres to the end of all the Assess/Treat bays in Area 522. Brookfield confirmed that this would be addressed.

We noted that the gap between the lead lined sheets fixed from the soffit and the sheet fitted from the floor had been in filled with a board which was not lead lined. Brookfield has confirmed that Knauf has approved a new detail drawing and has been given a 'B' Status by the NHS. We await a further response from Astins as to how the detail addresses the junctions at the studs and dwangs. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 108).

4.3.18 Roofs

We continue to inspect the roof work and review the QA checks.

4.3.19 Cladding/Courtyards

Cladding is substantially complete in courtyards 2, 3, & 4 and plant room 21 & 31. The "STO" system is substantially complete in courtyard 2, 3, 4 and 7. Brookfield are to carry out their final quality inspections and sign off. The standard and quality is generally to a good industrial standard.

Repairs and painting was carried out to two damaged panels and these were acceptable to the client. Brookfield await confirmation from Rukki that their Warranty is not compromised as a result of the repair/repaint. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 103).

4.3.20 Windows

Windows are progressing on the external elevations and courtyards in accordance with the specifications.

4.3.21 Fire protection

We still await dry film thickness results for the atrium steel in support of the fire proof certification. These must be for both the factory applied intumescent coating and the coating being applied on site. Brookfield has confirmed that they have been in communication with JD Pierce their sub contractor on the Steelwork and have received the following information;-

Intumescent paint logs for various components.
Steel Certs
Welding Certs

Brookfield has informed us that further works are being implemented on the above steelwork. This will require subsequent further information to be issued by JD Pierce, to supplement the information previously provided. Consequently Brookfield has confirmed that once they have this information they will be able to complete the

overall response to this item. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 54.

Following our Supervisor's Communication General Matters / Other Instruction (Cl 13.1) No 54 requesting dry film thickness results. We have asked Brookfield to provide evidence that all the steelwork on the structure that requires fire protection has been protected in accordance with the specification.

We observed on site that with external cladding panels being erected, access to some protected areas is no longer possible as can be seen in photo no 2. We have asked Brookfield that the hidden areas have been coated or will be coated. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 115).

4.3.22Equipment

Nothing to report.

4.3.23 Ducting

We have asked Brookfield to confirm that the fire damper actuator highlights in room EMC-011 can be accessed on completion of the cold water and ceiling installation. We still await a response. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 92).

4.3.24 Floors

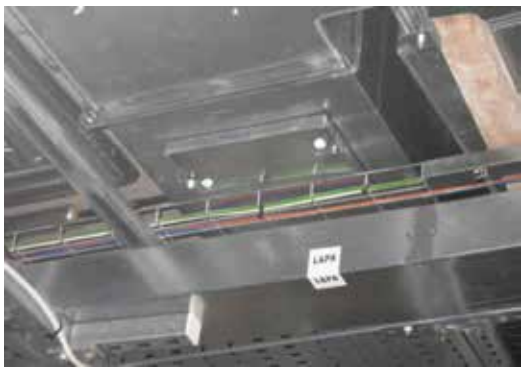
We asked Brookfield to confirm the floor flatness and levelness tolerances for the floors to the Atrium Bridge. We have also asked for the floor specification and finish to achieve the tolerances. Brookfield confirmed that the floor flatness, specification calls for an SR2 finish which is then prepared to accept vinyl. In terms of AGV's only Level 7 may be used for Transfer only (ie not carrying load) no issues with travelling over slight gradients associated with deadload deflection as long as no abrupt steps in level. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 120.

4.3.25 Blockwork

The quality and standard of workmanship of the blockwork at the curve of the south east elevations was not to a good industrial standard. Brookfield highlighted this problem and is subject to an NCR. The work is complete and Brookfield will carry out an inspection after the blockwork is cleaned.

4.4 Current Defects.

Duct access hatch blocked by chilled water pipework at ground floor area around DB cupboard AAW190. See photograph below. We have asked Brookfield to confirm when this will be rectified. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 56



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Restricted access to ductwork access hatch in corridor adjacent to Zone H near Stair Core F. Brookfield has intimated that the hatch is not restricted and access can readily be gained. We revisited the hatch and are still of the opinion that access to the hatch is not feasible as can be seen in Mercury's photograph which shows an attempt to access the hatch without the ceilings. We are still awaiting a response. (See Supervisor's Notification of Defect (CI 42.2) No 13).

Ductwork obstructed by modular frame Zone H. Brookfield is investigating this and will report. Still awaiting a response (See Supervisor's Notification of Defect (CI 42.2) No 14).

We carried out a joint inspection with Brookfield and confirm that the 'top hat flashing covers the fixings to the cladding which were previously visible. Consequently Supervisor's Notification of Defect (CI 42.2) No 16 is closed out.

BS5389 recommends that smoke detectors should not be mounted within 500mm of any walls or partitions. This does not appear to have been achieved in room AAW-384. We asked Brookfield to confirm when this has been remedied.

Brookfield has responded stating that BS5839 does recommend smoke detectors to be more than 500mm away from any obstruction, however, in some instances where the room overall size is less than 1100mm from wall to wall it is not possible to achieve this. The fire risk assessment will require that these rooms are to be protected such as electrical riser cupboards as shown in the photograph on the following page with the detector being centralized in the room. These rooms are protected but noted as a variation to BS5839 in the Fire Alarm Certificate.

Brookfield has confirmed that the functionality of the equipment is not compromised and the detector head fully functions within a 7.5 metre radius. Also, BS 5389 states that detectors should not be mounted in the way of obstructions, which would clearly be the case if it was centralized length wise in this room. The detector has been sited

as close as possible to the centre of the room to avoid obstructions. We shall continue to monitor the location of void detection but in this location Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 37 is closed out.

We noted during a joint inspection with Brookfield that insulation has been disturbed behind the boards at high level as a result of electrical installation work. If this is not corrected the acoustic quality of the partition will be adversely affected. We have asked Brookfield to confirm when this has been remedied. Brookfield intends to open up the wall to check if this has been resolved. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 39).

An AVSU penetration has been incorporated into a hazard room partition, on the corridor side of room CCW-019 Disposal Hold in accordance with drawing AST-XX-XX-DT-252-088 which does not show Kanuf board behind the AVSU. HTM 05-02 Table A1 states that the wall should have the integrity of 30 minutes and the method of exposure is to be each side separately.

We asked Brookfield to confirm that the section of partition housing the AVSU can achieve 30 minutes. Supervisor's Notification of Defect (CI 42.2) No 40 is closed, however we intend to witness an 85 point check to a similar partition on Level 2.

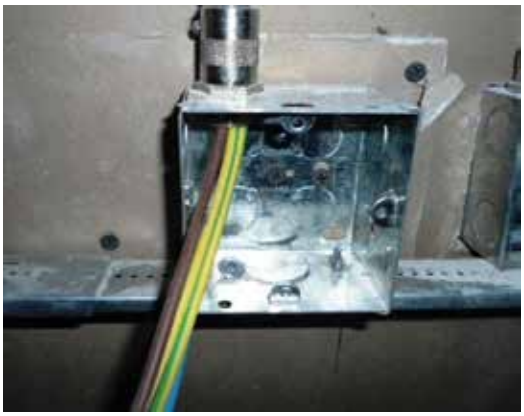
AVSU corridor side of room CCW-019

Brookfield has confirmed that the restrictive access to the ducting on Level 2 Zone D Intervention Theatre THE 228 has been resolved. The column in the room was increased in size which obstructed the route of the duct and therefore the duct was moved from the North wall to the West wall to allow suitable access to be installed. Consequently Supervisor's Notification of Defect (CI 42.2) (CI 13.1) No 42 is closed out.

Two sample areas of panels were repaired and painted. These were inspected and the finish was comparable with the original painted surface. The repair and over painting was agreed between Brookfield and NHS board at the Progress meeting on 13/05/13. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 44 is closed out.

We noted that there were gaps between lead lined noggins and vertical studs on Level 2. Following the re-issue of the drawing and rectification of the defects, a joint inspection of the work was carried out with Brookfield and found the work to be acceptable. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 45 is closed out

We brought to Brookfield's attention that a back box has been fixed by driving screws from outside to the inside leaving the sharp edge of the screws within the accessory box. Brookfield has advised us that the screws have been removed and provided us with photographic evidence. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 46 is closed out.



We have asked Brookfield to confirm the measures to address the restricted access problem to the ductwork access hatch on Level 3 Zone A near room GW1-042. See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 48).

We asked Brookfield to confirm that the support to all the curtain rails will be fitted in accordance with SHTM66 and the manufactures recommendations.
After a joint inspection we can confirm that angles fixed from the suspended ceiling up to the underside of the concrete soffit has been carried out. Consequently

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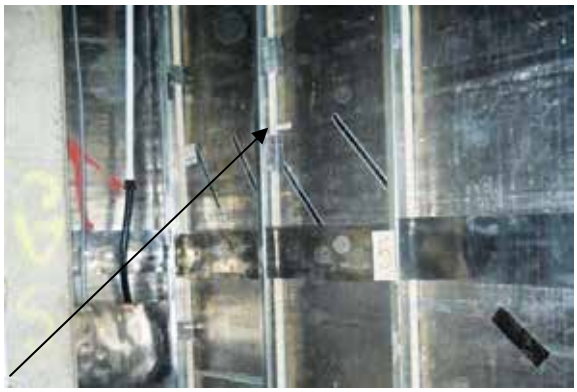
Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 49 is closed out

There are numerous locations where fixings for the lead lined panels have missed the studs/batts and have punctured the lead. (See photos below). We asked Brookfield to confirm the remedial measures to resolve this situation. Brookfield confirmed that remedial measures had been undertaken as part of Astins QITP prior to closure of the lead lined partitions. We witnessed an 85 point inspection on a lead lined partition on Level 2 and noted that remedial repairs had been carried out. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 50 is closed out.

Exposed screw.



Screw covered with lead.

There are partitions on Level 0 Area 529 which have screw fixings that have been fixed too close to the edge of the board.

The Knuaf/NBS Specification states that screws to be not less than 10mm from edge of board and this is not being achieved in many locations. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 51).

The protective membrane had been punctured in a few locations on Level 4 Roof Zone E. Brookfield has carried out the repairs and these have been witnessed by us. Consequently Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 52 is closed out.

Damaged Membrane

Area Repaired

Two access hatches are blocked by containment in the corridor. See photos and location below.

We have asked Brookfield to confirm when appropriate access has been provided so that we can re-inspect the hatches. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 52).

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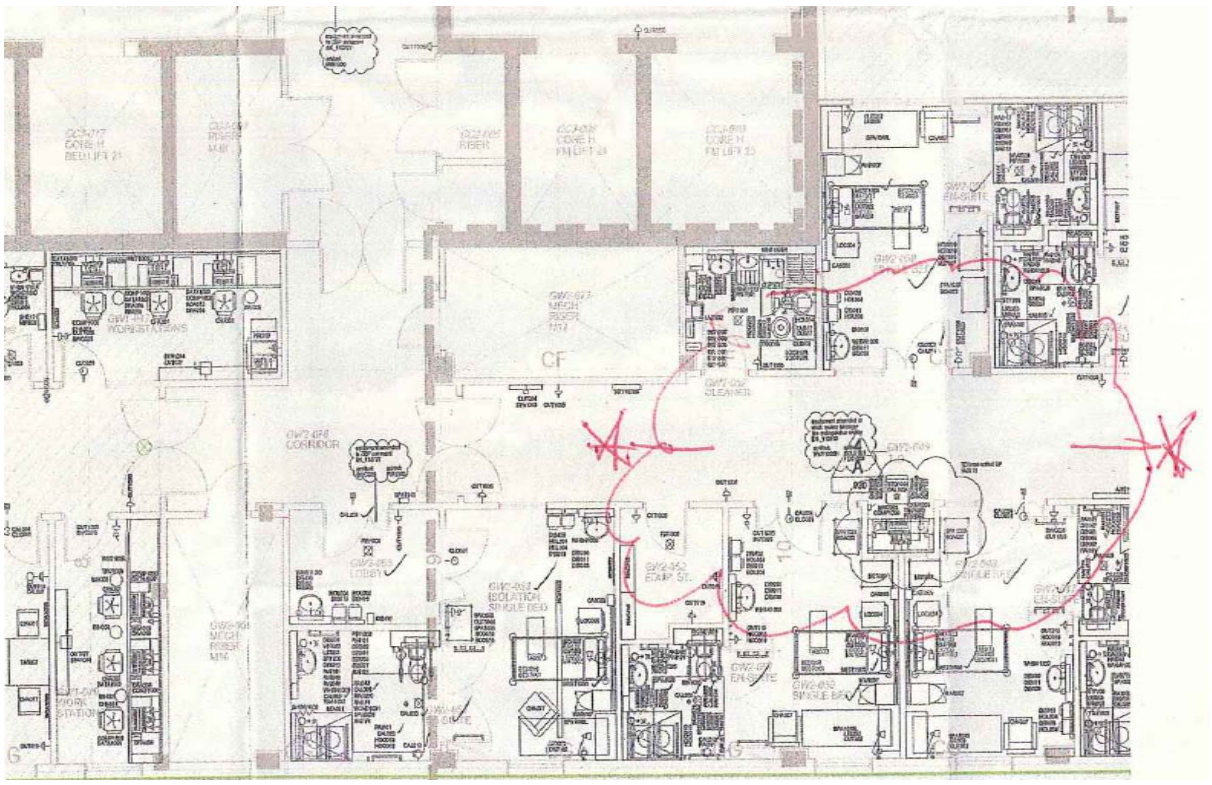


We have asked Brookfield to confirm when appropriate access has been provided so that we can re-inspect the hatches. (See Supervisor's Communication General Matters / Other Instructions (Cl 13.1) No 53).

We noted that the opening and closing turn handles which operates the internal blinds of the windows in Area1-528 were not operating properly. Some blinds were difficult to open and close and one turn handle at the single isolation room did not operate.

We asked Brookfield to confirm remedial measures and confirm that the operation of the blinds has been checked site wide.

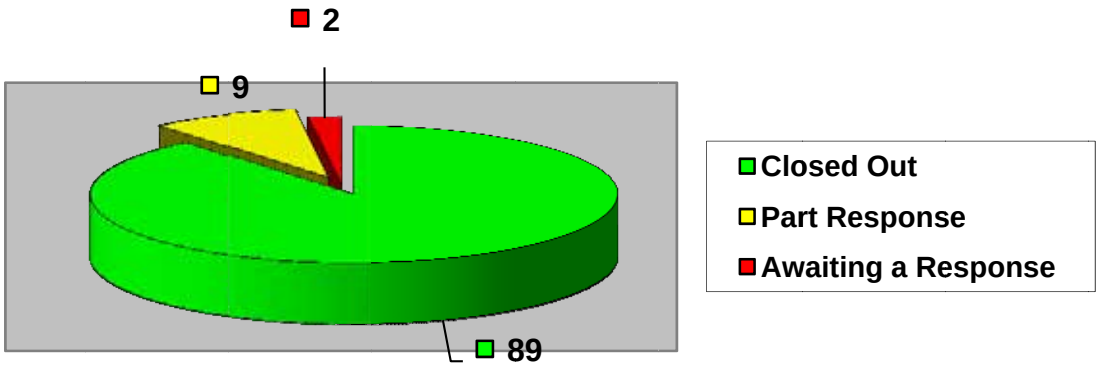
Following a meeting with TDSL and their supplier from Highline Visicom on Tuesday 4th June and subsequent viewing of the units on site the following was agreed.

Supplier confirmed the problem with the opening and closing turn handles which operates the internal blinds of the windows was an alignment issue with the glazing and operating knob on the screens. In Zone G the screens came to site with a faulty clip which was the underlying reason for the defect.

TDSL supplier will attend site w/c 17th June. During this visit all defective screens will be stripped out from the corridor side. Glazing re-aligned with the control knob and then re-fitted into the screens. Screens will then require to be redecorated. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 54).

We noted that there are areas of fire coating to the steelwork on the 11th floor Atrium Bridge which is damaged or cracked. We have asked Brookfield to confirm when the remedial work has been carried out to address these defects and to provide dry film test results for the steelwork in this area. (See Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 55).

5.0 INFORMATION REQUIRED



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Item No.	*Description*	*Date Requested*	*Comment*
Items 1 to 21 have been closed out			
22	Brookfield to provide us with their Air Test Procedures and Programme.	03/07/12	Response received.
Items 23 to 29 have been closed out			
30	Confirm when cabling is complete, water pumped out and batteries removed.	10/08/12	Response received.
Items 31 to 44 have been closed out			
45	See Supervisor's Communication No 30.	18/09/12	Response received.
46	Advise on proposals for preventing rain penetration	10/09/12	Closed out.
Items 48 to 53 have been closed out			
54	Provide dry film thickness results for factory applied intumescent and remedial repairs on site.	12/10/12	Response received.
55	Provide air method statement for air leakage tests.	12/10/12	Closed out.
56	Confirm remedial action to damaged steel framework.	15/10/12	Closed out.
57	Please confirm if the attached holes without bolts to the steelwork bridge connections reflects the design intent.	16/10/12	Closed out.
Items 58 to 64 have been closed out			
65	Confirm philosophy for void detection on Level 1 Gridline I-H & 1.1-2.1.	12/11/12	Response received.
Items 66 to 72 have been closed out			
73	Electrical containment appears to be restricting access to duct access hatch Adjacent to riser THE-212.	30/11/12	Closed out.
74	Confirm flow of water from the sprinkler head is t restricted.	30/11/12	Response received.
75	Confirm the access regime for sprinkler head maintenance / replacement.	30/11/12	Response received.
76	Confirm when 3m dead legs have been altered in CCW-031	30/11/12	Closed out.
77	Void detection appears inadequate and inaccessible due to plasterboard ceiling in CCW-051	30/11/12	Response received.
78	Hoist cabling is inadequately supported.	30/11/12	Response received.
79	Junction box appears to be inaccessible due to ceiling installation	30/11/12	Closed out.
Items 80 to 89 have been closed out			
90	Confirm void detector above ductwork provides adequate protection.	14/01/13	Response received.
91	Confirms access hatch shall be accessible.	14/01/13	Closed out.
92	Confirm that fire damper actuators highlights can be accessed on completion of the cold water and ceiling installation.	14/01/13	Open
93	Confirm void detector above ductwork provides adequate protection.	14/01/13	Response received.
Items 94 to 102 have been closed out			
103	Confirm on site painting of panels has the same life expectancy as the factory applied finish.	15/02/13	Open
104	Confirm safe access through the light fittings will not compromise the finished ceiling installation.	28/02/13	Closed out.
105	Provide Electronic Roof Integrity Tests for roofs on Levels 3&4. Confirm isolated area under the boiler will be finished in accordance with the manufacturers requirements and any damaged areas due to storing of materials are rectified.	11/03/13	Open

106	We have concerns materials and debris on roofs Level 2 Zone H and Level 4 Zone F will damage the membrane. Confirm all risks of damage are removed from the roof	11/03/13	Open	
107	Please investigate the crack in the ground floor, review with your designers and provide a brief summary report on likely causes, including proposed remedial action and timing.	22/03/13	Closed out.	
108	A detail in the construction of the lead lined partition on Level 1 is being used which has not been approved. Ensure that the detail has been approved.	22/03/13	Response received.	
109	Confirm when back to back electrical boxes have been repositioned.	27/03/13	Closed out	
110	We noted that there was restricted access to ductwork. Please confirm remedial measures to address this issue in the corridor near Atrium Void Core C.	27/03/13	Response received.	
111	Please check and confirm that the fixings to the steel angles to the wall at the 1st floor suspended composite deck are in accordance with the specifications/codes of practice.	28.03.13	Open	
112	Confirm when the protective covers on the void detectors in rooms CCW-053 EQ BAY L and CCW 066 STATUS LAB on Level 1 have been fitted and confirm that the other detectors are also fitted.	10.04.13	Open	
113	Confirm how you will manage the reoccurrence of insulation being disturbed or removed from partitions as a result of the installation of services.	10.04.13	Closed out	
114	Confirm that there is 25% spare capacity on cable basket.	02.05.13	Closed out	
115	Confirm all Atrium steelwork has been fire protected. Confirm that areas hidden by panels have received a protective intumescent coating.	07.05.13	Open	
116	Confirm that there are sufficient access panels in Zone D MH S4 and MH S5. Confirm that 50 mm waste pipes connecting to 100mm pipes at floor level without rodding points are compliant with Building Control.	03.05.13	Open	
117	Confirm procedures to ensure the work to the incomplete concrete base has sufficient structural integrity.	15.05.13	Response received.	
118	Confirm the final detailing to internal RHS columns which appear to be held up by adjoining steelwork.	15.05.13	Response received.	
119	Confirm measures to address areas of steelwork in the Children's Hospital Zone B which have significant paint damage.	15.05.13	Response received.	
120	Confirm flatness and levelness (including floor specification and finishes) to achieve tolerances.	16.05.13	Open	
121	Confirm the design philosophy in relation to air handling unit 21AHU16 supply duct transition does not would appear to comply with HVAC DW144 clause 11.6 & 11.7	16.05.13	Open	
122	Condensate discharges are routed to gullies are a potential trip hazard. Confirm that the CDM Coordinator has considered this problem and confirm if there are any measures to address this.	16.05.13	Open	
123	LTHW pumps are mounted on inertia bases however, there are no pump flexes. Vibration will transmit through pipework as a result. Please confirm if this has been considered and if there any measures are proposed to address this.	28.05.13	Open	
124	Confirm when remedial measures have been completed in relation to the damaged duct.	28.05.13	Closed out	

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6.0 SUPERVISORS TESTS AND INSPECTIONS

Tests not required	**N/A**
Tests required but not tested	**Req**
Tests required which has passed tests	**Pass**

	Tests			
Ref	Title	To be Notified by	Status	Test Date
01-41	Various tests undertaken from the 9/07/2012 to the 30/04/2013.			
42	Chilled water and heating ccts at L2 plant room 21 and at first floor level	Brookfield	Pass	15/05/2013
43	Substation 5A Pressure Test	Brookfield	Pass	17/05/2013
44	Substation 5B Pressure Test	Brookfield	Pass	22/05/2013
45	85 Point Check Level 0 529	Brookfield	Pass	14/05/2013
46	85 Point Check Level 1 537	Brookfield	Pass	16/05/2013
47	85 Point Check Level 2 522b	Brookfield	Pass	20/05/2013
48	85 Point Check Level 3 5xx	Brookfield	Pass	30/05/2013
50	Below ground drainage test Zone F Pour 4/5	Brookfield	Pass	14/05/2013
51	Below ground drainage test Zone C Pour 3	Brookfield	Pass	30/05/2013

Inspection not required	**N/A**
Inspection required	**Req**
Inspection complete	**Pass**

	Inspections			
Ref	Title	To be Notified by	Status	Inspection Date
Inspections 1 to 3 from 09/03/2013 to 20/03/2013				
1	85 point check to partition Level 0	Brookfield	Pass	10/04/2013

7.0 DEFECTS NOTIFICATIONS ISSUED

NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND ENERGY CENTRE

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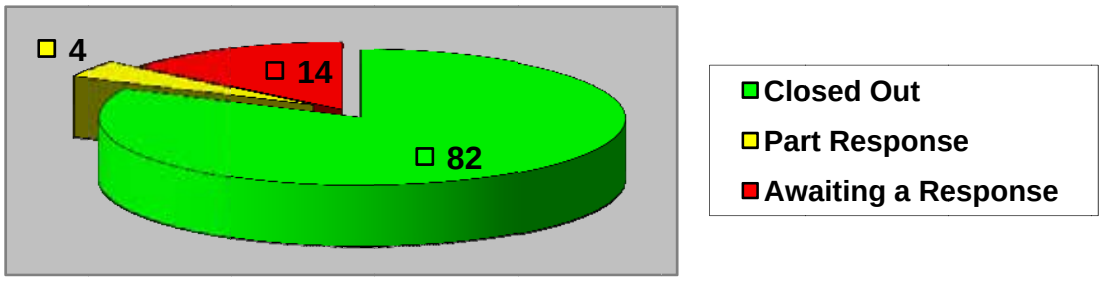

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Item No.	Description	Date Requested	Comment
Items 1 to 11 have been closed out			
12	Motorised damper inaccessible due to adjacent duct in Plant Room.	02.10.12	Closed.
13	Restricted access to ductwork access hatch in corridor adjacent to Zone H near Stair Core F	02.10.12	Response received.
14	Ductwork obstructed by modular frame Zone H.	02.10.12	Response received.
15	Part of stud, Level 2 Zone D cut away.	10.10.12	Closed
16	Fixing to cladding visible. Confirm when this will be addressed	18.10.12	Closed
Items 17 to 36 have been closed out			
37	Confirm that the smoke detect has been fitted in accordance with BS5389 in room AAW-384. E.g., not be mounted within 500mm of any walls or partitions.	14.01.13	Closed
38	Fire rated ductwork did not penetrate into the neighbouring space greater than 150mm as detailed on the approved design drawings in level 2 theatres.	14.01.13	Closed
39	Insulation dislodged at high level due to electrical work. Confirm when remedied.	16.01.13	Open
40	AVSU incorporated into hazard room partition. Confirm that the partition housing the AVSU can achieve 30 minutes on the corridor side of the partition.	20.02.13	Closed
41	Insulation removed and displaced from the partition at high level. Conform when this has been addressed.	21.02.13	Closed
42	Restrictive access to duct. Confirm when addressed.	26.02.13	Closed
43	Screws within the back boxes. Advise when this has been rectified.	05.03.13	Closed
44	Provide programme for replacing damaged cladding.	11.03.13	Closed
45	Please confirm the proposals to address the gaps between the lead lined noggins and confirm proposals are approved.	12.03.13	Closed
46	A screw is penetrating inside of the back box in room AAW-097. Confirm when this has been addressed.	03.04.13	Closed
47	Ducting inadequately supported.	05.04.13	Closed
48	Confirm remedial action to address the restricted access to the duct hatch.	09.04.13	Open
49	Confirm that all curtain rails will be fitted in accordance with the manufacturer's recommendations or provide details where there are changes to the standard detail.	12.04.13	Closed
50	Confirm when lead lined penetrations have been removed and holes sealed	09.05.13	Closed
51	Knauf boards not fixed in accordance with NBS Specifications. Boards fixed too close to edge of board.	14.05.13	Open
52	Confirm when penetrations through roof protection membrane have been repaired.	16.05.13	Closed
53	Confirm when appropriat5e access to hyat5ches in level 3 Zone A are provided.	16.05.13	Open
54	Faulty internal blinds. Confirm when remedial action has been completed.	30.05.13	Open
55	Confirm when damaged fire coating has been renewed and provide dry film test results.	30.05.13	Open
56	Confirm when restriction to access hatch has been addressed.	03.06.13	Open

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John Redmond
Capita Symonds
Technical Advisory Services

The Beacon, 8th Floor, 176 St Vincent Street, Glasgow G2 5SG

	Signed	Date
Originated by	John Redmond	6th June 2013
Completed by	David Ramsay	6th June 2013

NICE National Institute for Health and Care Excellence

NICE quality standard

Healthcare-associated infections

Quality standard

Published: 11 February 2016

www.nice.org.uk/guidance/qs113

Contents

This standard is based on PH36.

This standard should be read in conjunction with QS75, QS61, QS49, QS15, QS121, QS161 and QS168.

Introduction

This quality standard covers organisational factors in preventing and controlling healthcare-associated infections in secondary care settings.

Organisational factors include management arrangements, policies, procedures, monitoring, evaluation, audit and accountability. Secondary care settings include hospital buildings and grounds; inpatient, day case and outpatient facilities and services; elective and emergency care facilities; and hospital maternity units and services. Throughout this quality standard, the term 'hospital' is used for ease of reference to represent the organisation responsible for services provided in secondary care settings.

This quality standard should be read alongside NICE's quality standards on infection prevention and control and surgical site infection. Other related quality standards are listed in related NICE quality standards.

The quality statements that follow build on the Health and Social Care Act 2008: code of practice on the prevention and control of infections of practice.

For more information see the healthcare-associated infections topic overview.

Why this quality standard is needed

Healthcare-associated infections are a serious risk to patients, staff and visitors. They can cause significant morbidity to those infected and significant costs for the NHS. As a result, infection prevention and control is a key priority for the NHS.

Healthcare-associated infections cover any infection contracted:

- as a direct result of treatment in, or contact with, a health or social care setting

- as a result of healthcare delivered in the community
- outside a healthcare setting (for example, in the community) and brought in by patients, staff or visitors and transmitted to others (for example, norovirus).

The most well-known healthcare-associated infections, for which mandatory reporting is currently required, include those caused by meticillin-resistant *Staphylococcus aureus* (MRSA), meticillin-sensitive *Staphylococcus aureus* (MSSA), *Clostridium difficile* (*C difficile*) and *Escherichia coli* (*E coli*). Other gram-negative bacteria (including antibiotic-resistant bacteria) and norovirus can also cause healthcare-associated infections.

The English National Point Prevalence Survey (Health Protection Agency, 2012) identified that 6.4% of inpatients in acute care hospitals in 2011 had a healthcare-associated infection. The 6 most common types of healthcare-associated infections, which accounted for more than 80% of all healthcare-associated infections, were pneumonia and other respiratory infections (22.8%), urinary tract infections (17.2%), surgical site infections (15.7%), clinical sepsis (10.5%), gastrointestinal infections (8.8%), and bloodstream infections (7.3%).

The quality standard is expected to contribute to improvements in the following outcomes:

- hospital-acquired harm
- length of stay in acute care
- antimicrobial resistance
- avoidable morbidity
- avoidable mortality
- incidence of *C difficile* and MRSA
- patient experience
- avoidable hospital admissions
- accident and emergency department attendance.

How this quality standard supports delivery of

outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measurable improvements in the 3 dimensions of quality – patient safety, patient experience and clinical effectiveness – for a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 3 outcomes frameworks published by the Department of Health:

- NHS Outcomes Framework 2015 to 2016
- Adult Social Care Outcomes Framework 2015 to 2016
- Public Health Outcomes Framework 2013 to 2016.

Patient experience and safety issues

Ensuring that care is safe and that people have a positive experience of care is vital in a high-quality service. It is important to consider these factors when planning and delivering services that seek to prevent and control healthcare-associated infections.

Coordinated services

The quality standard for healthcare-associated infections specifies that services should be commissioned from and coordinated across all relevant agencies. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care and preventing and controlling healthcare-associated infections in secondary care settings.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality. Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality services related to healthcare-associated infections are listed in related NICE quality standards.

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All health, public health and social care practitioners involved in the prevention and control of healthcare-associated infections in secondary care settings should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard. Quality statements on staff training and competency are not usually included in quality standards. However, recommendations in the development source(s) on specific types of training for the topic that exceed standard professional training are considered during quality statement development.

Role of families and carers

Quality standards recognise the important role families and carers have in supporting people with healthcare-associated infections in secondary care settings. If appropriate, healthcare professionals should ensure that family members and carers are involved in the decision-making process about investigations, treatment and care and are also provided with advice and guidance on hygiene and infection prevention and control.

List of quality statements

Statement 1 Hospitals monitor healthcare-associated infections and other infections of local relevance to drive continuous quality improvement.

Statement 2 Hospitals work with local health and social care organisations to assess and manage the risk of infections in hospitals from community outbreaks and incidents.

Statement 3 Hospital staff have individual objectives and appraisals on infection prevention and control linked to board-level objectives and strategies.

Statement 4 Hospitals involve infection prevention and control teams in the building, refurbishment and maintenance of hospital facilities.

Statement 5 People admitted to, discharged from, or transferred between or within hospitals have information about any infections and associated treatments shared with health and social care staff to inform their care.

Quality statement 1: Surveillance

Quality statement

Hospitals monitor healthcare-associated infections and other infections of local relevance to drive continuous quality improvement.

Rationale

Mandatory national and local surveillance of healthcare-associated infections (such as *Staphylococcus aureus* [MRSA] and *Clostridium difficile* [*C difficile*]) provides information that can be used to assess the infection risk of people in hospital and inform the response. However, mandatory monitoring only covers a small number of healthcare-associated infections. Identification and monitoring of other infections of local relevance, including resistant organisms, contributes to a fuller understanding of the risk of infection to people in hospital. The results of monitoring can be used by staff across the organisation to help inform practice, review the effectiveness of responses, and review how well strategies to reduce healthcare-associated infections are working.

Quality measures

Structure

a) Evidence of local arrangements for hospitals to monitor healthcare-associated infections and other infections of local relevance.

Data source: Local data collection.

b) Evidence of local arrangements for the results of monitoring healthcare-associated infections and other infections of local relevance to be used across the organisation to inform and review objectives for quality improvement.

Data source: Local data collection.

Outcome

Incidence of healthcare-associated infections.

Data source: Local data collection and national data collection including NHS Outcomes Framework 2015 to 2016 indicator 5.2 (MRSA and *C difficile*); Clinical Commissioning Group [CCG] Outcome Indicator Set 2015 to 2016 indicators 5.3 (MRSA) and 5.4 (*C difficile*). National data derived from the Public Health England Mandatory Surveillance of MRSA, MSSA, E coli and C difficile.

What the quality statement means for service providers, health and social care practitioners, and commissioners

Service providers (hospitals) ensure that systems are in place to carry out mandatory monitoring of healthcare-associated infections and other infections of local relevance, including resistant organisms; and ensure that the results are shared across the organisation and used to drive continuous quality improvement.

Health and social care practitioners in secondary care (including hospital clinicians, nursing staff and allied healthcare professionals) report healthcare-associated infections, act on information provided to them about local infections to reduce infection risk, and adjust clinical practice for continuous improvement.

Commissioners (such as clinical commissioning groups) ensure that they commission services from hospitals that have systems to carry out mandatory monitoring of healthcare-associated infections and other infections of local relevance, including resistant organisms; and ensure that they share the results across the organisation to drive continuous quality improvement.

What the quality statement means for patients, service users and carers

People receiving treatment in, or visiting, hospitals can expect the hospital to monitor infection levels across all service areas to help improve services and minimise future infection rates.

Source guidance

Healthcare-associated infections: prevention and control. NICE guideline PH36 (2011), quality improvement statements 1 and 3

Definitions

Monitor healthcare-associated infections

Monitoring includes mandatory monitoring of healthcare-associated infections and also other infections that are of local relevance, including resistant organisms, within the hospital setting. Monitoring should be through a surveillance system that detects organisms and infections, and promptly registers any abnormal trends. Data from multiple sources (epidemiological, clinical, microbiological, surgical and pharmacy) need to be combined in real time, and should allow for timely recognition of incidents in different spaces (for example, wards, clinical teams, clinical areas and across the whole trust). Surveillance data in key areas should be regularly compared with other local and national data. [Adapted from NICE's guideline on healthcare-associated infections: prevention and control]

Continuous quality improvement

Improving the provision of services and practice by using a range of audit and statistical tools to assess the current situation, identify areas for improvement and measure the results. [NICE's guideline on healthcare-associated infections: prevention and control]

Quality statement 2: Collaborative action

Quality statement

Hospitals work with local health and social care organisations to assess and manage the risk of infections in hospitals from community outbreaks and incidents.

Rationale

Healthcare-associated infections are a serious risk to hospital patients, staff and visitors. Infections contracted outside a hospital setting can be brought into the hospital by patients, visitors and staff, and transmitted to others. By identifying and assessing potential risks from community outbreaks and incidents, hospitals can take action in collaboration with other local health and social care organisations, including public health services, to reduce the risk of infection.

Quality measures

Structure

a) Evidence of local arrangements for hospitals to monitor the risk of healthcare-associated infections from incidents and outbreaks in the community.

Data source: Local data collection.

b) Evidence of local arrangements for collaborative working between hospitals and other local health and social care organisations to investigate and manage the risks of healthcare-associated infection from incidents and outbreaks in the community.

Data source: Local data collection.

Outcome

Incidence of healthcare-associated infections.

Data source: Local data collection and national data collection including NHS Outcomes Framework 2015 to 2016 indicator 5.2 (MRSA and *C difficile*); Clinical Commissioning Group [CCG] Outcome Indicator Set 2015 to 2016 indicators 5.3 (MRSA) and 5.4 (*C difficile*). National data derived from the Public Health England Mandatory Surveillance of MRSA, MSSA, E coli and C difficile.

What the quality statement means for service providers, health and social care practitioners, and commissioners

Service providers (hospitals) participate in joint working initiatives with other health, public health and social care organisations beyond mandatory requirements to share information on outbreaks and incidents in the community, and assess and minimise the risks. Joint working initiatives can include agreeing a governance structure and lines of accountability between organisations; joint development of strategy, policy, pathway and shared targets; sharing information from risk assessments; and investigating and managing outbreaks and incidents of healthcare-associated infections.

Health and social care practitioners in secondary care (including hospital clinicians, nursing staff and allied healthcare professionals) participate in joint working initiatives and implement measures introduced in response to community incidents and outbreaks to minimise the risk of infections in hospital.

Commissioners (such as clinical commissioning groups) ensure that they commission services from hospitals that can demonstrate that they work collaboratively with local health and social care organisations to assess and manage the risk of infections in hospitals from community outbreaks and incidents.

What the quality statement means for patients, service users and carers

People receiving treatment in, or visiting, hospitals can expect the hospital to work with other local health and social care organisations to help prevent infections in the community spreading into the hospital. As a result of this work, hospitals may occasionally have to change the way that people receive treatment or visit hospitals. For example, a ward may be closed to visitors, or a person may be admitted to a single room to help

prevent infections spreading.

Source guidance

Healthcare-associated infections: prevention and control. NICE guideline PH36 (2011), quality improvement statements 3 and 6

Definitions

Community outbreaks and incidents

An outbreak is usually defined as 2 or more people experiencing a similar illness linked in place and time, or a single instance of a rare or particularly harmful organism. An outbreak is only declared following the identification, notification and investigation of an incident. For example, laboratory results may confirm that 2 illnesses are caused by the same organism or strain of an organism.

An incident includes events or situations needing investigation to see if action or management to reduce a risk is needed. An incident can also include a single case of a disease. In the context of this statement, an incident is taken to include any incident with the potential to expose people to infection risk. [Expert opinion]

Quality statement 3: Responsibilities of hospital staff

Quality statement

Hospital staff have individual objectives and appraisals on infection prevention and control linked to board-level objectives and strategies.

Rationale

Trust boards provide leadership in infection prevention and control, but all hospital staff have responsibility for, and are accountable for, infection prevention and control. Boards can help minimise the risk to patients and ensure continuous quality improvement by leading on and regularly reviewing all relevant infection prevention and control objectives, policies and procedures. A clear governance structure and accountability framework will allocate specific responsibilities to all staff. All staff having these responsibilities as clear objectives that are reviewed in appraisals and reflected in development plans will help ensure that board-level objectives are achieved and that the risk of healthcare-associated infection is minimised.

Quality measures

Structure

a) Evidence of local arrangements to ensure all staff have clear objectives in relation to infection prevention and control that are linked to board-level objectives.

Data source: Local data collection.

b) Evidence of local arrangements to ensure all staff have an appraisal and development plan that cover infection prevention and control.

Data source: Local data collection.

Process

a) Proportion of hospital staff who have individual infection prevention and control objectives that are linked to board-level objectives.

Numerator – the number in the denominator who have individual infection prevention and control objectives that are linked to board-level objectives.

Denominator – the number of hospital staff.

Data source: Local data collection.

b) Proportion of hospital staff who have an appraisal of their infection prevention and control objectives.

Numerator – the number in the denominator who have an appraisal of their infection prevention and control objectives.

Denominator – the number of hospital staff.

Data source: Local data collection.

c) Proportion of hospital staff who have a development plan that includes infection prevention and control.

Numerator – the number in the denominator who have a development plan that addresses individual needs for knowledge, abilities and skills in infection prevention and control.

Denominator – the number of hospital staff.

Data source: Local data collection.

What the quality statement means for service providers, hospital staff, and commissioners

Service providers (hospitals) in secondary care settings ensure that all staff have objectives in relation to infection prevention and control that are linked to the board's

objectives and strategies, that these objectives are appraised and included in development plans, and that staff are supported to carry out these objectives.

Hospital staff (including hospital clinicians, nursing staff, allied healthcare professionals, administrative staff and catering staff) in secondary care settings follow working practices and tasks on infection prevention and control described in their personal objectives; have feedback on their performance against these objectives through an appraisal; and are supported to ensure that learning, training and other development needs on infection prevention and control set out in a development plan are met.

Commissioners (such as clinical commissioning groups) ensure that they commission services from secondary care providers that appraise and support their staff to achieve their objectives on infection prevention and control.

What the quality statement means for patients, service users and carers

People receiving treatment in, or visiting, hospitals can expect that all hospital staff have the skills and knowledge needed to carry out infection prevention and control procedures in their area of work.

Source guidance

Healthcare-associated infections: prevention and control. NICE guideline PH36 (2011), quality improvement statement 4

Definitions

Hospital staff

All clinical and non-clinical staff, including support staff, volunteers, agency or locum staff and those employed by contractors. [Adapted from NICE's guideline on healthcare-associated infections: prevention and control]

Quality statement 4: Planning, design and management of hospital facilities

Quality statement

Hospitals involve infection prevention and control teams in the building, refurbishment and maintenance of hospital facilities.

Rationale

In a healthcare setting the built environment can play a significant role in the transmission of infection. The design of new buildings, as well as their refurbishment and ongoing maintenance, should allow good infection prevention and control practices. Involving infection prevention and control teams in the planning, design and maintenance of hospital facilities can ensure that needs are anticipated, planned for and met, and that the risk of healthcare-associated infections is minimised.

Quality measures

Structure

a) Evidence of local arrangements for involving infection prevention and control teams in the building and refurbishment of facilities in the hospital. Examples of evidence may include protocols covering infection prevention and control in the built environment; estate department procedures to engage infection prevention and control teams in new build and refurbishment projects; building and refurbishment project plans and schedules of work that show the involvement of infection prevention and control teams; and records of completed building and refurbishment works that show whether infection prevention and control requirements have been met.

Data source: Local data collection.

b) Evidence of local arrangements for involving infection prevention and control teams in the maintenance of facilities in the hospital. Examples of evidence may include protocols

covering infection prevention and control in the built environment; estate department procedures to engage infection prevention and control teams in maintenance works; maintenance plans and schedules that show the involvement of infection prevention and control teams; and records of completed maintenance works that show whether infection prevention and control requirements have been met.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (hospitals) in secondary care settings ensure that infection prevention and control teams are involved in planning, design and maintenance of hospital facilities, as part of managing and maintaining the whole estate to minimise the risk from infection. Providers should follow best practice guidance where available, such as Infection control in the built environment: Health Building Note 00-09 (Department of Health and Social Care, 2013), which identifies infection prevention and control issues and risks that need to be addressed at each stage of a new build or refurbishment project.

Healthcare professionals (including hospital clinicians and nursing staff) who are part of hospitals' infection and control teams are involved in the planning, design and maintenance of hospital facilities. This may include identifying design issues (such as provision of isolation facilities, decontamination facilities and hand hygiene facilities); agreeing the requirements for infection prevention and control; risk assessing the works to be undertaken and advising on the necessary measures to protect patients, visitors and staff; ensuring that control measures are implemented and adhered to; and attending estates and property project planning meetings.

Commissioners (such as clinical commissioning groups) ensure that they commission secondary care services from providers where infection prevention and control teams are involved in the planning, design and maintenance of hospital services and facilities.

What the quality statement means for patients, service users and carers

People receiving treatment in, or visiting, hospitals can expect the hospitals, and their related buildings and grounds, to be designed and looked after in a way that minimises the risk of infection.

Source guidance

Healthcare-associated infections: prevention and control. NICE guideline PH36 (2011), quality improvement statement 10

Quality statement 5: Admission, discharge and transfer

Quality statement

People admitted to, discharged from, or transferred between or within hospitals, have information about any infections and associated treatments shared with health and social care staff to inform their care.

Rationale

Potentially avoidable healthcare-associated infections can occur when people are admitted to, discharged from or transferred between or within hospitals. Sharing information on current infections, treatment and colonising organisms can result in better care and outcomes for people with, or at risk of, infections and can help to reduce the risk of infections being spread between care settings. A consistent approach to sharing information between health and social care practitioners involved in a patient's care pathway should ensure appropriate ongoing support, and minimise the risk of inappropriate management and transmission of infection. Information should be shared when arrangements are made for a person to move from the care of one organisation to another, or when arrangements are made to move a person within a hospital, while maintaining patient confidentiality and privacy.

Quality measures

Structure

Evidence of local arrangements to ensure information about any infections and associated treatments for people admitted to, discharged from, or transferred between or within hospitals, is shared with the health and social care staff responsible for the ongoing care.

Data source: Local data collection.

Process

a) Proportion of admissions to hospital, including transfers of patients from other hospitals, where information on infections and associated treatments is received.

Numerator – the number in the denominator where information on infections and associated treatments is received.

Denominator – the number of admissions to hospital of people with infections.

Data source: Local data collection.

b) Proportion of discharges from hospital, including transfers of patients to other hospitals, where information on infections and associated treatments is provided to health and social care staff responsible for ongoing care.

Numerator – the number in the denominator where information on infections and associated treatments is provided.

Denominator – the number of discharges from hospital of people with infections.

Data source: Local data collection.

c) Proportion of transfers of patients within a hospital where information on infections and associated treatments is provided to health care staff responsible for ongoing care.

Numerator – the number in the denominator where information on infections and associated treatments is provided to health care staff responsible for ongoing care.

Denominator – the number of transfers of patients between wards within a hospital.

Data source: Local data collection.

What the quality statement means for service providers, health and social care practitioners, and commissioners

Service providers (such as hospitals and social care providers) provide information about any infections, colonising organisms and associated treatments when they arrange for a person to be moved into or out of hospital, or between wards, to inform the ongoing care of that person and minimise the risk of transmission. If appropriate, information should also be shared with the providers of transport for a person moving into or out of hospital.

Health and social care practitioners (including hospital clinicians, nursing staff and practitioners in care homes) involved in hospital admission, discharge and transfer ensure that they share information with other healthcare professionals and social care practitioners to manage and support patients with an infection on an ongoing basis during admission, transfer and discharge.

Commissioners (such as clinical commissioning groups) ensure that they commission services from health and social care providers that have mechanisms in place to ensure that information about any infections, colonising organisms and associated treatments is shared as part of the transfer process and used to inform the ongoing care of patients admitted to, discharged from or transferred between or within hospitals.

What the quality statement means for patients, service users and carers

People who are admitted to, discharged from, or transferred between or within hospitals have information about any infections they have and their treatment, and any treatments they are having that include a risk of infection, shared with the health and social care staff responsible for their care.

Source guidance

Healthcare-associated infections: prevention and control. NICE guideline PH36 (2011), quality improvement statement 8

Definitions of terms used in this quality statement

Information about any infections and associated treatments

This includes information sharing to manage and support patients with existing infections – for example, transfer and isolation arrangements for them – during hospital admission, transfer and discharge. Information on infections and treatments being given for existing infections should also be shared with the health and social care practitioners who will be giving the continuing care, along with information relating to the ongoing use of medical devices (such as catheters) where there is a risk of healthcare-associated infections.

[Adapted from NICE's guideline on healthcare-associated infections: prevention and control].

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

See NICE's how to use quality standards for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

NICE's quality standard service improvement template helps providers to make an initial assessment of their service compared with a selection of quality statements. It includes assessing current practice, recording an action plan and monitoring quality improvement.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in development sources.

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and equality assessments for this quality standard are available.

Good communication between health, public health and social care practitioners and people with healthcare-associated infections, and their carers (if appropriate), is essential. Treatment, care and support, and the information given about it, should be both age-appropriate and culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with healthcare-associated infections in hospitals, and their carers (if appropriate), should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

Development sources

Further explanation of the methodology used can be found in the quality standards process guide.

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

Healthcare-associated infections: prevention and control. NICE guideline PH36 (2011)

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- Department of Health. The Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance (2015)
- Department of Health. Infection control in the built environment: Health Building Note 00-09 (2013)
- Health Protection Agency. Healthcare-associated infection: operational guidance and standards for health protection units (2012)

Definitions and data sources for the quality measures

NHS Outcomes Framework 2015 to 2016

Related NICE quality standards

- Flu vaccination: increasing uptake. NICE quality standard 190 (2020)
- Sepsis. NICE quality standard 161 (2017, updated 2020)
- Antimicrobial stewardship. NICE quality standard 121 (2016)
- Neonatal infection. NICE quality standard 75 (2014)
- Infection prevention and control. NICE quality standard 61 (2014)
- Surgical site infection. NICE quality standard 49 (2013)
- Patient experience in adult NHS services. NICE quality standard 15 (2012, updated 2019)

The full list of quality standard topics referred to NICE is available from the quality standards topic library on the NICE website.

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 4. Membership of this committee during the period the quality standard was produced included:

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About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, this may not always be appropriate in practice. Taking account of safety, shared decision-making, choice and professional judgement, desired levels of achievement should be defined locally.

Information about how NICE quality standards are developed is available from the NICE website.

See our webpage on quality standard advisory committees for details of standing committee members who advised on this quality standard. Information about the topic experts invited to join the standing members is available from the webpage for this quality standard.

This quality standard has been included in the NICE Pathway on prevention and control of healthcare-associated infections, which brings together everything we have said on a topic in an interactive flowchart.

NICE has produced a quality standard service improvement template to help providers make an initial assessment of their service compared with a selection of quality statements. This tool is updated monthly to include new quality standards.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning

or providing care that may be relevant only to England.

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Endorsing organisation

This quality standard has been endorsed by Department of Health and Social Care, as required by the Health and Social Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- British Kidney Patient Association
- British Association of Dermatologists (BAD)
- UK Clinical Pharmacy Association (UKCPA)
- MRSA Action UK
- College of General Dentistry

NHS GREATER GLASGOW & CLYDE

STANDARD OPERATING PROCEDURE (SOP)

FOR MINIMISING THE RISK OF *Pseudomonas aeruginosa* INFECTION FROM WATER

Applicable in all adult and paediatric intensive care units and neonatal units (Levels 1, 2 and 3)

Effective from: May 2018 Review date: May 2019 Version: 3

This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

SOP Objective

To minimise the risk of *Pseudomonas aeruginosa* infection in healthcare premises from water.

Key changes from previous version :

1. Additional comment re cleaning of humification tanks Appendix 1
2. Change from water sampling in all high risk areas to 'Those high risk areas in NHS GGC which have flow straighteners on water outlets in patient areas' on page 4 and page 10
3. Revised PA audit / checklist

Document Control Summary

Approved by and date	Board Infection Control Committee, NHS GGC Board Water Safety Group, NHS GGC
Date of Publication	23/05/18
Developed by	IPCT
Related Documents	Standard Infection Control Precautions (SICPs) - (NIPCM)
Distribution/Availability	NHSGGC Infection Prevention and Control web page www.nhsggc.org.uk/infectioncontrol
Lead Manager	Board Infection Control Manager
Responsible Director	Board Medical Director

Draft 2018

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Introduction

This SOP provides direction and guidance for ward based staff to meet their responsibilities as stated in *HPS(2017) Guidance for neonatal units (NNUs) (levels 1,2&3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water.* This document refers to critical control points 2 – 4 (inclusive) only. (Critical points 1, 5 and 6 are considered in the NHSGGC Water Safety Policy and Written Scheme 2016).

All wards / departments listed in the risk assessment for additional control measures to minimise the risk of *Pseudomonas aeruginosa* infection from water should be included in this guidance.

1. Responsibilities

Senior Charge Nurses (SCNs) must:

- Follow this SOP.
- Undertake flushing of taps on clinical hand wash basins in clinical areas on days when the Facilities exception reports highlight that daily cleaning of those sinks has not been possible.
- Keep records of flushing of these taps for at least one month.
- Inform a member of the local Estates Team if this SOP cannot be followed in relation to flushing water outlets.
- Inform a member of the local Estates Team of infrequently used outlets which could be removed.
- Allow members of the local Estates Team access to complete maintenance as appropriate.

Estates must:

- Undertake actions deemed the responsibility of the local Estates Department as per the Water Safety Policy and Written Scheme.
- Keep a record of outlets reported that are deemed to be infrequently used and actions taken by them to remove this risk.
- Provide a report of maintenance actions and issues/ anomalies to the Sector Water Safety Group.
- Support staff locally to undertake their responsibilities in terms of reducing risk associated with pseudomonas.

Managers must:

- Make this SOP available to their staff.
- Support SCNs in following this SOP.

Board Water Systems Safety Group must:

- Keep this SOP up-to-date.
- Audit compliance with this SOP.
- Provide guidance via the Water Systems Safety Policy.

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2. Critical Point 2: Flushing Water Outlets to reduce the risk of Pipework System Contamination

Flushing of water outlets is necessary to control the build-up of biofilm in water systems to reduce the risk of transmission of pathogens via the environment and equipment to patients.

The Senior Charge Nurse (SCN) in each unit has responsibility (under current guidance) to ensure that the following recommendations are complied with in their area. The SCN should ensure that:

1.1 All water outlets are flushed in high-risk environments (patient areas and areas where clinical procedures are prepared or performed) daily, first thing in am for 1 minute at full flow (but not so that splashing goes beyond the basin). This must be recorded. In practice this will be assigned to the Facilities department as part of the local cleaning schedule. Where this has not been possible e.g. access issues, then the flushing will be carried out by the SCN and a record kept (See Appendix 2).

1.2 Any problems or concerns relating to the safety, maintenance, reduced usage, any changes in use and cleanliness of all water outlets must be identified and reported to the ICT and the Estates Department as relevant.

3. Critical Points 3 -4

The check list at **Appendix 1** should be used by the SCN as a guide and assessment tool to provide assurance that risks from contamination by *P. aeruginosa* are managed as far as possible by ward staff in high risk areas.

Where units do not meet the guidance, an action plan should be developed to remedy any risks identified through this process.

Those high risk areas in NHS GGC which have flow straighteners on water outlets in patient areas, will be subject to 6 monthly water sampling for PA as per regime outlined in **Appendix 3**

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4. Critical Control Point 5: Surveillance and preparedness

IPCTs will:

- Include *Pseudomonas aeruginosa* from blood culture as an alert organism from all in-patient areas and from all specimens from ICUs, NICUs, PICUs and transplant units.
- Liaise with microbiology if further water testing required (e.g. suspected / confirmed outbreak)

Clinical Managers will:

- Support IPCT to undertake an assessment of the patients and ward
- Have a contingency plan for NICUs, PICU and ICUs to continue safe patient care without use of tap water, if identified as a source.

5. Critical Control Point 6: Investigation and control measures for clinical incidents

Where alert surveillance identifies *Pseudomonas aeruginosa* bacteraemia in one of the adult high risk areas, or in any specimen from NICUs and PICU, the IPCT will undertake immediate assessment to determine if this is healthcare associated. Consideration should be given to: previous colonisation / infection with PA; review of patient's care; possible reservoirs in the clinical area and all relevant microbiology results. The following action should be undertaken:

1 isolate of PA in a high risk unit: The IPCT will undertake an audit using the PA Ward Audit Checklist (Appendix 1). If no issues, then no further action. If actions required , liaison with SCN to support remedial action. Summarise actions in SBAR for IPCT and SCN.

2 isolates of PA in 2 patients in 2 weeks
The IPCT will undertake an audit using the PA Ward Audit Checklist (Appendix 1). An incident meeting will be arranged with IPCT, clinical team and relevant staff, including estates and or microbiology to agree investigation and action required. Minutes should be kept and the incident summarised in an SBAR for IPCT and Sector Management Team.

6. References

HPS (2017) Guidance for neonatal units (NNUs) (levels 1,2 &3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of *Pseudomonas aeruginosa* from water.

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Appendix 1: PA Ward Audit Checklist / Assessment Tool:

Critical Control Point 3: Preventing Direct Water Usage Colonising / Infecting Vulnerable Patients		**Requirement met Yes/No**	**Actions required/ completed**
1.1	**Washing Babies and high risk patients:** Patients are washed (inc. face, body wash, top & tail, bed bath, nappy change and immersion bath) using clean, fresh tap water/ commercial wipes.		
1.2	**Defrosting Breast Milk:** Breast milk is defrosted either: • in a designated milk fridge • outside fridge at room temperature OR • using a warming/ defrosting device designed to ensure no direct contact with the bottle/ syringe with non-sterile water. • Using sterile water warmed in a warming cabinet NB: Discard any milk not used once defrosted DO NOT USE WARM TAP WATER		
1.3	**Warming Breast/ Formula Milk:** • Milk is taken out of fridge one hour prior to use OR • Milk is warmed using a warming device designed to ensure no direct contact with the bottle/ syringe with non-sterile water. • Use warmed (in warming cabinet), sterile water		
1.4	**Use of Ice:** • Ice is not used for direct baby care in NNUs (all levels). • Ice for consumption by severely immunocompromised patients should be made with sterile water and not taken from an ice machine.		

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Critical Control Point 4: Preventing Indirect Contact with *P. aeruginosa* from Colonised/ Infected Patients		**Requirement met Yes/No**	
2.1	**Hand Wash Stations:** • Clinical hand wash sinks are used for hand washing only. • Clinical Hand wash sinks are cleaned at least daily as per National Cleaning Specification. • Hand hygiene product bottles are never topped up • Hand hygiene should be undertaken as per National Infection Prevention and Control Manual (NIPCM)		
2.2	**Aseptic Procedures:** • Aseptic procedures are prepared and/ or performed in an area where there are no concurrent procedures being undertaken that generate splashing which could contaminate a sterile surface. • Decontaminate all aseptic procedure surfaces with a detergent or alcohol wipe		
2.3	**Aerosol Generating Procedures:** Existing guidance in the NIPCM for aerosol generating procedures is followed.		
2.4	**Discarding Potentially Contaminated water/ fluids:** • Small volumes of fluid, e.g. ET/ ventilator condensate, are discarded into clinical waste bags. • Larger volumes, e.g. bath water etc, are safely transported to a sink (not a hand wash sink) or sluice.		

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Critical Control Point 4: Preventing Indirect Contact with *P. aeruginosa* from Colonised/ Infected Patients		**Requirement met Yes/No**	
2.5	**Suction/ Chest Drain Bottles:** Disposable suction container liners are sealed and discarded in a suitable container or solidifying gel is used prior to discarding in healthcare waste.		
2.6	**Equipment Decontamination: Incubators** All re-usable equipment is thoroughly dried including mattress and all other parts, following decontamination.		
2.7	**Humidifiers:** • Humidifiers on incubators: Only sterile or distilled water is used to fill and top up. • Re-usable humidifiers are decontaminated in a Central Decontamination unit (CDU). If not able to withstand reprocessing in a CDU, then manufacturer's instructions must be followed.		
2.8	**Storage of Equipment:** Patient equipment is not stored where they may be exposed to splash contamination.		
2.9	**Non-Clinical Procedures that create a spray:** • No fluid containers are topped up • Spray bottles are not used for cleaning solutions. • Spray bottles are not used in areas where aseptic procedures are being prepared or are ongoing. • Avoid use of spray bottles where possible		

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Appendix 2: Example of Flushing Record for high risk areas

DAILY FLUSHING OF WATER OUTLETS

ROOM NUMBER/ BED SPACE	DATE	SIGNATURE

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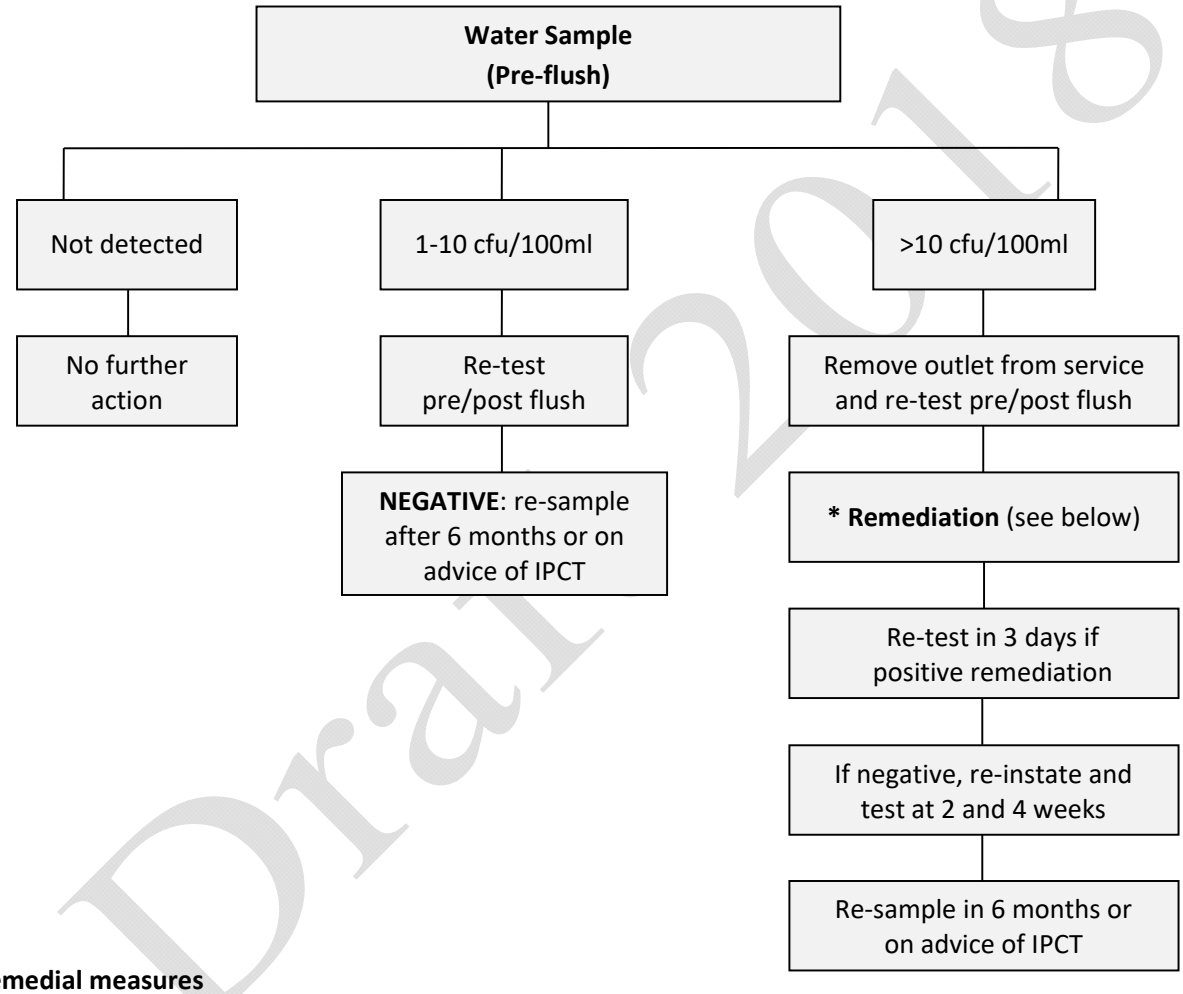
Appendix 3: Water testing protocol for Pseudomonas aeruginosa in NICU

High risk areas whose water outlets in patient areas have flow straighteners should be sampled 6-monthly

Water outlets which should be sampled include those with supply water that have:

- direct contact with patients
- used to wash staff hands before and after clinical procedures
- used to clean equipment that will have contact with patients



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*** Remedial measures**

Consider the following:

- Continue daily flushing while out of use
- If practical consider removal of flow straighteners
- Hand washing should be supplemented by the use of alcohol gel
- Check unit for little-used outlets and if possible remove
- Check pipework for deadlegs and blind ends

- Consider disinfection e.g. chlorine dioxide
- Consider replacement taps
- Ensure best practice in relation to handwash basins
- Use bottled water for baby bathing until re-test –ve

Interpreting pre and post flush counts
High counts pre-flush (> 10 cfu/100ml) and low post flush (<10cfu/100ml) suggests local water outlet problem.

High count pre and post flush (> 10cfu/100ml) suggests wider problem with the water supply. In this situation most outlets are likely to be positive and other points in the water system should be sampled.

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Check for updates

Journal of Infection Prevention

Editorial

Revisiting Florence Nightingale: International Year of the Nurse and Midwife 2020

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Heather P Loveday

This year sees the bicentennial anniversary of the birth of Florence Nightingale and has been designated the International Year of the Nurse and Midwife by the World Health Organization (WHO) and the International Council of Nurses in support of the Burdett Trust's Nursing Now campaign which culminates at the end of 2020. The campaign aims to increase the profile and influence of nurses globally, emphasising the central role they have in helping to deliver the sustainable development goal of universal health coverage globally.

Florence Nightingale was born in 1820, and during her 90-year lifetime, she made an outstanding contribution to nursing, public health and the design and management of hospitals. In two articles about Florence Nightingale, Bill Newsom suggested that three of her books, *Notes on Hospitals* (1859 and 1863), *Notes on Nursing* (1860) and *Introductory Notes on Lying-in Institutions* (1871), had an enduring influence on infection control (Newsom, 2003a, 2003b). More recently, the popular romantic perspective of Florence Nightingale as the "lady with the lamp" has come under critical scrutiny. She was by all accounts a difficult person to get along with, and her privileged upbringing lead to difficult relationships with medical staff and other nursing contingents in the Crimea (Small, 2017; Williams, 2008).

However, it is apparent from the many biographies that chart her life that Florence Nightingale possessed qualities and skills that remain highly relevant to nursing roles globally. Her observation and organisation skills; a commitment to the fundamental requirements of those with health needs; a recognition of the power of collecting, analysing and using data to illustrate the need for change; and her ability to engage politicians, scientific collaborators and the media to influence opinion and change are all qualities that are critical to infection prevention and control practitioners of today.

Importance of fundamental elements of care

In January 2019, the UK Government published "Contained and controlled: The UK's 20-year vision for antimicrobial resistance" and a "5-year national action plan to combat antimicrobial resistance 2019–2024" (Department of Health, 2019a, 2019b). Both continued to advocate the centrality of infection prevention as a means of minimising antimicrobial resistance (AMR) and preserving our ability to treat infection with available antimicrobials. Infection-prevention interventions are largely focused on taking the opportunity to avert the transmission of an infectious agent from a reservoir to a susceptible host. The factors that lead to a person becoming a susceptible host are legion, but globally the socio-economic deprivation experienced by sectors of the population in low-, middle- and high-income countries is among the most frequent. In Europe, there is evidence that in the 10 years since the global financial crisis, health inequalities play a role in the transmission of infection and infectious disease (European Centre for Disease Prevention and Control, 2013) and were exacerbated by cuts in public spending on public health and healthcare provision. Wilson (2018) suggested that the marked regional variation in *Escherichia coli* bloodstream infections may be due to a range of socio-economic factors, including reductions in social-care spending.

Florence Nightingale was a follower of Edwin Chadwick, a pioneer of public-health legislation. Her experience as a volunteer at the Middlesex Hospital in London during the Cholera outbreak in 1854 convinced her that the medical interventions of the day hastened the death of patients. Nightingale's assessment of the situation on her arrival at the army hospital in Scutari was influenced by her belief that good nursing was based on ensuring that patients were well fed, hydrated, clean, warm and comfortable; sharing wash cloths was discontinued, and the cleanliness of the environment was prioritised.

Over the past five years, nursing and infection-prevention practitioners have refocused on the importance of

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fundamental aspects of care such as early mobilisation (Stolbrink et al, 2014), adequate hydration (Wilson et al, 2018), nutrition (Fitzpatrick et al, 2019) and oral care (El-Rabbany et al, 2015) as being central to improving patient outcome and minimising the risk of healthcare-associated infection.

The "passionate statistician"

Florence Nightingale had the advantage of a liberal education that included mathematics, for which she showed a particular aptitude. Her use of data to drive sanitary reform in the army and later the wider public-health agenda (Kopf, 1916) resulted in her being elected as a Fellow of the Royal Statistical Society in 1858. Florence was influenced by the statistical methods and ideas of the Belgian astronomer, meteorologist and social statistician Adolphe Quetelet; throughout her early life and nursing experience in Europe and England, she collected reports, pamphlets and returns which she analysed and reported. On her return from the Crimea, Florence collaborated with William Farr, one of the foremost statisticians of the era, to analyse data provided by the army in addition to that she had collected herself. While she was aware of the high death rate at the hospital in Scutari, she had attributed it to poor nutrition, suboptimal treatment and delayed transfer to hospital from the battlefront. It was only when Farr helped her to analyse the data that she realised that more lives could have been saved if she had had a greater focus on basic sanitation. One of Nightingale's first books, *Notes on Matters Affecting Health, Efficiency, and Hospital Administration of the British Army* (1858), used statistical methods to compare the death rates of the army in peacetime with the civilian rate. Together with Farr, she showed that mortality was due to hospital conditions and concluded that "our soldiers are enlisted to die in barracks".

The National Action Plan (Department of Health, 2019b) includes the use of the WHO core components for effective infection prevention and control (IPC; Storr et al, 2017). Core component 4 focuses on healthcare-associated infections (HAI) surveillance and makes recommendations for local and national IPC surveillance. A strong recommendation (based on very low-quality evidence) indicates that local HAI and AMR surveillance and feedback to staff should be used to guide IPC interventions and detect outbreaks. Nationally, the recommendation is that national HAI surveillance programmes and feedback networks that can provide benchmarking should be established. The Public Health England Fingertips Database (Johnson et al, 2017) provides the above, but its use in driving improvement locally is yet to be evaluated. Driving improvement also requires robust design, observation and measurement skills to demonstrate and report the difference that improvement programmes have been effective. Mary Dixon-Woods (2019) comments on the lack of robust evaluation that underpins many of the improvement efforts that are undertaken in health care, and suggests that many quality-improvement initiatives are "pervaded by optimism bias. It is particularly affected by the 'lovely baby' syndrome, which happens when formal evaluation is eschewed because something looks so good that it is assumed it must work."

This links back to Nightingale's initial assumptions that delivering "clean care" (the lovely baby) would make a difference to the outcomes for soldiers nursed at Scutari when in fact they made very little difference, as she was later to realise through her analysis of the data.

Nightingale as an influencer

Florence Nightingale was an astute and perhaps manipulative influencer, having been born into a wealthy and well-connected family (Williams, 2008). The Nightingale family had three residences during the year, one in Derbyshire (Lea Hurst) where they spent the summer and early autumn, one in the New Forest (Embley) where they spent the winter, and from March to June, they were in London at the Burlington Hotel for the season. At Embley, their nearest neighbour was Lord Palmerston who held the offices of Foreign Secretary, Home Secretary and Prime Minister during his political career. Another close neighbour was Sidney Herbert who as Secretary at War was instrumental in sending Florence to the Crimea. Florence also became a media darling during and after her period at Scutari. She was a prolific writer of letters, and her sister Parthe ensured that Florence's observations were publicised in *The Times* and elsewhere. Public opinion was significantly altered by Nightingale's time in the Crimea and resulted in donations to fund the training of hospital nurses (Small, 2017).

Influencing the healthcare agenda is a political activity; Nightingale recognised this and used her connections to her advantage. Engaging with politicians and policymakers is essential if IPC practitioners are to drive change at a national and global level. The new UK AMR strategy (Department of Health, 2019a) continues to highlight the central importance of preventing infection. This provides a golden opportunity for practitioners to make clear the priorities for strengthening the evidence base for IPC and how the service is delivered across primary care, community and acute settings. This requires engagement with politicians and policymakers at a local and national level; building strong coalitions and collaborative partnerships with other professional societies creates a coherent and powerful voice for the issues that need to be addressed. These coalitions should be integrally involved in deciding on the optimal design of an IPC service and the knowledge and skills required in the workforce to prevent and address the socio-economic drivers of infection. The power of publication is obvious; Nightingale's obsession with data and its dissemination to influence change is something that IPC

practitioners should pursue. The *Journal of Infection Prevention* provides one outlet for sharing research findings and the outcome of improvement strategies with colleagues and those who make decisions about infection prevention policy. Finally, in the International Year of the Nurse and Midwife and 200th anniversary of Florence Nightingale's birth, we should not be afraid to "speak truth to power" in the pursuit of high-quality and safe care.

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All views expressed are my own.

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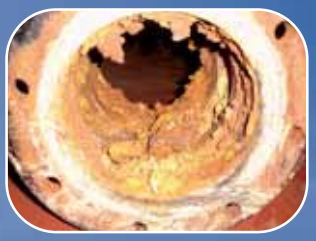

Water safety in buildings

Edited by: David Cunliffe, Jamie Bartram, Emmanuel Briand, Yves Chartier, Jeni Colbourne, David Drury, John Lee, Benedikt Schaefer and Susanne Surman-Lee

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Foreword

Extensive experience shows that poor design and management of water systems in buildings can cause outbreaks of disease. The types of building, water uses, disease outcomes and individuals affected are diverse. The health risks are preventable and can be readily controlled. However, evidence from outbreak detection suggests that the overall trend is increasing. With increasing global urbanization, the overall exposure of the human population to poorly designed or managed water systems in buildings is increasing rapidly. Consequently, the risk of disease outbreaks is also increasing. Actions to reduce the risk of disease should be considered a public health priority.

One of the challenges is that management of building water supplies is often overlooked. In many countries and regions, management actions for water supplies in buildings may fall outside the responsibility of the drinking-water supplier. This can be influenced by a range of factors, including ownership of assets and rights of access. Water safety plans (WSPs) for managing public water supplies are not typically extended to apply within buildings. In many cases, owners, managers or maintenance personnel are responsible for management of building water supplies, but awareness and application of drinking-water guidelines is often limited.

This text is one of series of supporting documents that provide guidance on implementing the World Health Organization (WHO) *Guidelines for drinking-water quality* (GDWQ) (WHO, 2008). It is intended to support improvement of water safety within buildings.

The third edition of the GDWQ (WHO, 2008) introduced the concept of WSPs within a *Framework for safe drinking-water* (see Figure 1.1 in the introduction, below). The framework focuses attention on effective preventive management and thereby disease prevention. The GDWQ include specific reference to issues associated with large buildings, such as health care facilities, schools and daycare centres, and recommend that these buildings have their own WSPs to ensure the maintenance of safe water supplies. The intention is that such building plans should complement the WSPs of water suppliers.

The issue of water safety in buildings and the need for additional guidance was identified as a priority at the meeting of government-nominated experts who finalized the third edition of the GDWQ. This led to the development of this document. The guidance provided in this document is based on the framework from the GDWQ (WHO, 2008), as well as other supporting texts, particularly those dealing with:

- *Guidelines for safe recreational water environments volume 2: swimming pools and similar environments* (WHO, 2006a)
- health aspects of plumbing (WHO/WPC, 2006)
- heterotrophic plate counts (Bartram et al., 2003)
- *Legionella* and the prevention of legionellosis (Bartram et al., 2007)
- pathogenic mycobacteria (Bartram et al., 2004).

The development of this document was guided by the recommendation of expert meetings hosted first in March 2005 (by the University of East Anglia, Norwich, United Kingdom),

then in December 2005 (by the WHO Collaborating Centre for Health Promoting Water Management and Risk Communication, Institute for Hygiene and Public Health, University of Bonn, Germany). These meetings were followed by meetings in February 2007 (by the Instituto Superiore di Sanita, Rome, Italy), in October 2007 (by the Scottish Executive, Edinburgh, Scotland), and finally in July 2008 (by the Federal Ministry of Health in Berlin, Germany). The development of this document was also guided by a series of critical reviews by specialists in the field.

The Department of Public Health and Environment (Programme on Water, Sanitation, Hygiene and Health, WHO) led the production of this document.

This document is written for the full range of "actors" who influence the overall safe management of building water supplies. In particular, it is directed to those who design, construct, manage, operate, maintain and regulate building water systems. It is intended to be a useful resource for the development of training and information material.

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Abbreviations and acronyms

GDWQ	World Health Organization *Guidelines for drinking-water quality*
IHR	International Health Regulations (2005)
PoE	point of entry
PoU	point of use
WHO	World Health Organization
WSP	water safety plan

1 Introduction

This document deals with all buildings where people use or are exposed to water, with a particular focus on buildings that include public use or shared facilities. Many of the principles also apply to sole occupancy dwellings and homes; however, it is not expected that management actions, such as the implementation of water safety plans (WSPs), will be applied in private homes.

Vulnerable population groups may be particularly susceptible to water-related hazards, and certain types of building are therefore of special concern. Important examples include medical and other health-care environments where the growth of a range of opportunistic waterborne pathogens, such as *Pseudomonas aeruginosa*, non-tuberculous *Mycobacteria* and *Legionella*, is a significant health concern and can lead to substantial and avoidable costs.

Outbreaks have been associated with both microbial and chemical contamination. A significant proportion of such waterborne disease is associated with contamination within buildings. This can arise from:

- direct contamination through faults in water systems (e.g. bird and small animal droppings into storage tanks) or leaching from inappropriate materials or corrosion (e.g. copper, lead, nickel, cadmium);
- indirect contamination through cross-connections between drinking-water systems and contaminated water or chemical storages;
- growth of indigenous microbes (e.g. *Pseudomonas aeruginosa*, non-tuberculous *Mycobacteria* and legionellae).

Guidance is provided for managing water supplies in buildings where people may drink water; use water for food preparation, washing, showering, swimming or other recreational activities; or be exposed to aerosols produced by water-using devices, such as cooling towers. These uses occur in a variety of buildings, such as hospitals, schools, child-care and aged-care facilities, medical and dental facilities, hotels, apartment blocks, sport centres, commercial buildings and transport terminals.

Although the focus of this document is managing water supplies within buildings, microbial and chemical hazards may sometimes also be introduced from water delivered to buildings from external sources.

The inadequate management of water in buildings has considerable health effects, as well as significant direct and indirect economic and social impacts. The World Health Organization (WHO) has identified that the benefits of all interventions to reduce risks from unsafe water outweigh costs by substantial margins (Hutton & Haller, 2004). In health-care settings, the costs of nosocomial infections, including those that are waterborne, are substantial and rising—in terms of both direct costs and reputational impacts (Anaissie et al., 2002). Travel and hotel stays are recognized as risk factors for legionellosis (Bartram et al., 2007). In Europe, approximately 20% of detected legionellosis cases are considered to be travel associated (Joseph, 2002; Bartram et al., 2007). Cases of legionellosis in

hotels have often received extensive and damaging publicity, with significant economic impacts due to reduced patronage.

The document does not deal with the management or protection of water resources, or the use of recycled water. Further detail on these aspects is provided in the supporting text, *Protecting groundwater for health* (Schmoll et al., 2006), the *Guidelines for safe use of wastewater, excreta and greywater* (WHO, 2006b) and a forthcoming text on surface water.

The guidance provided in this document is based on the *Framework for safe drinking-water*, from the WHO *Guidelines for drinking-water quality* (WHO, 2008). The framework is shown in Figure 1.1.

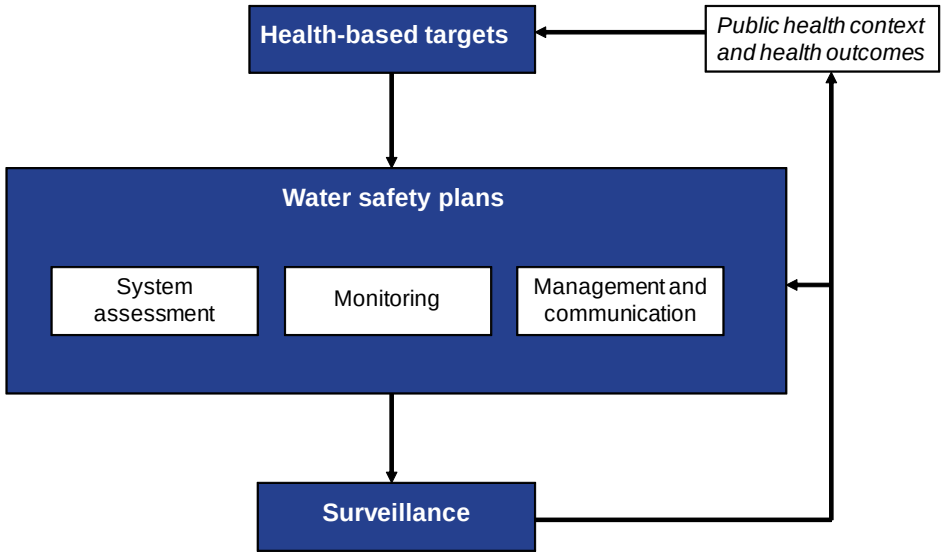

Figure 1.1 Framework for safe drinking-water

This document is divided into four sections:

- **Section 2** is made up of short introductions with principles that describe the core issues of water safety in buildings. It is organized into subsections that address hazards and risks, people and building types.
- **Section 3** deals with the role and responsibilities of stakeholders who influence the safety of water systems within buildings. Stakeholders can be involved in the planning, design, construction and renovation of buildings, as well as development of WSPs, and ongoing maintenance and operation of water systems.

- **Section 4** describes the steps in developing and implementing WSPs, and provides examples on how those key principles can be applied to buildings. This section is organized into subsections explaining how to assemble teams; understand the water system; identify hazards and assess risks; put in place control measures, operational monitoring and management procedures; and establish verification and supporting programmes.
- **Section 5** deals with the environment that supports the delivery of safe water within buildings but does not affect water quality directly. This section is organized into subsections addressing independent technical inspection and surveillance, disease surveillance and detection of outbreaks, regulatory and policy frameworks, and capacity building and training.

2 What are the issues?

This section describes the issues that confront engineers and planners when planning and implementing water safety plans (WSPs). It discusses water-system design, hazards and risk assessment, the end-users and building type.

2.1 Background

The World Health Organization (WHO) *Guidelines for drinking-water quality* (GDWQ) (WHO, 2008) describe a quality of water that is safe for a lifetime of consumption. The focus of the guidelines is the *Framework for safe drinking-water*, incorporating WSPs. This framework is applicable to all drinking-water systems, ranging from those serving the largest of cities to the smallest non-piped and household supplies. The framework is also applicable to delivery of drinking-water within buildings.

2.1.1 Purpose of WSPs

WSPs are the most effective means of consistently ensuring the safety of drinking-water supplies through a comprehensive risk-management approach that encompasses all steps, from source through treatment and distribution to consumers. The WSP approach is based on identifying all significant risks to public health, ensuring that effective controls and barriers are applied to minimize these risks to acceptable levels, and monitoring the operation of the controls and barriers to ensure that safety is maintained.

Application of WSPs and good management by those responsible for drinking-water production and distribution can assure drinking-water safety. However, management of building water systems can be complicated by a number of factors, including ownership of assets and rights of access that change on building property boundaries. Drinking-water systems in buildings are generally designed, installed and controlled independently from public water supplies. This contributes to buildings representing specific environments with specific hazards and hazardous events. Other complicating factors include:

- designated uses of buildings (e.g. hospitals, medical centres, residential care);
- use of supplementary water supplies, such as roof rainwater, greywater and water from private supplies (e.g. wells, bores and springs);
- supplementary point-of-entry treatment for water supplied from public systems;
- connection of drinking-water systems with water-using devices, such as cooling towers, evaporative condensers, boilers, swimming pools, washing machines, dishwashers, dental chairs, medical devices and industrial equipment;
- the vulnerabilities of people using buildings (e.g. in hospitals and aged-care facilities);
- the potential for multiple owners and shared assets, particularly in larger buildings.

In addition, buildings can have complex plumbing systems with at least two distinct systems for drinking-water and wastewater (sewage and greywater). In some buildings, a

third system might be installed to distribute recycled water (treated sewage or greywater) for uses such as toilet flushing. The drinking-water system is typically divided into two sections providing hot and cold water, and large buildings may incorporate a separate section conveying water for firefighting.

2.1.2 Factors that affect WSP operation

One of the consequences of the separation of ownership and oversight has been a tendency for water safety in buildings to be overlooked, or at best receive limited attention. While public water supplies are generally maintained by water utilities or agencies with particular expertise, this is often not the case with water supplies within buildings. A general perception can be that water systems in buildings connected to public supplies are safe, ignoring the potential for contamination (both chemical and microbial) and growth of waterborne opportunistic pathogens within the building water systems. This also applies to devices (e.g. cooling towers, boilers, washing machines, swimming pools, hot tub pools) and equipment. Water systems are often managed by general maintenance staff with little training or expertise in managing water quality. Regulatory authorities often establish working relationships and provide oversight of public water supplies, but this is more challenging with building managers. There may be a limited number of public water suppliers in urban areas, but many thousands of independently owned buildings.

As a result, there are many examples where faults within buildings have led to outbreaks of drinking-water-derived disease (Kuroki et al., 1996; CDC, 1997a; Blackburn et al., 2004; Robert Koch Institute, 2004; Yoder et al., 2004, 2008ab; Djiuban et al., 2006; Liang et al., 2006; Vianelli et al., 2006). These have included diverse outcomes such as outbreaks of gastrointestinal disease associated with contamination of drinking-water by *Cryptosporidium* and *Cyclospora*, legionellosis (Legionnaires' disease) associated with hot and cold water systems and cooling towers, and methaemoglobinemia from boiler fluid contamination of drinking-water. Aesthetic issues, such as taste and odours, can be caused by water stagnation and through back-siphonage from flexible hoses connected to devices such as washing machines and ice machines. Turbidity and colour can be caused by corrosion or resuspension of biofilms and sediments from storage tanks and hot-water tanks.

A common theme associated with outbreaks has been poor management of building water systems. Outbreaks can be prevented through design and application of WSPs. WSPs should deal with all sources of water, including community and private supplies (e.g. roof rainwater or groundwater) and should consider the characteristics and quality of the available sources. This includes determining whether community supplies have established WSPs. Building WSPs should be complementary to any existing plans developed by operators of community supplies. In these circumstances, drinking-water suppliers should provide assistance and information to building owners and managers responsible for developing WSPs.

Public health and regulatory authorities should provide guidance on development and implementation of WSPs. These authorities should also undertake surveillance to ensure that WSPs are operating effectively (see section 4).

2.2 System design

The basic requirements for establishing effective WSPs are good design and a sound knowledge of the physical characteristics of water systems. Water systems in buildings are often designed with limited attention to minimizing risks to public health. Retrofitting existing systems to improve management and safety is expensive. Every effort should be made in designing and constructing new systems to support the implementation of WSPs. This should include minimizing sources of hazards (e.g. stagnant water, long branch pipes and dead legs), as well as enabling access for monitoring and maintenance.

Knowledge of the characteristics of existing systems is often lacking, and in many cases there are no accurate, well-maintained maps of water systems. This is particularly true for large buildings and can be complicated in buildings that have been renovated or repaired. Pipework belonging to various networks (drinking-water, wastewater, recycled water, etc.) are often poorly labelled, which increases the likelihood of cross-connections and associated health risks. In addition, when problems arise, responses can be delayed by first having to map the system.

2.3 Hazard identification and risk assessment

Effective management of drinking-water systems in buildings requires a comprehensive understanding of the system, including the range of potential hazards, hazardous events and risks that may arise during delivery and use of water by occupants and visitors to buildings. It also requires an understanding of the quality and management of the water delivered to buildings. This can vary from high-quality, well-managed urban water supplies to poor-quality, intermittent community supplies or independent building-specific supplies.

2.3.1 Hazards

The GDWQ (WHO, 2008) describe a range of hazards that can threaten drinking-water supplies. All these hazards could enter buildings if present in external water supplies or could be introduced within buildings. Hazards include the following:

- **Enteric pathogens** (bacteria, viruses and protozoa) from faecal contamination can enter the system through faults in water supplies provided to buildings or within internal plumbing systems.
- **Environmental organisms** such as *Legionella* and *Pseudomonas* can grow in distribution systems and water-using devices, such as cooling towers and hot-tub pools. Growth is promoted by conditions such as low flow, stagnant water and warm water temperatures. In hospitals, a broader range of environmental bacteria and fungi such as *Acinetobacter* spp., *Aeromonas* spp., *Burkholderia cepacia* and *Aspergillus* have been identified as causes of nosocomial infection (Annaisie et al., 2002; Sehulster et al., 2004).
- **Chemicals** from external environmental, industrial and agricultural sources can enter the water-supply system. In addition, chemical hazards can be introduced from treatment processes, leached from unsuitable materials, or released from corrosion of pipework and fittings (e.g. copper, lead, cadmium and nickel) used in plumbing systems. Corrosion can be exacerbated by stagnation.

2.3.2 Hazardous events

Buildings represent specific independent environments that can include a wide range of conditions and situations (hazardous events), leading to the occurrence of hazards. The likelihood of hazardous events is influenced by the size and complexity of buildings and can be exacerbated by poor design, construction, operation and maintenance. These hazardous events include:

- poor flow and stagnation due to
  - poor design, including long branch pipes and dead ends
  - intermittent use or extended periods with no use (e.g. floors or wings of hotels with seasonal occupancy; schools during holidays);
- poor temperature control, including
  - inadequate heating capacity and poor design of hot-water systems, including long branch mains
  - elevated temperatures in cold-water systems due to proximity of hot-water systems and poor insulation;
- unsuitable materials used in plumbing
  - products that leach hazardous chemicals or support microbial growth
  - materials incompatible with the physical and chemical characteristics of water supplied to the building (leading to increased corrosion or scaling);
- open water-storage tanks allowing access of external contamination;
- cross-connections with independent water systems (e.g. roof rainwater), fire systems or recycled water systems, and inadequate backflow prevention from connected water-using devices (e.g. cooling towers, heat exchangers, boilers, washing machines, dishwashers) and liquid storages;
- poor management of water-using devices (e.g. cooling towers, drinking-water fountains, hot-tub pools and baths, swimming pools);
- poor management, maintenance and repair, exacerbated by inadequately mapped systems (e.g. schematic diagrams not updated following modifications) and poorly labelled pipework (e.g. distinguishing drinking-water, wastewater and recycled-water systems);
- unauthorized repairs and modifications (e.g. installation of point-of-use [PoU] devices such as carbon filters).

2.3.3 Risk assessment

Once potential hazards and hazardous events have been identified, the levels of risk need to be assessed so that priorities for risk management can be established. Risk assessments need to consider the likelihood and severity of hazards and hazardous events in the context of exposure (type, extent and frequency) and the vulnerability of those exposed.

Although many hazards may threaten water quality, not all will represent a high risk. The aim should be to distinguish between high and low risks so that attention can be focused on mitigating risks that are more likely to cause harm.

2.4 People who use buildings

Buildings represent specific environments and can provide specific services (e.g. hospitals, clinics, dental surgeries, aged-care facilities and schools). To determine the health risk associated with hazards from building water systems, it is necessary to consider:

- the vulnerability of people who work in, live in or visit the building
- the number of occupants and visitors
- the frequency and length of visits
- the types of water use and exposure.

2.4.1 Users of buildings

The types of people who use buildings will depend on the purpose of the buildings and services that are provided. Different groups can include:

- residents (e.g. of apartment blocks);
- long-term and short-term residents of hotels;
- hospital inpatients, outpatients and visitors;
- elderly residents in retirement complexes or aged-care facilities;
- dentists, doctors and nurses;
- patients at health-care centres and dental or medical clinics;
- visitors to museums, theatres, sports stadiums, shopping centres and garden centres;
- users of services (e.g. restaurants, food outlets and cafes);
- users of facilities (e.g. fitness centres, swimming pools, sporting clubs and leisure centres, ice rinks);
- workers in residential buildings;
- workers with particular exposures (e.g. lifeguards and swimming instructors);
- maintenance employees and contractors, particularly those with responsibilities relating to water systems and water-using devices;
- university and school students;
- very young children attending child-care facilities;
- prisoners.

2.4.2 Vulnerabilities

Those at greatest risk of waterborne disease are infants and young children, people who are immunocompromised, and the elderly. For most buildings, the health and vulnerability of users, visitors, residents and workers in buildings will be representative of the general population. However, some buildings will be used or visited by greater numbers of people who are more vulnerable to waterborne disease. These include very young children at child-care facilities and in hospitals; the elderly in retirement complexes or aged-care

facilities; patients attending doctors' surgeries; outpatients at hospitals and other health-care facilities; inpatients, particularly those who are immunocompromised (e.g. cancer patients); transplant patients; and those with acquired immunodeficiency syndrome. Patients with respiratory disorders may be more susceptible to waterborne organisms transmitted by inhalation (e.g. *Legionella* and mycobacteria).

Renal dialysis patients are vulnerable to microorganisms, endotoxins, toxins and chemical contaminants. This vulnerability was demonstrated in 1996 by the death of 50 patients after exposure to water contaminated by high levels of microcystin (Jochimsen et al., 1998; Pouria et al., 1998) and 10 patients from aluminium encephalopathy (Berend et al., 2001). In the latter case, a community desalinated water supply was used for dialysis without further treatment for a number of years. The deaths occurred when corroding ductile-iron pipes were coated with a cement mortar containing aluminium. Dialysis patients are also sensitive to chemical disinfectants used to disinfect drinking-water supplies (Ward, 1996; Davidovits et al., 2003; Hoenich, 2009).

Due to advances in medical care, the proportion of people in communities with greater susceptibility to disease is increasing, particularly in developed countries. Communities are ageing, and survival of cancer patients and transplant recipients is improving.

2.4.3 Exposure

Exposure will be influenced by the length of occupancy, the frequency and length of visits, the nature of the building and the type of user.

Length of exposure will range from permanent residents of apartment buildings to long-term employees and workers; regular attendees at universities, schools, fitness centres and swimming pools; long- and short-term hospital patients; occasional attendees at medical and dental surgeries; and occasional visitors to restaurants, hotels and museums.

The type and nature of exposure will vary. While consumption of drinking-water involves potentially the highest volume exposure, other transmission pathways need to be considered. Exposure could include direct ingestion of drinking-water or indirect consumption through food and beverages prepared at restaurants, food outlets, cafes, hotels and bed-and-breakfast facilities. Ingestion and contact with water could occur through normal bathing activities, as well as through the use of swimming pools, hydrotherapy pools and hot-tub pools. Aerosols from showers, hot- and cold-water outlets, hot-tub pools or cooling towers can be inhaled, as can disinfection by-products released into the air at indoor swimming centres. Aerosols can also be generated by decorative fountains, irrigation systems used in garden centres or misting devices used in food markets.

Exposure could be associated with equipment used in hospitals, such as humidifiers and nebulizers, or in dental surgeries.

Exposure could also occur though inappropriate uses of piped water supplies. For example, drinking-water supplies are generally not suitable without additional treatment to wash wounds and burns or to wash and rinse medical equipment. Water used for renal dialysis needs to be highly treated to ensure that it is microbially and chemically safe.

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2.5 Building types

Buildings can include specific environments that influence the level of risk associated with drinking-water systems. This can also be influenced by vulnerabilities of those who use and visit different types of buildings.

2.5.1 Large buildings

All buildings can represent sources of hazards and hazardous events. Large buildings can present particular challenges related to size and complexity. Drinking-water distribution systems in large buildings tend to be very long and complex, with many branch pipes. They can include large variations in flow, including very low flows at the end of long branches and dead legs. Plumbing systems are often poorly documented, particularly as buildings age and are modified or extended. Control over distribution systems in large buildings is also more difficult to maintain. Temporary or even extended periods of non-use of sections of buildings and associated plumbing systems are often poorly documented or managed.

Storage tanks can be used to maintain water pressure within the building (under-roof) or to provide buffering storage. The integrity of storage tanks needs to be maintained. In hot climates, the temperature of water—particularly in under-roof storage tanks—can increase and support the growth of environmental opportunistic pathogens.

Addition of PoU devices can occur without the knowledge of building management and maintenance staff. The potential for inadvertent cross-connections between drinking- and non-drinking- water systems increases in relation to the size and complexity of buildings. Large buildings are more likely to incorporate independent fire systems, which are prone to stagnation and the development of biofilms. Although they are generally supplied with mains water, these systems need to be kept independent through the installation of backflow-prevention devices. Ideally, fire systems should have a separate connection to the external mains water system.

The use of recycled water in large buildings is increasing; for example, greywater for toilet flushing (e.g. in environmentally friendly buildings). Recycled-water pipework and any accessible outlets should be marked to indicate that the water is not suitable for drinking. Where recycled-water systems are installed, there is a potential to lower flows and increase detention times in the drinking-water system due to reduced usage.

Large buildings are more likely to use evaporative condensers and cooling towers as part of air-conditioning systems and boilers to provide heating. Evaporative condensers and cooling towers can be sources of harmful microorganisms such as *Legionella*, while hazardous chemicals can be used to treat or condition boilers (e.g. nitrates and metaborate).

Particular types of large buildings include the following:

- **Educational facilities.** Schools, colleges, technical colleges, further education facilities and universities provide drinking-water for typical uses, as well as specialized uses in teaching and research laboratories and technical training facilities. Technical equipment using water and storages could present sources of hazards. Laboratories are also likely to include eye-wash stations and safety showers, which—like fire systems—are prone to stagnation and growth of biofilms unless flushed regularly.

Water use in educational facilities and associated buildings (residential, sport clubrooms, etc.) can be intermittent, with extended periods of stagnation possible, particularly during holidays.

- **Hotels.** Hotels can include recreational facilities such as swimming pools and hot-tub pools, and, in some cases, rooms can be provided with single-use hot-tub baths, which can be a source of environmental pathogens. Occupancy of hotels and other accommodation facilities can vary markedly depending on seasons; buildings, parts of buildings or floors may be closed during "off seasons". Associated water-using devices such as cooling towers and evaporative condensers may also be shut down for extended periods.
- **Conference centres.** Where accommodation is provided, these centres can include similar features to hotels.
- **Apartment blocks** (low rise and high rise)**.** Maintenance and management can be complicated by individual ownership or leasing of apartments. Risks in shared hot- and cold-water systems can be increased where individual apartments are used infrequently or remain empty for extended periods, and through connection of PoU treatment (e.g. carbon filters) and water-using devices such as washing machines and dishwashers, and by other modifications undertaken by tenants and apartment owners.
- **Office blocks.** Like apartment blocks, maintenance and management can be complicated by multiple ownership or tenancies.
- **Public buildings** (e.g. museums, art galleries, theatres and cinema complexes). A common concern with these buildings is maintaining hygiene and ensuring that drinking-water outlets are kept clean.
- **Shopping centres** can include decorative fountains, garden shops and fresh fruit and vegetable markets that use misting machines to keep produce fresh. These spray and mist devices produce aerosols that can disseminate organisms such as *Legionella* and *Mycobacterium* spp. if present. Centres can also include speciality shops such as hairdressing salons.
- **Factories, manufacturing industries and production centres.** These buildings can include storages of liquid chemicals and distribution systems that circulate water used for cooling or liquid coolants. Industrial buildings can include devices for worker safety, such as eye-wash stations and safety showers.
- **Transport terminals**. Transferring water at terminals to aeroplanes, ships, trains or buses needs to be managed to ensure that water safety is maintained. Specific guidance for aeroplanes and ships is provided in the WHO *Guide to hygiene and sanitation in aviation* (WHO, 2009) and the *WHO Guide to ship sanitation* (WHO, 2010). The hygiene and safety principles described in these guides should also be applied for trains and buses.

2.5.2 Hospitals

Hospitals can be very large buildings or complexes with extensive water systems. Due to the vulnerability of some patients, hospitals are more likely to provide additional treatment at the point of entry of external piped supplies. Common forms of treatment include filtration, disinfection, softeners and deionizers. Treatment is also likely where

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hospitals use private water supplies (e.g. wells, bores). These processes can represent sources of treatment chemicals (e.g. membrane de-scalants, coagulants, disinfectants and disinfection by-products). Wards and rooms are not always occupied continuously. This can provide intermittent flows or stagnation in water systems.

Drinking-water should be suitable for human consumption and for all usual domestic purposes, including personal hygiene for most patients. However, it may not be suitable for all patients or uses in a hospital, and further processing or treatment or other safeguards may be required. Patients in intensive or critical care facilities, including cancer wards, transplant wards and renal wards, can be immunocompromised and at increased risk from waterborne disease through ingestion, contact or inhalation. In wards where patients are in protected environments with filtered air and modified diets, equal attention needs to be paid to drinking-water, beverages and ice. There are many examples of legionellosis being recorded in hospitals (Bartram et al., 2007). Inhalation of aerosols from showers, hot- and cold-water outlets, nebulizers and humidifiers has been identified as a route of transmission, while aspiration from ice has been associated with infection of immunocompromised patients or those with significant respiratory impairments (WHO, 2007).

Drinking-water can contain a range of microorganisms that represent little concern through water consumption by most patients. However, some organisms (e.g. *Pseudomonas aeruginosa, Acinetobacter, Aspergillus*) can cause severe infections in those who are immunosuppressed or immunocompromised. They can also cause infections if present in water used to wash or irrigate wounds and burns; to wash medical devices, such as endoscopes and catheters; or in devices such as nebulizers and humidifiers. Water used for such purposes needs to be of a higher quality than described in the GDWQ (WHO, 2008) and may require additional processing, such as microfiltration, disinfection or sterilization, depending on use.

Renal dialysis requires large volumes of water that exceed the chemical and microbial quality requirements for drinking-water. Water used for dialysis requires special processing to minimize the presence of microbial and chemical hazards, including residual disinfectants.

Hot-water distribution systems may be maintained at lower temperatures (warm water) or have thermostatic mixing valves installed before outlets to reduce the risk of scalding (typically 41–45 °C). Warm-water systems or pipework downstream of mixing valves can provide environments for growth of environmental pathogens.

Hospitals may operate hydrotherapy pools as part of treatment regimes and include ice machines and drinking-water fountains.

2.5.3 Other medical and health facilities

Medical and health facilities include medical clinics, health centres, doctors' surgeries and dental surgeries. As in hospitals, risks can be elevated in these facilities due to the types of exposures involved and the potential vulnerabilities of some patients

Water of appropriate quality should be used in medical and dental equipment and procedures (e.g. washing and irrigation of wounds and burns). For example, dental chairs often include water systems that deliver water to high-speed equipment, de-scalers and rinsing sprays. These sprays can be inhaled and aspirated by patients. Dental water lines

can become colonized with bacteria, fungi and protozoa. Most of these organisms are of limited significance, but pathogenic species, including *Legionella*, *Pseudomonas aeruginosa* and *Mycobacterium* spp., have been detected (Sehulster et al., 2004).

2.5.4 Aged-care facilities and retirement homes

Aged-care facilities and retirement homes house elderly people who can be more susceptible to waterborne disease. In some cases, residents will have underlying illnesses that increase this susceptibility.

Like hospitals, water systems can be extensive and supply water to wards and rooms that are not always occupied. Hot-water distribution systems may be maintained at lower temperatures or have thermostatic mixing valves installed to reduce the risk of scalding.

2.5.5 Child-care facilities

Child-care facilities can cater for very young children who can be more susceptible to disease. Children's hygiene is not always well developed, and attention needs to be paid to keeping water outlets and toilets clean (Adams et al., 2009). Young children are also more susceptible to contaminants such as lead (WHO, 2008). Corrosion and leaching of metals such as lead can be exacerbated by intermittent water use, with stagnation over weekends and during holidays.

Hot-water distribution systems may be maintained at lower temperatures or have thermostatic mixing valves installed to reduce the risk of scalding.

2.5.6 Small hotels, bed-and-breakfasts, farmstays and campsites

Hotels, motels and bed-and-breakfasts provide water for drinking and bathing for guests and may use drinking-water supplies in water-using devices, such as swimming pools and hot-tub pools. In some cases, rooms can be provided with single-use hot-tub baths.

Some facilities may have private water supplies that can be potential sources of microbial and chemical hazards.

Campsites can include permanent buildings providing shared facilities (e.g. for cooking, bathing). In some cases, separate non-drinking-water supplies may be provided for bathing. These need to be appropriately marked using words as well as symbols, noting that the water is not suitable for drinking.

Like hotels, these accommodation facilities can be subject to seasonal use.

2.5.7 Sporting facilities and health centres

Sporting facilities and health centres can include sports grounds, stadiums, leisure centres, swimming pools, ice rinks, health clubs and fitness centres. These facilities can include swimming pools or hot-tub pools.

Swimming pools have been associated with outbreaks of illnesses such as cryptosporidiosis, and hot-tub pools with legionellosis and hypersensitivity pneumonitis (from mycobacteria). Indoor pools can generate elevated levels of chloramines and other disinfection by-products, which can lead to eye, nasal and respiratory irritation. Disinfection byproducts at indoor pool centres could be associated with asthma in children (Weisel et al., 2009).

At large sporting clubs, immersion pools and communal pools are used to assist recovery of competitors.

2.5.8 Garden centres and conservatories

Garden centres, greenhouses and conservatories typically use irrigation systems to water plants. In large centres, these irrigation systems can include storage tanks and sumps. Often, irrigation pipes include materials that are not suitable for contact with drinking-water.

Irrigation systems typically use spray and mist devices to produce aerosols, which can disseminate organisms such as environmental pathogens, if they are present. Water features and hot-tub pools on display in garden features may also generate aerosols. In warm environments (especially those exposed to sunlight), water in the irrigation pipes and hoses of these systems can heat up and cause microbial growth.

2.5.9 Detention centres, prisons and military barracks

These buildings can house large numbers of people in relatively confined spaces. Bathing and sanitary facilities are typically shared by groups of people, and breakdown in hygiene can be a source of microbial hazards. Due to the numbers of occupants in close proximity, the secondary spread of disease is likely.

2.5.10 Other buildings

Other buildings include restaurants, fast-food outlets, cafes, veterinary surgeries, ambulance and fire stations, beauty salons and hairdressers. Each type of building can include specific uses of water requiring appropriate management.

3 Roles and responsibilities

This section describes the roles of stakeholders and other responsible personnel to ensure that the water supply is safe. Many people are involved in water safety, from the initial water planners to ongoing operation and maintenance providers, and their range of duties is illustrated in this section.

3.1 Background

A large number of stakeholders can influence the safety of water systems within buildings. These stakeholders can be involved in the planning, design, construction and renovation of buildings, as well as development of water safety plans (WSPs), and the ongoing maintenance and operation of water systems. The specific titles of stakeholders and divisions of responsibilities will vary between different countries and jurisdictions, but the broad range of tasks will remain fairly consistent. Figures 3.1–3.3 (at the end of this section) provide examples of roles and responsibilities in one jurisdiction.

Stakeholders can include:

- building commissioners who are involved before construction of new buildings or renovation of existing buildings, such as developers, planning officers, architects, design engineers, builders, plumbers, manufacturers and suppliers;
- building operators, including building managers and owners, tenants and employers;
- employees, residents and users of buildings;
- service providers and specialist consultants who provide technical assistance, such as plumbers, maintenance contractors, water-treatment specialists, risk assessors and auditors;
- professional bodies who develop guidance and training;
- infection-control personnel in dental and medical facilities, and infection-control teams in hospitals and health-care facilities;
- regulators responsible for oversight of building and plumbing codes, public health requirements and occupational health and safety;
- public health and environmental health officials;
- standard-setting bodies and certification agencies;
- training providers;
- providers of laboratory services.

3.2 Building commissioners

A range of stakeholders can be involved in the design, construction and modification of buildings, including the installation of water systems. All stakeholders should be aware of relevant regulations, codes and standards and should implement requirements that apply to the building being commissioned. Many countries have codes and design standards that apply to water systems and devices, including cold- and hot-water systems, cooling towers, ice machines, swimming pools and hot tubs. In some cases, requirements are incorporated within building and plumbing codes, while in others codes and standards have been issued for specific components such as cooling towers. For further discussion, see section 4. Most countries have building and plumbing codes that include accreditation and approval requirements. However, these codes may not provide sufficient detail for the design of complex systems (e.g. direction on calculation of hot-water return-pipe capacities). Specific requirements for preventing the growth of microorganisms (notably avoiding long periods of stagnation of tepid water) may also not be included in these codes. Separate legislation and standards may apply to specific components of water systems (e.g. water-cooling devices, swimming pools, hot-tub pools). Where codes and standards do not provide sufficient detail, expert advice will need to be sought.

It is essential that those involved in design, construction and modification of buildings document their actions and ensure that final plans and specifications are provided to building owners and managers.

3.2.1 Developers

Developers are ultimately responsible for oversight of the entire process of construction and installation. This includes ensuring that appropriate design requirements and standards are applied.

Where buildings are intended for specific purposes (e.g. health facilities), particular requirements associated with the use should be determined through consultation with the user and from relevant legislation such as building codes and plumbing codes. Developers engage the architects, design engineers, builders, plumbers and others who design and construct buildings. Selected professionals and contractors should be familiar with the requirements associated with the intended use.

3.2.2 Planning officers

Planning officers can play a role relating to appropriate design of buildings and design and installation of water systems. Planners need to be aware of requirements relating to water systems. It is good practice for planning or development applications to be referred to health agencies for assessment of potential public health risks before approval is issued.

3.2.3 Architects

Architects are responsible for the overall design of buildings and need to have an understanding of the operation of, and requirements associated with, water supplies and devices that use water such as cooling towers. Good design can prevent or reduce many of the risks that can arise in water systems within buildings. Architects work in partnership with design engineers and other professionals who are responsible for construction details.

Designs need to take into account requirements associated with specific uses, such as:

- residential health care
- hospitals
- dental surgeries
- medical surgeries
- renal dialysis clinics
- schools
- food retailers
- hotels and guest accommodation (including specialist accommodation such as ski stations).

In the case of renovation or modification of existing and occupied facilities, architects should consult with users of the building. The extent of consultation will be influenced by the complexity of the project; however, it should include all those involved in management and maintenance of water systems. In the case of hospitals and health-care facilities, it should involve consultation with infection-control specialists.

3.2.4 Engineers

Design engineers are responsible for translating the architectural plans into building designs, taking into account structural integrity and ensuring compliance with building and plumbing standards. Project and construction engineers are responsible for completion of buildings, including installation of water systems. When buildings are being renovated, or existing structures are being modified, engineers provide a key role in establishing risk-management plans to minimize risks to people currently using the building. These risk-management plans should include instructions on how to deal with potential problems and disruptions to services, and they should ensure that technical standards and regulations are met. Risk-management plans should include education of maintenance and construction workers. Project engineers are typically responsible for final certification of satisfactory completion of building construction.

3.2.5 Plumbers

Protection of water quality and proper operation of water systems rely on plumbers. Plumbers should be appropriately qualified and have the competence and knowledge to design, install and maintain plumbing systems. Plumbers play a key role in managing risks by ensuring compliance with applicable standards and codes. In addition, plumbers and other plumbing professionals can play an important role in water conservation.

Well-designed plumbing systems are necessary to ensure that the installations are efficient, safe and appropriate for the different circumstances they serve. The design of a good plumbing service must be based on an understanding of the technical requirements and relevant regulatory restrictions. Where industry-based risk-management strategies and procedures have been established, they should be applied.

Plumbers have to ensure that water systems are intact and that intrusion of microbial and chemical contaminants is minimized. Unintended or unprotected cross-connections

should be prevented, and backflow-prevention devices should be installed where necessary. Only approved materials and devices should be used or installed.

Plumbing systems have to comply with building plans. All work has to be documented, and installations and modifications need to be included within building plans.

3.2.6 Manufacturers and suppliers

Anyone involved in the manufacture and supply of water systems components, and specialized equipment and devices (e.g. cooling towers, washing machines, water-using medical devices) should ensure that they are designed and constructed so that they are safe when used for their designated purpose. Components and devices should be designed, constructed and installed in compliance with existing codes and design standards. Systems need to be constructed from materials that are appropriate for the function of the water system and device. In addition, systems should be designed to enable ease of operation, cleaning, inspection and maintenance. Training should be provided to people who operate devices, where appropriate.

3.3 Building operators

Building operation and management can be undertaken by a range of different stakeholders, with specific responsibilities influenced by ownership and tenancy agreements. Legislative requirements may also assign responsibilities to specific parties. Requirements will generally include responsibilities relating to protecting the health and safety of residents and users of buildings. Employers have a specific duty to protect the health and safety of employees.

Building operation can be the responsibility of a building owner, leasing agency, building manager, tenants, employers or combinations of these parties. In some cases, building owners maintain control over infrastructure including water systems, but in other cases this task might be undertaken by a leasing or building management agency. Alternatively, occupiers and tenants may install and manage water devices. Regulations and codes of practice often identify responsibilities for a number of parties. For example, the Victorian Government (in Australia) has published *Legionnaires' disease: managing the health risk associated with cooling tower and warm water systems* (the Health *Legionella* Regulations) (Vic DHS, 2001), which identifies responsibilities for:

- owners of land to register certain types of water devices and to take all reasonable steps to ensure that a risk-management plan is prepared, reviewed and audited on an annual basis;
- owners or tenants of buildings to prevent conditions that may represent a risk to public health;
- owners, managers or controllers of water devices to undertake appropriate levels of maintenance;
- employers to maintain a safe workplace.

In other jurisdictions, assignment of responsibilities may be different, but the tasks remain generally consistent. The tasks and individual responsibilities should be described in a WSP. Whoever takes the lead role in building management needs to be responsible

for the design and implementation of the WSP, including ensuring completion and documentation of tasks assigned to competent employees or to specialist contractors.

Competence should be supported by training. Owners, managers or employers should ensure that those who are assigned to undertake specific tasks have appropriate levels of training. Additional training should be provided where required. In some countries, certification programmes have been established to provide evidence of training. Where such programmes have been established, owners, managers or employers should ensure that work is undertaken by employees or contractors with relevant certificates.

Building managers and employers need to communicate with residents, users of buildings and employees in relation to:

- potential risks associated with water systems;
- management plans developed for these systems;
- notification and information relating to any incidents that give rise to potential or perceived risks to public health; they should also report such incidents to the appropriate regulatory agencies.

3.4 Employees, residents and users of buildings

Employees, residents and users of buildings are often the first to detect change or faults in water systems. These could be detected due to changes in temperature, appearance, odour or taste of water; reduced flow; or leaks. Reporting of changes and faults should be encouraged, and mechanisms should be established to support reporting. Feedback should be provided on the outcome of investigations and any remedial action.

Employees and residents have responsibilities to operate and use water systems as intended and not to introduce modifications. For example, point-of-use devices should not be installed without permission from building managers. Devices and controls such as thermostats should not be altered without permission. This should be reinforced with education and communication from building managers.

3.5 Service providers and specialist consultants

Building operators may use service providers and consultants as sources of specialist skills that are not available within their own organization. Service providers and contractors can be used to undertake a wide range of services associated with water systems, including:

- installation of water-treatment devices and plumbing fittings
- routine and emergency maintenance
- risk assessments and development of WSPs
- audits.

Building operators should only engage providers who can demonstrate competence and compliance with relevant formal requirements (e.g. certification).

Service providers need to be able to demonstrate competence in undertaking tasks for which they contract. In some cases, certification programmes have been established.

In other cases, levels of service or training may be specified by industry associations. Service providers need to be able to provide evidence of compliance with established programmes and, where available, certification.

Service providers should provide evidence in the form of formal reports or certificates of completion to demonstrate that tasks have been completed in accord with requirements.

3.5.1 Risk assessors

Risk assessors need to have the expertise, knowledge and resources to undertake the task competently. Risk assessors should have expertise in:

- public health aspects of water quality;
- local legislative requirements, standards and codes of practice;
- development of WSPs;
- water systems in buildings, including water-using devices and equipment;
- identification of hazards and potential sources of these hazards;
- determination of risk;
- identification and assessment of appropriate control measures;
- operational monitoring procedures to ensure that the control measures remain effective;
- verification procedures.

In large buildings with complex water systems (e.g. hospitals), more than one risk assessor may be required to deal with the piped systems and the broad range of connected equipment and devices. Risk assessors need to comply with formal requirements, including certification and approval conditions established by regulatory agencies. If unacceptable risks are identified, they should be reported immediately to whoever commissioned the assessment. If a serious and potentially immediate risk to public health is identified, notification of the regulatory authority will be required.

3.5.2 Independent auditors

Some jurisdictions use and certify independent auditors to determine the effectiveness of WSPs and compliance with occupational health and safety requirements. Levels of knowledge and expertise, as well as the need to comply with formal requirements, are similar to those described for risk assessors. Auditors should also have expertise in assessing documentation and reporting mechanisms. Auditors may be required to submit reports of their findings to the regulatory agency.

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3.6 Professional bodies

Professional bodies (e.g. for dentists, medical practitioners, hospital engineers, nurses) can perform a number of functions, including:

- developing and advocacating for policies and codes of practice relating to water systems;
- establishing practical guidelines to support implementation of WSPs;
- training for members and their employees;
- identifying practical issues associated with implementation;
- providing mechanisms for gathering information relating to incidence of infection that may be related to water systems;
- reporting notifiable diseases and unusual or elevated incidence of disease to public health agencies;
- providing mechanisms for gathering information on successful management approaches.

3.7 Infection control

3.7.1 Infection-control coordinators

In small health facilities, clinics or surgeries, infection-control coordinators should be appointed to manage established control programmes. The coordinator could be the head of the facility or an employee trained for the task. The head of the facility is responsible for establishing the programme, ensuring that it is implemented, and ensuring that the coordinator has (or receives) appropriate training.

3.7.2 Infection-control teams

Hospitals and other health-care centres use infection-control committees and teams to prevent nosocomial infections, including those arising from water systems. The committees should include representatives from all relevant sections, including management, nursing, physicians, hospital engineers, microbiology, maintenance, cleaning and sterilization services, housekeeping and supply. These teams should contribute to ensuring that water systems are well managed, as follows:

- Management is responsible for establishing and supporting the infection-control team, and should ensure that staff have sufficient understanding of water systems and water-using devices within the building. Management should ensure that a WSP has been developed and implemented by appropriate staff.
- Nursing staff should be aware of the correct operation of relevant water-using devices and equipment and how this equipment should be cleaned and disinfected.
- Maintenance and hospital engineers are responsible for implementing WSPs, including operational monitoring; for example, monitoring temperatures in cold- and hot-water systems, monitoring disinfection residuals in water systems, and monitoring water-using devices such as hydrotherapy pools. They are also responsible for maintaining water systems and devices to ensure that they function as required at all times.

- Physicians are responsible for ensuring safe use of water systems, water-using devices and equipment. Physicians should consider the potential contribution of water systems to nosocomial infections.
- Microbiologists are responsible for monitoring cleaning, disinfection and sterilization, where appropriate, of water-using devices and equipment. They should be aware of appropriate procedures for collecting environmental samples.

Infection-control teams should contribute to internal reviews of WSPs. This should include periodic review of potentially waterborne nosocomial infections as an assessment of effectiveness of the plan. One approach could be to establish a subgroup with primary responsibility for water management. This subgroup should work with, and report to, the full team.

3.8 Regulators

A number of activities and requirements are subject to regulation. These include compliance with building and plumbing codes; occupational health and safety requirements; and codes applying to operation of devices, such as water-cooled air-conditioning plants, swimming pools and hot-tub pools. Implementation of these regulations may be administered by different agencies, including those with responsibilities for public health, environmental health and occupational health and safety. It is important that there is a shared understanding of agency responsibilities and the functions of different regulations to maintain consistency of purpose.

In some countries, the "regulator" may not be an institutional body but a public officer from an agency or authority (e.g. government agency, local health authority). The regulator will have the responsibility for dealing with specific technical issues covered by regulations. The regulator may operate through multilateral committees and expert consultants.

3.8.1 Public health agencies

Public health agencies are responsible for ensuring that public health standards are maintained. They may act in a number of areas, including surveillance and auditing of water systems; they may also help to set standards and codes, detect and investigate disease, and monitor disease trends. Public health agencies are responsible for ensuring compliance with regulations designed to protect public health, and that the actions required by regulations or by codes of practice are followed. This can include regulations and codes applying to specific devices, such as water-cooled air-conditioning plants, swimming pools and hot-tub pools. Required actions can include development of WSPs.

In the event of known or suspected disease outbreaks, public health officials are responsible for inspecting buildings, auditing WSPs and collecting water samples.

Public health officers are also responsible for issuing directions relating to remedial action, and issuing public notifications where required.

Disease surveillance

The role of public health agencies normally includes detecting and investigating disease, and monitoring disease trends (for more information, see section 5.2) Public health authorities need to establish criteria that would initiate an investigation and procedures on how such investigations will be performed. This should include procedures for identifying and confirming potential sources of disease. In the case of investigations involving illnesses associated with buildings, public health agencies should work with owners, managers and users of buildings. Advice and warnings may need to be issued to occupants and employees of buildings, as well as the general public. This should be done in a timely manner to reduce or contain public health impacts, and to provide appropriate information about the level of risk, responses and triggers for seeking medical attention.

Monitoring of disease trends can provide evidence of the need to improve management of water systems. Once a new strategy has been implemented, information on disease trends can provide evidence of the strategy's impact.

Public health agencies should establish networks with professional bodies to help detect disease, and to disseminate public health information.

3.8.2 Surveillance of water supplies

Independent surveillance of water supplies is an important element of quality assurance. Surveillance of water systems in buildings will include features similar to those applied to drinking-water supplies, but may also incorporate additional elements to deal with specific uses of the water, with water-using devices such as cooling towers, and with occupational health and safety needs. The resulting surveillance programmes may include a range of activities and agencies. For example, there could be specific surveillance programmes for cooling towers, swimming pools and other devices. Specific surveillance programmes could also involve agencies responsible for public health and for occupational health and safety.

The role of different agencies and the requirements for specific surveillance programmes should be identified and coordinated to avoid unnecessary duplication, and to ensure that appropriate levels of surveillance are applied to all parts of water systems in buildings. In some cases, surveillance could be performed by third parties such as contractors or registered auditors under programmes directed by regulators. Such programmes should include mechanisms to monitor the effectiveness of the third-party audits.

Surveillance and auditing should include processes for approving WSPs, as well as processes for verifying that WSPs are being implemented appropriately and protect public health effectively.

3.8.3 Occupational health and safety agencies

Occupational health and safety regulations can be administered by specific departments or agencies within government. In some jurisdictions, these regulations are the primary legislative mechanism applied to water-using devices (e.g. cooling towers, evaporative condensers), while in others they support or supplement public health legislation.

Administration of occupational health and safety requirements should be coordinated with other functions and regulations designed to protect public health from water systems. Administration may include either random or routine inspections of workplaces, and occupational health and safety inspectors should be aware of other requirements developed to control risks associated with water systems.

3.9 Standard-setting and certification bodies

Devices and materials used in water systems need to meet quality requirements and comply with applicable standards and codes of practice. Some countries have established standard-setting bodies and certification systems to provide assurance that, when used in accord with design specifications, devices and materials will perform as required and be safe. Standards can apply to the design, installation, maintenance and operation of devices such as cooling towers and evaporative condensers, swimming pools, hot-tub pools, hot-water systems and plumbing devices. Standards can also apply to materials used in plumbing systems, including pipework. Material standards can deal with physical attributes, and ensure that products do not give rise to unacceptable contamination of water or support microbial growth. Standards should include criteria for achieving and measuring compliance.

Certification is used to confirm that devices and materials used in water systems meet standards or alternative criteria. Certification can be undertaken by government agencies or private organizations. Certification agencies may assess data and information provided by manufacturers, undertake specific testing, or conduct inspections and audits. Certification may be issued subject to application of defined conditions. These conditions could identify specific applications and uses of certified products (e.g. where devices can and cannot be used).

Standards are typically developed in cooperation with manufacturers, technical experts, regulatory agencies, certifying agencies and consumers. Public health agencies should participate in developing or approving parts of standards that are intended to protect public health.

Standards can:

- represent technical provisions and norms to be adopted on a voluntary basis as good practice;
- be adopted as requirements by government or local government authorities;
- be adopted by reference in regulations.

Standard setting and certification also applies to sample collection and laboratory analysis. Samples need to be collected, stored and transported using established procedures and appropriate equipment (e.g. correctly prepared sample bottles). Similarly, laboratories need to be competent to perform the tests that they undertake. This includes using suitable methods, appropriate testing equipment, and qualified and capable personnel. Some countries have established standards supported by certification and accreditation systems for laboratory services.

3.10 Training providers

Design, installation and management of water systems can involve a range of personnel, all of whom must be competent to undertake assigned or required tasks. Training providers can provide courses to support competence. In some cases, course work can be combined with supervised "on-the-job" training. Training should be consistent with existing regulations, standards, codes of practice and requirements of regulatory authorities.

Training can be provided by water companies, professional associations (e.g. builders, plumbers, engineers, environmental health institutes, dental and medical associations) and specialist technical colleges and institutes. In some countries, training programmes are subject to certification and accreditation programmes. Training providers should ensure that they comply with the requirements of such programmes.

Training providers should regularly review the content of their courses. They should also consult with regulators and those seeking training to ensure that their needs are being met.

The aim of training programmes is to produce personnel with sufficient expertise and training to undertake specific tasks. However, measuring the level of competence can sometimes be challenging. Measuring competence is easier when tailor-made courses and certification programmes are available—and many countries have accreditation systems for professional and technical personnel. In some cases, requirements for accredited operators can be included in regulations.

Measuring competence is difficult when competence is based on degree of experience. A flexible approach to measuring may be needed, while ensuring that tasks are only performed by people who have sufficient expertise and knowledge. Codes and legislation that include reference to "competent persons" need to identify criteria for establishing competence, including qualifications, training requirements and relevant experience.

Figures 3.1–3.3 show an example of the roles and responsibilities of people involved in water safety.

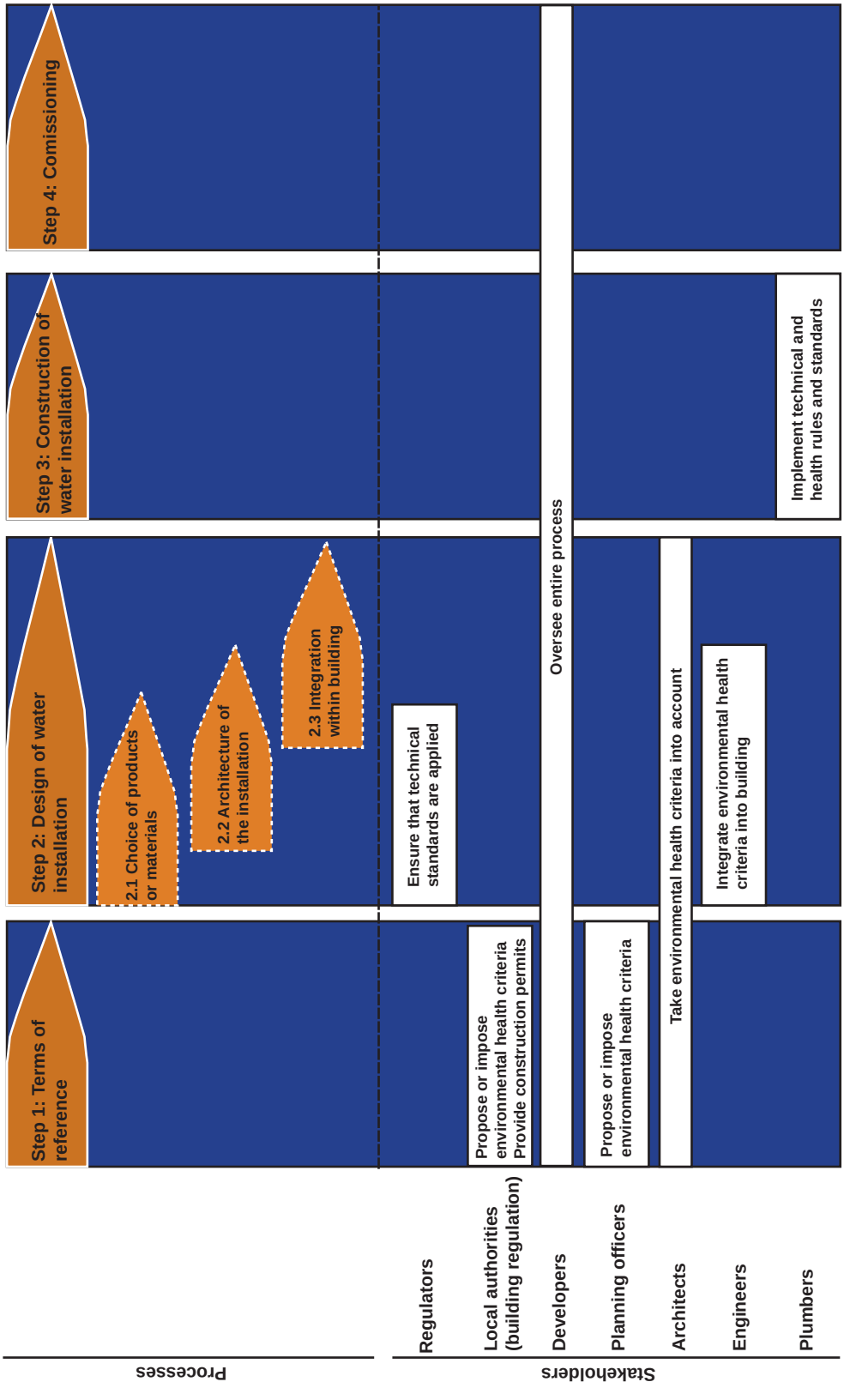

Figure 3.1 Roles and responsibilities for major projects or significant modifications

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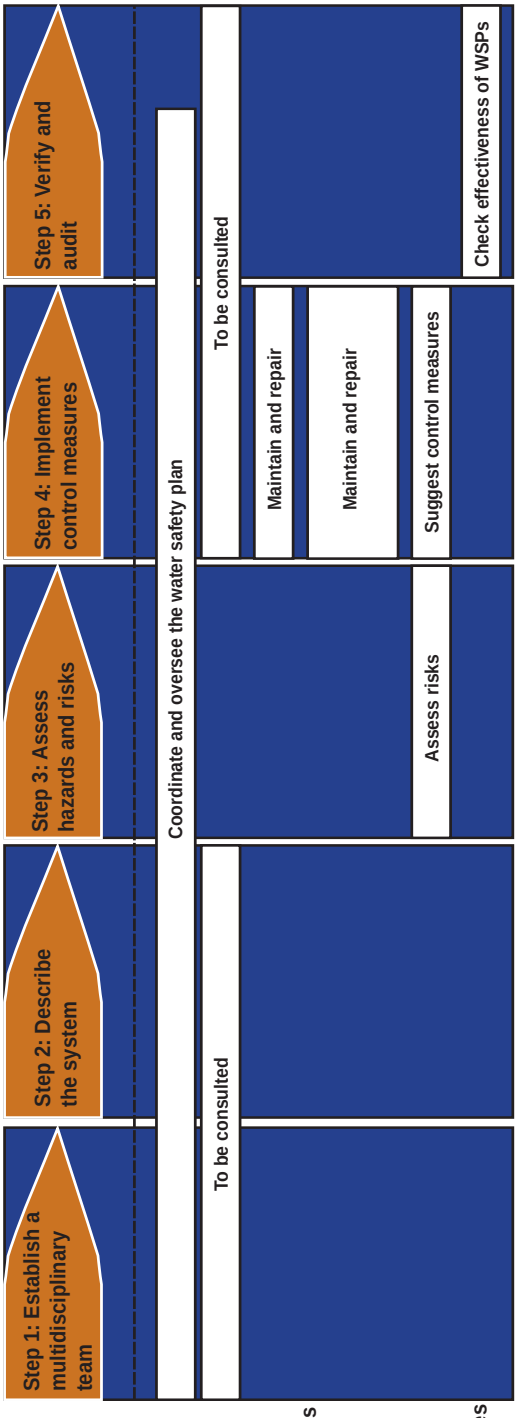

Figure 3.2 **Roles and responsibilities for existing installations**

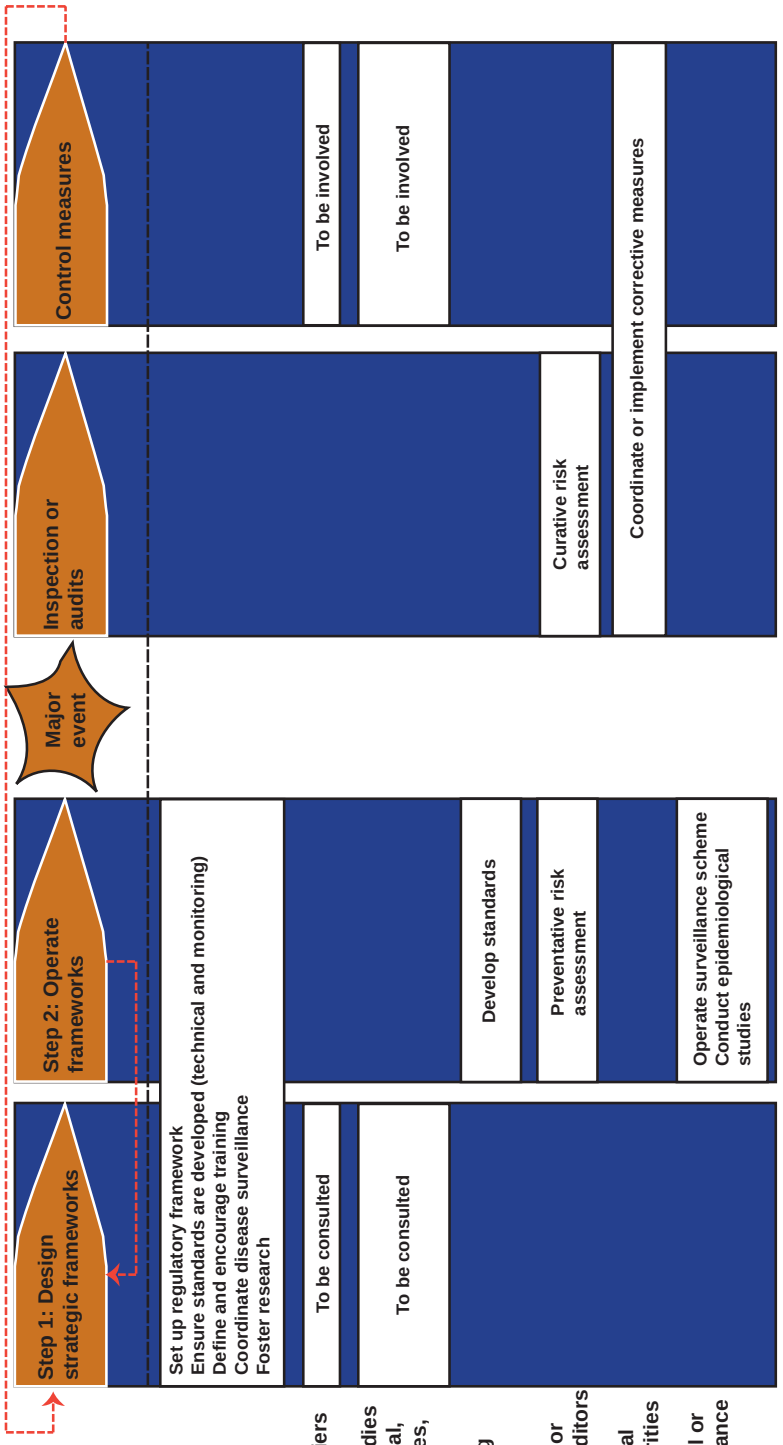

Figure 3.3 Roles and responsibilities for surveillance and supporting requirements

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4 Water safety plans

This section describes, in more detail, water safety plans (WSPs), including the steps required to set one up, and how the key principles can be applied to buildings. Information is also provided on how to organize a WSP team, and what actions to take if a water supply becomes contaminated.

This section also explains risk assessments, control measures, operational monitoring and management procedures. Information that should be considered when designing and constructing new installation systems is also provided.

4.1 Background

The continuous delivery of safe water requires effective management and operation throughout the water-supply chain, from catchments to consumer taps and points of use. The *Guidelines for drinking-water quality* (GDWQ) (WHO, 2008) indicate that this is most effectively achieved through the *Framework for safe drinking-water*, which encompasses the following elements:

- establishing health-based targets as "benchmarks" for defining safety of drinking-water;
- assuring safety by developing and implementing a WSP to systematically assess and manage risks;
- establishing a system of independent surveillance to verify that WSPs work effectively and are capable of consistently delivering water that meets the health-based targets.

WSPs provide a preventive risk-management approach that builds on other risk-management and quality-assurance principles. They systemize long-established principles and good practices in drinking-water supply, covering both water quality and quantity management issues. These principles also apply to management and use of water-using devices and equipment. WSPs for buildings should address drinking-water networks and consider connected devices and equipment.

The development and implementation of WSPs can be the responsibility of various stakeholders: while WSPs for water treatment and distribution of public water supplies are typically the responsibility of the supplier, WSPs for buildings are the responsibility of building owners or managers, with support from various other stakeholders, as discussed in section 3. The level of detail and complexity of WSPs will depend on the size and nature of the building, including the level of risks posed by the installation, and on the population exposed to the water system inside the building. Nevertheless, the implementation of well-designed WSPs is recognized as the most effective tool to ensure provision of safe water supplies.

Development of WSPs should not be considered as overwhelming or too complicated. The aim is straightforward: to ensure consistent supply of safe water to consumers. To a large extent, WSPs document established good practice, and the most important step is getting started.

Figure 4.1 provides an overview of the steps involved in developing a WSP.

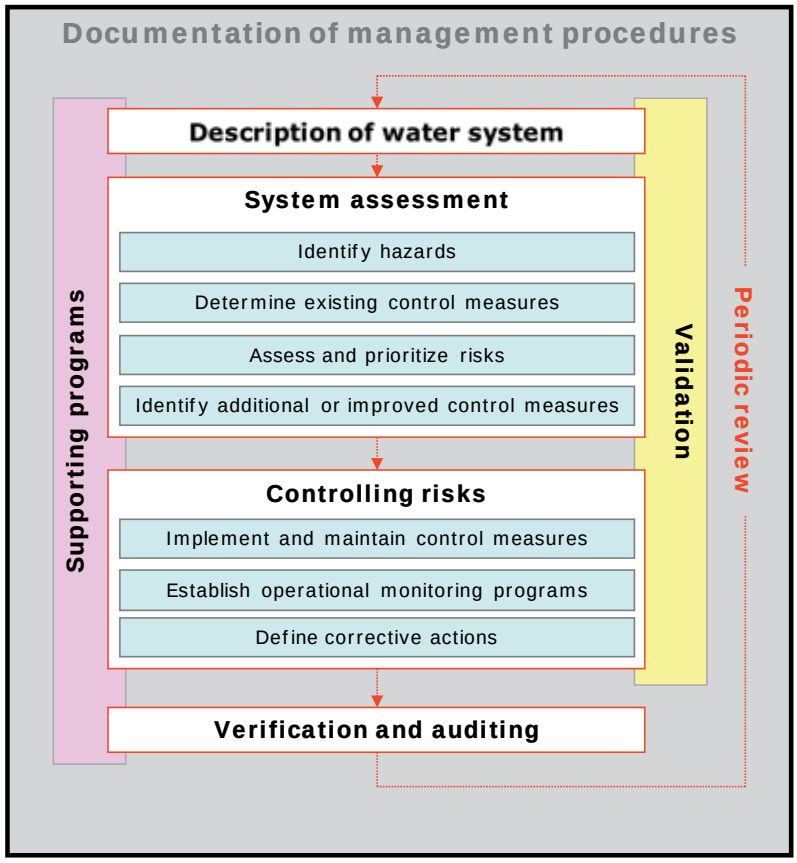

Figure 4.1 Summary of the steps involved in developing a water safety plan

4.2 Key principles of WSPs

WSPs are typically developed after the supply system has been designed and constructed. However, where possible, new or renovated systems should be designed and constructed in a way that supports implementation of WSPs. This should include identifying potential hazards, incorporating appropriate control measures (e.g. treatment processes) and considering practical aspects (e.g. ease of access for maintenance, inspection and monitoring).

Irrespective of when they are developed, WSPs should be working documents that are kept up to date and reviewed periodically to ensure that they remain current. WSPs should be reviewed if there are major changes to water supplies and uses.

The mechanisms by which WSPs are developed and applied can vary. In some cases, tasks associated with implementation could be undertaken by an owner, manager or employer. However, they could also be delegated or assigned to competent individuals employed within a building, or to specialist contractors. When tasks are either delegated

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or contracted, the owner, manager or employer retains the responsibility to ensure that those charged with performing designated functions are competent and that required tasks identified in the WSP are completed and documented appropriately.

4.3 Assembling a WSP team

Assembling a team is a core preparatory requirement for the development and implementation of a WSP in a building. The team will be in charge of developing and implementing the WSP—a role that includes identifying hazards, assessing risks, identifying and monitoring control measures, and developing incident protocols.

A responsible person (or WSP coordinator) needs to be identified to lead the team. This person should be either the building manager or a competent person delegated to this task by the manager. The WSP coordinator should have (or acquire) a good knowledge of the technical facilities in the building, and their daily work should be related to the building. Since the coordinator's primary task is to coordinate the process of WSP development and implementation, they should understand the principles associated with development and implementation of WSPs. However, a special technical knowledge in drinking-water and/or sanitation, while useful, is not necessarily required. The coordinator should have the authority to ensure that the WSP is implemented. A building manager is a good choice for the WSP coordinator.

The WSP coordinator needs to form a team of experts who will support WSP development and provide access to all relevant information needed. Team members should include the range of expertise needed for a thorough analysis of the building's water system. The team should include expertise in design, operation and management of drinking-water supplies; engineering; plumbing; and public health risk assessment. The team will include employees with relevant specialist expertise, as well as representatives of key users of the building water systems. Development of WSPs could also involve consultation with specialist contractors.

Some hazards that may compromise water quality in a building may be obvious to the building management; others may be more concealed. Therefore, it is essential that the WSP team is able to deal with all possible risks associated with delivering drinking-water. Managers of small buildings or facilities with simple water systems may not have "in-house" expertise. In this case, the manager or operators of the water system should coordinate development of the WSP and use health and water-quality expertise from external sources. This could include external agencies (e.g. health, water utilities), private consultants, or external specialists to provide expert advice. In some cases, health agencies may develop generic plans and guidance that can be applied.

4.4 Describing the water system

The first step of the WSP team is to compile available information on the design and operation of the water-distribution system in the building. This needs to be described in a comprehensive plan, starting with the nature and quality of water supplied to the building up to points-of-use (taps and outlets) by building occupants, users and visitors. The plan should document all components of the building water systems, including point-of-entry (PoE) and point-of-use (PoU) treatment, distribution systems (e.g. hot water, cold water, firefighting), water-using devices (e.g. swimming pools, cooling towers) and

specific water uses. An accurate description of the water system is essential to support the identification of hazards, allow risks to be assessed adequately and allow appropriate control measures to be identified.

4.4.1 Functions of water networks inside buildings

Drinking-water networks inside buildings have important differences from external public water-supply networks that need to be considered when analysing potential health hazards. In many buildings, at least two different drinking-water networks operate—that is, a cold-water and a hot-water system—with the following different design features and purposes:

- Cold-water networks are typically designed to deliver water under satisfactory pressure and flow rate at all taps. Parts of the system with large flow rate demands will guide the capacity of the network. Cold-water networks may also deliver water to fire-protection systems. In some circumstances, additional treatment may be provided to supply higher water quality (e.g. in health-care buildings). Cold-water networks should be designed to be efficient, with minimal stagnation, and should be insulated and separated from hot-water networks to minimize heat gain. They should also be protected against corrosion and other damage, to maximize their lifespan.
- The primary function of hot-water networks is to deliver sufficient quantities of water at satisfactory temperatures for its intended use, while limiting energy consumption. This may be achieved by storing hot water near PoUs, responding to demand peaks for large networks, and installing recirculation loops with short branch pipes to PoU to ensure supply of water on demand. Hot-water systems may incorporate temperature-reduction devices to reduce scalding. To reduce risks from *Legionella*, these should be placed close to PoUs. Networks should be designed to minimize areas with low flow or stagnation. Insulation of the piping system will minimize temperature loss.

Buildings will also generally include a wastewater network and may include other networks for delivering other types of waters (e.g. distilled water, rainwater, water for firefighting, greywater, recycled water). All networks need to be identified and labelled clearly. Networks of different water quality need to be kept separate and isolated from both the cold- and hot-water networks. Where the drinking-water system is intentionally connected to a water system, appropriate backflow prevention is needed when delivering non-drinking-water (e.g. water for firefighting).

4.4.2 Usages and water-use patterns

A good understanding of a water network includes establishing the uses of water throughout the building. Where there are multiple supplies of water (e.g. external drinking-water, roof rainwater and recycled water), the uses of each type of water should be identified.

Therefore, all water uses (planned and actual) should be established, as well as requirements for different user groups in a building. This analysis may be based on a list of different possible uses; for example, water for drinking, showering, preparing food, washing, cleaning, toilet flushing, technical uses, watering, firefighting or leisure activities. Specific uses (e.g. medical, dental) and supply to water-using devices (e.g. cooling towers, swimming pools, water coolers, water fountains) should be identified.

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Different water qualities and uses should be described clearly, using consistent nomenclature, particularly in buildings with common purposes (e.g. hospitals and health-care facilities). For example, Table 4.1 provides a description of water used in health-care facilities in France.

Water usages determine the water volume and flow rates that have to be provided at each PoU. This understanding, together with a knowledge of system capacities, is important for identifying the likelihood of low flows and areas of stagnation. Parts of buildings that have variable or seasonal occupancy rates should be identified.

Table 4.1 Nomenclature of waters used in health-care buildings in France

Quality 1. Water not submitted to any treatment within the health-care building
1.1: Water dedicated to drinking and food preparation
1.2: Water for regular care
Quality 2. Specific water treated within a health-care setting complying with defined criteria in accordance with usages
2.1: Bacteriologically controlled water
2.2: Hot water
2.3: Water from hydrotherapy pools
2.4: Water from hot tubs and shower jets
2.5: Water for haemodialysis
2.6: Purified water (drug preparation)
2.7: Highly purified water (for injection)
2.8: Drinking-water from fountains
Quality 3. Sterile waters
3.1: Diluents for injections
3.2: Water for irrigation (pouring water)
3.3: Sterilized drinking-water
Quality 4. Water for technical use[a]
4.1: Cooling network
4.2: Laundry
4.3: Boilers

[a] Water used as feed water and so on in, for example, cooling networks, boilers and laundry machines.
Note: only Quality 1, Quality 2 and Quality 3 are produced directly from the water network.
Adapted from Ministry of Health (France) (2004).

4.4.3 Understanding and documenting the design of the water system

Effective assessment of potential health hazards and risks requires a sound description and documentation of the physical structure of the building's water system (e.g. architecture, plumbing, materials, location of installations and equipment, connection to water-using devices) and its expected conditions of operation. Construction plans and any other available documentation of the building's infrastructure provide a good basis for system description. Drawing high-level, simple flow diagrams will help to capture the various elements of the building's water system, and will help to identify hazards, risks and controls.

The existing documentation and the flow diagram need to be verified by an on-site examination to confirm that they are up to date and correct. Water systems in buildings are often poorly mapped and not updated after repairs or renovations. The on-site examination should follow the delivery of water from PoE to all points of delivery or use within the building.

Elements to be examined and documented include (Figure 4.2):

- 1 point(s) of entry to the building, including possible PoE treatment;
- 2 possible building-specific sources of water and associated treatment;
- 3 water piping, storage systems and connections between drinking- and non-drinking-water systems, including intended connections (e.g. between drinking-water systems and fire systems) and unintended connections (e.g. between drinking-water systems and sewage or recycled-water systems);
- 4 devices for heating and supplying hot water;
- 5 hot-water piping systems;
- 6 equipment installed at PoU (e.g. dishwashers, washing machines, drinking- water fountains);
- 7 water treatment systems at PoU.

These elements are explained in more detail below.

1 Point(s) of entry

The most common source of drinking-water to buildings is an external piped water supply. The PoEs are often marked by a water meter on the property or building boundary. This is also the point where ownership and management responsibilities can change to the building owner. It is a critical point in terms of providing a basis for defining the physical scope of building WSPs. In some cases, buildings may have more than one PoE, and in other cases groups of buildings may be supplied through a single offtake and a shared meter. There could also be separate points of supply for firefighting. Each PoE should be identified, as well as their condition of use (permanent, intermittent, backup) and the way they are connected to the inner water system and to other entry points (i.e. whether they are interconnected or kept separate).

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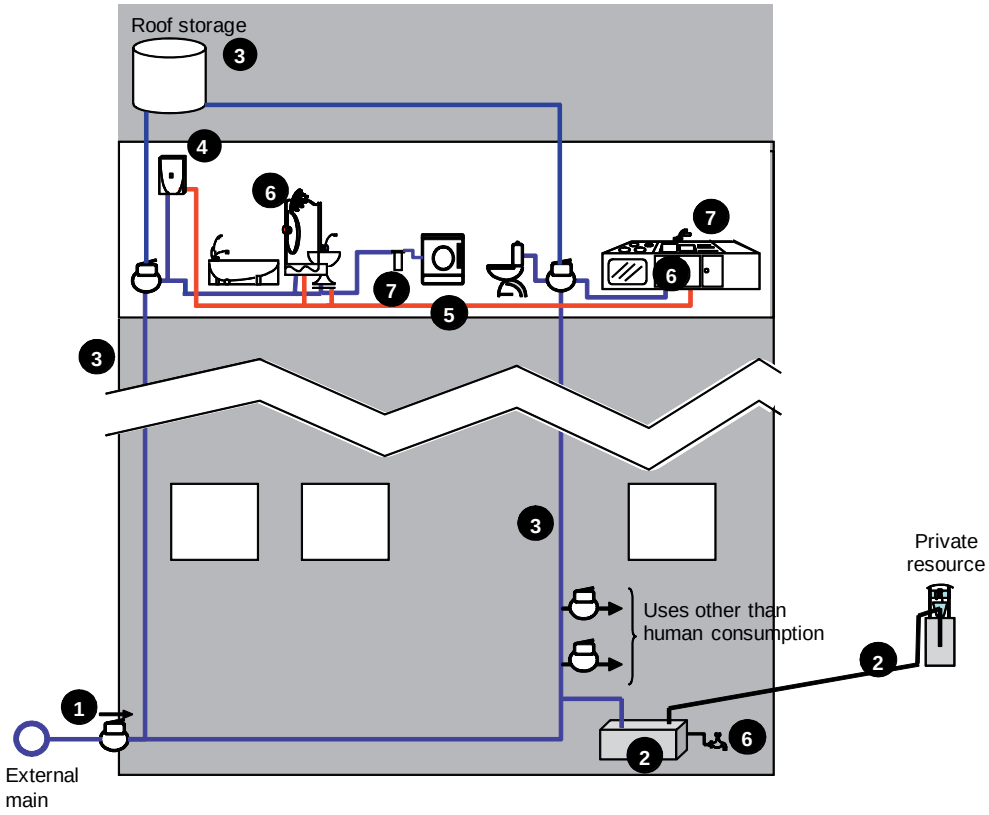

Figure 4.2 Typical components of water systems inside buildings

Issues that need to be considered include the:

- quality and composition of the delivered water (this needs to be obtained from the water supplier);
- continuity and quantity of water supply;
- conditions of accessibility to the PoE;
- presence of a water meter and of backflow-prevention systems to prevent contamination of the public network;
- responsibility of the water supplier in assuring water quality within the building; for example, it could be a requirement that the public water supply will not corrode building plumbing systems;
- treatment systems installed at the PoE (e.g. chlorinators, filters, water softeners, deionizers, activated carbon), including selection, storage, use and control of chemicals.

2 Possible building-specific sources of water and associated treatment

Buildings may use private sources of water or may augment external sources of water with building-specific sources, such as rainwater, wells, borewater and springs. If the water from the private source is not provided for human consumption (e.g. used for toilet flushing), safeguards (e.g. warning signs) must be installed to prevent this water being misused as drinking-water or being connected to the drinking-water supply.

The following questions need to be considered:

- What is the nature and location of the building-specific source?
- How is it protected from external pollution?
- How is it delivered to the building and what are the possibilities for contamination (e.g. through faults in pipework, open storage tanks, inappropriate materials in contact with water)?
- What kind of treatment is applied at the PoE?
- If the building-specific source is not used for drinking, what precautions are taken to ensure that the water is not misused or connected with the drinking-water supply?

3 Water piping, storage systems and cross-connections to non-drinking-water systems

Water piping systems in buildings vary in lengths, complexities, materials and designs. The structure of a piping system needs to be established by examining existing plans and by an on-site investigation. Plans should always be checked against reality, since they are not always updated when networks are upgraded or repaired. However, this can be difficult, particularly in large, complex buildings, because pipes are often concealed and embedded in walls or ceilings. It is important to catalogue as much of the system as possible and to document and retain all plans for future use. In particular, the following parts of the system should be identified:

- water-storage tanks (may be larger where water supplies are intermittent), including consideration of size in relation to inflow and usage requirements (total and peak flows) within the building, detention and integrity;
- points of delivery, including fixtures and connections to equipment (e.g. dishwashers, washing machines, medical equipment) and water-using devices (e.g. cooling towers, swimming pools, water fountains);
- inadvertent or unintended connections between drinking-water systems and non-drinking-water systems (lower or higher quality water);
- installation of backflow prevention between drinking-water systems and non-drinking-water systems (e.g. firefighting systems) and water-using devices;
- physical separation of cold- and hot-water systems and separation of drinking-water systems and non-drinking-water systems;
- labelling and identification of pipework;
- thermal insulation of piping systems;

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- temperatures;
- antisiphonage systems or valves;
- branch pipes and dead legs;
- areas with potential for intermittent or seasonal use;
- materials used in pipes and other components, including compliance with established certification or authorization schemes for materials used in contact with drinking-water;
- access for maintenance or disinfection.

Box 4.1 provides a case study of cryptosporidiosis associated with water shortages in a multipurpose building in Japan.

Box 4.1 Cryptosporidiosis associated with water shortage

From 30 August to 10 September 1994, there was an outbreak of cryptosporidiosis among the people who visited or worked in a multipurpose building in Hitatsuka, Kanagawa Prefecture, Japan. The multipurpose building was constructed in 1970, with six storeys above the ground and one below. There were 10 restaurants or bars, a dance studio, a clothing store, a post office and accommodation for employees in the building. An epidemiological survey revealed that 461 out of 736 people investigated complained of cholera-like or influenza-like illness. An investigation of the water system in the building found that there were two separate systems: one directly connected to the public water supply served drinking-water to the first floor, while the other delivered water from the second to sixth floors through a storage tank, which was also supplied from the public water supply. The storage tank was adjacent to a night-soil tank, wastewater tank and artesian springwater tank in the basement. The tanks were concrete and separated by a wall with holes to allow connections between the tanks. (This kind of tank design is not allowed in new regulations for buildings.) Although the purpose of the holes was not clear, they might have helped to discharge excess drinking-water from the storage tank to the night-soil or wastewater tanks. Water level in the wastewater tanks was kept below the holes by pumping to the public drain.

The epidemiological survey found that there were patients from every floor except the first. Polluted drinking-water was strongly suspected as a source of infection. According to the owner of the building, the wastewater pump was broken at the time of the outbreak. Several species of pathogenic bacteria were isolated from stool and water samples, but they were not considered to be the source of the outbreak. Oocysts of *Cryptosporidium parvum* were identified in 12 (48%) of the 25 stool samples, tap water, the storage tank and other tanks. It was concluded that the cause of this outbreak was drinking-water contaminated by *Cryptosporidium* oocysts following accidental malfunction of the wastewater drainage system.

Based on Kuroki et al. (1996).

4 Devices for heating and supplying hot water

The production of hot water is a common feature in buildings. Hot-water production may be instantaneous, or based on its storage in hot-water tanks. Buildings may be served by single hot-water systems or by multiple systems to supply individual floors, sections of buildings or living units. In large systems, hot-water production can be centralized in boiler rooms or provided by multiple units. Consideration should be given to the temperature of water in storage heaters and the capacity of systems compared with water usage.

Box 4.2 provides a case study of methaemoglobinemia (a disease characterized by a higher than normal level of methaemoglobin, which does not bind oxygen, in the blood), arising from nitrite-contaminated water.

Box 4.2 Methaemoglobinemia attributable to nitrite contamination of potable water through boiler fluid additives, New Jersey, 1992 and 1996

Two outbreaks of methaemoglobinemia were reported in 1992 and 1996. In the first outbreak, acute onset of illness was reported in 49 children from one school. Onset occurred within 45 minutes after lunch. Initial symptoms were blueness of lips and fingers, followed by nausea, abdominal pain, vomiting and dizziness. Fourteen children were hospitalized and treated with supplemental oxygen and methylene blue. All children recovered in 36 hours. In the second incident, six workers reported acute onset of blueness of the skin. Two of the workers were treated with supplemental oxygen and methylene blue. All recovered within 24 hours.

An investigation of the first incident found that the children had consumed soup diluted with a mixture of hot and cold tapwater. The soup contained 459 mg/L of nitrite, while the hot water contained 4–10 mg/L of nitrite. The hot-water boiler had been returned to service that morning after earlier servicing using a commercial conditioning fluid containing nitrite and sodium metaborate. Investigations found that a backflow-prevention valve preventing flow of water from the boiler to the drinking-water system was stuck in the open position. In addition, taps for the boiler treatment solution and the hot-water coil were in the same area but unlabelled. The water system was flushed, and the school discontinued heating water through boiler coils.

An investigation of the second incident also found that a faulty backflow-prevention valve had allowed boiler conditioning fluid to contaminate hot water used to prepare coffee.

Although the potential for this type of contamination from boilers was recognized with a regulatory requirement for backflow-prevention valves, there were no requirements for routine inspection, maintenance and replacement of valves. Maintenance of backflow-prevention devices used to prevent contamination of drinking-water is essential.

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5 Hot-water piping systems

Hot-water systems should be mapped and catalogued in a similar fashion to cold drinking-water systems. One of the problems associated with hot-water systems is balancing the need to maintain water temperatures above 50 °C to minimize risks from *Legionella*, while minimizing the risk from scalding. This applies particularly in aged-care and child-care facilities and health-care facilities. Hot-water piping systems can be installed as one unit at the scale of the entire building, or to serve sections of buildings.

When mapping hot-water systems, the following components and features should be identified:

- hot-water devices and storage vessels;
- thermal insulation of piping systems and physical separation from cold systems;
- the presence of looped distribution systems (circulating systems);
- temperatures throughout the system, including at most distal points and, in the case of looped systems, on point of return to heating devices;
- installation of temperature-control devices to reduce the risk of scalding (e.g. thermostatic mixing valves) and distance from these devices to PoU;
- length and numbers of branch pipes and dead legs;
- areas with potential for intermittent or seasonal use;
- materials in pipes and other components;
- access for maintenance or disinfection.

6 Equipment installed at PoU

Description of systems should identify all equipment using water.

Equipment at PoU varies in type, size and flow rates. Equipment includes sinks, taps, baths and showers, dishwashers, washing machines, medical devices, sprinkler systems, drinking-water fountains, decorative fountains and ice machines. All devices should be identified, together with frequency of use. Installation of backflow prevention should be recorded.

7 Water treatment systems at PoU

Treatment may be applied at PoU using devices such as carbon filters, membrane filters, water softeners, deionizers or ultraviolet disinfection systems. In large buildings, staff may install PoU devices such as carbon filters without approval. All PoU devices should be identified. Unauthorized equipment should be removed. Installation of backflow prevention should be recorded.

Issues to be considered include correct installation and maintenance. For example, filters need to be replaced regularly. Old carbon filters that have passed their “use-by” dates can support growth of large concentrations of microorganisms.

Existence of standards and regulations that apply to PoU equipment connected to water supplies should be determined. Where standards and regulations have been established, all equipment should be checked for compliance.

Box 4.3 provides a case study of a *Pseudomonas* outbreak in a haematology unit.

Box 4.3 Resolution of a *Pseudomonas aeruginosa* outbreak in a haematology unit with the use of disposable sterile water filters

In 2002, a high incidence of *Pseudomonas aeruginosa* bacteraemia was detected in a haematology unit in which severely neutropenic patients were admitted. A total of 61 of 1478 blood cultures were positive for *P. aeruginosa*, compared with 19 of 824 blood cultures performed in 2001.

In an initial investigation in June 2002, eight water samples were collected from bathrooms used by patients, but only one contained *P. aeruginosa*. However, when the outbreak persisted, a further 85 samples were collected. These included 46 samples of water from outlets such as taps, showers and water traps, as well as samples of detergent, air, and bathroom and toilet surfaces. Twenty-nine of the water samples contained *P. aeruginosa*, while none of the other samples were positive.

The installation of 0.2 µ membrane filters on taps and water heads significantly reduced the incidence of bacteraemia. In 2003 and 2004, *P. aeruginosa* was detected in 7 of 1445, and 11 of 1479 blood cultures, respectively.

Tapwater has been documented as a potential source of *P. aeruginosa* infections in hospital settings. Additional measures such as point-of-use treatment can reduce the risk of infection in high-risk patients.

Source: Vianelli et al. (2006).

4.5 Identifying hazards and hazardous events

In hazard identification, the WSP team is required to assess what could go wrong and where hazards and hazardous events could occur. The following sections discuss a range of possible generic hazards and hazardous events that may occur in buildings. However, it is important that hazards and related events are specifically identified for individual buildings under investigation.

Box 4.4 provides definitions of hazards, hazardous events and risk, in the context of risk management.

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Box 4.4 Definitions of hazards, hazardous events and risk

Effective risk management requires the identification of potential hazards and their sources, and potential hazardous events, and an assessment of the level of risk presented by each. In this context:

- a hazard is a biological, chemical, physical or radiological agent that has the potential to cause harm;
- a hazardous event is an incident or situation that can lead to the presence of a hazard (what can happen and how);
- risk is the likelihood of identified hazards causing harm in exposed populations in a specified time frame, including the magnitude of that harm and/or the consequences.

4.5.1 Microbial hazards

Faecal contaminants

In common with most drinking-water supplies, ingress of enteric pathogens (bacteria, viruses and protozoa) associated with faecal contamination can be a significant source of hazards. Faecal contamination can enter through public water supplies provided to buildings, building-specific water supplies, faults in internal plumbing systems (e.g. unroofed water-storage tanks, cross-connections with sewage systems or with recycled-water systems) and poor hygiene at PoU.

Growth of environmental organisms

Water systems in buildings can be prone to environmental microorganism growth, including potentially pathogenic species and nuisance species, which can cause off-tastes and odours. Environmental pathogens include *Legionella*, *Mycobacterium* spp. and *Pseudomonas aeruginosa*. Water-borne *Legionella* is strongly associated with buildings, while *Pseudomonas* has been identified as a particular concern in health-care settings (Anaissie et al., 2002; Exner et al., 2005) and water-using devices such as swimming pools and hot-tub pools (Yoder et al., 2004, 2008a; Djiuban et al., 2006; WHO, 2006a). In hospitals, a broader range of environmental microorganisms have been identified as causes of nosocomial infections, including *Acinetobacter* spp., *Aeromonas* spp., *Burkholderia cepacia, Serratia, Klebsiella, Stentrophomonas maltophilia* and fungi such as *Aspergillus, Fusarium* and *Exophilia* (Annaisie et al., 2002; Sehulster et al., 2004).

Small invertebrate animals can survive and grow in distribution systems under conditions that support microbial growth and biofilms (Ainsworth, 2004). These small animals are not of health concern but can reduce the acceptability of water supplies.

4.5.2 Chemical hazards

Chemicals from environmental and industrial sources, agriculture, water treatment and materials in contact with water can contaminate building systems. Contamination could be introduced from external community supplies, building-specific water supplies or distribution systems within buildings. Chemical quality of all water supplies used in buildings should be determined. For external supplies, this information should be available from water providers, while building-specific supplies will require monitoring (WHO, 2008).

Chemicals used in water-using devices can also represent hazards, either from back-siphonage from the devices or from storages kept within buildings. These chemicals can include disinfectants, antiscalants, coolants, heating fuels, oils and other chemicals used in boilers.

Materials

Chemicals that can be leached from materials used in pipework, solders and associated fittings include aluminium, antimony, arsenic, benzo(a)pyrene, bismuth, cadmium, copper, iron, lead, nickel, organolead, organotin, selenium, styrene, tin, vinyl chloride and zinc (WHO, 2008; Health Canada, 2009). Organic substances can be released from plastic pipes and fittings, flexible hoses, glues, adhesives and tank-lining materials (plastic and bitumen based). These substances may be direct hazards or may cause indirect problems by supporting microbial growth (e.g. from polymeric or elastomeric compounds).

In addition to potential health impacts, materials can contain chemicals that cause aesthetic problems. For example, iron and zinc do not produce health impacts, but rust will discolour water, while elevated levels of many metals such as zinc will add a metallic taste to water. Users will often assume that discoloured or poorly tasting water is unsafe.

If the materials are suitable for use in drinking-water systems and corrosion is controlled (see section 4.6), the concentrations of hazardous chemicals released into water supplies should not represent a health risk. However, hazardous concentrations could be released by unsuitable materials. Some countries have established programmes to certify products and materials used in drinking-water distribution systems.

Water-treatment chemicals

Water treatment is used in some buildings to either improve untreated water supplies or to supplement treatment applied by the drinking-water provider. It may also be used to produce water of higher quality required for specialist purposes (e.g. renal dialysis or manufacturing processes). Common forms of treatment include filtration, disinfection and softeners. Water-treatment chemicals, such as disinfectants and coagulants, and chemicals used to maintain treatment processes, such as membrane-cleaning agents, can represent hazards.

Annex 2 provides a summary of microbial and chemical hazards that can present a risk to building water supplies, including potential outcomes of infection or exposure as well as sources of exposure and methods for identification.

4.6 Hazardous events

4.6.1 Contaminated or intermittent water supply

The quality or quantity of external sources of piped water supplied to a building may be compromised due to intermittent supply, contaminated water or poor condition of the distribution system.

Those responsible for water supplies in buildings should liaise with operators of external piped water supplies to review the performance and previous history of the supply. This review should consider the quality (including contamination events) and quantity (volume,

reliability, frequency and length of interruptions) of the supply. The presence of buffering storages and alternative sources of water will influence the impact of interruptions to external supplies.

In cases where information on water quality of external supplies is inadequate, building managers may need to consider monitoring.

4.6.2 Ingress of contamination

Water sources

Contamination of building water systems can be caused by ingress of hazards into sources of external or building-specific supplies. Further information is provided in the supporting texts on protecting groundwater (Schmoll et al., 2006) and the GDWQ (WHO, 2008). Ingress of microbial and chemical contaminants can be caused by a range of hazardous events, including contamination of water sources by human and animal waste, industrial spills and discharges, inadequate treatment, inappropriate storage, pipe breakages and accidental cross-connections. Water utilities should provide warnings to building owners and managers when incidents threaten the safety of water delivered to buildings. Building owners should ensure that mechanisms have been established for notifications to be received and for appropriate responses to be initiated.

Building systems

Possible events leading to ingress of contamination can be determined by a systematic review of the system components, taking a “what-can-happen” brainstorming approach. The input of plumbing specialists, together with water microbiologists, is important in hazard identification. Any break or disruption to the integrity of drinking-water distribution systems can lead to ingress of microbial contamination. The likelihood of contamination events is increased where drinking-water and wastewater networks are installed in close proximity.

Box 4.5 provides a case study of water quality in rural health-care facilities.

Box 4.5 Water quality at rural South African health-care facilities

Water quality problems at health-care facilities in developing areas are often not only the result of on-site microbial deterioration but start with the quality of the water supplied to the facility. In South Africa, rural facilities have to rely on boreholes or surface water for their source of potable water. The water is often supplied without treatment, or after only limited treatment. The quality of the potable water used in health-care facilities in rural areas in South Africa is not monitored routinely. During 2006, a small study was conducted at 21 clinics in the Limpopo province in the north of South Africa to determine the microbial water quality of the drinking-water. Water was tested for *Escherichia coli*. General information on water supply and sanitation issues at the clinics was also collected.

Water availability was one of the most pressing problems experienced by many of the clinics. In many cases, this was blamed on inadequate technical support and maintenance. A significant percentage of the clinics studied used water that did not comply with South African drinking-water standards. This may have been partly due to the variety of sources upon which they need to rely, particularly when their primary source fails. A significant health risk to users was indicated by positive *E. coli* counts found in 14 of the 49 samples (29%), representing 38% of the clinics. This study highlighted the fact that health-care facilities in rural areas often receive water of inadequate microbial water quality, which could jeopardize the health of both patients and staff at the clinics.

Source: M du Preez, Council for Scientific and Industrial Research, South Africa.

Events that can lead to ingress of contamination include the following:

- Cross-connection of different water qualities (e.g. drinking-water and water of other quality) (USEPA, 2002) may not be readily apparent, because differences in physical appearance may not be recognized by users. Inadvertent connections may be introduced during maintenance and repair.
- Inadequate backflow prevention on PoU equipment can allow contaminated water or chemicals used in the equipment to flow back into and contaminate drinking-water systems.
- Leakage of chemicals or fluids, and cross-connections with chemical storages (e.g. heat transporters or corrosion-preventing additives associated with hot-water devices) can contaminate drinking-water (USEPA, 2002).
- Inadequate protection of building storage tanks can lead to contamination from the water supply. Similarly, unprotected tanks are at risk of faecal contamination from birds and vermin.
- Water supplies can be deliberately contaminated (Ramsay & Marsh, 1990).
- Hydrophobic compounds can migrate through plastic piping. Storing or using hydrocarbons or solvents close to plastic piping that is porous to hydrophobic compounds can contaminate drinking-water. Storing such products in boiler rooms can lead to increased migration of organic substances due to elevated temperatures.

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Box 4.6 provides a case study of poor water-supply management in a health-care facility.

Box 4.6 Poor management of a hospital water supply

A hospital in Eastern Europe with 400 beds has two separate water sources of water: an intermittent community supply that provides sufficient water, and a shallow on-site bore that provides salty water. The community supply is sourced from a well about 5 km from the hospital. This community supply is treated using a rudimentary, manually controlled chlorination device. The community supply is poorly protected from contamination at both the source and during distribution. Supply from the community system is limited by the availability of power to the whole system, coupled with inadequate pumping and storage capacity at the hospital.

As a result, the hospital has two internal systems. The first system distributes a mixture of water from the community supply and the on-site bore. This water is too salty to drink (it is classified as being non-drinkable), and is used for toilet flushing and to supply firefighting equipment. The second system delivers drinking-water from the community supply to about half the building. There is no labelling to distinguish between the two systems, even in rooms that have outlets from both systems. There is no evidence of backflow prevention in any parts of the plumbing systems.

When water is available from the community supply (about twice a day), it is collected and stored for later use in bathtubs, buckets and any other available containers. There is no hot-water system, no bathing facilities in the hospital, and no hand-washing facilities near toilets. Drainage pipes from some sinks are not sealed at the point of entry into floors. The plumbing system is prone to freezing, because the central heating system has not operated for more than 15 years.

A number of measures could lead to large improvements. The quality, management and constancy of the community supply could be greatly improved, but this is beyond the control of the hospital. The most pressing need at the hospital is to ensure that there is sufficient pump capacity and storage at the hospital to provide greater security of supply of water from the community system. This would allow disconnection of the on-site bore and reduce the need to collect water in open containers. Constant pressure in the hospital system would also reduce the likelihood of backflows and ingress of contaminated water. Sanitation at the hospital could be improved by providing more hand-washing facilities, ensuring that toilet facilities are functional and ensuring that drainage systems are maintained. The system should be examined for cross-connections, and, where necessary, backflow-prevention devices should be installed.

Alternative sources of water such as deep bores could be investigated.

Source: Prospal (2010).

4.6.3 Poorly controlled treatment

Installing water-treatment systems should improve water quality, if they are managed properly. However, potential hazards may arise from:

- lack of validation that treatment systems will be effective;
- incorrect installation (e.g. softening systems should be calibrated so that they do not produce water that could be corrosive);
- operation by staff with insufficient training and knowledge;

- inadequate monitoring and poor control;
- insufficient maintenance;
- inadequate response to equipment failures or poor monitoring results (e.g. inadequate disinfectant residuals);
- excessive doses of treatment chemicals (e.g. disinfectants) and poor control of chemicals used in maintenance of treatment processes (e.g. cleaning agents for membrane filters).

Disinfection by-products are likely to increase if disinfection is applied. While excessive doses of chlorine should be avoided, it is important that microbial control is maintained.

4.6.4 Microbial growth and biofilms

Water supplies in buildings connected to public or external supplies represent end-of-pipe systems. As such, they can often provide environments and conditions (e.g. low flows, stagnation) that are favourable for microbial growth and biofilm formation.

Environmental pathogens are often adapted to grow in biofilms, and growth can be greater in conditions that support biofilm development. In well-managed systems, biofilms will be thin and relatively well contained. Concern arises when these biofilms become too thick and start to disseminate throughout the system. Organisms in established biofilms can be difficult to remove. Poorly managed building water systems are prone to colonization, and biofilms can develop within pipes and on components such as washers, thermostatic mixing valves and outlets. Biofilms are extremely difficult to remove from all parts of the system once they are established, and they can be resistant to disinfectants, such as chlorine. Well-managed disinfection regimes that maintain disinfectant residuals through water systems can inactivate potential pathogens released into the aqueous phase, but this protection is lost if disinfectant residuals fall below effective levels.

Factors associated with microbial growth and biofilm formation in cold-water systems include:

- stagnation and low water flows;
- poor temperature control, which creates conditions supporting microbial growth; several environmental pathogens (e.g. *Legionella*) grow more quickly at body temperature (37 °C), and hot and cold water should therefore be kept above 50 °C and below 25 °C, respectively (inadequate separation and insulation of cold- and hot-water systems can lead to warming of cold water);
- scaling (because of its impact on hydraulics);
- scaling and corrosion, which provide rough surfaces that promote development of biofilms;
- suspended matter, which can provide nutrients favouring microbial growth, and create deposited sludges that support biofilms;
- source water that contains a high organic load (i.e. high total organic carbon);

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- inappropriate materials containing microbial nutrients in contact with water;
- poor maintenance and intermittent use of PoU equipment and devices (e.g. ice machines, cooling towers, old carbon filters past their "use-by" date), which can support microbial growth (e.g. *Listeria*, *Pseudomonas*, *Legionella* and fungi); for example, filters need to be replaced regularly.

The case study in Box 4.7 describes what can happen when a cold-water system fails.

Box 4.7 Outbreak of legionellosis due to failure in cold-water system

A hospital in Brandenburg, Germany, with more than 900 beds opened a new building and began to move patients from some older wards to the new one. The management of the hospital changed with the opening of the new building. Soon after starting operation of the new wards, seven patients were diagnosed with legionellosis. Samples had been collected from the hot-water distribution system before moving patients and had not contained *Legionella*. As soon as the outbreak was detected, the water distribution system was inspected. Use of water from showers and other utilities was restricted, filters were installed, and patients were subjected to stricter surveillance.

At the same time, alterations were made to the water-system operations, particularly the disinfection regimes. Details of theses alterations remain unclear due to the simultaneous change of management and limited availability of documentation. Afterwards, the system was checked again and was considered safe.

Six months later, another new building was opened, and again patients were moved from old wards to the new building. Again, the hot-water distribution was examined before the move, with no detection of *Legionella*. And again, five patients fell ill with legionellosis shortly afterwards.

A more in-depth inspection of the whole water system was conducted, along with immediate measures such as installing filters and carrying out disinfection procedures. Both new buildings had separate hot-water distribution systems. Both were only sparsely contaminated with *Legionella*. However, both buildings shared the same cold-water distribution system, and the temperature in these pipes was shown to be higher than allowed by technical standards (25 °C maximum allowed for cold water). Apart from insufficient insulation of the cold-water pipes, the hydraulics of the whole system had not been optimized, leading to stagnation. There were cross-connections with fire hydrants and pipe sizes that were inadequate.

Corrective measures introduced following the initial response (disinfection and installation of filters) comprised installation of regulation valves and recirculation pipes to avoid stagnation and heating of cold water. Changes in management had been associated with poor documentation associated with planning, construction and modifications. Documentation of the water distribution system and disinfection procedures was improved. A more detailed risk assessment was performed.

The two outbreaks following the opening of the biggest new hospital buildings in the region drew major public attention, and the new management faced severe criticism. Costs for corrective action to avoid closing the hospital (or at least the buildings affected) were remarkably high. Two of the twelve patients who were confirmed cases of legionellosis died. Legal action was pursued.

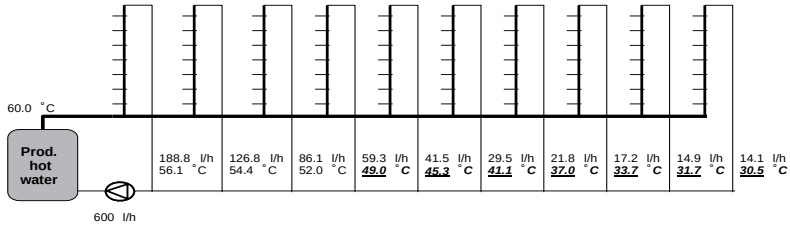
Adapted from Robert Koch Institute (2004).

Factors associated with biofilm formation and growth of environmental pathogens in hot-water systems include:

- insufficient heating capacity to cope with demand;
- poor temperature control, leading to reduction of hot-water temperatures below 50 °C; factors can include
  - poor insulation of hot-water systems
  - poor design, leading to low flow or stagnant areas (long branch pipes and dead ends)
  - installation of high-volume storage tanks that support stagnation and stratification (stratification can lead to lower water temperatures at the bottom of storage vessels)
  - failure to maintain water at sufficiently high temperatures in storage vessels (in some cases, temperatures in storage vessels may be reduced in a bid to save heating costs or to reduce risks of scalding by cooling the whole hot-water system)
  - insufficient equilibrium of permanent flow in looped systems or insufficient total flow rates to feed all parts of the piping system (see Box 4.8)
  - incorrect positioning or operation of temperature-reduction measures (e.g. thermostatic mixing valves); the main fault is locating these devices too far away from taps and outlets, creating long lengths of pipework containing warm water;
- corrosion and scaling, resulting in the accumulation of sediments and microorganisms at the bottom of storage tanks;
- inadequate cleaning and maintenance.

Box 4.8 *Legionella* hazard due to unbalanced looped hot-water systems

Looped hot-water networks are designed in such a way that the temperature in the loops is maintained because the loops are insulated and a minimum flow rate is maintained in each loop. For a given loop, the difference in temperature between the two points where it is connected to the main distribution circuit ("departure" and "arrival") is inversely proportional to the flow rate in the loop. For example, in a typical building with six levels, a 5 °C temperature difference may be maintained only under the condition that the flow rate in the loop is equal to or above 40 litres per hour. Very often, this condition can be attained only by specific valves that equilibrate flows among the loops. However, if the design or construction of such networks is poor, flows may not be balanced—that is, the first loops take the largest part of the flow rate, so that there is not enough flow for the last loops. As the figure below shows, this frequent type of fault can directly affect the temperature of the last loops, which can then become incubators of *Legionella* and other environmental pathogens at temperatures below 50 °C.



Example of unbalanced flow rates in a looped hot water system and its consequences on the temperature of circulated water

4.6.5 Release of hazards from materials and equipment

Unsuitable materials and equipment used in water systems may release hazardous substances into drinking-water (Health Canada, 2009). The chemicals could be contaminants in the materials (see section 4.5.2), be leached during initial use, or be leached due to elevated corrosion.

Stagnation of water within the building system can increase concentrations of hazardous chemicals released from materials. Intermittent use of end-of-plumbing fixtures (e.g. drinking-water coolers in schools) can result in the presence of elevated concentrations of heavy metals such as copper from copper piping or lead from brass fixtures.

Corrosion and scaling

A wide range of materials can be potential sources of chemicals through corrosion, including pipes, solders and fittings (Health Canada, 2009). Corrosion of materials in contact with water is natural and will eventually cause leakages or failures, allowing ingress of contamination. In addition, the formation of corrosion product layers can promote microbial growth. The aim is to keep corrosion to a minimum; however, it can be accelerated by a number of factors, including water quality (particularly pH, chloride and sulfate, disinfectant concentrations, organic materials), poor material quality, use of materials that are incompatible with the given water quality, poor installation (poor

welding, interconnection of different types of metal piping), water stagnation and temperature (Health Canada, 2009). Some waters, particularly those with low levels of dissolved minerals, can be corrosive for metal pipes and fittings, including copper, lead and brass (which often contains lead). Water utilities should be able to supply information on the characteristics of water supplied to buildings, including the likelihood of corrosion.

Water with high levels of hardness can cause increased scaling. Again, water utilities should be a source of information on hardness of incoming water supplies. Hot-water devices are particularly susceptible to scaling.

Scaling can cause energy losses (due to increased pumping and heating costs), resistance to disinfection, and premature failure of appliances (e.g. boilers and hot-water systems).

4.6.6 Specific uses

Sources of specific hazards can arise from specific uses (e.g. medical, dental), or from water-using devices, such as cooling towers, swimming pools, water coolers, water fountains or misting systems (e.g. in garden centres and conservatories).

Hazardous events associated with specific uses include:

- inadequate backflow prevention, allowing contaminated water or chemicals used in water-using devices to flow into drinking-water systems;
- aerosol formation (from showers, decorative fountains, etc.), providing potential exposure to respiratory diseases (e.g. legionellosis, mycobacterial hypersensitivity pneumonitis);
- poor maintenance and intermittent use, providing conditions that support microbial growth (e.g. *Listeria*, *Pseudomonas*, *Legionella* and fungi), corrosion (e.g. copper leaching from piping in drinking-water coolers) or leaching of chemicals from materials (e.g. plasticizer from plastic piping and tubing);
- inadequate treatment in swimming pools and hot-tub pools, allowing survival of enteric pathogens (e.g. *Giardia*, *E. coli* 0157, *Norovirus*) or growth of environmental pathogens (e.g. *Legionella* and *Pseudomonas*) (Craun et al., 2005; Pond, 2005; Sinclair et al., 2009).

4.6.7 Poor management (intermittent use)

Water distribution systems require proper management. Where parts of buildings and associated plumbing are not used for extended periods (e.g. months), the water system should be physically disconnected to avoid stagnation. Stagnant water can support growth of biofilms and environmental pathogens, such as *Legionella* and mycobacteria, and can contain elevated concentrations of chemicals released from pipework, such as copper and lead.

4.6.8 Construction work, renovations and repairs

If not properly planned and managed, renovation, repairs and modifications to buildings and associated water supplies can lead to introduction of microbial and chemical hazards. Where water distribution systems are extended, modified or repaired, there will be periods when flow is stopped and when pipework is intentionally cut and left open for periods, allowing potential ingress of contamination.

Hazardous events that could occur during construction, extension or repairs of systems include:

- the use of inappropriate materials—this can include using metallic products that are incompatible with existing materials in the system, causing corrosion;
- microbial or chemical contamination during repair or maintenance;
- accidental cross-connection between systems delivering different water qualities—renovation work may highlight deficiencies in labelling of existing pipework, which should be rectified;
- temporary switching to alternative supplies during construction, as well as introduction of temporary stagnation, dead legs and blind ends;
- failure to upgrade heating capacity when hot-water systems are extended;
- changes to the established equilibrium of operation in terms of hydraulic conditions, thermal capacity and corrosion risks; for example, renovating or altering the type of system described in Box 4.8 (above) could change performance, and extending the system may increase the total pressure too much for regulation valves to counterbalance, making equilibrium among loops impossible.

Extensions and renovations should not be assessed as separate entities from the existing system. Modifications can have wide-ranging ramifications on performance of the existing system through changing flow patterns, increasing capacity requirements and complexity. Renovations leading to change of use (e.g. from a commercial building to an apartment block) can be particularly complex and involve substantial changes to water systems and water usage. After construction, the existing system and extension should be considered as a single "new" system to be reassessed for potential hazardous events. WSPs will need to be reviewed and amended following any significant modifications.

Changes need to be recorded in system descriptions and distribution system maps.

4.6.9 Emergencies leading to contamination of external supplies

Major events such as flooding and other faults leading to contamination of external supplies (e.g. leading to a boil-water advisory) can contaminate building water supplies, including end-of-plumbing and PoU devices such as ice machines, beverage dispensers, drinking-water coolers and other water-using devices.

Alternative water supplies used in the event of an emergency may be a source of hazards and should be used with care.

4.7 Risk assessment

Risk assessment is a process by which identified hazards and hazardous events are evaluated to decide whether they represent a significant risk that needs to be controlled. The type of information that should be considered in a risk assessment is shown in Figure 4.3.

Risk assessments should take into account the number and vulnerability of exposed people and the type of exposure.

In the risk-assessment process, the important issue is to identify and prioritize unacceptable risks that need to be controlled. It is important not to get caught by identifying all risks and providing them with equal weighting.

Risk assessments can be applied at the time of planning or constructing a system; they can also be applied to an existing system. The preventive approach to include risk assessment with planning and construction is always preferable. Modifying existing systems, including retrofitting additional monitoring and control measures, is typically more expensive. Reactive risk assessments and modifications taken after harm has been caused can be complicated by political and legal influence, and time constraints.

Assessments for new buildings will identify risks that need to be controlled and the measures that need to be incorporated in the new water systems. Therefore, risk assessments should be conducted as early as possible within planning and design phases.

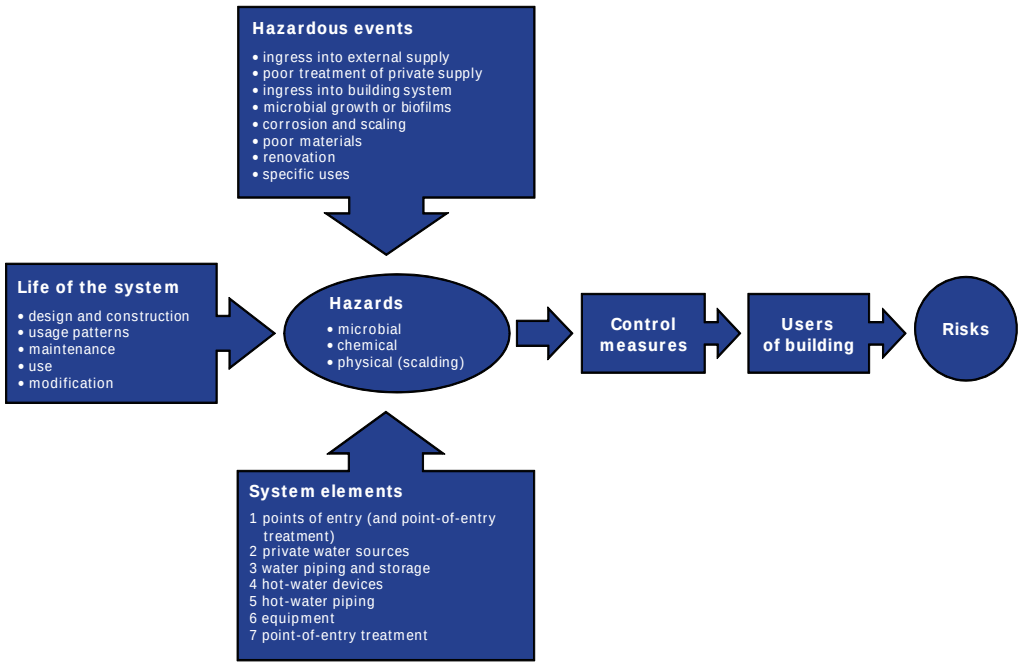


Figure 4.3 Types of information to consider in risk assessment

Risk assessments for existing buildings should identify and consider the effectiveness of established control measures. If the control measures are either insufficient or not effective, the risk-assessment process will identify significant risks and point to system modifications required to achieve water-quality targets. Therefore, the outcome of risk assessment is a plan of action that documents necessary additional or improved control measures, including time lines and responsibilities for their implementation. This should include establishing priorities for action.

Risk assessment and prioritization methods range from relatively simple team decision approaches, through semiquantitative, matrix-based approaches, to fully quantitative risk assessments (WHO, 2009). Which method is best in a given situation will depend on the complexity of the building water system assessed. The method of choice for a small or simple structured building may be qualitative team decisions based on the judgement and experience of the WSP team. For example, risks could be classified as significant,

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uncertain or insignificant. Those classified as significant should be considered as clear priorities for further action that could include application of additional control measures, while risks classified as uncertain may require further investigation.

Similarly, this type of approach could be applied to assess the risks from contamination or failure of external supplies. Where data are available on performance in the preceding years (e.g. over the past 5–10 years), a risk assessment could be based on:

- one or no major contamination or water-shortage events in the past 5–10 years, safe supply resumed after less than two days (= reliable public distribution);
- one to two major contamination or water-shortage events per year, resumed after less than two days (= generally satisfactory public distribution; PoE treatment may be considered for high-risk buildings or populations); or
- frequent major contamination or water-shortage events (= public distribution is not sufficiently reliable; PoE treatment or alternative sources should be considered).

Risk assessments for more complex buildings with a range of different water usages and technologies may benefit from a more formal and structured approach. In all cases, the WSP team needs to decide on a consistent risk-assessment methodology.

Tables 4.2 and 4.3 illustrate one approach for assessing and ranking risks. In this approach, the likelihood of a hazard occurring is combined with the severity of consequences to provide a risk matrix and is particularly applicable to hazardous events. The tables can be varied to meet the needs of the organization undertaking the risk assessment. For example, the numbers of categories for likelihood and consequence could be reduced.

Table 4.2 Example of a simple risk-scoring matrix for ranking risks

	Severity of consequences				
Likelihood	**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Almost certain					
Likely					
Moderately likely					
Unlikely					
Rare					

Table 4.3 gives an example of descriptors that can be used to rate the likelihood of occurrence and severity of consequences. A “cut-off” point must be determined above which all hazards will require immediate attention. There is little value in expending large amounts of effort to consider small risks. For example, in the first instance, a cut-off point could be those risks above the bold line. Once these risks are managed, the cut-off point could be lowered.

For some hazards, it may be possible to incorporate a quantitative risk assessment. This assessment can provide a numerical estimate of whether the risk is tolerable or unacceptable. For chemicals, this estimate can include guideline values. For microbiological quality, quantitative risk assessment can be applied using a four-step process involving hazard identification, dose–response determination, exposure assessment and risk characterization. Hazardous events that lead to chemical guideline values being exceeded, or to high levels of microbial risk, should be considered unacceptable and hence require management.

The risk assessment should consider the effectiveness of existing control measures. Where risk remains unacceptably high, alternative or additional controls will be required (after existing measures have been considered). These additional measures must be evaluated in a supplementary risk assessment after additional control measures have been put in place.

Table 4.3 Examples of definitions of likelihood and severity categories that can be used in risk scoring

Item	Definition
Likelihood categories	
Almost certain	Once per day
Likely	Once per week
Moderately likely	Once per month
Unlikely	Once per year
Rare	Once every five years
Severity categories	
Catastrophic	Potentially lethal to all people using the building, including vulnerable groups (e.g. immunocompromised patients, infants and the elderly), following acute exposure
Major	Potentially harmful to all people using the building following acute exposure
Moderate	Potentially harmful to vulnerable groups (e.g. immunocompromised patients, infants and the elderly) following chronic exposure
Minor	Potentially harmful to all people using the building following chronic exposure
Insignificant	No impact or not detectable

Regardless of which method is preferred, any decision taken in the risk assessment needs to be documented to ensure that decisions are sufficiently transparent for external examination (e.g. in audits) and to allow reassessment in periodic reviews.

Further information on hazards, risks and responses is provided in Box 4.9.

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Box 4.9 Example of a risk assessment

A water safety plan (WSP) team investigated the water system in a school building for 600 pupils. The building included a gymnasium with two shower rooms (40 showers in total). The WSP team found the following problems:

- One distribution pipe within the building was made of lead. This pipe delivers water to three bathrooms and one small kitchen.
- One small leakage in a pipe in the basement was identified.

Hot water was prepared from a centralized system in the main building at a temperature of 60 °C. There was no circulation loop. The hot-water pipes supplying water to the showers in the gymnasium were not insulated properly. Cold-water pipes were close to the hot-water pipes.

The WSP team prepared the following table for the risk assessment and for the decision about additional control measures.

Risk assessment and additional control measures for an example water system

	Hazard 1	Hazard 2	Hazard 3
Hazard or hazardous event	Lead pipe	Leaking pipe	Temperature loss from heater to shower; maximum water temperature at shower at 48 °C
Hazard type	Chemical contamination by lead	Chemical and microbial contamination	Microbial growth (Legionella)
Current control measure	None	None	Thermostatically controlled water heating
Basis for risk assessment	Daily consumption of lead-contaminated water at the taps in the bathrooms and in the small kitchen by children is likely	A breakdown of the water supply is not considered likely in the near future	It is very likely that there are long stagnation periods of the warm water supplying the showers. Temperatures below 60 °C will occur, and the potential for the growth of Legionella is high. Also, elevated temperatures in cold-water pipes are likely. These could support growth of Legionella.
Risk	**Major**	**Low–minor**	**Major**
Further investigations	Water analysis for lead	Check integrity of distribution system Check material compatibility Check corrosion	Temperature profiling of the system Check water heaters Check water system usage Water analysis for Legionella

Box 4.9 Example of a risk assessment *continued*

Risk	Major	Low–minor	Major
New or modified control measures	Short term: • Provide information to the teachers and pupils that water can only be drunk at certain taps • Label the taps that deliver lead-contaminated water Long term: • Replace all lead pipes	Replace with appropriate material	Short term: • Close showers Long term: • Install a warm-water circulation system, proper thermal insulation of warm-water and cold-water pipes

4.8 Control measures

Control measures are barriers to risks. They need to be identified and implemented for hazards identified as a significant priority. In the context of a WSP, control measures are defined as those steps in drinking-water supply that directly affect drinking-water quality, either by preventing the occurrence of significant hazards or by inactivating, removing or reducing them to acceptable levels.

Control measures can include a wide range of activities and processes. They can be:

- preventive (and be incorporated in design, planning, construction and commissioning)
- treatment (e.g filtration, disinfection, softeners)
- technical (e.g. temperature control, maintenance procedures)
- behavioural (e.g. measures that influence how water is used).

Control measures must be defined specifically and precisely for all significant risks, and adapted to the local conditions. They should never be imprecise or vague.

While the type and number of control measures will vary for each supply system, their collective implementation and maintenance is essential to ensure that water quality is controlled effectively.

Adequate control measures may already be established in many buildings. However, after reviewing their effectiveness in the course of system assessment, additional measures may need to be identified or existing measures may need to be modified. Improvement plans should be designed to deal with significant risks. Optimum solutions may not be economically, technically or socially feasible in the short term, and improvement plans may need to set short-, medium- and long-term goals.

Table 4.4 (at the end of this section) provides examples of control measures. Some of the control measures are applied during design and installation, while others involve a range of practical measures, including flushing, cleaning, disinfection and other routine maintenance procedures. Simple systems will require fewer control measures than more complex systems in large buildings.

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While control measures are directed at ensuring water quality, there may also be preventive actions and responses applied to maintain constancy of supply. These could include installation of sufficient buffering storage tanks or identification of alternative sources of water. Examples are included in Table 4.4.

4.8.1 Validation

All control measures should be validated to ensure effectiveness. Validation is the process of obtaining evidence that control measures are effective and achieve the required results. Validation can take the form of intensive monitoring during commissioning or initial implementation of a new or modified control. Alternatively, validation can take the form of assessing technical data from published studies or data provided by manufacturers (preferably confirmed by independent certification). This is a common approach used in assessing treatment processes. Validation can also be informed by successful implementation in other buildings.

Validation will typically only apply under certain conditions and these will typically be defined by operational limits. For example, chlorination could be validated (confirmed) as being effective if a minimum chlorine residual of 0.5 mg/l is achieved. In this case, 0.5 mg/l is used as a lower limit in operational monitoring (see section 4.9).

4.8.2 Ingress of contamination

Microbial contamination

Control measures to reduce ingress of microbial contamination from water sources can include water treatment at the PoE. This is particularly important where the quality of the source water cannot be guaranteed or where improved quality water is required—for example, in health-care facilities that accommodate patients with increased risk of infection.

Water treatment can be used:

- at PoE to
  - supplement treatment applied by the drinking-water provider
  - improve untreated building-specific water supplies or supplementary sources of water (e.g. rainwater);
- before devices such as hot-water systems or specialized equipment to improve water quality;
- at PoU (e.g. carbon filters, membrane filters).

Common forms of treatment include filtration, disinfection, softeners and carbon filters. Selection of PoE devices will be based on the nature of the source water (surface water, groundwater, rainwater, etc.), susceptibility to contamination (e.g. by human and livestock waste), the intended use of the water and the vulnerability of users.

Within buildings, control measures include ensuring the physical separation of systems transporting different qualities of water (e.g. drinking-water from sewage). These systems should be clearly marked to ensure that the possibility of inadvertent cross-connections is minimized during maintenance, repairs and renovations. Where systems and devices

are connected to drinking-water systems (e.g. firefighting supplies, cooling towers), backflow devices need to be installed to prevent ingress of contaminated water. Many countries have technical guides on how this should be achieved.

Where possible, positive pressure should be maintained to reduce the likelihood of ingress of external contamination. Pressure fluctuations should be minimized for the same reason.

Chemical and physical contamination

Control measures to ensure the physical and chemical quality of water entering buildings can include treatment at PoE. This could apply to either public or building-specific water supplies. The selection of appropriate solutions will depend on the nature of the chemical contamination. Selection of PoE devices should be based on expert advice.

Common forms of treatment include water softeners, deionizers, activated carbon and filtration.

Microbial growth and biofilms

Pathogen-control strategies inside buildings should prevent the development of conditions that can foster growth of hazardous environmental pathogens, such as *Legionella* and *Pseudomonas aeruginosa*.

Control measures should focus on good design principles and temperature management, and limit the development of biofilms. Systems should be designed and operated to maximize circulation and flows (avoiding stagnation, low flows, long branch pipes and dead ends, poor distribution of flow among branch pipes, etc.). Water temperatures should be kept below 20 °C in cold-water systems and above 50 °C in hot-water systems. Pipes carrying hot water should be insulated, while cold-water systems should be protected from heat sources. Ideally, hot water should be stored at above 60 °C and circulated at 50 °C or higher. In tropical and hot climates, keeping cold-water systems below 20 ºC during summer months is difficult. In these cases, using alternative controls (e.g. reducing stagnation, low flows and other risk factors) will have a higher priority.

Temperature reduction to reduce the risk of scalding in hot-water systems (e.g. by using thermostatic mixing valves) should be applied as close as possible to PoU. Distribution systems that incorporate multiple loops should be designed to ensure that flow rates can be equilibrated among the various loops. The capacity to disinfect hot-water systems using elevated temperatures or chemical processes should be considered. If PoE disinfection is installed to reduce the risk of microbial growth, it should be maintained and monitored to ensure effectiveness.

Additional safety measures may be applied in buildings or parts of buildings used by higher risk populations. This could include PoU devices (e.g. filters or ultraviolet disinfection units) installed on showers and taps. Effectiveness of these devices has been demonstrated in high-risk areas of health-care facilities, such as intensive-care units, for control of *Legionella* and *Pseudomonas* (Exner et al., 2005; Trautmann et al., 2008). Use of these devices should also be considered as a general measure where there are concerns about the quality of water entering buildings. Installation should be accompanied by ongoing maintenance and replacement programmes. Poorly maintained devices will not perform effectively and may support growth of biofilms.

4.8.3 Materials and equipment

Degradation, corrosion and scaling

The aim is to minimize corrosion and hence control the release of chemical hazards and extend the life of pipework and associated equipment. In many countries, water suppliers are required to provide water that is not aggressive (likely to cause corrosion in internal plumbing systems). However, this is not always the case, and building owners may need to implement control measures.

Corrosion can be controlled by:

- selection of suitable materials (i.e. not only more "resistant" material but also a better quality of the same material);
- minimizing water stagnation;
- preventing galvanic corrosion by avoiding contact between different metals;
- preventing bacterial regrowth (biofilm formation);
- treating water (e.g. removing corrosive ions such as chloride);
- adding corrosion inhibitors (e.g. polyphosphates, sodium silicates);
- encouraging corrosion "competition" with cathodic protection (e.g. using sacrificial galvanic anodes that dissolve instead of the piping material, or using inert electrodes powered by an external source of direct current in water-storage tanks).

Water with high levels of hardness can cause increased scaling. Increased temperature can exacerbate scaling, and hot-water devices and heating elements are particularly susceptible. A common control measure to reduce scaling is installation of water softener to reduce hardness.

4.8.4 Specific uses and water-using devices

Risks associated with specific uses (e.g. medical, dental) and water-using devices can be controlled by measures directed towards reducing contamination and preventing direct exposure to contaminated water or aerosols. Where devices are connected to drinking-water systems, the ingress of contamination to the main supply should be prevented by installing appropriate backflow-prevention devices.

All devices need to be maintained to minimize microbial growth and biofilm formation. Control measures for these types of devices should be based on regular cleaning, flushing of piping and tubing, and disinfection. Where devices produce sprays, possible exposure to fine aerosols should be minimized. This can be achieved by reducing release from devices such as cooling towers (e.g. by installing drift eliminators) or, where possible, reducing public exposure by operating systems outside opening hours (e.g. irrigation systems in garden centres).

Many countries have regulations and standards that apply to water-using devices. These regulations and standards can include general requirements such as requiring installation of backflow prevention on equipment connected to drinking-water supplies. Regulations may also specify application of control measures, including water treatment, disinfection and regular cleaning for specific devices such as cooling towers, swimming pools, hot-tub pools and hot-tub baths. Further information on control measures for these devices

can be found in *Guidelines for safe recreational water environments volume 2: swimming pools and similar environments* (WHO, 2006a) and *Legionella and the prevention of legionellosis* (Bartram et al., 2007).

4.8.5 Management, maintenance and repair

Water treatment devices at PoE and PoU and water-using devices should be cleaned regularly to minimize microbial growth and corrosion (softeners and carbon filters may be colonized if not adequately maintained). Water-using devices should be decommissioned when not in use, and drained where possible. Water-using devices such as cooling towers and evaporative condensers will often require cleaning and decontamination before being returned to service. Devices such as drinking-water fountains should be flushed following periods of non-use (e.g. school holidays).

4.8.6 Construction and renovation

In new buildings and upgraded parts of buildings, appropriate planning, construction and commissioning provides the first opportunity to apply control measures for preventing hazards and minimizing risks.

Planning

Initial planning of new buildings and upgrades for existing buildings often give little attention to water quality and hygiene issues. Functional and aesthetic features of a new building are generally given higher priority. Planning and designing safe water systems normally has to adapt to a physical framework that is already set. Planning of water systems is commonly left to subcontractors or subordinates in teams of designers. If not integrated in early stages of planning, there can be major consequences for the functionality and safety of water distribution within the building. Malfunction of water installations and subsequent retrofitting and remedial action can be very expensive and can interrupt construction or commissioning. Therefore, it is important to include specialists for water utility planning as soon as possible.

Definitions of water usage in new buildings are often imprecise, particularly in multipurpose buildings. This can be exacerbated where the intended uses of a new building are not known or are subject to substantial changes during the planning phase. Owners may not have decided where to put certain devices and end-of-use equipment, and can often be unaware of consequences and associated risks. Calculations of water usage and appropriate dimensions of the water distribution system are essential to ensure that systems are designed with appropriate capacities. This involves consideration of how the system and any associated equipment are to be used (e.g. numbers of users, frequency). Both over- and under-estimation of water capacity can compromise safety. As much detail as possible about projected water use and equipment requirements must be obtained from owners or intended users of buildings. Dual plumbing systems incorporating recycled water for toilet flushing and other non-drinking uses are becoming more popular. Installation of these systems will reduce water usage through drinking-water systems, and unless this taken into account it will lead to over-capacity and increased risks of stagnation.

In some cases, building owners are not the users or managers of buildings. For example, hotel buildings are quite often built and owned by companies other than those responsible for operating and managing the hotel. Early consultation between the various parties,

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including documentation of water-installation issues, is recommended to prevent the need for modifications during commissioning.

It may help to learn from existing buildings and transfer this experience to new, comparable projects. In most cases, pre-existing examples of safe water distribution systems are available. Dealing directly with manufacturers and providers of equipment (e.g. dimensions for water boilers or tanks) is useful, but design engineers may be a better source of information, because water hygiene depends on the whole system, rather than on individual components.

Construction phase

The initial plan for water distribution facilities should be followed wherever practical. If changes are made, they need to be incorporated into an amended plan; this includes changes to materials or dimensions of pipework and equipment. It is not appropriate to use working sketches from the planning office that do not reflect the actual installation.

Risks of biofilm formation or corrosion can be reduced by using only materials that are certified for use with drinking-water. Using incorrect or inferior—and possibly cheaper—alternatives will generally incur high costs for subsequent corrective measures.

Special care must be taken with procedures that are known to be crucial for system performance. It is essential that only water of drinking quality comes in contact with fittings and materials, even during construction. Alternatively, measures should be taken to ensure that the dead water is completely removed and the new fittings are flushed before being commissioned.

Pressure tests for distribution systems can be critical. Sometimes, water of lower quality is used for this purpose. While draining, flushing and high-dose chlorination can reduce risks from contamination, they may not always be completely successful. The pressure test should be used (with air, oil-free gas or drinking-water) to avoid this risk of residual contamination. If lower quality water is used, the system must be thoroughly drained and disinfected afterwards.

Timing also needs to be considered. Construction of a large building is often done in several phases. It is important to keep all finished parts of the water installation dry until the whole system is commissioned for routine operation. Introducing water into the system too early (e.g. weeks or months before a system becomes fully operational) can cause long-term problems. Retained water will become stagnant and support growth of biofilms, which are difficult to remove. Wherever possible, water should only be added to the system as a final step before it becomes operational. If this is not possible, sections that remain stagnant for extended periods should be thoroughly drained and disinfected before the system is commissioned.

4.9 Operational monitoring of control measures

A key requirement in identifying control measures is that performance can be monitored. Thus, operational monitoring procedures need to be established for each newly identified or existing control measure. Operational monitoring is used to assess the performance of individual control measures to ensure that they are working effectively, as designed. Monitoring frequencies should be selected to ensure that corrective actions can be introduced in a timely fashion to prevent loss of control and development of hazardous situations.

WSPs should incorporate a monitoring plan to answer the following questions:

- What will be monitored?
- How will it be monitored?
- Where will it be monitored?
- When and how often will it be monitored?
- Who will do the monitoring?
- Who will receive the results for analysis and, where necessary, ensure appropriate remedial responses are implemented?

Operational monitoring does not necessarily involve complex and time-consuming microbial or chemical tests. It rather takes the form of a planned sequence of inspections of observable features. As summarized in Table 4.4, many of the operational monitoring requirements involve regular inspection (e.g. checking structural integrity of storage tanks) or auditing of maintenance procedures (e.g. checking that PoU devices have been maintained according to manufacturers' instructions). Operational monitoring can include relatively simple field measurements, such as monitoring for turbidity, the appearance of the water, temperature and chlorine residuals. The general principle is that frequent performance of quick field tests is preferable to infrequent and expensive laboratory-based testing. Poor performance of hot-water systems can be detected more quickly and on an ongoing basis through monitoring of water temperatures, rather than by testing for pathogens such as *Legionella*, *Pseudomonas* or mycobacteria.

For each control measure, operational limits defining acceptable performance need to be identified and applied to operational monitoring parameters. These limits are typically identified during validation of control measures and can take the form of upper or lower limits or tolerance ranges. For example, this could include identifying a minimum temperature of 50 °C for hot-water systems and a maximum temperature of 20 °C for cold-water systems to prevent the growth of environmental pathogens, such as *Legionella*. Control measures are considered to be effective if monitoring results comply with the limits. If these limits are not met, corrective actions need to be taken immediately to bring the measure back under control. Corrective actions must be specific and predetermined, where possible, to enable rapid implementation. For hot-water systems, this includes identified actions to ensure that temperatures above 50 °C are restored and maintained. In some cases, it can be useful to set preliminary targets that provide an early warning if control measures are not be performing as well as possible. If these targets are not met, corrective actions can be implemented before control is lost. For example, if the low temperature limit in a hot-water loop is 50 °C, a preliminary target at which action is initiated could be 53 °C.

4.10 Management procedures and corrective responses

All aspects of WSPs need to be documented in a management plan. This includes system mapping, hazard identification, risk assessment, identification of control measures, monitoring programmes, corrective actions, improvement plans and communication strategies. Much of the management plan will describe monitoring and maintenance

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procedures that will be routinely followed on a day-to-day basis during normal performance. Many of these procedures will relate to sensible and practical measures to maintain cleanliness, hygiene, integrity and performance of systems. The key is to ensure that procedures are precisely described, with clear directions on what needs to be done and who will do it. However, documentation should also include corrective actions and response to incidents and failures. Many potential incidents are predictable (e.g. ingress of contamination, microbial growth and biofilms), and specific responses can be identified. A procedure also needs to be developed to deal with unpredictable events. This should take the form of an incident-response plan dealing with general principles, including responsibilities and communication requirements.

4.10.1 Ingress of contamination from external water sources

Chemical and microbial contamination may enter the distribution system of the buildings from external water supplies. If contamination is detected in a public water supply, advice should be provided to building owners or managers by the water supplier. This should include advice on recommendations for users of the water, alternative sources, responses implemented by the water utility, and estimated time frames for return to normal operation.

Depending on the contamination and potential impacts, the following measures could be considered for building water supplies:

- **Prevent the consumption of contaminated water.**
  - Provide advice to all users of the building that water from the building system should not be consumed. Label taps and outlets with appropriate advice.
  - Consider the need to provide bottled, packaged or tankered water to the building users. The building owner should ensure that the alternative source of water is safe and, if tankers are used, that they are suitable for delivering safe drinking-water.
  - Switch to an uncontaminated source of water to the building, if possible.
  - Use mobile treatment units (e.g. temporary chlorinators) to produce safe drinking-water, if contamination is likely to persist for an extended time. Monitor the operation of treatment devices to ensure that they produce safe drinking-water.
- **Disinfect the system.**
  - If microbially unsafe water is or was supplied to the building, it will be necessary to disinfect and flush the whole water system. This process should be monitored by on-line and field measurement of disinfectant concentrations at outlets throughout the building. The effect of the disinfection should be verified by microbiological analysis.
- **Flush the system.**
  - If chemically contaminated water is or was supplied to the building, it will be necessary to flush the whole water system. The effect of flushing should be verified by chemical analysis.

4.10.2 Ingress of contamination from building systems

If ingress of contamination in the building is identified, the source must be eliminated. Other corrective actions and responses could include the following:

- **Prevent the consumption of contaminated water.**
  - Issue advice to all users of the building or users of mains water in the affected section of the building that the water supply should not be consumed. Label taps and outlets with appropriate advice.
  - Consider the need to provide bottled, packaged or tankered water to building users while remedial action is taken. The building owner should ensure that the alternative source of water is safe and, if tankers are used, that they are suitable for delivering drinking-water.
- **Disinfect the system.**
  - In the event of microbial contamination, it will be necessary to disinfect and flush the whole water system or the affected sections of the system, depending on the type and extent of the contamination. This process should be monitored by on-line and field measurement of disinfectant concentrations at outlets throughout the building. The effect of disinfection should be verified by microbiological analysis.
- **Flush the system.**
  - In the event of chemical contamination, it will be necessary to flush the whole water system or the affected sections of the system. The effect of flushing should be verified by chemical analysis.

Failure of point of entry

PoE treatment devices need to be monitored to ensure that they function effectively. Non-compliance with critical limits should lead to an immediate assessment of impacts and remedial action. Further actions will depend on the nature and significance of the treatment (e.g. disinfection of a building-specific water supply compared with secondary disinfection of a treated external water supply).

Where PoE treatment is required to produce safe drinking-water from unsafe private or public supplies, responses and actions could be similar to those applied to contaminated external supplies. If the PoE treatment (e.g. water softeners) improves water quality but is not critical for safety or the performance of other control measures, the responses will not be as substantial and warnings about consuming the water will not be required.

4.10.3 Microbial growth and biofilms

If impacts from microbial growth are detected (e.g. discoloured water, odours, off-tastes, and slimes and sludges in water-using devices), it is likely that water systems will require disinfection and flushing. Hot-water systems can be "pasteurized" by flushing with water at temperatures greater than 60 °C (preferably greater than 70 °C). Users should be notified when disinfection or "pasteurization" is implemented. Water hotter than 60 °C can cause severe scalding, while water containing high levels of disinfectants can have objectionable tastes and odours for some users. Water-using devices will also require cleaning and disinfection.

The source of microbial growth should be examined. For example, the performance of treatment used in water-using devices should be checked. Where water temperatures

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are too high in cold-water systems or too low in hot-water systems, the cause should be investigated and corrected. This could include examining separation of systems, insulation, temperatures produced by water heaters, location and performance of thermostatic mixing valves, and flow rates in all branches—particularly in return mains.

The operation of the system should be checked to determine whether usage patterns have changed and whether areas of water stagnation have been introduced.

4.10.4 Release of hazards from materials and equipment

Improvement programmes should be established to reduce or stop the release of hazards by replacing the responsible components within the distribution system. Where this involves large amounts of pipework and fittings, this may need to be a staged process. For example, if there are large numbers of lead-based pipes (in some cases, most pipes in a building could contain lead), it is often impractical to replace it all at once. Depending on the extent and significance of contamination and potential impacts, the following measures should be considered:

- **Prevent the consumption of contaminated water where the water is considered unsafe.**
  - Issue advice to all users of the building or users of mains water in the affected section of the building that the water supply should not be consumed. Label taps and outlets with appropriate advice.
  - Consider the need to provide bottled, packaged or tankered water to the users of the building while remedial action is taken. The building owner should ensure that the alternative source of water is safe.
- **Flush the system.**
  - It may be necessary to flush the whole water system or the affected sections of the system. It may be appropriate to implement regular flushing programmes (e.g. for lead contamination; USEPA, 2002; Ontario Ministry of the Environment, 2010). The effect of flushing should be verified by chemical analysis.
- **Prevent corrosion.**
  - Corrosion can lead to chemical contamination. If the contamination includes hazardous chemicals, then similar management procedures applied to ingress of chemical contamination (see above) should be considered. Corrosion can affect the taste and appearance of water. If this occurs, building water supplies should be flushed to reduce concentrations of corrosion products.
  - Corrosion can also lead to faults that allow microbial contamination. Faults should be immediately repaired following standard maintenance procedures. This should include flushing and disinfection of affected parts of distribution systems.

4.10.5 Specific uses and water-using devices

Corrective actions and responses associated with incidents and failures detected in water for specific uses normally focus on taking remedial action and preventing exposure.

Where faults and contamination are detected, a standard response is to stop use or operation of the device until remedial action has been taken. Procedures describing when and how to shut down devices, and how to clean and decontaminate them, should be documented

and made available. These procedures should include monitoring requirements that must be met before devices are returned to service.

Advice should be issued to users of the building or users of specialized equipment when the devices are not available. Devices should be labelled with appropriate advice.

Where water is used for specific medical or dental procedures, alternative sources may be required. Procedures should be established to ensure that alternatives are available.

Box 4.10 provides a case study of *Legionella* infection from a private hot tub.

Box 4.10 *Legionella* infections from a private whirlpool (hot tub) in Sweden

In mid-February, a middle-aged Swedish man fell severely ill with legionellosis. The cultivation of his sputum sample showed growth of *Legionella bozemanii*, an unusual species in Sweden.

Since the patient had not recently travelled abroad, an investigation to find the source of infection was initiated by the department of communicable disease control and prevention in Stockholm County. The man was staying at his summer cottage during the incubation time. The water supply to his cottage was delivered through a long pipe via his neighbour's property. Water in the pipe was suspected to be the source of infection, and so the water was sampled and analysed for the presence of *Legionella*, but none was detected. On further questioning, the patient recalled that he had visited a friend and they had bathed in the friend's whirlpool bath.

The owner of the whirlpool was contacted and was found to be suffering from protracted symptoms of a respiratory tract infection. He had taken a course of penicillin for about two months, with no effect on his symptoms. Serological results later showed raised titres of antibodies to *Legionella bozemanii*.

At the end of April, samples were taken from the whirlpool, and very high concentrations of *Legionella bozemanii/anisa* were detected in the whirlpool water (3 600 000 cfu/l). The bacteriological analysis also showed high numbers of *Pseudomonas aeruginosa* and very high numbers of heterotrophic bacteria (>30 000 cfu/ml). These results indicated that the whirlpool had not been maintained correctly.

The owner of the whirlpool stated that he had maintained the whirlpool according to the manufacturer's maintenance instructions, although he had changed the filter more often than was recommended. The whirlpool has a volume of about 3 m^3; the owner changed the water every second week, and added chlorine (manually) as a disinfectant. The owner of the whirlpool contacted people who had visited him previously and had bathed in the whirlpool. He reported that about 40 people had developed mild respiratory symptoms after their visit.

The growth of the unusual *Legionella bozemanii/anisa* may have been due to the fact that the water used in the household was a mixture of well water and water from a nearby lake. Outbreaks caused by whirlpools distributing *Legionella* are becoming more frequent. Outbreaks of Pontiac fever with high attack rate are more common, but legionellosis outbreaks also occur.

Whirlpools are commonly installed in public places such as hotels, gyms or hot tubs, and poor maintenance of whirlpools is common. This was the first time that a private whirlpool had been found to be the vehicle of legionellosis in Sweden, but it is likely that the number of people contracting an infection with milder symptoms from their private whirlpools is underestimated.

Guidelines have been produced for hotels and public places to help reduce the risk of whirlpools becoming sources of *Legionella*.

Source: de Jong et al. (2004).

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4.10.6 Emergencies affecting external supplies

The quality of alternative water supplies provided in emergencies should be verified. Where treatment of these supplies is implemented, operational procedures and monitoring will be required to ensure that acceptable performance is achieved.

As part of remediation following a contamination event, the entire distribution system, including water-using devices, PoU and end-of-pipe devices will need to be flushed and possibly disinfected or decontaminated. Treatment systems such as water softeners, deionizers and filtration systems will need to be regenerated, backwashed or recommissioned before being returned to service. Small PoU filters could harbour contamination and may need replacing.

4.11 Management procedures for new buildings or major upgrades

Water systems, particularly in major buildings, tend to be complex in terms of both their geometry and the technical elements being installed. It is challenging to operate such systems correctly. In addition, personnel who will take responsibility for the new building may not have extensive expertise or training.

Thus, commissioning of water systems in buildings can have a critical influence on the quality of water. The design, construction and function of water systems, as well as management procedures, need to be documented by the constructer of the building and by manufacturers of specific devices and specialized equipment installed in buildings. Operating instructions and maintenance plans should be included. The instructions must cover details about the proper operation of the drinking-water supply system and about adequate functional checks. The nature, scope and frequency of inspections should be specified.

For buildings with specific requirements and potentially vulnerable users (e.g. hospitals, residential homes for the elderly, nursery schools), a specific hygiene plan should be established in cooperation with a hospital hygienist, the responsible public health authority and, if necessary, the water supplier.

A complete documentation folder of management plans and procedures should contain detailed plans of the system and technical fact sheets for all installed components (e.g. water filters, disinfection systems, drinking-water heaters), water-using devices (e.g. cooling towers) and specialized equipment (e.g. medical equipment, dental chairs).

Commissioning should incorporate a management and instruction protocol, which must be signed by both parties (manufacturer and operator of the system). There must also be an appropriate handover process to ensure that the building manager or operator is aware of all features and technical specifications of water systems, devices and associated equipment in the building. The responsible operator has to be informed about reporting requirements, legal obligations, codes of practice, national standards, technical rules and training requirements. Hygiene training may be required.

At the time of commissioning, water quality should be documented by hygienic testing of microbial and chemical quality in an adequate set of drinking-water samples. Initial higher intensity monitoring (additional samples and parameters) might be necessary, depending on intended use of the facility, outcomes of inspection, any irregularities during construction or commissioning, and delays in beginning of regular use (see section 4.8.5). In these cases, a water-quality expert should be consulted.

4.12 Verification

Verification is required to provide reassurance that WSPs are effective and water systems as a whole operate safely. Verification typically includes two components:

- testing water quality
- auditing WSPs.

4.12.1 Water-quality testing

The extent of water-quality testing will be influenced by the size and characteristics of the building, and the reliability and quality of the external water supply. In most buildings that have reliable, high-quality water supplies, there will be limited requirements for independent verification. Part of the responsibilities of the water utility is to ensure that the chemical and microbiological quality of water delivered to buildings is safe. The water utility should provide results on request.

Testing of water-quality safety in buildings is generally only required where:

- additional building-specific sources of water are used to augment the external supply;
- the building has specific purposes that increase potential risks (e.g. hospitals and other health-care facilities);
- water-using devices such as cooling towers, swimming pools and hot tubs are installed;
- management actions are established to minimize ongoing sources of contamination (e.g. flushing to deal with lead contamination).

Where additional building-specific sources of water are used, verification should include traditional indicators of faecal contamination, such as *E. coli*, and chemical parameters. The range of chemical parameters and frequency of testing will depend on the source of the water supply. Guidance on verification of microbial and chemical quality is provided in the GDWQ (WHO, 2008). In health-care buildings, particularly those incorporating intensive-care units, verification may include testing for specific microorganisms such as *Legionella* in hot-water systems. Further guidance is provided in *Legionella and the control of legionellosis* (Bartram et al., 2007). Verification of water quality in water-using devices such as cooling towers and swimming pools may also include testing for specific organisms. Further guidance is provided in *Guidelines for safe recreational water environments volume 2: swimming pools and similar environment* (WHO, 2006b). In some countries, verification of water-using devices may be a regulatory requirement.

The quality of water allocated to specific uses may also need to be verified. The parameters included in monitoring will depend on the specific requirements of the end use.

4.12.2 Water safety plan audits

Verification should include audits of WSPs to demonstrate that the plans have been properly designed, are being implemented correctly and are effective. As described in the GDWQ (WHO, 2008), factors to consider include:

- all significant hazards and hazardous events have been identified
- appropriate control measures have been included

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- appropriate operational monitoring procedures have been established
- appropriate operational limits have been defined
- corrective actions have been identified
- appropriate verification monitoring procedures have been established.

Audits should be included in internal reviews by building managers. Audits by independent experts should also be considered. Independent audits may be required by regulatory authorities or accreditation agencies for certain types of buildings (e.g. health-care facilities) or where buildings use independent sources of water.

4.13 Supporting programmes

Supporting programmes are activities that support implementation of WSPs and assurance of water quality. Operators, maintenance staff, employees and users of buildings may have limited knowledge of WSP principles, technical aspects and good practice associated with water supplies in buildings. Therefore, an important component is developing training and education programmes for personnel who are involved in activities that influence the delivery of safe water, and personnel for whom it is critical to use water safely (e.g. health-care professionals).

Section 5 provides further information on training.

Codes of good operating practices and hygiene are also important components of supporting programmes. These can be captured in standard operating procedures that include but are not limited to:

- hygienic use of water supplies
- hygienic practices in maintaining water supplies, water-using devices and equipment
- hygienic practices in performing repairs
- calibration of monitoring equipment
- instructions on access to equipment and modification of systems
- training requirements for maintenance staff.

The case study in Box 4.11 describes the response to a hospital water supply after contamination with *Pseudomonas aeruginosa*.

Box 4.11 Contamination of a hospital water supply with *Pseudomonas aeruginosa* in Germany

Pseudomonas aeruginosa in concentrations up to and above 100 organisms per 100 ml were detected in the water supply to a new hospital building in a number of locations and on repeated occasions during 2005–06. The colonization could not be eliminated, despite repeated thermal disinfection and implementation of continuous chlorine dioxide disinfection. As a result, the building was vacated, and an expert consultant was engaged to provide advice.

An ultraviolet plant was installed at the point of entry to the water system. The water system was intensively flushed and decontaminated with higher doses of chlorine dioxide disinfection for three days. This was augmented by intermittent dosing with hydrogen peroxide, as recommended in guidelines of the German Association for Gas and Water. After decontamination, there were only isolated detections of *Pseudomonas* (downstream of the pressure-increasing system).

Further measures included replacing and disinfecting the pressure-increasing system, and placing the ultraviolet plant before the pressure-increasing system.

Following these actions, it was decided to:

- move patients and employees into the building to avoid further stagnation (regular water throughput);
- establish an incident plan;
- continue microbiological testing.

Ongoing testing has shown that the strategy has been successful, with no further contamination. The alternative was to completely replace the water distribution system at a projected cost of approximately €2 million.

Source: Exner, Pleischl & Koch (personal communication, 2007).

4.14 Periodic review

Periodic review is a key requirement of effective WSPs; for example, after every three to five years or after significant changes of the supply system. Periodic review ensures regular updates of system assessment and management procedures, and also allows for the inclusion of incremental improvement strategies in system upgrades.

WSPs can become out of date due to modifications to water systems, changes in water uses, and changes in building ownership or tenancies. Therefore, WSPs should be reviewed whenever substantial changes occur.

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Table 4.4 Examples of hazards, hazardous events and responses

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Intermittent supply				
Loss of water supply (isolated event)	• Back up water systems (e.g. alternative supply, standby disinfection facilities) • Ensure carted water is available	• Measure disinfectant residuals (e.g. chlorine concentration), pH • Monitor levels of water in storage tanks • Monitor integrity of storage	• Develop contingency plans to deal with emergencies • Establish procedures for activating back-up systems • Establish procedures before resuming the water supply or use	• Inform building occupants or users on what to do during interruption • Communication protocol with water utility • Train operational and maintenance staff in use of back-up systems
Intermittent supply (regular event)	• Back up water systems (e.g. alternative supply, standby disinfection facilities) • Ensure carted water is available • Provide large storages for supply during interruptions	• Monitor water pressure or water availability • Record times of water availability and water usage • Measure disinfectant residuals (e.g. chlorine concentration), pH • Monitor levels of water in storage tanks • Monitor integrity of storage	• Establish procedures for activating back-up systems • Establish procedure before resuming the water supply or use	• Inform building occupants or users on what to do during interruptions • Discuss the communication protocol with water utility • Train operational and maintenance staff in use of back-up systems

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Contamination of external supply entering the building				
Poor microbial quality (long term)	• Install PoE treatment systems (e.g. filtration and disinfection) • Install PoU devices (e.g. filtration) • Back up systems (alternative supply, standby disinfection facilities) • Ensure carted water, packaged water or bottled water supplies are available • Issue advice to boil water • Isolate building from external supply	• Measure disinfectant residuals (e.g. chlorine concentration), pH • Monitor turbidity if PoE treatment includes filtration • Monitor performance of PoU devices and equipment • Monitor use of carted or bottled water • Ensure water is boiled before use • Monitor cross-connection control preventing ingress of external supply	• Develop procedures for operating PoE systems and treating back-up supplies • Develop procedures for maintaining PoU devices (these should be consistent with manufacturers' instructions) • Identify sources of bottled, packaged or tankered water supplies • Restore disinfection • Restore filtration if provided • Monitor water quality (verification)	• Develop communication procedures for informing building occupants or users • Discuss communication protocol with water utility • Establish contracts with bottled, packaged or tankered water suppliers • Train operational and maintenance staff in use of back-up systems
Poor chemical quality (long term)	• Install PoE treatment systems (e.g. deionizers, softeners, activated carbon) • Install PoU devices (e.g. filtration) • Provide an alternative supply • Ensure carted water, packaged water or bottled water supplies are available • Isolate building from external supply	• Monitor operation of PoE treatment • Monitor performance of PoU devices and equipment • Monitor treatment of back-up supply • Monitor use of carted or bottled water • Monitor cross-connection control preventing ingress of external supply	• Develop procedures for operating PoE systems and treating back-up supplies • Develop procedures for maintaining PoU devices (these should be consistent with manufacturers' instructions) • Monitor water quality (verification)	• Train operational and maintenance staff in use of back-up systems

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Contamination of external supply entering the building *continued*				
Poor microbial quality (short term) (e.g. treatment failure, pipe breakage, natural disasters)	• Back up systems (alternative supply, standby disinfection facilities) • Ensure carted water, packaged water or bottled water supplies are available • Issue advice to boil water	• Measure disinfectant residuals (e.g. chlorine concentration), pH • Monitor appearance (turbidity, colour) and odour of water • Monitor use of carted or bottled water • Ensure water is boiled before use	• Develop contingency plans to deal with emergencies • Provide alternative sources of water (bottled, packaged water or tankered supplies) • Issue advice to boil water • Liaise with water utility on repair of external system • Develop a procedure for flushing and disinfecting internal supply when the water quality of external supply is restored • Verify water quality after normal supply is restored	• Communicate with water utility, including about incident protocol • Establish communication procedures for informing building occupants or users during incident and recovery • Develop a communication protocol with water utility • Train operational and maintenance staff in use of back-up systems
Poor chemical quality (short term) (e.g. treatment failure, pipe breakage, natural disasters)	• Back up water systems (e.g. alternative supply, with standby disinfection facilities) • Ensure that carted water, packaged water or bottled water supplies are available	• Monitor appearance (turbidity, colour) and odour of water	• Develop contingency plans to deal with emergencies • Provide alternative sources of water (bottled, packaged water or tankered supplies) • Activate back-up systems • Develop a procedure for flushing the system when the water quality of external supply is restored • Verify water quality after normal supply is restored	• Establish communication with water utility, including incident protocol • Develop communication procedures for informing building occupants or users during incident and recovery • Develop a communication protocol with water utility • Train operational and maintenance staff in use of back-up systems

Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Contamination of internal supply				
Pipe breaks or entry of contamination into storage tanks	• Regularly inspect systems, including water-storage tanks • Minimize pressure fluctuations • Ensure that the water distribution system is designed properly • Install pressure-reducing valves	• Monitor water pressure • Check turbidity, signs of corrosion or unusual taste	• Develop procedures for repairing or replacing broken pipes • Develop a procedure for disinfecting and flushing affected areas • Develop a procedure for inspecting, repairing and disinfecting storage • Identify sources of bottled or packaged water, or tankered supplies	• Develop procedures for building occupants or users to report loss of supply or changes in appearance, taste and odours • Use materials and pipes that are certified as being suitable • Train operational and maintenance staff on selection of materials and procedures for repairing faults
Cross-connection of different water qualities (chemical or microbial contamination)	• Physically separate and label water systems delivering different water types or removing sewage/greywater • Minimize accidental or unintended cross-connections and provide backflow prevention where required • Maintain positive pressure in the distribution system	• Monitor integrity of system separation and inspect system labelling • Monitor operation of backflow-prevention devices	• Develop procedures for installing or replacing pipework and fittings • Remove unintended cross-connections. • Develop a procedure for disinfecting and flushing affected areas	• Develop communication procedures for informing building occupants or users • Provide instructions for maintenance staff and plumbers or fitters installing new or replacement pipework and equipment
Connection with PoU devices and equipment	• Install appropriate backflow-protection systems • Prevent huge pressure variation in pipe network • Maintain continuous pressure	• Monitor performance of PoU devices and equipment • Monitor operation of backflow-prevention devices	• Develop procedures for installing and connecting devices and equipment to distribution systems	• Provide instructions for people who install equipment • Follow plumbers' codes of practice

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Contamination of internal supply *continued*				
Poor maintenance of equipment and PoU devices, leading to microbial growth or corrosion	• Monitor performance of equipment and PoU devices • Ensure that the system is maintained in accordance with manufacturers' instructions • Install appropriate backflow-protection systems	• Monitor performance of PoU devices and equipment • Monitor appearance of water for signs of growth (discolouration, turbidity, odours) or corrosion	• Develop procedures for maintaining devices (consistent with manufacturers' instructions)	• Train maintenance staff
Backflow from chemical storages Inadequate backflow prevention on equipment	• Minimize connections and provide backflow prevention where required	• Monitor operation of backflow-prevention devices • Monitor use of chemicals	• Develop procedures for installing and connecting storages to distribution systems	• Provide instructions for people who install chemical storages • Follow plumbers' codes of practice

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Sewerage or septic systems				
Aerosol contamination	• Install water traps in sewage lines • Filter double traps in high-risk environments • Prevent contamination from septic tanks	• Monitor integrity of system separation	• Develop procedures for installation during construction and upgrades	• Follow plumbers' codes of practice
Cross-connection with drinking-water system	• Ensure separation from water systems and appropriate labelling and marking of pipework and fittings	• Monitor separation of system	• Develop procedures for installation during construction and upgrades • Remove unintended cross-connections. • Develop a procedure for disinfecting and flushing affected areas • Identify sources of bottled or packaged water, or tankered supplies	• Follow plumbers' codes of practice
PoE treatment				
Incorrect operation and interruption to treatment	• Assign staff to perform maintenance • Monitor operation of processes (e.g. that ultraviolet lights and chlorinators are functioning) • Install alarms on key processes • Have a standby generator	• Measure disinfectant residuals (e.g. chlorine concentration), pH • Monitor turbidity if PoE treatment includes filtration	• Develop procedures for operating PoE systems • Restore disinfection • Restore filtration if provided	• Train operational and maintenance staff

Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
PoE treatment *continued*				
Inadequate maintenance	• Assign staff to perform maintenance • Ensure processes are maintained according to manufacturers' instructions	• Monitor the effectiveness of maintenance procedures	• Develop maintenance procedures	• Train operational and maintenance staff
Overdosing with treatment chemicals or release of treatment chemicals into distribution systems	• Ensure dosing equipment and storages are maintained • Avoid overdesigning chemical storage capacities • Minimize cross-connections and provide backflow prevention where required	• Monitor use of chemicals	• Develop procedures for operating PoE systems, including calibration of dosing systems • Restore correct doses	• Train operational and maintenance staff
Microbial growth and biosystems				
Complex systems	• Apply additional disinfection at PoE • Sanitize or disinfect hot-water systems regularly • Install PoU devices (e.g. filtration)	• Measure disinfectant residuals (e.g. chlorine concentration), pH, after PoE device, and monitor disinfectant residuals in system • Monitor disinfectant residuals and temperature during sanitization • Monitor performance of PoU devices and equipment	• Restore disinfection • Develop procedures for sanitization and flushing • Develop procedures for maintaining PoU devices (consistent with manufacturers' instructions)	• Develop communication procedures for informing building occupants and users during sanitization • Train operational and maintenance staff in use of PoE treatment and sanitization procedures

Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Microbial growth and biosystems *continued*				
Stagnation and low water flows (cold systems)	• Avoid overdesigning capacities • Remove the causes of fluctuation (e.g. high peak water demand, fire drills) • Prevent negative pressure • Flush systems that are not used frequently • Isolate areas that are not used for extended periods • Remove dead legs and minimize length of branch pipes	• Monitor appearance, taste and odour of water • Monitor use of water throughout the building	• Develop procedures for isolating sections of water systems that are not in use • Develop procedures for sanitization and flushing	• Develop procedures for building occupants or users to report loss of supply or changes in appearance, taste and odours • Train operational and maintenance staff
Stagnation and low water flows (hot systems)	• Avoid overdesigning capacities • Flush systems that are not used frequently • Isolate areas that are not used for extended periods • Remove dead legs and minimize length of branch pipes	• Monitor appearance, taste and odour of water • Monitor temperature • Monitor use of water throughout the building	• Develop procedures for isolating sections of water systems that are not in use • Flush all taps on weekly basis if not being used regularly • Develop procedures for sanitization and flushing	• Develop procedures for building occupants or users to report loss of supply or changes in temperature, appearance, taste and odours • Train operational and maintenance staff
Intermittent/ seasonal use/closed hospital wards	• Isolate areas not in use • Drain system and disinfect on return to service	• Monitor occupancy and use of water throughout the building	• Develop procedures for isolating sections of water systems that are not in use • Develop procedures for returning supply before reopening closed sections • Develop procedures for sanitization and flushing	• Train operational and maintenance staff

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Microbial growth and biosystems *continued*				
Poor temperature control (cold systems)	• Insulate cold- and hot-water pipes. • Keep systems physically separate	• Monitor temperature	• Investigate and remove sources of elevated temperatures	• Follow plumbers' codes of practice
Low water temperatures in hot-water storage vessels	• Adjust heater temperature • Ensure sufficient energy delivery (e.g. with distant hot-water supply) • Check heater thermostat • Maintain temperatures above 50 °C in distribution system • Maintain temperatures above 60 °C in storage vessels • Install temperature-reduction devices as close as possible to PoU • Insulate system • Avoid stagnation and low flow areas (minimize branch pipes, dead ends, etc.) • Ensure sufficient capacity for maximum flows	• Monitor temperatures in storage vessels, distribution systems and at PoU • Monitor maintenance of temperature-reducing devices	• Develop procedures for operating hot-water systems, including remedial action if temperatures are too low	• Develop procedures for building occupants or users to report low temperatures • Train operational and maintenance staff • Follow plumbers' codes of practice
Inappropriate materials	• Select appropriate materials (where certification schemes have been established, use only authorized materials)	• Check that only authorized materials are used	• Develop procedures for selecting materials • Replace unsuitable materials	• Train operational and maintenance staff on selection of materials • Follow plumbers' codes of practice

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Microbial growth and biosystems *continued*				
Poorly maintained PoU devices	• Assign staff to perform maintenance • Ensure devices are maintained according to manufacturers' instructions • Check and/or install appropriate backflow-protection systems	• Monitor performance of PoU devices and equipment • Monitor appearance of water for signs of growth (discolouration, turbidity, odours) or corrosion • Monitor production and release of aerosols	• Develop procedures for maintaining devices (consistent with manufacturers' instructions)	• Train maintenance staff
Poor control of looped water supplies	• Check design and operation of pipe loops • Check flow rates in circulated loops, and recalculate equilibrium conditions among loops	• Monitor water pressures and temperatures	• Repair systems so that flows are balanced	• Train operational and maintenance staff
Materials				
Release of organic substances	• Select appropriate materials • Where certification schemes have been established, use only authorized materials	• Check that only authorized materials are used • Where solvents are used during installation, monitor application and curing	• Develop procedures for selecting materials and using solvents • Replace unsuitable materials	• Develop procedures for building occupants or users to report odours • Train operational and maintenance staff on selection and use of materials • Follow plumbers' codes of practice

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Materials *continued*				
Entry of organic substances through plastic piping	• Select appropriate pipe material, particularly in areas where solvents or hydrocarbons are stored • Avoid inappropriate materials in areas where solvents or hydrocarbons are stored or manipulated	• Check that only authorized materials are used • Monitor chemical storages	• Develop procedures for selecting materials • Replace unsuitable materials • Develop procedures for storing chemicals	• Follow procedures for building occupants or users to report odours and tastes • Train operational and maintenance staff on selection of materials • Follow plumbers' codes of practice
Corrosion and scaling				
Poor installation	• Choose quality materials • Follow national or international choice and construction rules • Use active protection of pipes (e.g. sacrificial anodes, anticorrosion products)	• Check appearance of water (red-brown for rust, blue-green at outlets for copper)	• Develop procedures for installing piping and fittings	• Develop procedures for building occupants or users to report changes in appearance, taste and odours • Follow plumbers' codes of practice
Dissolution or corrosion of metals (from pipework, fittings, drinking-water fountains, etc.)	• Follow correct installation • Select appropriate materials • Avoid interconnection of incompatible metal materials • Use PoE chemical treatments to reduce corrosion • Flush pipework regularly • Flush drinking-water fountains regularly after interruptions to use (weekends, holidays, etc.) • Install PoU devices	• Check appearance of water (red-brown for rust, blue-green at outlets for copper) • Monitor performance of PoE and PoU devices and use of chemicals • Monitor performance of flushing programmes	• Develop procedures for installing piping and fittings • Develop procedures for operating PoE and PoU devices • Develop procedures for implementing flushing programmes	• Train operational and maintenance staff in the operation of PoE and PoU equipment • Follow plumbers' codes of practice

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Corrosion and scaling *continued*				
Incompatibility with incoming water quality	• Check incoming water quality and recommendations relating to materials used in distribution systems • Install water softeners to reduce water hardness	• Monitor development of scale (particularly on hot-water elements) • Check appearance of water	• Develop a procedure for consulting with water supplier about materials compatible with water quality • Develop procedures for operating PoE devices	• Train operational and maintenance staff in the operation of PoE equipment • Follow plumbers' codes of practice • Follow advice from water utilities on characteristics of external water supply
Specific uses				
Contamination of dental hygienic equipment, dental assembly (water for mouth washing, wash basin, cooling dynamic tools, auxiliary uses)	• Ensure effective disinfection • Allow easy cleaning and disinfection of the assembly and the material in contact with water • Install adequate backflow prevention • Use suitable material in contact with water (no natural rubber, no nickel plating)	• Monitor implementation of disinfection and cleaning • Check operation of backflow prevention	• Document procedures • Repeat cleaning and disinfection if there are doubts about cleanliness	• Train staff to ensure that procedures are understood and applied

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Specific uses *continued*				
Exposure to aerosols from contaminated cooling towers and evaporative condensers	• Maintain devices (check to see if regulations or standards have been developed) • Maintain cleanliness • Decontaminate regularly (e.g. twice per year) • Decontaminate on return to service • Drain system when not in use • Install biocide dosing • Install drift eliminators • Install outlets away from fresh air inlets to air-conditioning systems	• Monitor cleanliness of devices • Monitor operation of treatment systems (antiscalant, disinfection) • Monitor implementation of maintenance procedures • Inspect and maintain drift eliminators	• Make sure the system is designed according to established standards • Develop procedures for operating and maintaining devices • Develop procedures for cleaning and decontamination • Develop procedures for shut-down and reactivation	• Follow codes of practice for installation, operation and maintenance • Train operational and maintenance staff
Contamination of hot tubs, whirlpools, water display	• Drain and clean regularly • Ensure continuous filtration and disinfection	• Measure disinfectant, pH, turbidity	• Develop procedures for operating and maintaining devices • Develop procedures for cleaning and decontamination	• Follow codes of practice for operation and maintenance • Train operational and maintenance staff
Contamination of respiratory system equipment	• Drain and clean regularly • Disinfect at PoU (ultraviolet radiation) • Ensure backflow prevention is adequate • Wash nebulizers with sterile water and dry thoroughly	• Inspect the system and equipment regularly • Monitor disinfection procedures • Monitor implementation of maintenance procedures	• Develop procedures for operating and maintaining devices • Develop procedures for cleaning and decontamination	• Train operational and maintenance staff

Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Specific uses *continued*				
Contamination of humidifiers	• Maintain droplets separator • Maintain and clean the generator, and disinfect the PoU (e.g. using ultraviolet radiation) • Ensure air catchments are far from polluted area (e.g. cooling towers) • Avoid condensed water recovery • Ensure that the system design separates droplets of critical size, and does not allow stagnation	• Inspect humidifiers regularly • Monitor disinfection procedures • Monitor implementation of maintenance procedures	• Develop procedures for operating and maintaining devices • Develop procedures for cleaning and decontamination	• Train operational and maintenance staff
Drinking-water coolers	• Ensure that coolers are used or flushed regularly to prevent excessive corrosion or leaching of metals, particularly in buildings with seasonal use or extended closures (e.g. schools)	• Inspect drinking-water coolers regularly • Monitor implementation of maintenance procedures	• Develop procedures for maintaining devices, including flushing after periods of low or no use	• Develop procedures for building occupants or users to report changes in taste and odours • Train operational and maintenance staff
Contamination of decorative fountains	• Clean and maintain regularly • Completely drain system for cleaning • Use appropriate water disinfectant	• Inspect fountains regularly • Monitor implementation of maintenance procedures	• Develop procedures for operating and maintaining devices • Develop procedures for cleaning and decontamination	• Train operational and maintenance staff
Contamination of eye wash stations and safety showers	• Flush stagnant water frequently • Disinfect the system regularly • Replace with bottles for eye wash	• Inspect regularly • Monitor implementation of maintenance procedures, including flushing and disinfection	• Develop procedures for operating and maintaining devices • Develop procedures for cleaning and disinfection	• Train operational and maintenance staff

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Construction work				
Use of inappropriate materials	• Select appropriate materials (where certification schemes have been established, use only authorized materials)	• Check that only authorized materials are used	• Develop procedures for selecting materials	• Train designers and builders on selection of materials • Follow plumbers' codes of practice
Microbial or chemical contamination events during repair or maintenance works Temporary switching to alternative supply Temporary stagnation, dead legs and blind ends Extensions of existing installations (which may change the established equilibrium of operation in terms of hydraulic conditions, thermal capacity and corrosion risks)	• Pre-plan extensions to ensure that they are appropriately designed and installed (design should take into account the characteristics and requirements of the existing system) • Isolate new sections from existing systems until integrity can be ensured • Flush and disinfect new construction before it is connected • Ensure that new work is inspected and certified by a qualified plumber or engineer before use • Thoroughly test the operation of the new system in combination with existing infrastructure	• Ensure that design requirements are followed, and that installation procedures are monitored • Monitor isolation of the sections under construction.	• Develop rocedures for constructing and installing new systems, equipment and devices	• Train designers and builders • Follow plumbers' codes of practice • Follow auditing and certification procedures for completed work before commissioning

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Table 4.4 Examples of hazards, hazardous events and responses *continued*

Hazards and hazardous events	Control measures	Operational monitoring	Management procedures, protective actions	Supporting programmes
Construction work *continued*				
Accidental or unintended cross-connection between systems delivering different water qualities	• Ensure that new work is inspected and certified by a qualified plumber or engineer before use • Check connections with existing systems • Ensure that all new work is labelled appropriately • Install backflow-prevention devices where required to protect drinking-water systems	• Ensure that design requirements and installation procedures are followed • Monitor isolation of the sections under construction	• Develop procedures for constructing and installing new systems, equipment and devices	• Train designers and builders • Follow plumbers' codes of practice • Follow auditing and certification procedures for completed work before commissioning

PoE = point of entry; PoU = point of use.

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5 Supporting environment

This section describes the roles of supporting personnel to ensure the smooth running of water safety plans (WSPs). This includes surveillance, inspection, outbreak detection, regulatory and policy frameworks, and capacity building and training.

5.1 Independent inspection and surveillance

5.1.1 Inspection

Independent inspection and surveillance of drinking-water systems is essential for ensuring that systems are well designed and are managed and operated in a manner that protects public health. Independent inspections and surveillance can be undertaken during construction and major renovations of buildings, or can be applied to existing buildings.

Independent technical inspections are often required as part of construction and renovation of buildings. For example, engineering inspections and certification of plumbing systems can be required under building and plumbing codes. These inspections should include assessments of public health impacts of drinking-water systems and associated devices. Public health agencies should also be consulted as early as possible during design and construction to assess the suitability of water systems, including the selection, installation and monitoring of control measures. Where possible, public health agencies should assess and approve WSPs developed for new buildings and new or renovated water systems, particularly in buildings where potential health risks can be high (e.g. health facilities).

Independent technical inspections of existing buildings can be undertaken by auditors or specialists with expertise in areas such as WSPs, plumbing, water treatment, operation of water devices (e.g. water-cooled air-conditioning, swimming pools, hot tubs), water microbiology, infection control, and occupational health and safety. Technical inspections can be commissioned by building managers to provide assurance that systems are being operated so that they protect public health and are consistent with regulatory requirements. Remedial action or improvements identified by such independent inspections should be documented and implemented. In some circumstances, independent inspections may be included as part of accreditation activities. For example, accreditation of facilities such as hospitals or hotels can include independent inspection of drinking-water systems and WSPs. Independent inspections can also be a regulatory requirement. Outcomes of these inspections should be documented within WSPs.

5.1.2 Surveillance

Surveillance is one of the five key components of the *Framework for safe drinking-water* (WHO, 2008) and is necessary to verify that WSPs are well designed and correctly implemented. Surveillance is a specific and ongoing activity that should be undertaken by public health agencies to assess and review the safety of drinking-water systems. As well as being a measure of compliance with regulatory requirements, surveillance helps to protect public health by promoting ongoing improvement, and by contributing to the early detection of water quality risk factors and the subsequent selection of appropriate

remedial actions. Ensuring timely implementation of corrective action and targeted improvement can prevent waterborne disease.

Surveillance of drinking-water systems in buildings can involve audits, direct assessment or, ideally, a combination of these two approaches. Audits will generally include reviewing and approving new WSPs, as well as routine auditing of implementation of individual WSPs. Direct assessment involves testing of water quality. The advantage of audits is that they assess the capability to consistently produce safe drinking-water, while direct assessment assesses whether safe drinking-water was produced at the time of testing. Direct audits are more useful when they are included as part of broad surveys.

Both approaches require the surveillance agency to understand drinking-water systems and the way in which WSPs are applied, as well as the capability to undertake audits and respond to significant water incidents. In addition, direct assessments require the surveillance agency to have expertise in identifying appropriate monitoring locations and parameters, and collecting samples. They must also have access to testing facilities, be able to interpret results, and provide reports to building managers.

There are large numbers of buildings in urban centres, and routine surveillance of all building water systems will generally be impossible. Effective planning and development of surveillance programmes should identify priorities based on levels of risk. This requires an analysis of the types of buildings to be included in surveillance programmes, together with information on building characteristics and risk factors associated with building occupiers and users. Characteristics to be considered include:

- building types (hotels, apartments, hospitals, aged-care facilities, hospices, clinics, schools, child care, recreation centres, etc.);
- size and location of buildings and numbers of people potentially exposed;
- vulnerability of occupiers or users of buildings (residents, workers, patients, elderly or very young people, etc.);
- type and size of water systems (drinking-water supplies, hot-water systems, water-cooled air-conditioning systems, swimming pools, hot tubs, etc.);
- expertise of building operators and employees;
- availability of specialist service providers;
- geographical and climatic conditions (e.g. temperature, humidity, climate variability).

In many cases, surveillance may be based on occasional surveys. However, buildings such as hospitals and aged-care facilities should be audited at least once per year. Specific surveillance may be conducted for buildings that are closed for extended periods and reopened (e.g. schools and seasonal hotels). Targeted surveillance may be performed for specific devices and equipment, such as cooling towers, evaporative condensers, swimming pools and hot tubs. In some countries, this type of targeted surveillance may be required by specific legislation.

Surveillance can be undertaken or coordinated by central public health authorities in conjunction with regional and local offices, or with environmental health departments within local government. Programmes should be based on practical considerations, taking into account the capability of surveillance agencies. Greater attention should be focused on buildings that have potentially higher risks.

When designing surveillance programmes, consideration should be given to whether surveillance will be the responsibility of public health agencies or third parties (e.g. specialist auditors), certified or approved by these agencies, or a combination of both. Where third parties are used, the public health agency needs to retain responsibility for implementing the surveillance programmes. The public health agency should also provide directions on the frequency of inspections and audits, as well as the procedures to be applied. Public health agencies should receive and assess third-party reports and communicate assessments with building owners and managers.

Audits

Audits are on-site assessments, from intake to tap, of the whole water system—including sources, transmission infrastructure, treatment processes, storage, distribution systems, maintenance and monitoring programmes, and water uses within the building. Audits should embrace all water systems existing within the building, such as cold-, hot- and warm-water treatment and distribution systems; water-cooled air-conditioning systems; swimming pools; hydrotherapy pools; and hot-tub pools. The objective is to evaluate the ability of building management to produce and deliver safe drinking-water, as well as water of quality suitable for other specific uses within a building (e.g. in clinics, dental surgeries).

Audit-based approaches rely on data and information being provided by building owners and managers. This will include descriptions of water systems and end uses, results of operational monitoring to check that control measures are working effectively, results of monitoring at point of delivery to assess compliance with water-quality requirements, and evaluation of consumer satisfaction and complaints. Information should also be provided on independent inspections, internal audits, previous surveillance audits, and implementation of remedial action and improvement programmes.

Audits will normally focus on the design and implementation of WSPs. This could include:

- reviewing the building's water systems to examine whether all systems and uses are included and described accurately in WSPs;
- ensuring that WSPs consider all appropriate regulations, codes, guidelines and accreditation requirements;
- examining records to ensure that the system is being managed according to the WSP;
- assessing whether operational monitoring parameters have been kept within operational limits, that compliance was maintained, and that appropriate action was taken to respond to non-compliance, where necessary;
- ensuring that verification programmes are in place, that results demonstrate effectiveness of WSPs, and that appropriate action was taken to respond to non-compliance;
- examining maintenance records;
- assessing whether systems have been operated by appropriate personnel or appropriate service providers;
- ensuring that regulatory requirements have been met;

- examining reports of independent inspections and internal audits;
- ensuring that all actions and results have been documented and reported according to the WSP;
- assessing incident plans, contingency measures, and communication and reporting protocols;
- assessing supporting programmes and strategies for improving and updating the WSP.

Audits may involve interviewing building managers, operators and technical staff involved in water-system management. A final report should be completed at the end of the audit to formally notify the building owner or manager of the findings. The report may be used for future compliance actions and inspections and should summarize the findings of the survey, remedial action and recommended improvements, together with timelines for implementing actions and improvements.

Targeted audits should be conducted after substantial changes to the source, distribution system or treatment process, and in response to significant incidents.

Audits conducted in response to significant incidents detected by building operators should focus on verifying that:

- the incident was investigated promptly and appropriately
- the incident was reported to appropriate authorities in a timely fashion
- the cause was determined and corrected
- the incident and corrective actions were documented
- the WSP was reassessed and amended, where necessary, to avoid a similar situation.

Direct assessment

Direct assessment involves the collection and analysis of water quality by the surveillance agency. It does not replace requirements for audits, and should not be used to reduce the frequency of audits. Results should always be reported to building managers and should complement verification testing.

5.1.3 Incidents, emergencies and outbreaks

Additional inspections will be required in the event of incidents, emergencies (including natural disasters) and waterborne outbreaks. This will involve inspection of WSPs and of associated water systems. Investigations will normally require immediate collection of water samples. Wherever possible, samples should be collected before remedial actions are taken—as long as this does not cause unnecessary delays. This is important in trying to establish the cause of outbreaks.

The types of systems inspected will depend on the nature of the incident or outbreak. For example, investigations of waterborne gastroenteritis will be different from investigations of waterborne legionellosis. The former will focus on systems delivering water for ingestion, either directly or through food production; the latter will focus on systems containing water between 20 °C and 50 °C, and producing aerosols.

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Following an outbreak, a further inspection will be required to ensure that any required remedial action has been taken, and that WSPs have been amended to minimize the likelihood of recurrence. The effectiveness of remedial action and amended WSPs should be verified by water-quality testing.

5.1.4 Supporting programmes

Surveillance should incorporate complementary health promotion and educational components. It should be seen as an activity to maintain or improve public health standards in a collaborative approach. Regulations should allow for penalties and sanctions, but these should only be imposed as a last resort.

Building owners and managers should be aware of the standards required by surveillance agencies, the purpose of audits and inspections, how audits will be performed, what features will be examined, and what information is required from building managers during an audit.

5.1.5 Reporting and communication

Reporting and feedback are essential elements of a successful surveillance programme and should support the development of effective remedial strategies. Outcomes of surveillance should always be reported to building managers. Annual reports should be prepared by coordinating authorities and distributed to all agencies involved in surveillance activities (e.g. national, regional and local agencies).

Agencies responsible for surveillance should also develop strategies for disseminating and explaining outcomes of surveillance to building occupiers and users.

5.1.6 Use of information

Information gained from surveillance programmes should be collated and assessed. This information is an invaluable source of data on effective management of water systems, and can help to identify recurrent causes of problems. Analysing collated data may identify common factors associated with potential water contamination, such as inadequate or ineffective treatment processes, structural conditions (e.g. impacts of water-main breaks, faulty valves or hydrants), hydraulic capacity (e.g. low-pressure complaints, rusty or coloured water occurrence), leakage (e.g. pro capita water demand), or water quality deficiencies due to cross-contaminations or to unintended uses.

Collated information can also be used to review relative health risks presented by different types of buildings and circumstances; it can also be used to refine surveillance programmes.

5.2 Disease surveillance and detection of outbreaks

5.2.1 Purpose of disease surveillance programmes

Establishing and verifying effective disease-control programmes, including WSPs, requires effective surveillance programmes. These surveillance programmes should provide:

- accurate and timely information on disease occurrence
- early detection and notification of outbreaks
- assessment of responses to outbreaks
- efficient monitoring of intervention programmes.

The World Health Organization (WHO) *Guidelines for drinking-water quality* (WHO, 2008) define the reduction of disease and outbreaks as health outcome targets. Reducing disease provides the most direct evidence of the success of WSPs, while continued disease provides evidence that WSPs are inadequate and require modification. While the immediate response to detection of disease is necessarily reactive, the subsequent responses can be proactive in identifying and eliminating building-specific and systemic risks.

Many countries have mechanisms for surveillance and reporting of communicable diseases. The importance of these mechanisms is reinforced by the International Health Regulations (IHR) (WHO, 2005), which call for Member States to apply and—where necessary—strengthen capabilities for surveillance, reporting, notification and communication of infectious disease. While surveillance programmes often include waterborne organisms, specific surveillance of water as a source of disease is generally not well developed or coordinated. This includes waterborne disease associated with buildings.

5.2.2 Structure of disease-surveillance systems

The structure of disease-surveillance systems is governed by a number of factors, including legislation, the strategy for implementing surveillance, responsible agencies, and stakeholders and communication (WHO, 2006c).

Legislation

Public health legislation, including the IHR, provides the regulatory framework governing the identification, reporting and communication of notifiable diseases.

Public health legislation can also include requirements for health-care facilities to implement infection-control capabilities, while legislation dealing with occupational health and safety can include requirements relating to control of specific diseases, such as legionellosis.

Strategy

Disease-surveillance strategies depend on the nature of the diseases under investigation, the objectives of surveillance, the methods for conducting surveillance, and the application of data in informing public health practice. Countries may have multiple

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disease-surveillance systems operating simultaneously. Some will be aimed at early detection and response to outbreaks; others will focus on monitoring longer term disease trends, or the impact of interventions and control programmes. Each type of surveillance has specific characteristics. Disease surveillance used in health-care facilities is typically more active and immediate than surveillance of the outcomes of interventions, such as disease-control regulations or longer term public health programmes.

Disease-surveillance strategies can include:

- ongoing monitoring of reporting of communicable diseases by medical practitioners and laboratories;
- short-term and long-term analysis of results;
- investigation of clusters of illness or increased incidence of disease.

Monitoring of waterborne disease generally lags behind general disease surveillance (Bartram et al., 2002; Hunter et al., 2003). One of the principal factors is that most of the diseases transmitted by ingestion of contaminated water are transmitted in higher frequencies from other sources, such as food and person-to-person contact. This makes assessing the contribution of water difficult. In Europe, only 2% of gastrointestinal disease between 1986 and 1996 was linked to water (Bartram et al., 2002). Based on epidemiological investigations and intervention studies, estimates for the United States of America have placed the contribution at 8–12% (Colford et al., 2006; Messner et al., 2006).

Hence, while national and regional surveillance systems typically incorporate enteric organisms that can be waterborne, confirming association with water supplies is generally limited to outbreaks.

Some countries have established systems for detecting and reporting waterborne outbreaks. These data indicate that waterborne disease outbreaks associated with large water supplies have been substantially reduced, and that the proportion of outbreaks associated with buildings has increased (Blackburn et al., 2004; Yoder et al., 2004, 2008ab; Djiuban et al., 2006; Liang et al., 2006). In 2003–2004, the classification of waterborne disease by the United States Centres for Disease Control and Prevention was modified to include specific categories dealing with plumbing deficiencies (Liang et al., 2006).

Some diseases are exclusively waterborne; for example, legionellosis (caused primarily by *Legionella pneumophila*) and dracunculiasis (caused by *Dracunculus medinensis*). For these organisms, disease surveillance has been an important tool in supporting implementation of control measures. Waterborne legionellosis is strongly associated with building water supplies.

Initially, improved surveillance can detect an increased prevalence of disease. This has been reported for legionellosis in Europe (Bartram et al., 2007). Furthermore, improved surveillance provides a more accurate basis for establishing the need for, effect of and benefit of interventions. For example, in Australia, disease surveillance has demonstrated the effectiveness of *Legionella* regulations in reducing both the occurrence of the organism in cooling towers and the frequency of disease (Vic DHS, 2007).

Disease surveillance strategies can be tailored to deal with specific issues. For example, surveillance in health-care facilities is likely to involve a different spectrum of diseases

from those included in general surveillance schemes, due to the increased and varied vulnerabilities of patients and residents. As described in section 2, organisms such as *Acinetobacter*, *Aspergillus*, *Burkholderia*, *Klebsiella* and *Pseudomonas* have been associated with disease in health-care facilities.

Priority diseases and case definitions

It is not economically possible or practical to monitor all diseases. General surveillance systems should include diseases of national public health importance. WHO has produced guidance for selection of priority diseases, including waterborne diseases (WHO, 2006d, 2006e).

Specific disease-surveillance systems, such as those in health-care facilities, should target diseases of public health concern within the setting in question. The range of agents can vary within buildings; for example, within health-care facilities, renal dialysis patients are more susceptible than other patients to endotoxins, toxins and chemical contaminants in water used for dialysis.

Disease surveillance of water supplies in buildings will generally involve microbial pathogens, but should also consider chemical agents such as corrosion products (e.g. copper, lead, nickel and cadmium). Surveillance for chemicals is uncommon; prevention is by far the preferable approach. However, surveillance has been performed for lead (in blood) in certain circumstances (CDC, 2010).

Case definitions should be identified and documented for all priority diseases. A national register of case definitions should be developed and applied in all disease-surveillance schemes.

Responsible agencies and stakeholders

Public health surveillance is typically coordinated at a national level by ministries of health, and operates at national, regional and local levels. Coordination and oversight of operations by a central agency is essential.

Infection-control teams in health-care facilities play a key role in public health surveillance. Similarly, in commercial and industrial buildings, occupational health services play a role in disease surveillance. In some countries, control of legionellosis is regulated at least in part by occupational health legislation (Bartram et al., 2007).

Coordination of all disease surveillance activities is important to support efficiency and to avoid duplication.

Reporting and communication

Reporting and communication support the collection of disease information, dissemination of outcomes, implementation of immediate responses, and longer term interventions.

Reporting systems should be established to ensure that information moves from the point of generation (i.e. disease detection) to collection and coordination agencies. Standard operating procedures should be established for reporting. The procedures should deal with transmission of routine data, as well as data on suspected and confirmed outbreaks. Procedures should be communicated to everyone involved in disease surveillance.

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Communication between all stakeholders involved in disease surveillance is essential. Coordination of all disease-surveillance activities undertaken by national, regional and local authorities, infection-control teams and occupational health services is required to ensure effective reporting of disease, timely detection of outbreaks, implementation of responses and longer term control measures.

Disease-surveillance strategies typically involve reporting by medical practitioners and laboratories. Timeliness and accuracy of reporting are crucial. In addition, systems should be established to ensure that results of disease surveillance undertaken by infection-control teams are routinely reported to coordinating agencies. Outbreaks detected in health-care facilities should be reported immediately.

Communication of outcomes is required. This can include routine reports, as well as issuing of warnings and advice to health practitioners, the public and managers of buildings. It is important to have communication procedures in place to deal with suspected or confirmed outbreaks of potentially waterborne disease. For example:

- the detection of outbreaks of legionellosis could result in communication with building owners during the outbreak about immediate action (e.g. precautionary decontamination of cooling towers);
- outbreaks of waterborne cryptosporidiosis could lead to issuing of advice to operators of leisure centres and swimming pools regarding practices to avoid primary and secondary transmission;
- increased incidence of nosocomial disease will require communication with staff and managers of health-care facilities.

Mechanisms should be established to facilitate this communication before outbreaks occur.

After a disease outbreak, communication should be widened to include information on the lessons learnt, and how practices will be used or applied to minimize the likelihood of recurrence.

Communication should also include sharing of information between agencies and stakeholders. For example, this should include establishing communication networks for infection-control teams, to help identify common problems, causes and interventions. Disease surveillance at a regional level should be supported by a national communication system. Higher levels of travel have increased the spread of diseases across boundaries; therefore, communication should be extended across borders to meet obligations of the IHR (2005) and also to share experiences and lessons learnt.

Disease-surveillance guidelines and standards

Effective disease-surveillance systems are underpinned by comprehensive standards and guidelines. These standards and guidelines should define priority diseases, and include case definitions, notification and reporting requirements, responsibilities, data management, evaluation, immediate and long-term responses, outbreak preparedness and training.

Guidelines should deal with related aspects, such as infection control in health-care facilities (WHO, 2002; Sehulster et al., 2004) and laboratory procedures such as standard methods and quality control.

5.2.3 Disease surveillance for water supplies in buildings

Disease surveillance for disease associated with buildings is a subset of general surveillance. However, building water supplies have some specific characteristics:

- The water systems and hence the sources of disease are typically discrete and defined.
- Buildings such as hospitals, medical clinics, aged-care facilities and child-care centres can cater for subgroups with increased vulnerabilities.
- In health and aged-care facilities, infection-control teams play a central role in surveillance.

Microbial pathogens represent the greatest risk associated with building water supplies, but toxic chemicals such as heavy metals, industrial compounds, coolants and boiler fluids can also cause illness.

Microbial disease and outbreaks associated with buildings can be detected by active surveillance by national or regional agencies and infection-control teams, by passive processes such as reporting by medical practitioners and other health-care professionals, or through anecdotal reporting by building users.

Acute disease caused by building-specific chemicals (e.g. boiler fluid) is generally detected by passive processes, while chronic and acute disease caused by heavy metals (e.g. copper and lead) can be detected by either passive processes or broader investigations. The latter could be implemented where there is evidence of systematic issues such as corrosion of plumbing systems caused by public water supplies.

5.2.4 Disease-surveillance strategies for waterborne disease

Surveillance of waterborne disease can be included in a range of programmes with different functions and characteristics. These can include surveillance of:

- national and regional incidence of infectious disease
- waterborne disease outbreaks
- specific diseases, to measure incidence and the need for intervention
- disease in specific settings, such as health-care facilities.

National and regional incidence of infectious disease

National and regional surveillance programmes can include specific waterborne diseases such as cholera, legionellosis and dracunculiasis. For these diseases, the outcomes of disease surveillance can be used to assess longer term trends as well as the outcome of intervention programmes.

National and regional programmes typically include diseases that may be waterborne. General surveillance does not identify endemic waterborne disease without the addition of ancillary epidemiological studies (Calderon & Craun, 2006), but can detect waterborne outbreaks—although the sensitivity is poor (Padiglione & Fairley, 1998; Craun et al., 2004).

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Waterborne disease outbreaks

The likelihood of detection of waterborne disease outbreaks can be increased by augmenting infectious-disease programmes with specific mechanisms to promote reporting of such outbreaks. The data from outbreaks can be used to identify important pathogens, water-system deficiencies and interventions to reduce waterborne disease (Craun et al., 2006). The best example of outbreak detection is in the United States of America, where statistical data on waterborne disease outbreaks have been collected and reported since the 1920s (Djiuban et al., 2006; Yoder et al., 2008ab). Recent surveillance data indicate that a substantial proportion of outbreaks in recreational water and drinking-water was associated with buildings such as sports centres, hotels, schools, child-care centres, nursing homes, hospitals and restaurants. Diseases were caused by a range of agents, including *Cryptosporidium*, *Giardia*, *Shigella*, *Legionella*, *Pseudomonas*, *Norovirus*, copper and ethylene glycol (Blackburn et al., 2004; Yoder et al., 2004, 2008ab; Djiuban et al., 2006; Liang et al., 2006).

The reports have highlighted water-system deficiencies, such as cross-connections in buildings and the need for improved control of opportunistic pathogens such as *Legionella* and *Pseudomonas*.

Specific diseases

Surveillance for legionellosis is a good example of a targeted monitoring programme and has been well documented elsewhere (Bartram et al., 2007). Surveillance has been used to identify the prevalence of disease, the need for improved control, and the success of intervention programmes (WHO, 2006c; Vic DHS, 2007).

Infection control

Infection rates in health-care facilities are an indicator of the quality of care, including the safety of the environment. Surveillance is used to monitor incidence of disease, identify risk factors and evaluate the impact of interventions. Waterborne disease involving organisms such as *Acinetobacter*, *Aspergillus*, *Burkholderia*, *Klebsiella*, *Legionella*, mycobacteria, *Pseudomonas* and *Stenotrophomonas* has been identified as cause for increased concern in health-care facilities (Annaisie et al., 2002; Sehulster et al., 2004).

Results of disease-surveillance programmes have been used to identify control measures to minimize the risk of infection associated with building water supplies (Sehulster et al., 2004; Bartram et al., 2007).

Review

The results of disease-surveillance programmes should be subject to regular review to identify trends, including increases and decreases in disease rates, changes in patterns of disease, the occurrence of emerging disease and the impacts of control measures. Outcomes and any recommendations arising from reviews should be reported.

5.2.5 Detection of outbreaks

Outbreaks are generally defined as two or more cases linked in location and time. Waterborne outbreaks associated with water supplies in buildings represent preventable failures in WSPs. All outbreaks should be investigated to confirm occurrence, identify the source, implement immediate control measures, and identify the need for longer term and general changes in management programmes.

Agencies and teams involved in disease surveillance should establish investigation protocols to respond to outbreaks. Early detection of outbreaks and appropriate, timely responses will reduce the size and impact of outbreaks. Pre-planning promotes rapid responses and avoids planning on the run, which is very likely to lead to poor coordination, mistakes and delays.

Outbreak investigations follow a sequence of activities that includes:

- pre-planning
- outbreak confirmation
- case definition
- outbreak description
- hypothesis generation and confirmation
- control and prevention
- communication.

Pre-planning

Pre-planning should identify who should be involved in the investigation of outbreaks. This should include responsibilities, leadership and coordination. Methods for investigating outbreaks and basic requirements (e.g. case definitions, data transfer and communication procedures) should be identified.

Outbreak confirmation

An increase in reported cases or detection of specific pathogens in clinical samples is generally the first sign of an outbreak. However, it is important to confirm that the apparent outbreak is real. Factors that have been shown to contribute to "pseudo-outbreaks" have included increased detection due to increased testing, contamination of clinical samples, false positive tests and coincidence of unrelated cases (CDC, 1995, 1997b, 2009; Regan et al., 2000; Kressel & Kidd 2001; Blossom et al., 2008).

Case definition

Once an outbreak is confirmed, a case definition should be developed to establish criteria for inclusion. The definition should include descriptions of place and time of onset, and specific biological and clinical criteria (symptoms and test results). Cases could be categorized as definite, probable or possible, based on the level of data available. Case definitions may also change during investigations as new information becomes available.

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Outbreak description

A detailed description of the outbreak should be generated as investigations progress. The description could include information on numbers of cases, place, time, sex, age and movement. Epidemic curves and mapping of geographical distribution can provide evidence of sources of contamination and whether they are from single, intermittent or ongoing events (WHO, 2002; Hunter et al., 2003).

Hypothesis generation and confirmation

As the outbreak description develops, it should be possible to formulate hypotheses on sources of infection and routes of transmission, and identify possible control measures. Confirmation is necessary, even in cases that appear to have an obvious source. Hypotheses will be strengthened, refined, modified or discarded as the investigation continues. For waterborne outbreaks, confirmation will generally involve collecting and analysing water samples, and assessing the design and implementation of WSPs for failures. Genetic typing of isolates is an important tool for identifying sources of cases, and can support or reject hypotheses (Heath et al., 1998; Hunter et al., 2003; Gilmour et al., 2007). Epidemiological methods such as case–control studies are also used to test hypotheses by comparing risk factors between groups of cases and controls without disease (WHO, 2002).

It is important to identify the correct source of disease and to avoid going public with unconfirmed hypotheses. Pressure to identify sources quickly should not be allowed to compromise accuracy. Failure to identify the correct source can lead to expensive and ineffective interventions.

Control and prevention

A priority in all investigations is to identify and implement effective control measures. The aims are to:

- interrupt the chain of transmission and minimize the magnitude of the outbreak
- prevent future outbreaks.

The selection of control measures will require consultation with appropriate experts such as environmental microbiologists and water-treatment specialists. Outbreak investigations should assess the success of control measures, while ongoing disease surveillance should be implemented to monitor continued effectiveness. This type of surveillance will include monitoring of disease and the efficacy of the control measure. In the long term, monitoring of preventive control measures will take precedence.

Communication

During investigations, timely and accurate information should be provided to public health authorities (if not leading the investigation), building owners and managers, patients and, where appropriate, the public. Where there is uncertainty—for example, in the identification of sources—this should be communicated.

Full reports should be prepared at the end of outbreaks, describing events, interventions, lessons learnt and recommendations to prevent further occurrence. These reports should be made available to appropriate agencies, authorities, and building owners and managers involved in operation of water supplies.

5.2.6 Lessons learnt from disease surveillance and investigations

Results of disease-surveillance activities and outbreak investigations must be used to inform practices, and measures applied to reduce waterborne disease. The decrease in drinking-water waterborne outbreaks in the United States of America since the 1980s has been attributed to more stringent regulation (NRC, 2006). Events such as the Milwaukee outbreak of cryptosporidiosis in 1993 (MacKenzie et al., 1994) contributed to the development of regulations. At the same time, the proportion of outbreaks and illness associated with buildings has increased (Blackburn et al., 2004; Yoder et al., 2004, 2008ab; Djiuban et al., 2006; Liang et al., 2006). Water supplies in buildings are typically not included within the scope of national drinking-water regulations.

However, lessons learnt from disease surveillance and outbreak investigations have been used to reduce risks associated with building water supplies. The clearest example of this is the development of guidelines and regulations for controlling waterborne legionellosis (see *Legionella and the prevention of legionellosis*; WHO, 2007). Other examples include increased attention on cross-connection control and backflow prevention (USEPA, 2002; NRC, 2004) and the development of guidelines for preventing waterborne disease in health-care facilities (WHO, 2002; Sehulster et al., 2004).

On a national, regional and local level, it is important to learn from the application of control measures to deal with waterborne disease. Documentation, reporting and communication networks should support cataloguing of incidents and the sharing of experience in detecting deficiencies and implementing responses. Where appropriate, these can be translated into guidance and regulation to minimize risks of disease.

5.3 Regulatory and policy frameworks

National governments, together with regional and local authorities, are generally deemed to be responsible for ensuring that consumers are provided with safe and wholesome water in sufficient quantity. Typically, this responsibility will lie within the ministry of health, although sometimes other agencies, such as those responsible for environmental protection, may play a role. The actions and responsibilities of these authorities and agencies need to be supported by legislative and regulatory tools. However, the diversity of constitutional and legal systems makes it impossible to define a single accepted way for developing and implementing legislation. Nevertheless, there are a number of common principles that should be applied.

5.3.1 Purpose of legislation

Legislation should define responsibilities, functions and obligations of agencies charged with ensuring compliance with drinking-water quality requirements. Legislation should also provide these agencies with necessary powers to administer laws and regulations. For instance, the requirements of surveillance within buildings can be hindered by difficulties for national, regional or local authorities in gaining access to undertake inspections and audits. This needs to be considered in regulatory frameworks. Responsibilities for water quality also need to be identified. This should include responsibilities of drinking-water suppliers and the managers, operators or owners of water systems in buildings.

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As discussed throughout this document, the most effective way of assuring drinking-water safety in buildings is the application of WSPs that cover all issues, from planning and construction to surveillance of tapwater quality. The central role of WSPs should be reinforced and supported by regulatory and policy frameworks.

In addition to drinking-water legislation, many countries have established standard-setting bodies and certification systems. Standards and codes of practice can apply to a broad range of activities that can influence construction and management of drinking-water systems in buildings. These can include standards relating to construction of buildings, installation of plumbing, water systems and sewage systems, as well as the design, installation, maintenance and operation of devices such as cooling towers and evaporative condensers, swimming pools, hot-tub pools, hot-water systems and plumbing devices. Standards could also apply to sampling, testing and accreditation of technical experts (e.g. plumbers) and auditors.

Tables 5.1–5.3 summarize the tools needed by legislators for addressing WSP implementation in accordance with national legislation, technical regulations, standards and codes of practice.

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Table 5.1 Management legislation

Area of management legislation	Issues for legislator or regulator	Issues for standard-setting and certification agencies
Building construction and commissioning (as far as the water distribution system is concerned)	• Award the right of inspection entry, at building stages, to those responsible for regulating and certifying water systems • Enforce the WSP-in-building approach • Enforce by law the certification scheme for everyone involved, and their role	• Provide construction and plumbing standards • Provide codes of good practice for each category of work • Provide commissioning procedures and testing methods for water distribution systems and individual components, as required • Establish training and certification programmes for everyone involved
Maintaining required water quality	• Enforce mandatory WSPs for buildings of specified characteristics (size; kind of occupancy; public or open to public, etc.) • Identify responsibilities for at least the following: – owners – building managers – WSP managers • Identify independent regulatory agencies for performing technical inspection • Establish procedures for monitoring and reporting for health protection (implemented by the building manager and an independent health authority; for health-care premises, this is implemented by infection-control teams)	• Prepare general and specific WSPs according to the characteristics of the building (size; type); these should include definitions of major risks (microbiological, chemical, hydraulic) and responses to major events (natural catastrophes) • Provide a training and certification programme for those involved (identified in legislation) • Develop standards, guidance and a code of good practice for the operation and maintenance of water distribution systems in general, and for individual components and devices, as required
Surveillance	• Set the minimum surveillance requirements for WSPs • Identify independent entities for implementing the surveillance programme (public and/or third party) and specify their scope and given authority • Ensure independent entity has right of access and inspection of WSPs • Ensure the independent entity has the authority to order actions deemed necessary for protecting consumer health and safety	• Define WSP surveillance programmes (frequency, required analyses, etc.) • Establish accreditation scheme for independent entities performing surveillance of WSPs • Establish accreditation schemes for laboratories

WSP, water safety plan.

Table 5.2 Technical regulations

Area of technical regulation	Issues for legislator or regulator	Issues for standard-setting and certification agencies
Building permission	• Set minimum requirements for water supplies and specifications in buildings (e.g. pressure, flow rate) • Set minimum requirements for the sewage system connection • Set requirements for alternative water sources (private wells, etc.)	• Set standards for water supplies • Set standards for sewage systems
Materials and products intended for contact with drinking-water	• Define criteria based on: – mechanical characteristics related to safety and performance (durability, energy consumption, noise) – fitness for contact with drinking-water	• Set standards for testing: – mechanical characteristics – fitness for contact with drinking-water (migration or release of hazardous chemicals, support of microbial growth, etc.)
Surveillance of water quality at the consumer tap	• Define water-quality standards, and keep them up to date • Define criteria for collecting representative water samples • Define appropriate analytical methods	• Identify methods for taking water samples for chemical, physical and microbial analyses
Installation of water systems inside buildings	• Define requirements per product standards, including, if available, those related to safety, hygiene, energy savings • Define requirements for preventing unintended cross-connection and installation of backflow prevention, where required	• Set standards for internal installations, including: – general requirements – design principles – piping system design – installation – operation and maintenance • Set standards for connecting appliances and equipment to water distribution systems (washing and dishwashing machines, humidifiers, etc.) • Set standards for PoE and PoU devices, including operation and maintenance instructions
Installation of swimming pools, hot tubs, and other recreational water devices	• Define and update the water-quality standards • Define safety rules • Identify roles and responsibilities • Define “public” and “private” swimming pools • Ensure rights of inspection to regulatory entities for public pools	• Set standards for designing, operating and maintaining pools and accessories • Set standards for water treatment (filters, disinfection, etc.)

Table 5.2 Technical regulations *continued*

Area of technical regulation	Issues for legislator or regulator	Issues for standard-setting and certification agencies
Installation of systems conveying water for special purposes (e.g. in health-care facilities, child care)	• Define criteria for assessing the compatibility of activities within buildings with occupancy • Set general requirements for water systems intended for special purposes (e.g. increased safety levels and protection) • Set specific requirements, as needed or advisable	• Develop quality standards for each type of special water • Set standards for water-treatment devices
Hot-water and cold-water storage within dwellings	• Define requirements for independent technical inspection	• Set standards for storage tanks and associated equipment, including design, operation and maintenance
Hot-water systems	• Define requirements for preventing health risks (e.g. from *Legionella*) and suitable water specifications (e.g. temperature) • Define requirements for independent technical inspection	• Set standards for designing, operating and maintaining heating, storage and delivery, including temperature control
Water-using cooling devices (cooling towers, evaporative condensers)	• Define requirements for preventing health risks (e.g. from *Legionella*) • Define requirements for independent technical inspection	• Set standards for designing, operating and maintaining cooling systems

PoE, point of entry; PoU, point of use.

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Table 5.3 Links between legislation, regulations and standards

Area of regulation	Major issues for legislators	Major issues for standard-setting and certification agencies
Suitability of equipment for purpose	• Define requirements for establishing and operating certification schemes	• Define and manage certification scheme
Materials and products intended for the contact with drinking-water	• Establish a certification scheme	• Test schemes
Management of building system for safety, including maintenance and servicing	• Assign responsibilities of owner and manager	• Provide guidance and codes of good practice on cleaning, disinfection for systems and associated devices (e.g. swimming pools)
Independent oversight of building water safety	• Provide for independent oversight (surveillance) • Define scope of authority of independent agency (different types of building) • Ensure right of access and inspection for independent entity • Require analysis by accredited laboratories • Require that sampling and analyses comply with recognized methods	• Define frequency of inspections or audit • Define criteria for audits • Establish and operate accreditation schemes for inspectors and auditors • Establish and operate accreditation schemes for laboratories • Establish processes for accrediting sampling and analytical methods
System installation and commissioning	• Oversee licensing or industry self-regulation of plumbers	• Set standards and codes of good practice for plumbing • Set accreditation scheme for plumbers
Construction of buildings, including requirements for ensuring water-related environments are safe	• Set requirements for an entity to establish and update construction standards	• Establish a body to provide and maintain standards
Health-care settings	• Identify special provisions in high-risk environments • Identify responsibilities of health service providers	• Establish a body to provide and maintain standards and ongoing guidance on good practice
Drinking-water quality standards	• Assign authority to a suitable body to establish and update standards • Specify consultation requirements • Assign enforcement requirements	• Develop criteria for standard setting • Oversee the consultation process • Process enforcement

5.4 Capacity building and training

A wide range of responsibilities is associated with ensuring safety of water within buildings. The principles, including WSPs, are captured within the *Framework for safe drinking-water*. The risk-management principles described in the framework also apply to other devices, such as water-cooled air-conditioning plants, swimming pools and hot-tub pools (WHO, 2006a; Bartram et al., 2007).

All the stakeholders identified in section 3 need to have the appropriate skills to perform their specific functions related to provision of safe water supplies. This includes building commissioners and designers, building managers, employees, public health agencies, auditors, professional bodies and infection-control practitioners.

It is not practical or realistic to expect that all stakeholders will have the capacity to perform all functions. Training will need to be tailored for each group of stakeholders. Training provided to employees responsible for drinking-water systems will differ from training provided to employees responsible for water-cooled air-conditioning plants, swimming pools or hydrotherapy pools. However, all stakeholders need to have a basic understanding of risk-management principles associated with WSPs, including the identification of hazards, the assessment of risks and management strategies applied to control these risks. Each stakeholder should be aware of how their specific responsibilities fit within and contribute to the design and implementation of WSPs. They also need to be aware of the consequences of failure. Too often, this is not the case (Hrudey & Hrudey, 2005).

Overall, therefore, training programmes must be coordinated to ensure consistency of intent and understanding. In this way, all activities associated with water systems can contribute to a consistently high standard of design, construction, operation, maintenance and management.

General training should be available on:

- risk-management principles;
- development and application of WSPs; this should include training on applying WSPs in specialized settings (e.g. for infection control in medical and dental surgeries and renal dialysis clinics);
- risk assessment;
- control measures, including treatment;
- operational procedures, including monitoring and maintenance;
- emergency actions and responses.

In addition, specialized training may include the following components:

- For professionals involved in designing or modifying buildings and water networks
  - water-quality regulation, standards and guidelines
  - information on the importance of water quality and implications of failure
  - setting water-quality targets (e.g. environmental and building quality labels, certification)

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  - prevention of microbiological and chemical contamination, including major mistakes to be avoided (e.g. poor-quality water resources; accidental or unintended cross-connections; poor design of water distribution networks, waste systems and venting systems; poor design of storage systems)
  - maintenance and sampling requirements.
- For plumbers
  - water-quality regulations, standards and guidelines
  - responsibilities and legal obligations
  - evidence of links between construction practices and water quality at the tap (e.g. impacts of welding practices on resistance to corrosion, use of incompatible materials, inappropriate pipe diameters, accidental or unintended cross-connections)
  - water-system design, construction rules and good practices.
- For auditors
  - detailed knowledge of national and local water standards and guidelines applying to system design and construction
  - detailed knowledge of all aspects of WSPs
  - auditing practices applied to the domain of water quality.
- For regulators
  - understanding determinants of other disciplines that affect WSPs in their domain (e.g. health regulators should have an understanding of the main determinants of building design and construction)
  - building and plumbing regulations, standards and codes of practice.
- For building managers
  - importance of water quality and implications of failure
  - water-quality regulation, standards and guidelines
  - responsibilities and legal obligations
  - water-system design and construction
  - WSPs
  - maintenance and surveillance of water systems
  - supervision of water-system audits and risk assessments
  - event and incident management
  - audits of contractors' qualifications and competence.

- For employees responsible for specific installations (e.g. water-cooled air-conditioning plants, swimming pools, hydrotherapy pools)
  - importance of water quality and implications of failure
  - detailed knowledge of national and local design, construction, auditing and maintenance standards and guidelines for such installations
  - prevention of microbiological and chemical contamination specific to such installations
  - periodic feedback from others' field experience and major mistakes to be avoided (e.g. through specialist workshops, industry associations).

Mechanisms for providing this training and building capacity include formal courses that are accredited by national educational agencies, professional associations, industry-operated training courses, in-house training and mentor programmes, workshops, seminars and conferences. Training could be provided in stand-alone courses or within broader training programmes provided for specialists such as infection-control practitioners or plumbers. Where possible, training should be supported by provision of manuals, fact sheets and guidelines on websites. Contact details for appropriate experts or appropriate agencies should also be provided.

Feedback from field experience should be organized and documented to support training programmes, so that professionals can benefit from others' experience. Training and information sessions based on the presentation of field experience have been found to attract high levels of interest and increase the recognition and appreciation of water-quality issues and shared responsibilities. This type of networking and sharing of experiences can be valuable and effective. It should be encouraged.

Training should be documented, and records of all employees who have participated in training should be maintained. Skills and knowledge need to be maintained through attendance at refresher courses or at workshops and seminars that can reinforce existing qualifications.

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Annex 1 Model water safety plan—daycare facility for children

I Hazard identification, hazard assessment and risk characterization

Position	Potential hazard	Cause	Risk (likelihood and consequences)	Preventive or control measures
1.1	Contamination of the system with chemicals and/or microorganisms	Using cross-connections to other systems	High	• Avoid cross-connections • Design inspection records • Ensure that only appropriately qualified people are permitted to carry out connection work • Ensure that external professionals inspect or maintain the system
1.2		Flooding	Moderate–high	• Install adequate backflow-prevention devices • Establish an emergency plan • Train staff for flooding situation
1.3		Backflow resulting from reduced pipe pressure	Moderate	• Install adequate backflow-prevention devices • Ensure mandatory functionality check of backflow devices
1.4		Corrosion of pipes, valves, etc.	Moderate	• Install fine filter after water meter • Install adequate material, pipe dimension and system design
1.5		Do-it-yourself repairs in the system	Moderate	• Target educational activities to building owners or managers • Ensure that external professionals inspect or maintain the system

I Hazard identification, hazard assessment and risk characterization *continued*

Position	Potential hazard	Cause	Risk (likelihood and consequences)	Preventive or control measures
2.1	Microbial growth (e.g. *Legionella*, *Pseudomonas*) in the system	Stagnation of water in pipes with dead end	High	• Ensure a regular flushing of all pipes • Avoid dead pipes and long pipes • Identify areas at risk of stagnation • Reduce the length of tap pipes to minimize stagnation volume
2.2		Intermittent use (shower, hosepipe, social room, office, vacation)	High	• Ensure regular use of the system • Ensure regular flushing of the system • Construct shut-off valves near main pipes or near frequently used pipes and drainpipes after shut-off • Cut off unused pipes
2.3		Inadequate temperature in the warm-water system (heater temperature too low)	High	• Ensure adequate heater temperature and adequate supply of circulation pump • Construct adequate insulation of pipes and heaters
2.4		Inadequate temperature in cold-water system	High	• Ensure adequate cold-water temperature in the system • Separate cold-water pipes from heater and warm-water pipes • Ensure adequate insulation of pipes
2.5		Inadequate system material used	Moderate	• Use material according to current guidelines and standards
2.6		Warm-water flows are not hydraulically balanced	High	• Ensure adequate pipe dimension • Ensure that adequate flows are maintained through all parts of the distribution system • Replace simple valves with temperature-adjustable valves
2.7		Heater sludge (forces growth of microorganisms)	Moderate	• Inspect, maintain and clean the heater regularly

I Hazard identification, hazard assessment and risk characterization *continued*

Position	Potential hazard	Cause	Risk (likelihood and consequences)	Preventive or control measures
2.8	Local microbial contamination of the system	Inadequate tap hygiene (e.g. contaminated showerhead, aerator)	High	• Inspect and maintain tap hygiene • Ensure that work practices for maintenance comply with standard procedures
3.1	Leach-out of organic compounds into drinking-water	Inappropriate materials used, or stagnation	Moderate	• Use certified materials • Record material requirements
4.1	Biofilm growth	Water flow is too low, resulting in colonization of surfaces	Moderate	• Inspect the zones of concern, and put in place a plan to increase flows in these areas • Flush pipework
4.2		Poor chemical water quality leaving the treatment plant (e.g. post-treatment precipitation of floc, iron/manganese precipitation)	Moderate	• Ensure a regular cleaning and flushing programme is in place, especially through low-flow and dead-end areas
4.3		Poor microbial water quality leaving the treatment plant and introduced in the distribution system	Moderate	• Install filter to reduce some pathogens (e.g. protozoa) • Ensure a regular cleaning and flushing programme is in place, with additional chlorination especially through low-flow and dead-end areas
4.4		Inadequate material used	Moderate	• Use certified materials • Use materials according to current guidelines and standards
5.1	Sediment deposits	Inadequate cleaning programme	Moderate	• Install sediment filters to reduce sediments • Ensure an adequate cleaning programme is in place (particularly for fine filters, etc.)
5.2		Water velocity is too high	Moderate	• Ensure that pipes are of adequate dimension • Control the opening and closing valves, and starting pumps
6.1	Damage of the supply system	Natural disaster	Moderate	• Establish an emergency plan • Create an emergency communication schedule • Train staff for this situation

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II Operational monitoring and management

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
1.1	Contamination of the system with chemicals or microorganisms	Cross-connections to other systems	• Provide job sheets and procedures to staff • Check security devices (safety valves like backflow prevention devices, etc.) at cross-connections	• Sufficient quality of job sheets • Security devices installed adequately	• Installation of cross-connections complies with guidelines, codes of practice and accepted standards • Backflow-prevention devices installed according to guidelines, codes of practice and accepted standards • Tapwater quality conforms with national drinking-water guideline values after cross-connection	• Maintenance procedures for backflow-prevention devices • Avoidance of cross-connections and removal of inadequate installation of cross-connections
1.2		Flooding	• Ensure that emergency plan is up to date and that responsible staff have been instructed on its use	• Update intervals of emergency plan (e.g. annual updating) are kept and responsibilities are checked	• Emergency plan complies with guidelines, accepted standards and references	• Emergency plan providing essential information for flooding situation (e.g. pipe materials, security devices, responsibilities, emergency numbers) • Review and update of emergency plan and assignment of responsibilities following incidents

II Operational monitoring and management *continued*

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
1.3	Contamination of the system with chemicals or microorganisms (continued)	Backflow resulting from reduced pipe pressure	• Inspect and maintain the functionality and security of devices regularly (e.g. backflow-prevention devices) • Monitor pressure and flow in the system	• Inspection every six months; maintenance at least once a year • Backflow-prevention devices leak-proofed, functional • Normal fluctuation of pressure and water flow	• Installation and maintenance of backflow-prevention devices according to guidelines, accepted standards and references	• Maintenance procedures for backflow-prevention devices
1.4		Corrosion of pipes, valves, etc.	• Record pipe material and pipe dimension, date of installation • Inspect pipes for corrosion damage	• Inspection intervals are kept • Corrosion damage is not observable	• Recording and maintenance of pipe material comply with guidelines, accepted standards and references	• Purchasing specifications for pipes and fittings • Immediate inspection of pipes • Replacement of heavily damaged pipes with adequate pipe material
1.5		Do-it-yourself repairs in the system	• Inspect and maintain the system regularly • Provide regular training to building owners and managers	• Inspection or maintenance occurs at least once a year • Do-it-yourself repairs are well conducted • Certification of training	• Plumbers' certification complies with national standards • Installation, construction of pipes, as well as tapwater quality, comply with guidelines, accepted standards and references	• Procedures for inspection, management and training • Employment of only those plumbers with certification • Immediate shut-down of pipes and tap devices followed by reinstallation of pipes

II **Operational monitoring and management *continued***

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
2.1	Microbial growth (e.g. *Legionella, Pseudomonas*) in the system	Stagnation of water in pipes with dead ends	• Record length of dead-end pipes and pipes at risk of stagnation • Monitor regular flushing programme	• The length of water pipes' dead ends are ≤10 times of the pipe diameter or ≤3 litres in volume	• Construction of pipes complies with guidelines, accepted standards and references	• Procedures and programmes for regular flushing • Disconnection of dead ends
2.2		Intermittent use (shower, hosepipe, social room, office, vacation)	• Ensure regular use of tap devices • Inspect and maintain shut-off valves regularly, and check drainage pipes • Monitor a regular flushing programme	• Tap devices are used at least every third day • System is flushed regularly (take pipe volume) if system is out of use for more than four weeks • Shut-off valves are inspected at least every six months, and maintenance occurs at least once per year	• Inspection, maintenance, installation and construction of pipes and tapwater quality comply with guidelines, accepted standards and references	• Inspection, maintenance and flushing programmes and procedures • Totally shut off areas with intermittent use
2.3		Inadequate temperature in warm-water system (e.g. temperature in heater too low)	• Monitor warm-water temperature	• Warm-water temperature in heater at least 60 °C and in the whole system only temporarily below 60 °C • Circulation system not more than 5 °C below heater temperature in backflow of circulation	• Construction of pipes (insulation) and water temperature comply with guidelines, accepted standards • Tapwater quality follows national guideline values for drinking-water quality	• Programme and procedures for temperature monitoring • Pipes, heater and valves are insulated • Increased heater temperature • Adequate circulation

II **Operational monitoring and management *continued***

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
2.4	Microbial growth (e.g. *Legionella, Pseudomonas, Aeromonas*) in the system (continued)	Inadequate temperature in cold-water system	• Monitor cold-water temperature	• Cold-water temperature in the whole system below 20 °C, only temporarily below 25 °C (European standard)	• Construction of pipes (insulation) and water temperature comply with guidelines, accepted standards • Tapwater quality follows national guideline values for drinking-water quality	• Programme and procedures for temperature monitoring • Renew al of pipe insulation, or reinstall or pipes moved in the system
2.5		Inappropriate system material used	• Check and document pipe, valves and additional equipment material regularly, and update knowledge • Check microbial parameters and indicator parameters	• Regular check and documentation of pipe material is carried out	• Pipe material that complies with guidelines, accepted standards is used • Tapwater quality follows national guideline values for drinking-water quality	• Purchasing specifications for system materials • Immediate check and documentation of pipe material • Replacement of critical system components
2.6		Warm-water supply hydraulically unbalanced	• Inspect and maintain temperature of adjustable valves regularly • Monitor temperature in the system	• Inspect valves every six months, and maintain at least once per year • Keep temperature above 58 °C in the warm-water system	• Certification of temperature-adjustable valves • Water quality after valves follows national drinking-water guideline values	• Inspection, maintenance and monitoring programmes and procedures • Replacement of defective, damaged valves

II **Operational monitoring and management *continued***

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
2.7	Microbial growth (e.g. *Legionella, Pseudomonas, Aeromonas*) in the system (continued)	Heater sludge (forces growth of microorganisms)	• Inspect and maintain the heater annually, and monitor the cleaning programme	• Inspect and maintain intervals at least once per year • Ensure that sediment deposit in heater is not observable	• Inspection and maintenance of heater comply with guidelines and accepted standards • Microbiological parameters and indicator parameters follow national guideline values after heater maintenance at heater exit	• Maintenance and cleaning programmes and procedures • Cleaning and removal of sludge • Thermal or chemical disinfection
2.8	Local microbial contamination of the system	Inadequate tap hygiene (e.g. contaminated showerhead, aerator)	• Inspect showerheads, aerators, etc. regularly • Check microbiological parameters and indicator parameters after maintenance of tapwater devices	• Inspection of showerheads, aerators, etc. at least once per year • Turbidity < 1 NTU; *E. coli*, coliforms = 0, normal trend of colony counts after tapwater devices	• Inspection complies with guidelines, accepted standards and references • Tapwater quality follows national guideline values for drinking-water quality	• Inspection, maintenance, cleaning and testing procedures and programmes • Thermal or chemical disinfection • Replacement of tap devices
3.1	Leach-outs of organic compounds from pipe materials into drinking-water	Inappropriate material used or stagnation	• Check material requirements • Authorize only experienced staff (checking job sheets)	• Sufficient knowledge of staff about material used in the system and update of knowledge about system materials	• Use of material complies with guidelines, accepted standards and references	• Purchasing specifications for system materials • Procedures for selecting staff (including qualifications) • Searching for experienced staff and replacement of inappropriate material

II Operational monitoring and management *continued*

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
4.1	Biofilm growth	Water flow is too low, resulting in colonization of surfaces	• Monitor water flow and pressure in the system	• Adequate water flow in the system	• Water flow complies with references and national standards	• Procedures and programmes for monitoring water flows and pressures • Adjustment of pipe dimension to the system • Check of functionality of temperature-adjustable valves, and replacement of defective valves
4.2		Poor chemical water quality leaving the treatment plant (e.g. post-treatment precipitation of floc, iron/ manganese precipitation)	• Monitor the flushing programme of the system regularly • Monitor iron, manganese, chloride, etc.	• Electrical conductivity and pH are normal • Turbidity <1 NTU after flushing programme	• Water treatment solutions comply with guidelines, accepted standards and references • Tapwater quality follows national guidelines for drinking-water quality	• Flushing and monitoring programmes and procedures • PoU water treatment before entering installation system (activated carbon filter, pH regulation)
4.3		Poor microbiological water quality leaving the treatment plant and in the distribution system	• Inspect and maintain the filter regularly • Check microbiological parameters or indicators in the system	• Inspection or maintenance intervals at least every six months • Turbidity <1 NTU and *E. coli*, coliforms = 0	• Tapwater quality complies with national guidelines for drinking-water quality	• Inspection, maintenance and monitoring programmes and procedures • Thermal or chemical disinfection • Boiling of tapwater

II **Operational monitoring and management *continued***

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
4.4	Biofilm growth (continued)	Inappropriate material used	• Check and document pipe, valves and additional equipment material regularly, and update knowledge • Check microbiological parameters and indicator parameters	• Regular check and documentation of pipe material is carried out	• Pipe material used complies with guidelines, accepted standards • Tapwater quality follows national guideline values for drinking-water quality	• Purchasing specifications for system materials • Immediate check and documentation of pipe material • Replacement of critical system components
5.1	Development of sediments	Inadequate cleaning programme (e.g. maintenance of filter)	• Check elements of cleaning programme according to current standards (e.g. regular maintenance of filters)	• Essential system elements in cleaning programme included	• Cleaning programme complies with guidelines, accepted standards and references	• Inspection, maintenance and monitoring programmes and procedures • Update of cleaning programme according to guidelines, accepted standards and references
5.2		Water velocity too high	• Check pipe dimension • Inspect or maintain controlled openings and closing valves and pumps	• Adequate system flow	• Inspection and maintenance comply with guidelines, accepted standards and references	• Design specifications • Inspection, maintenance and monitoring programmes and procedures • Removal of sediments by cleaning procedures • Replace pipe with inadequate dimensions

II **Operational monitoring and management *continued***

Position	Hazard	Cause	Monitoring procedures	Critical or operational limit (reference value)	Validation or verification	Management procedures, including corrective actions
6.1	Drainage of the supply system	Natural disaster	• Ensure that emergency plan is up to date, and that responsible staff have been instructed in its use	• Emergency plan completed and updated	• Emergency plan complies with guidelines, accepted standards and references	• Emergency plan providing essential information for disasters (e.g. responsibilities, emergency call numbers) • Update and audit of emergency plan

NTU, nephelometric turbidity unit; PoE, point of entry; PoU, point of use.

Annex 2 Potential biological and chemical hazards in building water supplies

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Bacteria				
Acinetobacter	Variable, depending on type of infection	Nosocomial infections, including urinary tract infections, pneumonia, bacteraemia, secondary meningitis and wound infections. Diseases are predisposed by factors such as malignancy, burns, major surgery and weakened immune systems, particularly in neonates and elderly people.	Free-living organisms that grow in distribution systems. Conditions such as low flows that promote biofilms are likely to support growth. Exposure through contact or inhalation of aerosols.	Cultures from cases and isolation from implicated water.
Campylobacter	1–10 days (usually 2–4 days)	Abdominal pain, diarrhoea (with or without blood or faecal leukocytes), vomiting, chills and fever. The infection is self-limited and resolves in 3–7 days. Relapses may occur in 5–10% of untreated patients. Other less common clinical manifestations of *C. jejuni* infections include reactive arthritis and meningitis. Several reports have associated *C. jejuni* infection with Guillain-Barré syndrome, an acute demyelinating disease of the peripheral nerves.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Exposure through ingestion of faecally contaminated water.	Cultures from stools and isolation from implicated water.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Bacteria *continued*				
Escherichia coli (enteroinvasive or enterotoxigenic)	10–12 hours seen in outbreaks up to 24–72 hours	Profuse watery diarrhoea without blood or mucus; abdominal cramping and vomiting.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies.	Demonstration of *E. coli* isolates from stools that are enterotoxigenic or enterohaemorrhagic.
E.coli O157:H7 (enterohaemorrhagic)	2–10 days with a median of 3–4 days	Bloody or non-bloody diarrhoea, severe abdominal cramps and occasional vomiting, fever infrequent. Between 2% and 7% of cases can develop the potentially fatal haemolytic uraemic syndrome, which is characterized by acute renal failure and haemolytic anaemia. Children younger than five years are at most risk of developing haemolytic uraemic syndrome.	Exposure through ingestion of faecally contaminated water.	Demonstration of *E. coli* of same serotype in implicated water and stools in persons.
Klebsiella and other Gram-negative bacteria (*Serratia marcesans, Stentrophomonas maltophilia, Aeromonas, Burkholderia cepacia, Enterobacter*)	Variable depending on organism and type of infection	*Klebsiella* spp. and other Gram-negative bacteria can cause invasive infections in hospitals, involving the bloodstream, urinary tract, respiratory tract, eyes and wounds. On rare occasions, *Klebsiella* spp., notably *K. pneumoniae* and *K. oxytoca*, may cause serious infections, such as destructive pneumonia. Patients at highest risk are those with impaired immune systems, such as the elderly or very young, patients with burns or excessive wounds, those undergoing immunosuppressive therapy, or those with HIV infection.	Free-living organisms that grow in distribution systems. Conditions such as low flows that promote biofilms are likely to support growth. Exposure through contact or inhalation of aerosols.	Cultures from cases and isolation from implicated water.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Bacteria *continued*				
Legionella spp.	2–10 days (usually 5–6 days) 5 hours to 3 days (usually 1–2 days)	Legionellosis (pneumonic illness). Fever, non-productive cough, headache, abdominal pain, nausea, diarrhoea, respiratory failure. Pontiac fever is a milder, self-limiting disease with a high attack rate and an onset (five hours to three days) and symptoms similar to those of influenza: fever, headache, nausea, vomiting, aching muscles and coughing.	Free-living organisms that grow in water between 25 °C and 50 °C. Growth promoted by low flows and development of biofilms. Sources include: • cooling towers, evaporative condensers; • domestic hot-water systems that include sections that operate between 25 °C and 50 °C; • humidifiers; • hot tubs and spas; • dental water lines at a temperature above 25 °C; • ice machines; • other water sources, including stagnant water in fire sprinkler systems that contain water between 25 °C and 50 °C. Exposure through inhalation of aerosols or aspiration.	Identification of urinary antigen, serum antibodies or *Legionella* from the case. Isolation of *Legionella* from implicated water matching the type found in the case.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Bacteria *continued*				
Non-tuberculous or atypical *Mycobacterium* spp. (*M. gordonae, M. kansasii, M. marinum, M. xenopi, M. scrofulaceum, M. avium, M. chelonae, M. intracellulare* and *M. fortuitum*)	1 week to 2 months	Atypical *Mycobacterium* spp. can cause a range of diseases involving the skeleton, lymph nodes, skin and soft tissues, as well as the respiratory, gastrointestinal and genitourinary tracts. Manifestations include pulmonary disease, Buruli ulcer, osteomyelitis and septic arthritis.	High densities can form in biofilms on the insides of pipes and taps. Non-tuberculous *Mycobacterium* can colonize, survive, persist, grow and multiply in tapwater. Sources include distribution systems, hot- and cold-water taps, ice machines, heated nebulizers, hot tubs, footbaths and showerhead sprays. Multiple routes of transmission, including ingestion, inhalation and contact.	Cultures from cases and isolation from implicated water.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Bacteria *continued*				
Pseudomonas aeruginosa	Ranges from 8 hours to 5 days, depending on type of infection	*Pseudomonas aeruginosa* can cause a range of infections, but rarely causes serious illness in healthy individuals without some predisposing factor. It predominantly colonizes damaged sites such as burn and surgical wounds, the respiratory tract of people with underlying disease, and physically damaged eyes. From these sites, it may invade the body, causing destructive lesions or septicaemia and meningitis. Cystic fibrosis and immunocompromised patients are prone to colonization with *P. aeruginosa*, which may lead to serious progressive pulmonary infections. Water-related folliculitis and ear infections are associated with warm, moist environments such as swimming pools and hot tubs. Diseases are predisposed by factors such as malignancy, burns, major surgery and weakened immune systems, and groups such as the elderly or neonates are particularly at risk.	Common environmental organism with growth promoted by conditions that support biofilm development (low flows or stagnant water). Commonly associated with poorly maintained and disinfected hot tubs, whirlpools, swimming pools or saunas. Multiple routes of transmission, including ingestion, inhalation and contact.	Isolation of *P. aeruginosa* from cases and implicated water or demonstration of presence by specific immunodiagnostic test (e.g. direct fluorescent antigen) or by PCR.
Salmonella *Salmonella* Typhi	6–72 hours (usually 12–36 hours) 3 to more than 60 days (usually 8–14 days)	Diarrhoea lasting three to five days accompanied by fever and abdominal pain. Usually the disease is self-limiting. Other less common manifestations include reactive arthritis, endocarditis, meningitis, pericarditis, pyoderma or pyelonephritis. Insidious onset of fever, headache, malaise, constipation or diarrhoea, anorexia.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Exposure through ingestion of faecally contaminated water.	Cultures from cases and isolation from implicated water. Cultures from cases and isolation from implicated water.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Bacteria *continued*				
Shigella	12 hours to 1 week (usually 1–3 days)	Abdominal cramps, fever and watery diarrhoea occur early in the disease. All species can produce severe disease, but illness due to *S. sonnei* is usually relatively mild and self-limiting. In the case of *S. dysenteriae*, clinical manifestations may proceed to an ulceration process, with bloody diarrhoea and high concentrations of neutrophils in the stool. The production of Shiga toxin plays an important role in this outcome.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Exposure through ingestion of faecally contaminated water.	Cultures from cases and isolation from implicated water.
Vibrio cholerae 01 or 0139	A few hours to 5 days (usually 2–3 days)	The initial symptoms of cholera are an increase in peristalsis followed by loose, watery and mucus-flecked “rice-water” stools that may cause a patient to lose as much as 10–15 litres of liquid per day. Non-toxigenic strains of *V. cholerae* can cause self-limiting gastroenteritis, wound infections and bacteraemia.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Exposure through ingestion of faecally contaminated water.	Isolation of toxigenic *V. cholerae* 01 or *V. cholerae* 0139 from implicated water and from stool or vomit of ill persons, or significant rise (fourfold) in vibriocidal antibodies.
Viruses				
Adenoviruses	1–12 days, depending on illness	Adenoviruses cause a wide range of infections, including gastroenteritis, acute respiratory diseases, pneumonia, pharyngoconjunctival fever, cervicitis, urethritis, haemorrhagic cystitis, epidemic keratoconjunctivitis (“shipyard eye”), and pharyngoconjunctival fever (“swimming pool conjunctivitis”). Different serotypes are associated with specific illnesses; for example, types 40 and 41 are the main cause of enteric illness.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Multiple routes of exposure, including ingestion, inhalation or contact with faecally contaminated water.	Identification of virus in stools using culture-based methods. Identification using PCR, ELISA or latex agglutination. Identification in water using PCR or culture-based techniques.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Viruses *continued*				
Calicivirus *Norovirus* and *Sapovirus*	10–96 hours (usually 24–48 hours)	Nausea, vomiting and abdominal cramps. Usually about 40% of infected people present with diarrhoea; some have fever, chills, headache and muscular pain. Since some cases present with vomiting only and no diarrhoea, the condition is also known as “winter vomiting disease”.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Identification of virus in stools by PCR, ELISA or radioimmunoassay. Positive detection (electron microscopy) of virus in vomit or stool in ill people, or by serology. Identification in water using PCR.
Enteroviruses	12 hours to 35 days, depending on illness	The spectrum of diseases is broad and ranges from a mild febrile illness to myocarditis, meningoencephalitis, poliomyelitis, herpangina, hand-foot-and-mouth disease and neonatal multi-organ failure. The persistence of the viruses in chronic conditions such as polymyositis, dilated cardiomyopathy and chronic fatigue syndrome has been described.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion or inhalation of faecally contaminated water.	Identification of virus in stools using culture-based methods or PCR. Identification in water using culture-based methods or PCR.
Hepatitis A virus	15–50 days (median 28–30 days)	Severe damage to liver cells. In general, the severity of illness increases with age. The damage also results in the failure of the liver to remove bilirubin from the bloodstream, causing the typical symptoms of jaundice and dark urine. After a relatively long incubation, there is a characteristic sudden onset of illness, including symptoms such as fever, malaise, nausea, anorexia, abdominal discomfort and eventually jaundice. Although mortality is generally less than 1%, repair of the liver damage is a slow process that may keep patients incapacitated for six weeks or longer.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Positive anti-HAV IgM test, or liver function tests compatible with hepatitis in people who drank implicated water. Detection of HAV RNA in blood and stools. Identification in water using PCR.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Viruses *continued*				
Rotavirus	24–72 hours	Acute infection has an abrupt onset of severe watery diarrhoea with fever, abdominal pain and vomiting; dehydration and metabolic acidosis may develop, and the outcome may be fatal if not appropriately treated.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Identification of virus in stools by PCR, ELISA or latex agglutination. Positive detection (electron microscopy) of virus in vomit or stool in ill people, or serology. Identification in water using PCR.
Protozoa				
Cyclospora cayetanensis	1–11 days (median 7 days)	Watery diarrhoea, abdominal cramping, weight loss, anorexia, myalgia and occasionally vomiting or fever. Relapsing illness often occurs.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Demonstration of *C. cayetanensus* in stools of two or more ill people.
Cryptosporidium parvum	1–12 days (median 7 days)	*Cryptosporidium* generally causes a self-limiting diarrhoea, sometimes including nausea, vomiting and fever, which usually resolves within a week in normally healthy people, but can last for a month or more.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Isolation of *C. parvum* oocysts from implicated water and from stools, or identification in intestinal fluid or small bowel biopsy specimen, or demonstration of *C. parvum* antigen in stools by a specific immunodiagnostic test (e.g. ELISA).

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Protozoa *continued*				
Entamoeba hystolytica	A few days to several months or more (commonly 2–4 weeks)	About 10% of infected people present with dysentery or colitis. Symptoms of amoebic dysentery include diarrhoea with cramping, lower abdominal pain, low-grade fever and the presence of blood and mucus in the stool. The ulcers produced by the invasion of the trophozoites may deepen into the classic flask-shaped ulcers of amoebic colitis. *Entamoeba histolytica* may invade other parts of the body, such as the liver, lungs and brain, sometimes with fatal outcome.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Isolation of *E. hystolytica* from stools of ill people, or demonstration of *E. hystolytica* trophozoite in tissue biopsy, culture or histopathology.
Giardia lamblia	3 to more than 25 days (median 7–10 days)	Symptoms generally include diarrhoea and abdominal cramps; however, in severe cases, malabsorption deficiencies in the small intestine may be present, mostly among young children. Giardiasis is self-limiting in most cases, but it may be chronic in some patients, lasting more than one year, even in otherwise healthy people.	Contamination caused by ingress of faecal contamination through faults in treatment or distribution of water supplies. Ingestion of faecally contaminated water.	Isolation of *G. lamblia* cysts from implicated water, or isolation of *G. lamblia* from stools of ill people, or demonstration of *G. lamblia* trophozoite in duodenal fluid or small bowel biopsy, or demonstration of *G. lamblia* antigen by specific immunodiagnostic test (e.g. DFA).
Chemicals				
Heavy metals (e.g. copper, lead, nickel and cadmium nickel)	Acute: <1 hour (5 min – 8 hours)	Range of chemical symptoms depending on the metal. Initial acute symptoms may include gastroenteritis (e.g. copper), but broader symptoms range from neurological impacts to kidney damage and cancer.	Ingestion of water containing excessive concentrations due to leaching associated with corrosion or stagnant water.	Demonstration of concentrations of metals in water exceeding guideline values.
Nitrite (e.g. in boiler treatment fluid)	1–2 hours	Methaemoglobinemia, nausea, vomiting, cyanosis, headache, dizziness, dyspnoea, trembling, weakness, loss of consciousness.	Ingestion of water contaminated by backflow or cross-connection of devices such as boilers to drinking-water supplies.	Demonstration of concentrations of nitrites in water exceeding guideline values.

Etiologic agent	Incubation period	Clinical symptoms	Source of exposure	Confirmation of waterborne disease
Chemicals *continued*				
Organic chemicals (e.g. benzo(a)pyrene, styrene, vinyl chloride)	Chronic, many years	Most likely symptom is cancer from long-term exposure.	Ingestion of water contaminated by inappropriate materials used in plumbing.	Demonstration of concentrations in water exceeding guideline values.
Water treatment chemicals (e.g. chlorine)	Acute (chlorine)	Substantial tastes and odours.	Ingestion of water containing excessive concentrations of chlorine.	Demonstration of concentrations in water exceeding guideline values.

DFA, direct fluorescent antigen; ELISA, enzyme-linked immunosorbent assay; HAV, hepatitis A virus; HIV, human immunodeficiency virus; IgM, immunoglobulin M; PCR, polymerase chain reaction; RNA, ribonucleic acid.
Source: Information adapted from Percival et al. (2004), Heymann (2008) and WHO (2008).

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Glossary

Accreditation	An official authorization or certification to a person, organization or laboratory that has the credential to deliver certain tasks; certification to a laboratory, institution or someone who has met the standard required by an official authority (WHO, 2009). Accreditation provides an independent assessment of competency that provides confidence to users of services.
Actor	Individuals, groups or organizations that influence the overall safe management of building water supplies, including those who design, construct, manage, operate, maintain and regulate building water systems.
Aerosol	A suspension of fine solid or liquid particles in a gas, such as air.
Backflow	The unintended reverse flow of water or other substances into distribution pipes of drinking-water from an unintended source that is capable of polluting the drinking-water (American Society of Sanitary Engineering, 2007).
Backflow protection	Devices that prevent backflow (e.g. one-way valves, air gaps).
Back-siphonage	The reverse flow of water within a water-supply system due to negative pressures in the pipe system, enabling atmospheric pressure to force the flow of water backwards through a siphon action (World Plumbing Council, 2008). The reversing of normal flow resulting from negative or subatmospheric pressures in the distribution piping of a drinking-water supply system (WHO and WPC, 2006).
Biocide	A diverse group of poisonous substances, including preservatives, insecticides, disinfectants and pesticides, used to control organisms that are harmful to human or animal health, or that cause damage to natural or manufactured products.
Biofilm	A slimy matrix produced and inhabited by bacteria, which enables the bacteria to adhere to a surface and carry out certain essential biochemical processes.
Certification (personnel)	A programme to substantiate the capabilities of personnel by documenting their experience and learning in a defined area of endeavour (Symons et al., 2000).
Community acquired	Cases of illness that are not acquired in a health-care, travel or domestic (i.e. the patient's home) setting (Bartram et al., 2007). Community-acquired cases of legionellosis can almost always be attributed to inhalation of aerosols from devices such as cooling towers, hot tubs, industrial equipment and indoor fountains.

Component	Appliance, equipment. A device in which potable water is used and/or modified (e. g. water heater, chemical dosing unit, coffee-machine, toilet).
Contamination	Presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption, or on other inanimate objects, including conveyances, that may constitute a public health risk (WHO, 2005). Presence of a disease agent on or in food, or any object that may come into contact with food (WHO, 2007).
Control	In a case–control study, the control group is the group of people who do not have the disease or condition of interest, and who are used to compare with those people who do.
Control measure	Any action and activity that can be used to prevent or eliminate a water safety hazard or reduce it to an acceptable level.
Cooling tower	Heat-transfer device in which warm water is cooled by evaporation in atmospheric air. Cooling towers usually incorporate an air fan for forced air movement, a circulating water pump, a water spray system and a cooling coil (World Plumbing Council, 2008).
Corrective action	Any action to be taken when the results of monitoring at the control point indicate a loss of control.
Corrosion	A surface reaction causing a gradual erosion of the material affected (WHO & WPC, 2006). The gradual deterioration or destruction of a substance (usually a metal) or its properties as a result of a reaction with the substance's surroundings (Symons et al., 2000).
Cross-connection	Any connection, physical or otherwise, between a drinking-water system and non-drinking-water, where contamination can enter the drinking-water supply lines by back pressure, back-siphonage, and backflow occurring in the water-supply system (American Society of Sanitary Engineering, 2007). Any physical connection or arrangement between two otherwise separate piping systems or containment means, one of which contains potable water, and the other water or fluid of unknown or questionable safety (WHO & WPC, 2006).
Dead leg	A length of water-filled pipe where there is little or no flow.
Disinfectant	An agent that destroys or inactivates harmful microorganisms (Symons et al., 2000).

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Disinfection	The supply of safe drinking-water through the destruction of microbial pathogens (bacteria, viruses and protozoa), involving reactive chemical agents. It is used for surface waters and for groundwater subject to faecal contamination (WHO, 2008). The procedure whereby health measures are taken to control or kill the insect vectors of human diseases present in baggage, cargo, containers, conveyances, goods and postal parcels (WHO, 2005). The process of destroying or inactivating pathogenic organisms (bacteria, viruses, fungi and protozoa) by either chemical or physical means (Symons et al., 2000).
Disinfection by-product	The formation of chemical by-products (inorganic or organic) that results from the use of chemical disinfectants in water treatment (WHO, 2008).
Domestic water	Water used for all usual domestic purposes, including consumption, bathing and food preparation (WHO, 2008). Pertaining to municipal (household) water services as opposed to commercial and industrial water. The term is sometimes used to include the commercial component (Symons et al., 2000). Water that is delivered for normal personal use within a household, school or commercial premises (World Plumbing Council, 2008).
Enforcement	Administrative or legal procedures and actions to require compliance with legislation or associated rules, regulations or limitations (Symons et al., 2000).
Exposure	Concentration or amount of a particular agent that reaches a target organism, system or (sub)population in a specific frequency for a defined duration (WHO, 2004a). Contact between an agent and a target (WHO, 2004b).
Greywater	Water from the kitchen, bath or laundry, which generally does not contain significant concentrations of excreta (WHO, 2006b). Untreated household-used water, such as wash or rinse water from a sink, bathtub, or other household plumbing fixture, except a toilet (Symons et al., 2000).
Guidelines	Minimum requirements of safe practice to protect health or derive numerical guideline values.

Hardness	Hardness in water is caused by dissolved calcium and, to a lesser extent, magnesium. It is expressed as the equivalent quantity of calcium carbonate. Hardness above about 200 mg/litre can result in scale deposition, particularly on heating. No health-based guideline value is proposed for hardness (WHO, 2008). Hardness is caused mainly by the presence of calcium and magnesium in the water. Scale formation and excessive soap consumption are the main concerns. When heated, hard waters have a tendency to form scale deposits, which shorten the life of water heaters and other appliances (Health Canada, 2009).
Hazard	In the context of this document, a hazard is a biological, chemical or physical agent in water, or a condition of water, with the potential to cause an adverse health effect.
Hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population.
Hazardous event	An event that introduces hazards to, or fails to remove them from, the water supply (Bartram et al., 2009).
Health-based target	Target based on critical evaluation of health concerns.
Hot tub	Facilities that are designed for sitting in (rather than swimming); contain water usually above 32 °C; are generally aerated; contain treated water; and are not drained, cleaned or refilled for each user. Hot tubs are also called spa pools, whirlpools, whirlpool spas and heated spas.
Infection	The entry and development or multiplication of an infectious agent in a host. Infection may or may not lead to disease symptoms (e.g. diarrhoea) (WHO, 2006b). The entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk (WHO, 2005). The presence in the body of viruses or organisms, such as bacteria, protozoa, fungi or helminths, which multiply or develop, completing all or part of their lifecycle within the tissues of an animal or human host (infection may or may not lead to a disease state) (WHO et al., 1996).
Legislation (primary and secondary)	Law enacted by a legislative body or the act of making or enacting laws (WHO, 2006b). Primary legislation is the law-making legislation, which is also known as enabling legislation, and can be found in the form of an Act, a statute or a bill. Subordinate legislation is legislation that is subordinate to the primary law-making legislation. It cannot make laws or change Acts, statutes or bills (World Plumbing Council, 2008).

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Maintenance	Activities aimed at keeping existing capital assets in serviceable condition (e.g. by repairing water-distribution pipes, pumps and public taps) (WHO, 2000).
Material	The substance from which a product is made.
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters, to assess whether a control point is operating within design specifications.
Multiple barrier approach	The multiple barrier approach in drinking-water is the concept of using more than one type of protection or treatment in series in a water-treatment process to control contamination (Symons et al., 2000).
Operational monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is operating within design specifications (e.g. for wastewater turbidity treatment) (WHO, 2008).
Outbreak	An epidemic limited to localized increase in the incidence of a disease (e.g. in a village, town or closed institution) (McMichael et al., 2003). A waterborne outbreak is a situation in which at least two people experience a similar illness after exposure to water (and possibly food) and the evidence suggests a probable water source (WHO, 2007).
Pathogens	Any microorganisms that cause disease in an organism, through direct interaction (infection) (Schmoll et al, 2006).
pH	The pH of a solution is the negative common logarithm of the hydrogen ion activity (WHO, 2008): $pH = -\log (H+)$ An expression of the intensity of the basic or acid condition of a liquid (WHO, 2006b).
Plumbing	The piping, fixtures and appliances within a property; and all the work associated with the design, installation, removal, alteration or repair of piping, fixtures and appliances in connection with drinking-water supply, non-drinking-water supply and drainage systems that flow in and out of buildings and between given connection points to points of use or disposal (World Plumbing Council Working Group, 2008).
Point of consumption	Draw-off point. Those points in the potable water installation from which water can be drawn.
Point-of-entry (PoE) treatment	A treatment device applied to the drinking-water entering a house or building for reducing contaminants in the drinking-water distributed throughout that house or building (Symons et al., 2000).
Policy	The set of procedures, rules and allocation mechanisms that provide the basis for programmes and services (WHO, 2006b).

Recycled water	Water that has been treated so that its quality is suitable for particular specified purposes, such as irrigation, toilet flushing or possibly drinking (WHO, 2006b). Sources of recycled water include sewage and greywater.
Risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent (WHO, 2008). The likelihood of a hazard causing harm in exposed populations in a specified time frame, including the magnitude of that harm (WHO, 2008).
Risk assessment	A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern, as well as the characteristics of the specific target system. The overall process of using available information to predict how often hazards or specified events may occur (likelihood) and the magnitude of their consequences (adapted from AS/NZS 4360:1999).
Risk management	Decision-making process involving considerations of political, social, economic and technical factors with relevant risk-assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options, and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation, emission and exposure control, and risk monitoring (WHO, 2004a). The systemic evaluation of the water-supply system, the identification of hazards and hazardous events, the assessment of risks, and the development and implementation of preventive strategies to manage risks (WHO, 2006b).
Sensitive or vulnerable population	Vulnerable groups or populations are people who might be vulnerable to the effects of exposure because of their development stage (e.g. children) or because of pre-existing health conditions (e.g. asthmatics and air pollution).
Spa pool	A facility that is designed for sitting in (rather than swimming); contains treated water usually above 32 °C; is usually aerated; and is not drained, cleaned or refilled for each user. Also known as a hot tub, whirlpool, whirlpool spa, heated spa, bubble bath or jacuzzi.
Stakeholder	Person or entity with an interest or 'stake' in the outcome of a particular action or policy (McMichael et al., 2003).
Storage (cistern)	Tank or storage container in which water is stored (American Society of Sanitary Engineering, 2007).

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Surveillance	The systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information, for assessment and public health response as necessary (WHO, 2005).
Thermostatic mixing valves	Tempering valves that are typically temperature-activated. Used to mix hot and cold water to achieve a predetermined outlet temperature, and that are fitted between the water heater and the point of use to control the distribution temperature. Slightly different temperature ranges are used in some countries.
Turbidity	Cloudiness caused by the presence of suspended matter in water (WHO, 2008).
Validation	The process of obtaining accurate and reliable evidence that a water safety plan is effective.
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with a water safety plan.
Water safety plan	A comprehensive risk-assessment and risk-management approach that encompasses all steps in water supply, from catchment to consumer.
Water system (external or building-specific)	An external system is one that provides multiple users and can be either publicly or privately owned. A building-specific supply is defined as an individual and isolated drinking-water system that is distinct from any external water system.

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Extensive experience shows that poor design and management of water systems in buildings can cause outbreaks of disease. The types of building, water uses, disease outcomes and individuals affected are diverse. The health risks are preventable and can be readily controlled. However, evidence from outbreak detection suggests that the overall trend is increasing. With increasing global urbanization, the overall exposure of the human population to poorly designed or managed water systems in buildings is increasing rapidly. Consequently, the risk of disease outbreaks is also increasing. Actions to reduce the risk of disease should be considered a public health priority.

This document provides guidance for managing water supplies in buildings where people may drink water; use water for food preparation; wash, shower, swim or use water for other recreational activities; or be exposed to aerosols produced by water-using devices, such as cooling towers. These uses occur in a variety of buildings, such as hospitals, schools, child and aged care facilities, medical and dental facilities, hotels, apartment blocks, sport centres, commercial buildings and transport terminals.

This text is one of a series of supporting documents that provide guidance on implementing the World Health Organization's *Guidelines for drinking-water quality* (WHO, 2008). It is intended to support the improvement of water safety within buildings.

The target audience for this document includes the full range of "actors" who influence the overall safe management of building water supplies. In particular, it is directed at those who design, construct, manage, operate, maintain and regulate building water systems. This document is intended to be a useful resource for the development of training and information material.

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Chapter 41. Preventing Health Care–Associated Infections

Amy S. Collins

Background

The occurrence and undesirable complications from health care–associated infections (HAIs) have been well recognized in the literature for the last several decades. The occurrence of HAIs continues to escalate at an alarming rate. HAIs originally referred to those infections associated with admission in an acute-care hospital (formerly called a nosocomial infection), but the term now applies to infections acquired in the continuum of settings where persons receive health care (e.g., long-term care, home care, ambulatory care). These unanticipated infections develop during the course of health care treatment and result in significant patient illnesses and deaths (morbidity and mortality); prolong the duration of hospital stays; and necessitate additional diagnostic and therapeutic interventions, which generate added costs to those already incurred by the patient's underlying disease. HAIs are considered an undesirable outcome, and as some are preventable, they are considered an indicator of the quality of patient care, an adverse event, and a patient safety issue.

Patient safety studies published in 1991 reveal the most frequent types of adverse events affecting hospitalized patients are adverse drug events, nosocomial infections, and surgical complications.[1, 2] From these and other studies, the Institute of Medicine reported that adverse events affect approximately 2 million patients each year in the United States, resulting in 90,000 deaths and an estimated $4.5–5.7 billion per year in additional costs for patient care.[3] Recent changes in medical management settings have shifted more medical treatment and services to outpatient settings; fewer patients are admitted to hospitals. The disturbing fact is that the average duration of inpatient admissions has decreased while the frequency of HAIs has increased.[4, 5] The true incidence of HAIs is likely to be underestimated as hospital stays may be shorter than the incubation period of the infecting microorganism (a developing infection), and symptoms may not manifest until days after patient discharge. For example, between 12 percent and 84 percent of surgical site infections are detected after patients are discharged from the hospital, and most become evident within 21 days after the surgical operation.[6, 7] Patients receiving followup care or routine care after a hospitalization may seek care in a nonacute care facility. The reporting systems are not as well networked as those in acute care facilities, and reporting mechanisms are not directly linked back to the acute care setting to document the suspected origin of some infections.

Since the early 1980s HAI surveillance has monitored ongoing trends of infection in health care facilities.[8] With the application of published evidence-based infection control strategies, a decreasing trend in certain intensive care unit (ICU) health care-associated infections has been reported through national infection control surveillance[9] over the last 10 years, although there has also been an alarming increase of microorganism isolates with antimicrobial resistance. These changing trends can be influenced by factors such as increasing inpatient acuity of illness, inadequate nurse-patient staffing ratios, unavailability of system resources, and other demands that have challenged health care providers to consistently apply evidence-based recommendations to maximize prevention efforts. Despite these demands on health care workers

and resources, reducing preventable HAIs remains an imperative mission and is a continuous opportunity to improve and maximize patient safety.

Another factor emerging to motivate health care facilities to maximize HAI prevention efforts is the growing public pressure on State legislators to enact laws requiring hospitals to disclose hospital-specific morbidity and mortality rates. A recent Institute of Medicine report identified HAIs as a patient safety concern and recommended immediate and strong mandatory reporting of other adverse health events, suggesting that public monitoring may hold health care facilities more accountable to improve the quality of medical care and to reduce the incidence of infections.[3] Since 2002, four States (Florida, Illinois, Missouri, and Pennsylvania) set legislation mandating health care organizations to publicly disclose HAIs.[10, 11] In 2006, the Association for Professionals in Infection Control and Epidemiology (APIC) reported that 14 States have mandatory public reporting, and 27 States have other related legislation under consideration.[12] Participation in public reporting has not been regulated by the Federal sector at this time. Some hospital reporting is intended for use solely by the State health department for generating confidential reports that are returned to each facility for their internal quality improvement efforts. Other intentions to utilize public reporting may be aimed at comparing rates of HAI and subsequent morbidity and mortality outcomes between different hospitals. This approach is problematic as there is currently a lack of scientifically validated methods for risk adjusting multiple variations (e.g., differences in severity of illnesses in each population being treated) in patients' intrinsic and extrinsic risks for HAIs.[13–15] Moreover, data on whether public reporting systems have an effective role in reducing HAIs are lacking.

To assist with generating meaningful data, process and outcome measures for patient safety practices have been proposed.[13, 14, 16] Monitoring both process and outcome measures and assessing their correlation is a model approach to establish that good processes lead to good health care outcomes. Process measures should reflect common practices, apply to a variety of health care settings, and have appropriate inclusion and exclusion criteria. Examples include insertion practices for central intravenous catheters, appropriate timing of antibiotic prophylaxis in surgical patients, and rates of influenza vaccination for health care workers and patients. Outcome measures should be chosen based on the frequency, severity, and preventability of the outcome events. Examples include intravascular catheter-related blood stream infection rates and surgical-site infections in selected operations. Although these occur at relatively low frequency, the severity is high—these infections are associated with substantial morbidity, mortality, and excess health care costs—and there are evidence-based prevention strategies available.[17, 18]

Definitions of Health Care-Associated Infections

The Centers for Disease Control and Prevention (CDC) developed baseline definitions for HAIs that were republished in 2004.[19] HAIs were defined as those that develop during hospitalization but are neither present nor incubating upon the patient's admission to the hospital; generally for those infections that occur more than 48 to 72 hours after admission and within 10 days after hospital discharge. Some hospitals use these definitions exactly as written; other hospitals may use some but not all of the CDC definitions; and other health care facilities may need to modify or develop their own definitions. Whatever definition is used, it should be consistent within the institution and be the same or similar to those developed by CDC or those used by other investigators. Having standard definitions is useful if the health care facility wants

to compare surveillance results or performance measures within its various medical/surgical specialties, against those of other health care institutions, or with national published data.

Patient Risk Factors for Health Care–Associated Infections

Transmission of infection within a health care setting requires three elements: a source of infecting microorganisms, a susceptible host, and a means of transmission for the microorganism to the host.

Source of Microorganisms

During the delivery of health care, patients can be exposed to a variety of exogenous microorganisms (bacteria, viruses, fungi, and protozoa) from other patients, health care personnel, or visitors. Other reservoirs include the patient's endogenous flora (e.g., residual bacteria residing on the patient's skin, mucous membranes, gastrointestinal tract, or respiratory tract) which may be difficult to suppress and inanimate environmental surfaces or objects that have become contaminated (e.g., patient room touch surfaces, equipment, medications). The most common sources of infectious agents causing HAI, described in a scientific review of 1,022 outbreak investigations,[20] are (listed in decreasing frequency) the individual patient, medical equipment or devices, the hospital environment, the health care personnel, contaminated drugs, contaminated food, and contaminated patient care equipment.

Host Susceptibility

Patients have varying susceptibility to develop an infection after exposure to a pathogenic organism. Some people have innate protective mechanisms and will never develop symptomatic disease because they can resist increasing microbial growth or have immunity to specific microbial virulence properties. Others exposed to the same microorganism may establish a commensal relationship and retain the organisms as an asymptomatic carrier (colonization) or develop an active disease process.

Intrinsic risk factors predispose patients to HAIs. The higher likelihood of infection is reflected in vulnerable patients who are immunocompromised because of age (neonate, elderly), underlying diseases, severity of illness, immunosuppressive medications, or medical/surgical treatments. Patients with alterations in cellular immune function, cellular phagocytosis, or humoral immune response are at increased risk of infection and the ability to combat infection. A person with a primary immunodeficiency (e.g., anemia or autoimmune disease) is likely to have frequently recurring infections or more severe infections, such as recurrent pneumonia.[21] Secondary immunodeficiencies (e.g., chemotherapy, corticosteroids, diabetes, leukemia) increase patient susceptibility to infection from common, less virulent pathogenic bacteria, opportunistic fungi, and viruses. Considering the severity of a patient's illness in combination with multiple risk factors, it is not unexpected that the highest infection rates are in ICU patients. HAI rates in adult and pediatric ICUs are approximately three times higher than elsewhere in hospitals.[22]

Extrinsic risk factors include surgical or other invasive procedures, diagnostic or therapeutic interventions (e.g., invasive devices, implanted foreign bodies, organ transplantations, immunosuppressive medications), and personnel exposures. According to one review article, at least 90 percent of infections were associated with invasive devices.[23] Invasive medical devices bypass the normal defense mechanism of the skin or mucous membranes and provide foci where

pathogens can flourish, internally shielded from the patient's immune defenses. In addition to providing a portal of entry for microbial colonization or infection, these devices also facilitate transfer of pathogens from one part of the patient's body to another, from health care worker to patient, or from patient to health care worker to patient. Infection risk associated with these extrinsic factors can be decreased with the knowledge and application of evidence-based infection control practices. These will be discussed in further detail in Chapter 42, "Targeting Health Care–Associated Infections: Evidence-Based Strategies."

Prolonged hospitalization, due to a higher acuity of illness, contributes to host susceptibility as there is more opportunity to utilize invasive devices and more time for exposure to exogenous microorganisms. These patients are also more susceptible to rapid microbial colonization as a consequence of the severity of the underlying disease, depending on the function of host defenses and the presence of risk factors (e.g., age, extrinsic devices, extended length of stay). Exposure to these colonizing microorganisms is from such sources as (1) endemic pathogens from an endogenous source, (2) hospital flora in the health care environment, and (3) hands of health care workers. A study related to length of hospitalization examining adverse events in medical care indicated that the likelihood of experiencing an adverse event increased approximately 6 percent for each day of hospital stay. The highest proportion of adverse events (29.3 percent) was not related to surgical procedures but linked instead to the subsequent monitoring and daily care lacking proper antisepsis steps.[24]

Means of Transmission

Among patients and health care personnel, microorganisms are spread to others through four common routes of transmission: contact (direct and indirect), respiratory droplets, airborne spread, and common vehicle. Vectorborne transmissions (from mosquitoes, fleas, and other vermin) are atypical routes in U.S. hospitals and will not be covered in this text.

Contact transmission. This is the most important and frequent mode of transmission in the health care setting. Organisms are transferred through direct contact between an infected or colonized patient and a susceptible health care worker or another person. Patient organisms can be transiently transferred to the intact skin of a health care worker (not causing infection) and then transferred to a susceptible patient who develops an infection from that organism—this demonstrates an indirect contact route of transmission from one patient to another. An infected patient touching and contaminating a doorknob, which is subsequently touched by a health care worker and carried to another patient, is another example of indirect contact. Microorganisms that can be spread by contact include those associated with impetigo, abscess, diarrheal diseases, scabies, and antibiotic-resistant organisms (e.g., methicillin-resistant *Staphylococcus aureus* [MRSA] and vancomycin-resistant enterococci [VRE]).

Respiratory droplets. Droplet-size body fluids containing microorganisms can be generated during coughing, sneezing, talking, suctioning, and bronchoscopy. They are propelled a short distance before settling quickly onto a surface. They can cause infection by being deposited directly onto a susceptible person's mucosal surface (e.g., conjunctivae, mouth, or nose) or onto nearby environmental surfaces, which can then be touched by a susceptible person who autoinoculates their own mucosal surface. Examples of diseases where microorganisms can be spread by droplet transmission are pharyngitis, meningitis, and pneumonia.

Airborne spread. When small-particle-size microorganisms (e.g., tubercle bacilli, varicella, and rubeola virus) remain suspended in the air for long periods of time, they can spread to other people. The CDC has described an approach to reduce transmission of microorganisms through

airborne spread in its *Guideline for Isolation Precautions in Hospitals.*[25] Proper use of personal protective equipment (e.g., gloves, masks, gowns), aseptic technique, hand hygiene, and environmental infection control measures are primary methods to protect the patient from transmission of microorganisms from another patient and from the health care worker. Personal protective equipment also protects the health care worker from exposure to microorganisms in the health care setting.

Common Vehicle. Common vehicle (common source) transmission applies when multiple people are exposed to and become ill from a common inanimate vehicle of contaminated food, water, medications, solutions, devices, or equipment. Bacteria can multiply in a common vehicle but viral replication can not occur. Examples include improperly processed food items that become contaminated with bacteria, waterborne shigellosis, bacteremia resulting from use of intravenous fluids contaminated with a gram-negative organism, contaminated multi-dose medication vials, or contaminated bronchoscopes. Common vehicle transmission is likely associated with a unique outbreak setting and will not be discussed further in this document.

Responsibility for Risk Reduction

Infection Control Department's Program Responsibilities

In 1985, the Study of the Efficacy of Nosocomial Infection Control (SENIC) project was published, validating the cost-benefit savings of infection control programs.[8] Infection control programs were proven to be effective as hospitals with certain practices reduced their infection rates by 32 percent, compared with an *increase* of 18 percent in hospitals without these components over a 5-year period.[8, 26] Essential components of effective infection control programs included conducting organized surveillance and control activities, a trained infection control physician, an infection control nurse for every 250 beds, and a process for feedback of infection rates to clinical care staff. These programmatic components have remained consistent over time and are adopted in the infection control standards of the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, JCAHO). The evolving responsibility for operating and maintaining a facility-wide effective infection control program lies within many domains. Both hospital administrators and health care workers are tasked to demonstrate effectiveness of infection control programs, assure adequate staff training in infection control, assure that surveillance results are linked to performance measurement improvements, evaluate changing priorities based on ongoing risk assessments, ensure adequate numbers of competent infection control practitioners, and perform program evaluations using quality improvement tools as indicated.

Infection Control Personnel

It has been demonstrated that infection control personnel play an important role in preventing patient and health care worker infections and preventing medical errors. An infection control practitioner[27] (ICP) is typically assigned to perform ongoing surveillance of infections for specific wards, calculate infection rates and report these data to essential personnel, perform staff education and training, respond to and implement outbreak control measures, and consult on employee health issues. This specialty practitioner gains expertise through education involving infection surveillance, infection control, and epidemiology from current scientific publications

and basic training courses offered by professional organizations or health care institutions.[28, 29] The Certification Board of Infection Control offers certification that an ICP has the standard core set of knowledge in infection control.[30, 31, 32]

Over time, the workload responsibilities of the ICP have significantly increased to encompass additional administrative functions and regulatory compliance reporting, sometimes covering prevention of infection activities in other facilities that belong to the health care system (e.g., long-term care, home care, and outpatient settings). The expanding scope of ICP responsibilities being performed with limited time and shrinking resources has created an imbalance in meeting all tasks, leading to regular completion of only essential functions and completing less essential functions when time permits. In a 2002 ICP survey examining resource allocations, the activity consuming the greatest amount of mean estimated time was surveillance, followed by education, prevention strategies to control transmission, infection control program communication, and outbreak control. In examining the tasks and the time allocations necessary to complete essential infection control responsibilities, a recent expert review panel recommended new and safer staffing allocations: 1 full-time ICP for every 100 occupied beds. Further staffing levels and recommendations are included for different types of health care facilities by bed size.[33] To maximize successful completion of current reporting requirements and strategies for the prevention of infection and other adverse events associated with the delivery of health care in the entire spectrum of health care settings, infection control personnel and departments must be expanded.[34]

Nursing Responsibilities

Clinical care staff and other health care workers are the frontline defense for applying daily infection control practices to prevent infections and transmission of organisms to other patients. Although training in preventing bloodborne pathogen exposures is required annually by the Occupational Safety and Health Administration, clinical nurses (registered nurses, licensed practical nurses, and certified nursing assistants) and other health care staff should receive additional infection control training and periodic evaluations of aseptic care as a planned patient safety activity. Nurses have the unique opportunity to directly reduce health care–associated infections through recognizing and applying evidence-based procedures to prevent HAIs among patients and protecting the health of the staff. Clinical care nurses directly prevent infections by performing, monitoring, and assuring compliance with aseptic work practices; providing knowledgeable collaborative oversight on environmental decontamination to prevent transmission of microorganisms from patient to patient; and serve as the primary resource to identify and refer ill visitors or staff.

Prevention Strategies

Multiple factors influence the development of HAIs, including patient variables (e.g., acuity of illness and overall health status), patient care variables (e.g., antibiotic use, invasive medical device use), administrative variables (e.g., ratio of nurses to patients, level of nurse education, permanent or temporary/float nurse), and variable use of aseptic techniques by health care staff. Although HAIs are commonly attributed to patient variables and provider care, researchers have also demonstrated that other institutional influences may contribute to adverse outcomes.[35, 36] To encompass overall prevention efforts, a list of strategies are reviewed that apply to the clinical

practice of an individual health care worker as well as institutional supportive measures. Adherence to these principles will demonstrate that you H.E.L.P. C.A.R.E. This acronym is used to introduce the following key concepts to reduce the incidence of health care–associated infections. It emphasizes the compassion and dedication of nurses where their efforts contribute to reduce morbidity and mortality from health care–associated infections.

Hand Hygiene

…so they shall wash their hands and their feet, that they die not:
and it shall be a statute for ever to them…
Exodus 30:21 Revised Standard Version

Overview. For the last 160 years, we have had the scientific knowledge of how to reduce hand contamination and thereby decrease patient infections from the seminal work on hand washing by the Hungarian obstetrician, Ignaz Semmelweis. Epidemiologic studies continue to demonstrate the favorable cost-benefit ratio and positive effects of simple hand washing for preventing transmission of pathogens in health care facilities.[37, 38] The use of antiseptic hand soaps (i.e., ones containing chlorhexidine) and alcohol-based hand rubs also effectively reduce bacterial counts on hands when used properly. Even though the clear benefits of hand washing have been proven in multiple settings, the lack of consistent hand-washing practices remains a worldwide issue. In a resource-poor area of Pakistan, a recent household hand-washing campaign demonstrated a 50 percent lower incidence of pneumonia in children younger than 5 years compared to households that did not practice hand washing. Children under 15 years in hand-washing households had a 53 percent lower incidence of diarrhea and a 34 percent lower incidence of impetigo. Hand washing with plain soap prevented the majority of illnesses causing the largest number of childhood deaths globally.[39] The World Alliance for Patient Safety, formed by the World Health Organization, has adopted infection reduction programs—in both developed and developing countries—as its first goal.[40, 41] The World Alliance for Patient Safety advocates a “clean care is safer care” program, in which health care leaders sign a pledge to take specific steps to reduce HAIs in their facilities. Hand hygiene is the first focus in this worldwide initiative.

Understaffing and hand hygiene. Hospitals with low nurse staffing levels and patient overcrowding leading to poor adherence to hand hygiene have been associated with higher adverse outcome rates and hospital outbreak investigations.[34, 42, 43] In an ICU setting,[44] it was demonstrated that understaffing of nurses can facilitate the spread of MRSA through relaxed attention to basic infection control measures (e.g., hand hygiene). In a neonatal ICU outbreak,[45] the daily census was above the maximum capacity (25 neonates in a unit designed for 15), and the number of assigned staff members was fewer than the number necessitated by the workload, which resulted in relaxed attention to basic infection-control measures (use of multidose vials and hand hygiene). During the highest workload demands, staff washed their hands before contacting devices only 25 percent of the time, but hand washing increased to 70 percent after the end of the understaffing and overcrowding period. Ongoing surveillance determined that being hospitalized during this period was associated with a fourfold increased risk of acquiring an HAI. These studies illustrate an association between staffing workload, infections, and microbial transmission from poor adherence to hand hygiene policies.

Time demands. A perceived obstacle is that time to complete patient care duties competes with time needed for hand washing, particularly in technically intense settings such as an ICU. Hospital observational studies demonstrate that the frequency of hand washing varies between

hospital wards and occurs an average of 5 to 30 times per shift, with more hand washing opportunities in an ICU.[46] With time limitations due to patient acuity demands or nurse-patient ratios and limited availability of sinks, the use of waterless, alcohol-based hand rubs has been shown to improve health care workers' compliance with hand hygiene practices in the ICU.[47]

Hand washing behaviors. Observational studies have found that on average, health care workers adhere to recommended hand hygiene procedures 40 percent of the time (with a range of 5 to 80 percent).[44] These studies implemented various interventions to improve hand washing, but summarized effects by measuring responses over a short time frame, without demonstrating long-lasting behavioral improvements. Two studies demonstrated the use of multidisciplinary interventions to change the organizational culture on frequency of hand washing that resulted in sustained improvements during a longer followup time period.[48, 49]

Behavioral theories that examine the relationship of multiple factors affecting behavioral choices have been applied to the complex issue of hand washing compliance. These theories illustrate the influence of the individual *intention* to perform hand washing and organizational influences that affect the outcome behavior. The Theory of Planned Behavior has been studied in this context, acknowledging that the intention to wash hands involves a person's (1) attitude whether or not the behavior is beneficial to themselves, (2) perception of pressure from peers, and (3) perceived control on the ease or difficulty in performing the behavior.[50–53] These perceptions are also influenced by the strength of the person's beliefs about the significance of the outcomes of the behavior; the normative beliefs, which involve the individual evaluation of peer expectations; and control beliefs, which are based on a person's perception of their ability to overcome obstacles that obstruct their completion of the behavior.

Monitoring compliance. Although standards for hand hygiene practices have been published with an evidence-based guideline[44] and professional collaborations have produced the *How-to-Guide: Improving Hand Hygiene,*[54] there is no standardized method or tool for measuring adherence to institutional policy. Varying quality improvement methodologies and a lack of consensus on how to measure hand hygiene compliance have made it difficult to determine the effectiveness of hand hygiene expectations within and across health care settings. The Joint Commission has instituted a partnership with major infection control leadership organizations in the United States and abroad to identify best approaches for measuring compliance with hand hygiene guidelines in health care organizations though its Consensus Measurement in Hand Hygiene (CMHH) project. The participating organizations include APIC, CDC, the Society for Healthcare Epidemiology of America, the World Health Organization World Alliance for Patient Safety, the Institute for Healthcare Improvement, and the National Foundation for Infectious Diseases. The final product of this project, due to be completed in early 2008, will be an educational monograph that recommends best practices for measuring hand hygiene compliance.[55]

Summary. Hand hygiene adherence and promotion involve multiple factors at the individual and system level to provide an institutional safety climate for patients and health care staff. Methods used to promote improved hand hygiene require multidisciplinary participation to identify individual beliefs, adherence factors, and perceived barriers. Program successes have been summarized and should be reviewed to establish improved hand hygiene as a priority program at your facility.[44, 56, 57]

Hand Hygiene: Key Points

- The practice of appropriate hand hygiene and glove usage is a major contributor to patient safety and reduction in HAIs. It is more cost effective than the treatment costs involved in a health care–associated infection.
- Joint Commission infection control standards include hand washing and HAI sentinel event review, which are applicable to ambulatory care, behavioral health care, home care, hospitals, laboratories, and long-term care organizations accredited by the Joint Commission.
- Hand hygiene is the responsibility of the individual practitioner and the institution. Developing a patient safety culture backed by administrative support to provide resources and incentives for hand washing is crucial to a successful outcome.
- Hand hygiene promotion should be an institutional priority.
- Select methods to promote and monitor improved hand hygiene. Monitor outcomes of adherence to hand hygiene in association with reduced incidence of HAI.
- Establish an evaluation model to recognize missed opportunities for appropriate hand hygiene.

Environmental Cleanliness

The health care environment surrounding a patient contains a diverse population of pathogenic microorganisms that arise from a patient's normal, intact skin or from infected wounds. Approximately 10^6 flat, keratinized, dead squamous epithelium cells containing microorganisms are shed daily from normal skin,[58] and patient gowns, bed linens, and bedside furniture can easily become contaminated with patient flora. Surfaces in the patient care setting can also be contaminated with pathogenic organisms (e.g., from a patient colonized or infected with MRSA, VRE, or *Clostridium difficile*) and can harbor viable organisms for several days. Contaminated surfaces, such as blood pressure cuffs, nursing uniforms, faucets, and computer keyboards,[59, 60] can serve as reservoirs of health care pathogens and vectors for cross-contamination to patients. Studies have demonstrated that health care workers acquire microorganisms on gloved hands without performing direct patient contact and when touching surfaces near a colonized patient.[59, 61] Another study determined that a health care worker's hand became contaminated after entering a regular patient's room (one who was not on contact precautions) and only touching common surfaces close to the patient (bed rails, bedside table), without direct patient contact. The same hand contact was done by other personnel in unoccupied rooms that had been terminally cleaned after patient discharge. Ungloved hands became contaminated with low levels of pathogenic microorganisms more than 50 percent of the time, even from surfaces in rooms that had been terminally cleaned after patient discharge.[62] It is important to consider this likelihood of hand contamination could occur (contamination would also apply to the external surface of gloves, if worn) and to perform routine hand hygiene to bare hands or ungloved hands to reduce hand contamination before touching clean**,** general-use surfaces (e.g., computer keyboard, telephone, med cart, medical record, cleaning supplies, etc.). Proper disinfection of common surfaces and proper hand hygiene procedures (after direct contact to surfaces or contact with glove usage) is also critically important to reduce direct or indirect routes of transmission.[63] Persistence of environmental contamination after room disinfection can occur and has been recently demonstrated to increase the risk of transmission to the next susceptible room occupants.[64–66]

Thus, patients with known colonization or diseases with multi-drug-resistant organisms or *Clostridium difficile* require Contact Precautions in addition to the Standard Precautions to reduce the risk of transmission from the patient and the contaminated environment to others.

Nurses can ensure clean medical equipment is used between patients and can work with environmental services personnel to maximize clean conditions in and around patient rooms. It is necessary to consistently perform hand hygiene after routine patient care or contact with environmental surfaces in the immediate vicinity of the patient. Infection control procedures are recommended to reduce cross-contamination under the following situations:[67]

1. Use EPA-registered chemical germicides for standard cleaning and disinfection of medical equipment that comes into contact with more than one patient.
2. If *Clostridium difficile* infection has been documented, use hypochlorite-based products for surface disinfection as no EPA-registered products are specific for inactivating the spore form of the organism.
3. Ensure compliance by housekeeping staff with cleaning and disinfection procedures, particularly high-touch surfaces in patient care areas (e.g., bed rails, carts, charts, bedside commodes, doorknobs, or faucet handles).
4. When contact precautions are indicated for patient care (e.g., MRSA, VRE, *C. difficile*, abscess, diarrheal disease), use disposable patient care items (e.g., blood pressure cuffs) wherever possible to minimize cross-contamination with multiple drug-resistant microorganisms.
5. Advise families, visitors, and patients regarding the importance of hand hygiene to minimize the spread of body substance contamination (e.g., respiratory secretions or fecal matter) to surfaces.

A patient safety goal could be to adopt a personal or an institutional pledge, similar to the following: I (or name of health care facility) am committed to ensuring that proper infection control and environmental disinfection procedures are performed to reduce cross-contamination and transmission so that a person admitted or visiting to this facility shall not become newly colonized or infected with a bacterium derived from another patient or health care worker's microbial flora.

Leadership

Health care workers dedicate enormous effort to providing care for complex medical needs of patients, to heal, to continuously follow science to improve the quality of care—all the while consciously performing to the best of their ability to *Primum non nocere* (First, do no harm). Though medical errors and adverse events do occur, many can be attributed to system problems that have impacted processes used by the health care worker, leading to an undesired outcome. Health care workers evaluate their professional impact based on outcomes that demonstrate that medical and nursing orders are completed properly, that a sentinel event did not occur, clinical judgment was properly utilized to improve patient care, and that most patients leave in stable or better health than when they arrived. With all the complicated patient care administered, if the patient did not acquire an infection during a hospitalization, is that an indication that all patient care interactions were practiced aseptically? Or could the lack of infection be attributed to some process interactions where the patient received a microbial exposure that was less than the threshold needed to acquire an infection or, fortuitously, the patient had enough natural immunity to ward off a potential infection? Although success is measured by an outcome with or without infection, we should consistently practice in such a manner to reduce patient exposure to exogenous microorganisms, which would consequently reduce the risk of infection.

Responsibility for risk reduction involves the institution administrators, directors, and individual practitioners. It is clear that leaders drive values, values drive behaviors, and

behaviors drive performance of an organization. The collective behaviors of an organization define its culture. The engagement of nursing leaders to collaborate with coworkers and hospital administrators in safety, teamwork, and communication strategies are critical requirements to improve safe and reliable care. Developed and applied concurrently, they weave a supporting framework for the effective implementation of new technologies and evidence-based practices.[68] If patients are not receiving all the evidence-based care that is indicated (regardless of a noninfectious outcome measure), then we have a professional obligation to demonstrate leadership to develop the methods to improve that care. The challenge is how to develop and sustain the change necessary to translate infection prevention knowledge into everyday clinical practice. As each person accepts his or her role in that responsibility, that leadership and role model example will influence a standard culture and expectation for all health care workers and support personnel to implement best practices.

Each institution must communicate the evidence-based practices to health care staff, have access to expertise about infection control practices, employ the necessary resources and incentives to implement change, and receive real-time feedback of national and comparative hospital-specific data.

> Health care institutions simply must expect more reliable performance of essential infection-control practices, such as hand hygiene and proper use of gloves. It is no longer acceptable for hospitals with substandard adherence to these basic interventions to excuse their performance as being no worse than the dismal results in published reports. Most institutions still tolerate defect or failure rates in hand hygiene of 40 percent or more—levels that would be considered shocking in any other industry[69] (p. 274).

Institution improvements should focus on process improvements that sustain best practices, using multifactorial approaches, and a commitment from the top administration through all levels of staff and employees to implement best practices.[70]

Proper Use of Personal Protective Equipment

Infection control practices to reduce HAI include the use of protective barriers (e.g., gloves, gowns, face mask, protective eyewear, face shield) to reduce occupational transmission of organisms from the patient to the health care worker and from the health care worker to the patient. Personal protective equipment (PPE) is used by health care workers to protect their skin and mucous membranes of the eyes, nose, and mouth from exposure to blood or other potentially infectious body fluids or materials and to avoid parenteral contact. The Occupational Safety and Health Administration's Bloodborne Pathogens Standard states that health care workers should receive education on the use of protective barriers to prevent occupational exposures, be able to identify work-related infection risks, and have access to PPE and vaccinations.[71]

Proper usage, wear, and removal of PPE are important to provide maximum protection to the health care worker. However, PPE may not be 100 percent protective, individual work practices may lead to exposure (e.g., needlestick injury), breaches in PPE might occur, and some breaches may go unrecognized. All PPE should be removed when leaving the patient care area.[25] Gloves prevent gross contamination of the hands when touching body fluids, reduce the likelihood that microorganisms present on the hands of personnel will be transmitted to patients during invasive or other patient care procedures, and reduce the likelihood that hands of personnel contaminated with microorganisms from a patient or a fomite can transmit these microorganisms to another

patient. Gloves may have small, unapparent defects or may be torn during use, and hands can become contaminated during removal of gloves,[72–75] thus hand hygiene is essential before donning another pair of gloves.

Various types of masks, goggles, and face shields are worn alone or in combination to provide barrier protection. A surgical mask protects a patient against microorganisms from the wearer and protects the health care worker from large-particle droplet spatter that may be created from a splash-generating procedure. When a mask becomes wet from exhaled moist air, the resistance to airflow through the mask increases. This causes more airflow to pass around edges of the mask. The mask should be changed between patients, and if at anytime the mask becomes wet, it should be changed as soon as possible. Gowns are worn to prevent contamination of clothing and to protect the skin of health care personnel from blood and body fluid exposures. Gowns specially treated to make them impermeable to liquids, leg coverings, boots, or shoe covers provide greater protection to the skin when splashes or large quantities of potentially infective material are present or anticipated. Gowns are also worn during the care of patients infected with epidemiologically important microorganisms to reduce the opportunity for transmission of pathogens from patients or items in their environment to other patients or environments. When gowns are worn, they must be removed before leaving the patient care area and hand hygiene must be performed.

Improper use and removal of PPE can have adverse health consequences to the health care worker. During the 2003 severe acute respiratory syndrome (SARS) outbreak in Canada, 44 percent of the probable SARS cases were in health care workers. After institutional implementation of SARS-specific infection control precautions, 17 workers developed disease. Fifteen were interviewed to determine their knowledge and work practices that could have contributed to their infection. Only 9 (60 percent) reported they had received formal infection control training; 13 (87 percent) were unsure of the proper order in which to don and remove PPE; 6 (40 percent) reused items (e.g., stethoscopes, goggles, and cleaning equipment) elsewhere on the ward after initial use in the room of a SARS patient; and 8 (54 percent) were personally aware of a breach in infection control precautions. Fatigue and multiple consecutive shifts may have contributed to the transmission.[76]

From the experiences observed during the SARS outbreak, CDC developed training materials to increase the safety of the health care worker environment through improved use of PPE by health care personnel. Posters (bilingual), slides, and video information are available on the CDC Web site: http://www.cdc.gov/ncidod/dhqp/ppe.html.

Consistent Evidence-Based Practices

Professional organizations for infection control and health care epidemiology publish evidence-based guidelines regarding the practice of health care infection control, strategies for surveillance and prevention, and control of HAIs in U.S. health care facilities. These consensus-based scientific publications provide priority recommendations on the basis of the existing scientific data; theoretical rationale; and applicability of well-designed experimental, clinical, or epidemiologic studies to prevent HAIs in different patient care settings. Additionally, the Joint Commission's initiative, Shared Visions—New Pathways 2004 accreditation process, focuses on continuous compliance with its standards, which contributes to health care organizations' maintenance of safe, quality care and improved organizational performance.[77]

Despite the high educational level of health care workers and knowledge of aseptic practices, adherence to published infection control precautions is not consistently applied.[78] In one study, a

self-reported questionnaire demonstrated that although all health care providers knew the appropriate protective barrier equipment required for a particular patient care interaction, their reasons for nonadherence included perceived time constraints (64 percent), inconvenience (52 percent), and presumption that the patient was not infected (34 percent).[79] The observed rate of compliance was inversely related to the years of health care experience.

Translation of evidence-based guidelines into clinical practice may require more than reliance on an individual practitioner's knowledge and intentions. Organizational interventions may be necessary to better understand the barriers that impede the process of effectively reviewing and implementing evidenced-based practices into daily clinical practice.[80–83] Standard policies and standards of practice should be time specific, measurable, and should also define the specific population of patients that will be affected. When the institution implements an evidence-based guideline that updates the current policy, a multidisciplinary intervention should be planned to ensure staff concurrence with the change; agreement that the new approach is crucial; an assurance that there will be adequate staff, knowledge, and resources to implement the change; and a method to evaluate the impact of the change.[84]

Antimicrobial-Resistance Campaign

"In theory, there is no difference between theory and practice. But in practice, there is."
Jan L. A. van de Snepshceut, computer scientist and educator

Background. After the first use of penicillin in the 1950s, antibiotic resistance developed rapidly in some bacteria such as *Staphylococcus aureus.* Over the last several decades, a shift in the etiology of more easily treated pathogens has increased toward more antimicrobial-resistant pathogens with fewer options for therapy. Infections from antimicrobial-resistant bacteria increase the cost of health care, cause higher morbidity and mortality, and lengthen hospital stays compared to infections from organisms susceptible to common, inexpensive antimicrobials. Antimicrobial resistance has continued to emerge as a significant hospital problem affecting patient outcomes by enhancing microbial virulence, causing a delay in the administration of effective antibiotic therapy, and limiting options for available therapeutic agents. In a 2003 Institute of Medicine report, antimicrobial resistance was noted as a paramount microbial threat of the 21st century.[85]

Burden of organisms. Rates of antimicrobial resistance among hospital and community pathogens have increased considerably during the past decade. More than 70 percent of the bacteria that cause hospital-associated infections are resistant to at least one of the drugs most commonly used to treat these infections.[86] According to 2003 National Nosocomial Infections Surveillance System data from ICU patients, 60 percent of *Staphylococcus aureus* isolates were resistant to methicillin, oxacillin, or nafcillin (MRSA)—an 11 percent increase from data reported the year before.[87] There was a nearly 50-percent increase in nonsusceptible *Klebsiella pneumoniae* isolates to 3rd generation cephalosporins between 2002 and 2003. Although the rate of vancomycin-resistant enterococcus (VRE) has shown a less drastic increase than previous years, it still increased 12 percent in 2003 (for a total of 28.5 percent of all enterococci isolates).

Another recent national survey of antimicrobial resistance trends and outbreak frequency was performed among U.S. hospitals (those hospitals having at least 50 beds, both general medical and surgical services, and accreditation by the Joint Commission) using the American Hospital Association annual survey data set.[88] A total of 494 of the 670 hospital laboratories (74 percent) responded. Antimicrobial resistance rates were highest for oxacillin-resistant *Staphylococcus*

aureus (ORSA, also referred to as MRSA) (36 percent); two-thirds of the hospitals reported increasing MRSA rates, 4 percent reported decreasing rates, and 24 percent reported MRSA outbreaks.

Mechanism of antibiotic resistance. The treatment of bacterial infections is not a straightforward process. Bacterial microorganisms are initially susceptible to a new antibiotic, but over time, as use of the antibiotic increases, new generations of the organism will selectively adapt by developing antibiotic resistance. These organisms have the ability to undergo protective spontaneous mutation within themselves or acquire an exogenous antibiotic-resistant gene through genetic transfer from another organism, which enables it to inactivate an antibiotic or nullify its killing activity. The human microbial population includes a combination of susceptible bacteria and antibiotic-resistant bacteria. Antimicrobial usage changes the competitive balance of the microbial population by decreasing the amount of susceptible bacteria, providing an opportunity for resistant bacteria to flourish. Areas within hospitals such as ICUs that have high rates of antimicrobial usage also have the highest rates of antimicrobial resistance.

Patients can acquire an antibiotic-resistant organism through other mechanisms. Increased antibiotic treatments received in community settings can lead to the presence or colonization of antimicrobial-resistant organisms in the community population, which can be introduced into the hospital by patients on admission. These colonized organisms may not be detected if the patient is admitted for noninfectious reasons. This underscores the need for routine hand hygiene after all patient care, not just after care to patients on Contact Precautions. Often, it becomes apparent that silent transmission has occurred when the newly discovered presence of a resistant organism can be traced back to another patient who is later found to have been infected or colonized with the resistant organism. More frequently, however, the exact source of resistant organisms or the source of transmission within the institution remains undetermined.

Prevention of antibiotic-resistant organisms. Authors of evidence-based guidelines on the increasing occurrence of multidrug-resistant organisms propose these interventions: stewardship of antimicrobial use, an active system of surveillance for patients with antimicrobial-resistant organisms, and an efficient infection control program to minimize secondary spread of resistance.[89–91] Antimicrobial stewardship includes not only limiting the use of inappropriate agents, but also selecting the appropriate antibiotic, dosage, and duration of therapy to achieve optimal efficacy in managing infections. A prospective study on hospital mortality due to inadequate antimicrobial treatment demonstrated that the infection-related mortality rate for patients receiving inadequate antimicrobial treatment (42 percent) was significantly greater than the infection-related mortality rate of patients receiving adequate antimicrobial treatment (17.7 percent) in a medical or surgical ICU setting.[92]

Earlier guideline recommendations by professional organizations were published between 1995 and 1997 for the prevention of antimicrobial resistance in hospitals.[93–95] To evaluate the application of the recommendations, a cross-sectional survey was performed to determine what types of antimicrobial-use programs were being used among 47 U.S. hospitals participating in the ICU component of the CDC's National Nosocomial Infections Surveillance System.[96] All 47 hospitals had some established programs, although their practices did not meet all of the published recommendations. For example, one programmatic practice was to consult with an infectious disease physician or pharmacist (used 60–70 percent of the time) to discuss initial antimicrobial options; however, only 40 percent reported a system to measure compliance with administering the recommended antimicrobial agent. The Cochrane Collaboration reviewed 66 published papers to develop "interventions to improve antibiotic prescribing practices for

hospital inpatients."[97] Interventions were aimed at varying outcomes (e.g., increase/decrease treatment, regimen, timing of dosing, restrictive or persuasive methods to reduce unnecessary antibiotic use). Studies showed that about half of the time, hospital physicians were not prescribing antibiotics properly. Nonetheless, most interventions demonstrated some improvement in antibiotic prescribing to reduce antimicrobial resistance or hospital-acquired infections. Hospital campaigns to prevent antimicrobial resistance include steps to (1) employ programs to prevent infections, (2) use strategies to diagnose and treat infections effectively, (3) operate and evaluate antimicrobial use guidelines (stop orders, restrictions, and criteria-based clinical practice guidelines), and (4) ensure infection control practices to reduce the likelihood of transmission.[98] Nurse practitioners have a role as part of the health care team diagnosing and treating infections appropriately and should be familiar with strategies to improve antimicrobial use. All health care workers play a critical role in reducing the risk of transmission.

Based on the factors contributing to antibiotic resistance in health care settings that were identified through data collection, guidelines, professional recommendations, and scientific research, the CDC compiled several tools in 2002 to increase awareness in health care settings. The Campaign to Prevent Antimicrobial Resistance in health care settings utilizes four strategies to increase awareness and encourage the best practices for antibiotic use and interventional programs to prevent resistance: prevent infection, diagnose and treat infection effectively, use antimicrobials wisely, and prevent transmission. Laminated cards, posters, slide sets, and fact sheets that can be used in a health care setting to promote recognition and utilization are listed at http://www.cdc.gov/drugresistance/healthcare/default.htm. A summary of the CDC's 12-step program and specific nursing interventions is provided in Appendix 2.

Summary of key concepts. A program that only scrutinizes and monitors antimicrobial use will not be effective to reduce antimicrobial resistance; it must also implement proper infection control measures and have laboratory, surveillance, and administrative support. The optimal strategy for control of antibiotic-resistant organisms is not the same for every health care facility as this individually depends on the levels of endemic colonization, presence of one or more resistant organisms, and levels of infection (low or outbreak levels). The ICP and hospital epidemiologist at each facility are valuable resources to provide programmatic education and recommend targeted infection control measures (e.g., use of personal protective barriers, hand hygiene resources, patient placement/segregation, and admission surveillance cultures). Similar to the example of antibiotic consultation practices and outcome measures, this plan will have little effect or opportunity to reduce the morbidity and mortality of infectious complications unless there is committed organizational support, including expert recommendations that are adopted into daily practice routines. Nursing personnel have the most patient contact and the most opportunity to interrupt the chain of transmission through adherence to consistent aseptic practices.

Respiratory Hygiene and Cough Etiquette

Respiratory viruses are easily disseminated in a closed setting such as a health care facility and can cause outbreaks that contribute to the morbidity of patients and health care staff. Personnel and patients with a respiratory illness commonly transmit viruses through droplet spread. Droplets are spread into the air during sneezing, talking, and coughing and can settle on surfaces. Transmission occurs by direct contact with mucous membranes or by touching a contaminated surface and self-inoculating mucous membranes. Respiratory viruses can sometimes have aerosol dissemination.

Precautions to prevent the transmission of all respiratory illnesses, including influenza, have been developed.[99] The following infection control measures should be implemented at the first point of contact with a symptomatic or potentially infected person. Occupational health policies should be in place to guide management of symptomatic health care workers.

1. Post visual alerts (in appropriate languages) at the entrance to outpatient facilities instructing patients and escorts (e.g., family, friends) to notify health care personnel of symptoms of a respiratory infection when they first register for care.
2. Patients and health care staff should consistently practice the following:
   a. Cover the nose/mouth when coughing or sneezing.
   b. Use tissues to contain respiratory secretions and dispose of them in the nearest waste receptacle after use.
   c. Perform hand hygiene after having contact with respiratory secretions and contaminated objects or materials.
3. During periods of increased respiratory infection activity in the community or year-round, offer masks to persons who are coughing. Either procedure masks (i.e., with ear loops) or surgical masks (i.e., with ties) may be used to contain respiratory secretions. Encourage coughing persons to sit at least 3 feet away from others in common waiting areas.
4. Health care personnel should wear a surgical or procedure mask for close contact (and gloves as needed) when examining a patient with symptoms of a respiratory infection. Maintain precautions unless it is determined that the cause of symptoms is not an infectious agent (e.g., allergies).

Evaluation

The ICP or a nurse on a specific patient care unit should design a periodic evaluation program of infection control practices, including aseptic technique practices. Evaluation methods include a self-assessment survey of intended practices, direct observational assessments by another health care worker or a patient, and self-completion of checklists that review work practices and identify opportunities for improvement within the health care operations. If deficiencies or problems in the implementation of standardized infection control procedures are identified, further evaluation activities (e.g., root-cause analysis) may be indicated to identify and rectify the contributing factors to the problem.[100]

Most evaluation reviews are generated after a major, life-threatening error occurs, which usually happens infrequently. Historically, when an evaluation determined that a process completed by personnel was deficient, problem-solving efforts focused on the identification of the specific individual(s) who “caused” the problem. Later, quality improvement efforts focused on developing a culture of safety and recognized that additional contributions to errors were due to complex, poorly designed systems. The advantage of an evaluation that reviews system problems is that it encourages health care professionals to report adverse events and near misses that might be preventable in the future, while balancing the identification of system problems with holding individual providers responsible for their everyday practices. Improvement is impossible without evaluation reports to provide data on the factors that contribute to mistakes and lead to subsequent individual and system changes that support safer practices.[101]

An evaluation strategy examining process measures include the following examples:

- Document staff use of maximum sterile barriers (cap, mask, sterile gown, sterile gloves, large sterile sheet) and aseptic technique for the insertion of central intravenous catheters or guidewire exchange.
- Document timing of antibiotic prophylaxis when used in surgical patients (e.g., within 1 hour of incision).
- Document if hand hygiene is performed and clean or sterile gloves are worn before assessing a catheter insertion site or changing a dressing on intravascular catheters.
- Document time elapsed from when patient culture (microbiology and susceptibility) results are reported and when the appropriate isolation precautions are instituted (patient room placement, signs, PPE used, disposable equipment used, medical record documentation, etc.).
- Ensure that staff (nurses, doctors, and housekeeping) enter a contact isolation room using the specified personal protective barriers (e.g., gloves, gown) on each entry.
- Ensure that staff properly remove PPE after leaving a patient's room.
- Assess the annual rates of influenza vaccination for health care workers and other personnel eligible to receive vaccination; assess the rates of influenza vaccination for patients.
- Ensure that needle disposal containers are no more than three-quarters full at time of disposal.
- Periodically monitor and record adherence with the hand hygiene guidelines: the number of times personnel washed their hands divided by the number of hand-hygiene opportunities, computed by ward or by service. Provide feedback to personnel regarding their performance.
- Monitor the volume of alcohol-based hand rub (or detergent used for handwashing or hand antisepsis) used per 1,000 patient days.
- When outbreaks of infection occur, assess the adequacy of health care worker hand hygiene.
- When a patient with a known colonization or infection with a multidrug-resistant organism (e.g., MRSA, VRE) is transferred to your facility, evaluate effectiveness of system notification to health care personnel in the receiving facility.
- Record compliance with hospital policy for catheter-site dressing changes.

Research Implications[*]

1. Research and apply behavioral and management sciences to achieve implementation of evidence-based clinical guidelines and compliance with infection prevention policies.
2. Develop methods to improve the appropriateness of antimicrobial use based on identified antimicrobial control measures and institution microbial susceptibility patterns.
3. Collect data for the economic impact of HAIs and other adverse effects and resulting return of investment for prevention methods.
4. Identify specific components of infection prevention and control programs and staffing in health care institutions that are effective (and cost effective) in reducing rates of infection.

[*] Adapted from Lynch et al. 2001[104] and Aboelela et al. 2006.[105]

5. Improve health care institution information systems for seamless review of appropriateness of infection control-related care based on patient diagnosis.
6. Determine standard indices for measurement of effectiveness and cost of infection control measures.
7. Measure effect of staffing changes (reduced personnel, prolonged work hours, varying levels of formal education) on patient outcomes related to infectious outcomes of morbidity and mortality (e.g., colonization of microorganisms, postoperative wound infections, and catheter-related infections).
8. Design studies so that independent effects of specific interventions can be identified.
9. Monitor the implementation of interventions in a multicenter study to examine a cause-and-effect response and differentiate between efficacy and effectiveness.
10. Develop interdisciplinary research teams to improve the rigor and sophistication of studies conducted.

Conclusions

It is the responsibility of all health care providers to enact principles of care to prevent health care–associated infections, though not all infections can be prevented. Certain patient risk factors such as advanced age, underlying disease and severity of illness, and sometimes the immune status are not modifiable and directly contribute to a patient's risk of infection. Depending on the patient's susceptibility, a patient can develop an infection due to the emergence of their own endogenous organisms or by cross-contamination in the health care setting. Benefits of antimicrobial therapy will alter the microbial flora by reducing one microbial presence but may allow the emergence of another, causing a new infection (e.g., antibiotic-associated diarrhea).

Nurses can reduce the risk for infection and colonization using evidence-based aseptic work practices that diminish the entry of endogenous or exogenous organisms via invasive medical devices. Proper use of personal protective barriers and proper hand hygiene is paramount to reducing the risk of exogenous transmission to a susceptible patient. For example, microorganisms have been found in the environment surrounding a patient and on portable medical equipment used in the room. Environmental surfaces around a patient infected or colonized with a multidrug-resistant organism can also become contaminated. Health care workers should be aware that they can pick up environmental contamination of microorganisms on hands or gloves, even without performing direct patient care. Proper use and removal of PPE followed by hand hygiene will reduce the transient microbial load that can be transmitted to self or to others. Identified aseptic and infection control practices have been proven to reduce the dissemination of organisms to a single patient, to prevent repeated transmissions that contribute to an outbreak situation among multiple patients, or to become established in the health care environment as endemic hospital flora.

Nursing has many complicated scopes of practice, which challenge time management, priority setting, and efficiency of practice. Although system and administrative support is beneficial to supporting aspects of nursing care, direct care is performed by individuals. Every individual nurse focuses on making a difference throughout the daily workloads and enormous responsibilities but changes in a patient's medical condition can become overwhelming. One nurse comes to mind who found the resolve to make significant strides within the patient ward dealing with chronically overwhelming situations. She was administratively responsible for

directing and addressing the challenges of all patients' chronic wound infections, ongoing cross-contamination, lack of needed medical supplies and equipment, severe understaffing, working extra shifts, and still finding time to provide care and comfort to patients. By her personal efforts to improve wound care, aseptic practices, and hand hygiene among all nursing and medical staff, mortality dropped in a dramatic decline from 33 percent to 2 percent within a 9-month period.[102] These sustained and dedicated efforts to reduce patient infections and improve patient care in light of overwhelming adversity set a standard of practice for all nurses to follow. That nurse was Florence Nightingale, defining the art of nursing in the 1850s. Although medical care is more advanced and technically more complex since that time, it was the dedication of a nurse (like you) to ensure aseptic practices despite the significant nursing demands of patient care that makes the difference for the patients—then and now.

National surveys of the public have repeatedly found nursing to be one of the most trusted professions. The public trusts us to provide safe care and employ best practices by following certain principles: (1) to not work while having an infectious illness, (2) to be knowledgeable about the methods to protect our patients from transmission of disease, (3) to perform aseptic practice and monitor patient infections, (4) to participate in quality improvement initiatives to reduce infections, and (5) to provide care even if it means self-risk from infection. As nurses we have an ethical obligation to meet that trust and uphold the highest standards for our patients and the public, whether we are providing direct care, teaching about proper health care, or overseeing nursing practice.[103]

It has been demonstrated that nursing and medical practices can pick up transient microorganisms from intact patient skin and from environmental surfaces. Although the amount of contamination is not quantified and the exact incidence is not apparent, it does occur. Hand hygiene and aseptic practices before caring for a susceptible patient can reduce the transient carriage and transfer of microorganisms. The protective benefits of infection control using evidence-based practices are cost effective and numerous: they not only contribute to the best individual patient care outcome, but also protect health care workers, increase public awareness in all health care settings about infection control issues, and maintain the highest standards in nursing, which positively contributes to our goal for the best possible patient and public health outcomes.

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Appendix 1. Resources

Federal Agencies

Agency for Healthcare Research and Quality
Measuring health care quality, outcomes, and effectiveness, etc.
http://www.ahrq.gov/

Centers for Disease Control and Prevention: CDC for Healthcare Providers
Health care infections, hepatitis, antimicrobial resistance, health care worker protection. Slide presentations. Fact sheets. http://www.cdc.gov/CDCForYou/healthcare_providers.html

Guidelines http://www.cdc.gov/ncidod/dhqp

Prevention of Catheter-Associated Urinary Tract Infections, 1981
Environmental Infection Control in Healthcare Facilities, 2003
Hand Hygiene in Healthcare Settings, 2002
Preventing Healthcare-Associated Pneumonia, 2003
Guidelines for Infection Control in Health Care Personnel, 1998
Infection Prevention and Control in the Long-Term Care Facility, 1997
Guideline for Isolation Precautions in Hospitals, 1996
Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2002
Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006
Guideline for Prevention of Surgical-Site Infection, 1999
Public Health Service Guidelines on the Management of Exposure to HBV, HCV, and HIV with PEP Recommendations, 2001
Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post-Exposure Prophylaxis, 2005
Guidelines for Preventing the Transmission of M. *tuberculosis* in Health Care Settings, 2005

Food and Drug Administration
Information for Health Professionals (Medical Devices, Drugs, etc.)
http://www.fda.gov/oc/oha/default.htm

U.S. Department of Health and Human Services
Pandemic Flu.
http://pandemicflu.gov/

National Institutes of Health: National Institute of Allergy and Infectious Diseases
Health, science, research, research funding, news.
http://www3.niaid.nih.gov/

Occupational Safety and Health Administration
Hospital eTool (health care hazards, infection, housekeeping, nursing homes)
http://www.osha.gov/SLTC/etools/hospital/hazards/infection/infection.html

Professional Organizations

American Nurses Association
Center for Occupational and Environmental Health
Occupational health, RNno harm, influenza posters, safe needles.
http://www.nursingworld.org/MainMenuCategories/OccupationalandEnvironmental.aspx

Association for Professionals in Infection Control and Epidemiology
Educational brochures, assorted topics; Protect Our Patients Campaign.
http://www.apic.org/Content/NavigationMenu/Education/EducationResources/Educational_Brochur.htm
Community-associated MRSA references.
http://www.apic.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentFileID=5801

Joint Commission (Joint Commission on Accreditation of Healthcare Organizations)
Infection control initiatives, standards.
http://www.jointcommission.org/PatientSafety/InfectionControl/

National Quality Forum
Health care quality and reporting.
http://www.qualityforum.org/

Society for Healthcare Epidemiology of America (SHEA)

Guidelines, outbreak resources, drug-resistant organisms.
http://www.shea-online.org/index.cfm

Journals, Articles

MedlinePlus Infection Control (National Library of Medicine)
http://www.nlm.nih.gov/medlineplus/infectioncontrol.html

Infection Control and Hospital Epidemiology online journal (SHEA)
http://www.journals.uchicago.edu/ICHE/home.html

American Journal of Infection Control online journal (APIC)
http://www.apic.org/Content/NavigationMenu/Publications/AJIC/AJIC.htm

Hand Hygiene Resources

Centers for Disease Control and Prevention
Posters, brochures, media kit.
http://www.cdc.gov/handhygiene/default.htm

Institute for Healthcare Improvement
Improving Hand Hygiene. A Guide for Improving Practices among Healthcare Workers.
http://www.ihi.org/IHI/Topics/CriticalCare/IntensiveCare/Tools/HowtoGuideImprovingHandHygiene.htm

World Health Organization
Guidelines on Hand Hygiene in Healthcare. Advanced draft available.
http://www.who.int/patientsafety/information_centre/documents/en/index.html

U.S. Department of Veterans Affairs
Infection—Don't Pass It On (posters, stickers, buttons).
http://www.publichealth.va.gov/InfectionDontPassItOn/Default.htm

Appendix 2. Campaign To Prevent Antimicrobial Resistance in Health Care Settings

Centers for Disease Control and Prevention

Adapted from information on http://www.cdc.gov/drugresistance/healthcare/default.htm

Strategy	Steps	Related Fact	Nursing Actions
Prevent Infection	1. Influenza and Pneumococcal vaccinations	Predischarge immunizations of at-risk hospital patients and health care personnel will prevent infections.	♦ Give influenza and *pneumococcal* vaccine to at-risk patients before discharge. ♦ Receive annual influenza vaccinations.
	2. Get the catheter out	Catheters and other invasive devices are the # 1 exogenous cause of hospital-onset infections.	Use catheters— ♦ Only when essential. ♦ With proper insertion and care protocols. ♦ Only as long as needed.
Diagnose and Treat Infection Appropriately	3. Target the pathogen	Appropriate therapy (correct regimen, timing, dosage, route, and duration) saves lives.	♦ Culture the patient. ♦ Verify empiric therapy is to a likely pathogen and definitive therapy is treating a known pathogen.
	4. Access the experts	Infectious disease expert collaboration improves the outcome of serious infections.	Incorporate guidance from infectious disease experts into daily care plan. All full-time, part-time, and contract staff should know and utilize recommendations.
Use Antimicrobials Wisely	5. Practice antimicrobial control	Programs to improve antibiotic use are effective.	Know your pharmacy policies on ordering, restrictions, switching, and stopping. Utilize or develop online ordering with computerized decision support/rationale.
	6. Use local data	The prevalence of resistance can vary by time, locale, patient population, hospital unit, and length of stay.	Know the common organisms in your clinical area and the effective antibiotics used to treat each infection.
	7. Treat infection, not contamination	A major cause of antimicrobial overuse is “treatment” based on results of patient cultures that become contaminated.	Utilize proper protocols to collect patient blood and other specimens for culture. Submit to laboratory in proper medium/collection containers and within the recommended time.
	8. Treat infection, not colonization	A major cause of antimicrobial overuse is “treatment” based on colonization.	Be familiar with practice guidelines for clinical assessments of new symptoms (i.e., fever) in critically ill patients and when cultures are warranted.
	9. Know when to say “no” to vanco	Vancomycin overuse promotes emergence, selection, and spread of resistant pathogens.	Be familiar with hospital policy on proper vancomycin utilization and when it should be discouraged (e.g., routine surgical prophylaxis and the exceptions, etc.).

Strategy	Steps	Related Fact	Nursing Actions
	10. Stop antimicrobial treatment	Failure to stop unnecessary antimicrobial treatment contributes to overuse and resistance.	Be aware of the patient's infection status and need for an antibiotic. Stop or don't use antibiotics when ♦ The infection is cured; ♦ Cultures are negative and infection is unlikely; and ♦ Infection is not diagnosed.
Prevent Transmission	11. Isolate the pathogen	Patient-to-patient spread of microorganisms can be prevented.	Practice strict aseptic technique to prevent transmission of organisms. Strict oversight of proper contact precautions when used and proper room disinfection.
	12. Break the chain of contagion	Health care personnel can spread antimicrobial-resistant pathogens from patient to patient.	Clean hands can pick up and transfer microorganisms. Hand hygiene is essential—set an example for others.

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Investigation of two cases of *Mycobacterium chelonae* infection in haemato-oncology patients using whole-genome sequencing and a potential link to the hospital water supply

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SUMMARY

Background: Haemato-oncology patients are at increased risk of infection from atypical mycobacteria such as *Mycobacterium chelonae* which are commonly found in both domestic and hospital water systems.
Aims: To describe the investigation and control measures following two patient cases of *M. chelonae* and positive water samples in the study hospital.
Methods: Water testing was undertaken from outlets, storage tanks and mains supply. Whole-genome sequencing (WGS) was used to compare patient and positive water samples. The subsequent infection control measures implemented are described.
Findings: The WGS results showed two main populations of *M. chelonae* within the group of sampled isolates. The results showed that the patient strains were unrelated to each other, but that the isolate from one patient was closely related to environmental samples from water outlets, supporting nosocomial acquisition.
Conclusions: WGS was used to investigate two patient cases of *M. chelonae* and positive water samples from a hospital water supply. Relevant control measures and the potential for chemical dosing of water systems to enhance proliferation of atypical mycobacteria are discussed.

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Introduction

Mycobacterium chelonae is an environmental opportunistic mycobacterium found in hospital water systems and household plumbing [1]. It belongs to the non-tuberculous (atypical) group of mycobacteria (NTM) and is classified as a rapid grower [2]. Clinically, it can cause cutaneous lesions, bacteraemia, and invasive infections of bone and lung.

This study used whole-genome sequencing (WGS) to analyse *M. chelonae* isolates from patients and hospital water samples

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following investigation of *M. chelonae* infection in two paediatric haemato-oncology patients over a 12-month period. One patient presented with a bacteraemia and the other presented with skin lesions in proximity to a Hickman line site. Both children are now in remission from the original disease, and do not require treatment for infection. Analysis of data for the preceding 10 years for all Glasgow hospitals revealed four other cases of *M. chelonae* bacteraemias in haemato-oncology patients (one in each of 2011, 2013, 2016 and 2018). Three of these cases were from a different city hospital campus.

Methods

Water testing

In response to a second case of *M. chelonae* infection in a 12-month period, water testing of outlets (pre- and post-flush) was undertaken in wards and departments where patients had been nursed. Water was also taken from basement storage tanks and the incoming mains supply. One hundred millilitres of water was filtered on to Middlebrooks agar and incubated aerobically at 35°C for 42 days. Plates were examined weekly for evidence of bacterial growth. If bacteria were present, smear microscopy using pre- and post-flush staining was performed. Acid-fast bacilli smear-positive samples were sent to the Scottish Mycobacteria Reference Laboratory for identification. Clinical and water isolates were identified using GenoType Mycobacteria CM v2.0 (Hain Lifescience, Nehren, Germany) after Genolyse extraction, in accordance with the manufacturer's instructions.

Whole-genome sequencing of patient and environmental isolates

There is no recognized molecular typing scheme available for *M. chelonae* to assess genetic relatedness. The mutation rate for *M. chelonae* is unknown, and published literature on the utility of WGS for investigation of *M. chelonae* is difficult to find, so this investigation was performed on a research basis alone.

Briefly, genomic DNA was extracted from heat-inactivated mycobacteria using a modified QIAamp DNA Mini Kit (Qiagen, Hilden, Germany) protocol using silica glass beads (adapted from Köser et al., 2013) [3]. Following Nextera XT DNA library preparation (Illumina, Cambridge, UK), paired-end sequencing was performed using 500 v2 Illumina MiSeq kits producing 2 x 250-bp reads.

Reference-based mapping was used to determine the genetic relationship between different strains based on single-nucleotide polymorphism (SNP) analysis. To identify SNPs, sequence reads were aligned to a reference genome of *M. chelonae* CCUG47445 (accession number CP007220) [4] using SMALT (http://www.sanger.ac.uk/science/tools/smalt-0). The default mapping parameters and SNP filtering were as described previously [5]. Recombination was detected in the genomes using Gubbins (http://sanger-pathogens.github.io/gubbins/) [6]. The Gubbins results were used to filter out the SNPs predicted to be associated with recombination and identify core-genome SNPs. Phylogenetic reconstruction using core SNPs was performed using RAxML Version 8.2.8 [7], using a GTR model with a gamma correction for intra-site rate variation.

To look more closely at the genetic relationship between each of the clades, reads were mapped to a de-novo genomic assembly of a representative of each clade (i.e. a more similar sequence than *M. chelonae* CCUG47445). Fastq files from MiSeq sequencing were assembled *de novo* with Velvet [8]. This has been done in WGS investigations of other mycobacteria to increase the number of successfully mapped reads, thus improving the accuracy of mapping [9].

Results

In total, 147 unfiltered water samples from outlets (taps and showers) in two paediatric haemato-oncology inpatient wards and an operating theatre complex were tested between 16th April 2019 and 24th June 2019. Atypical mycobacteria, subsequently identified as *M. chelonae*, were detected from all three areas. Sixty-eight of 147 (46%) water samples from outlets tested positive, with 34 of 68 (50%) having counts >100 colony-forming units/mL. An additional five samples were taken from water storage tanks (post-filtration) and all were negative. Three mains samples were taken by Scottish Water, and one of these tested positive for *M. chelonae*. Multiple other Gram-negative isolates (predominantly *Cupriavidus pauculus*) and fungi were also isolated from water, as described previously [10]. WGS was undertaken on 31 isolates.

The WGS results showed that there were two clonal populations within the group (Clades 1 and 2; Figure 1). The pairwise core-genome SNP distance distinguishing the two clades was ~20,000 SNPs, illustrating that they do not share a recent common ancestor and are genetically distinct. Isolates within each clade appeared to be closely related (<100 SNPs; SNP differences distinguish the isolates in each clade), which suggests that each population had separate recent common ancestors. The isolate from Patient 1 was genetically diverse from the isolates in Clade 1 and Clade 2, and was therefore considered unrelated. The SNP distance distinguishing Patient 1 from Clade 2, the genetically closest clade, was approximately 2000 SNPs. In Clade 1, the isolate from Patient 2 was firmly placed amongst the isolates sampled from the environment, although on a longer branch. The environmental isolates appear to be closely related (in terms of SNP differences), with some shown to be indistinguishable from each other. The maximum pairwise SNP distance distinguishing isolates in this clade was 19 SNPs. In addition, a number of environmental isolates (3854, 3123, 3856, 3800, 3846, 3862 and 3808) were closely related to Patient 2, as shown by SNP distances of six to eight SNPs on the tree (Figure 2). The positive water sample from the mains supply was in Clade 1, and was unrelated to patient isolates.

Discussion

M. chelonae was first discovered from the lung tissue of sea turtles by Friedmann in 1903 [11]. The organism is ubiquitous in the environment but is a rare cause of infection. Most commonly, it is associated with skin lesions, but immunosuppressed patients such as haemato-oncology patients may present with bacteraemias and disseminated infections. *M. chelonae* has been found in rivers, lakes, seawater, wastewater from

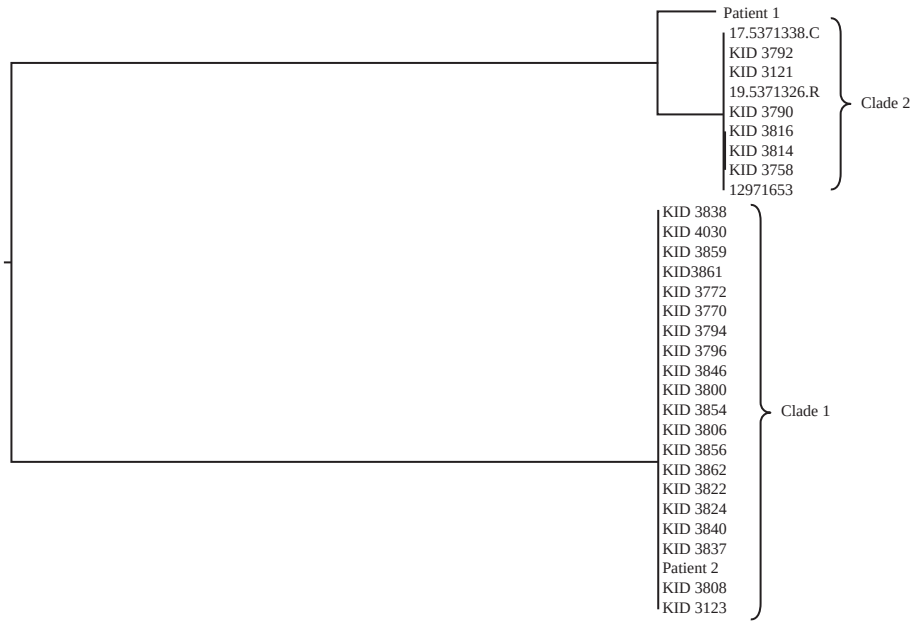

Figure 1. Diversity of the sampled *Mycobacterium chelonae* population. The maximum likelihood phylogenetic tree was built using core single-nucleotide polymorphisms (SNPs) with SNPs in regions of recombination removed. Sequence data were mapped to the *M. chelonae* CCUG47445 reference. The tree is midpoint rooted, and two clades were identified that are distinguished by less than 100 SNPs. The approximate SNP distance that distinguishes the two clades is approximately 38,000 SNPs.

hospitals, and drinking water samples [12]. Atypical mycobacteria in water systems are more resistant to chlorine, chlorine dioxide and chloramine than other organisms [13]. Warm water in premise plumbing is ideal for their proliferation, and there are extensive surfaces available for biofilm formation [13].

In some studies, water samples obtained from homes had lower rates of cultures yielding NTM than hospitals. Rates of atypical mycobacterial colonization of potable water systems ranged from 60% to 100% in hospitals, haemodialysis units and dental offices [14]. In one study in Berlin which tested two hospitals and four homes, mycobacteria were isolated predominantly from hospitals. Over 50% of samples from both hospitals contained mycobacteria, compared with only 9% from a home environment [15]. *M. gordonae* was the most common atypical mycobacterium isolated, and *M. chelonae* was also found.

With regards to virulence factors, *M. chelonae* and other NTM have a lipid-rich outer membrane which aids survival in the environment [16]. This membrane also protects against the effects of high temperature and disinfectants. NTM demonstrate surface hydrophobicity, enabling attachment to surfaces where they will grow in biofilm. The surface hydrophobicity also means that they are readily aerosolized, which is one of the routes of transmission to patients [16]. Direct contact with contaminated water can also lead to infection.

Few nosocomial outbreaks of *M. chelonae* have been reported. The first reported outbreak of nosocomial infection with an identified source was in patients undergoing liposuction in the USA [17]. Twelve patients were infected, and the organism was traced to plumbing in the procedure room. Multiple sources of contamination were identified, involving rinsing of instrumentation in tap water and inadequate disinfection/sterilization processes [17]. In another large outbreak involving 35 patients with laparoscopy port site infections, the source of *M. chelonae* was traced to water stored for rinsing instruments [18]. The organism was found in biofilm in the base of disinfectant trays and in the outer sleeves of re-usable instruments. No further cases were detected following dismantling and manual cleaning of laparoscopic equipment followed by ethylene oxide gas sterilization [18]. A contaminated humidifier was implicated in four cases of *M. chelonae* eye infections in patients who had undergone a LASIK (laser eye) procedure. Three of the four patient isolates were indistinguishable on pulsed-field gel electrophoresis from the humidifier isolate, with the fourth isolate being closely related. No further cases were detected after disposal of the humidifier and upgrading of the air-handling system [19].

In patients with cancer, atypical mycobacteria can cause exit-site infections, tunnel infections or catheter-related bacteraemias, some of which can lead to disseminated infection [20]. Outbreaks and isolated cases of atypical mycobacteria have been described in haemato-oncology patients with links to the hospital water. Five patients in one adult haemato-oncology ward developed bloodstream infection secondary to atypical mycobacteria, four cases with *M. mucogeniucm* and one with *M. canariasense*. Both of the organisms were identified in the water supply to the ward, and were identical to patient isolates on 16S-rRNA sequencing [21].

In another paediatric setting, a 20-year review of oncology patients in a US children's hospital, combined with a literature review of other reported cases, described 85 atypical mycobacteria infections in this patient group. Eighteen cases were disseminated infections and 42 cases were central-line-associated bloodstream infections (CLABSIs). Thirty-one percent of CLABSIs were associated with hospital outbreaks [22].

In a paediatric haemato-oncology ward, five patients developed *M. mucogenicum* bloodstream infection over a 6-

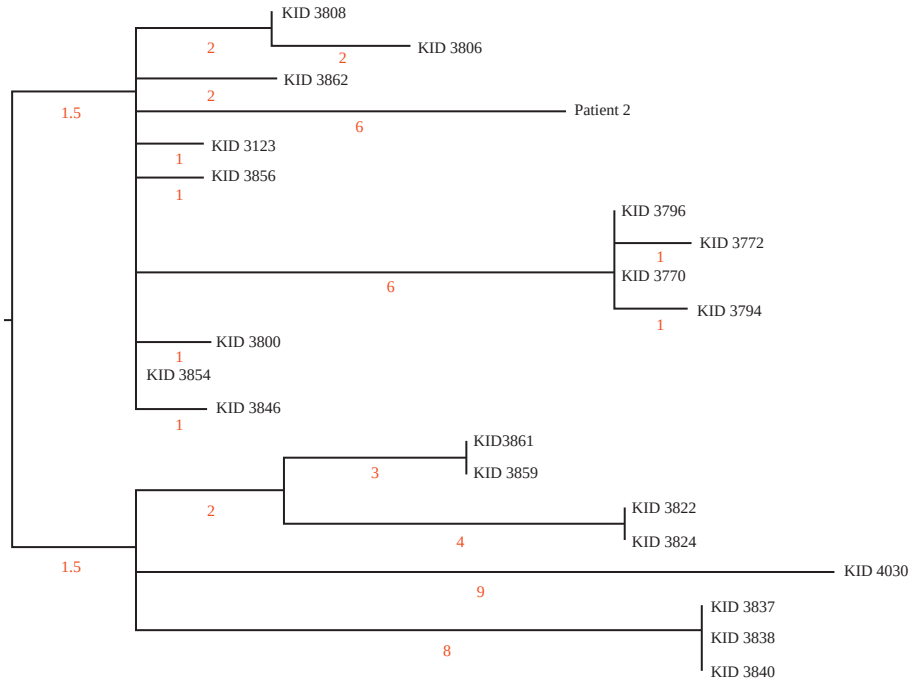

Figure 2. Diversity of Patient 2 and the environmental *Mycobacterium chelonae* population. The maximum likelihood phylogenetic tree was built using core single-nucleotide polymorphisms (SNPs). Sequence data were mapped to a de-novo assembly of Patient 2 isolate reference. The tree is midpoint rooted, and the SNP distances associated with the branch lengths are indicated in red text.

month period. Samples of water from taps indicated that they were the likely source, and this was confirmed by typing [2]. In this incident, levels of chlorine in the water were intermittently low and may have contributed to bacterial growth. A review of exit sites of central lines revealed that these were not covered properly during bathing, which may have facilitated colonization [2]. Similarly, following a cluster of atypical mycobacterial infections in haemato-oncology patients, no more cases were identified following the introduction of central venous catheter control measures, despite the bacteria continuing to be identified in the water system [23]. These control measures included new connectors and a line dressing which could remain *in situ*, covering the line site whilst patients showered [23]. A single case of disseminated *M. fortuitum* infection in a patient with leukaemia was investigated and linked to showerhead water in one hospital [24].

Increasingly, WGS has been used for investigation of mycobacterial relatedness, proving more discriminatory than MIRU-VNTR typing for *M. tuberculosis* [25], and allowing global comparisons of *M. abscessus* complex [26] and *M. chimaera* [27] in the investigation of possible mycobacterial transmission. In these studies, five, 20 and 13 SNP differences were associated with possible epidemiological linkages, respectively. Although well-defined reference strains in many NTM such as *M. chelonae* are lacking, the present study demonstrated a useful role that allows comparisons with isolates elsewhere.

Control measures for atypical mycobacteria in water systems include: increasing the water temperature to 55°C; application of point-of-use filters (POUFs); replacement of showerheads to those with large holes; and monthly disinfection of showerheads. Aerators should also be removed from taps [16]. In the study hospital, POUFs were *in situ* on the haemato-oncology wards following a previous water incident, and these were subsequently extended to all areas that patients might visit in the hospital. A programme of regular disinfection of showerheads was also undertaken. Quarterly cleaning and disinfection of showerheads and hoses was undertaken via a service exchange procedure. Following removal, parts were dismantled and physically cleaned. They were then submerged in a solution of Showerhead Plus Legionella specific descaler and biocide for a minimum contact time of 2 min.

Showerheads, in particular, offer a moist, warm and nutrient-rich environment for atypical mycobacteria to proliferate and form biofilms [28]. In one study, biofilms from showerheads were highly contaminated with atypical mycobacteria, 100-fold above background water contents [20].

The study hospital is a new-build hospital which opened in 2015. It is not clear whether atypical mycobacteria were present prior to testing in 2019, or whether their presence and detection were enhanced by the introduction of a chlorine dioxide dosing system in late 2018 to control a widespread water contamination issue [10]. On completion of each stage of the installation, chemical treatment of the domestic cold-water system commenced at a level of 1.0 mg/L for 24—48 h. Once the residual level of chlorine dioxide reached 0.1 mg/L in each part of the system, microbiological monitoring commenced. Once the residual level reached 0.2 mg/L in each part of the system, the associated plant output was reduced in stages until the residual level was 0.4 mg/L and the plant output was between 0.5 and 0.7 mg/L as a final continual water treatment baseline value. The domestic hot-water system presented an additional challenge of chlorine dioxide when exposed to high temperature gasses off. Therefore, the treatment was set at 2—4mg/L centrally to achieve a residual level of 0.5—1.0mg/l at hot water outlets peripherally.

The WGS results show that there were two main populations of *M. chelonae* within the group of sampled isolates. The limited number of SNP differences observed within each population suggests that the diversification may have happened fairly recently, but it is not possible to confirm the time scale over which this has occurred without understanding the mutation rate of the organism and/or the time of sampling. These WGS results suggest that the isolate from one patient (Patient 2) was closely related to environmental isolates from water outlets. Epidemiologically this fitted, with the patient linked in time and place to these outlets. Whilst no link with Patient 1 was established, no contemporaneous water results were available from the time this patient developed infection, so a water source in the hospital cannot be excluded completely. Whilst there were POUFs on outlets in wards, there were none in the theatre anaesthetic rooms where patients underwent procedures such as line insertions. Therefore, there was a splash risk from the proximity of sinks. This highlights the importance of applying POUFs throughout the full patient pathway.

In conclusion, haemato-oncology patients are at increased risk of infection from atypical mycobacteria such as *M. chelonae*. Atypical mycobacteria are a common finding in hospital water systems, and a single case of atypical mycobacteria infection should prompt consideration of water as a source. Water systems which are being treated with disinfectants may be of particular risk as they remove competing organisms and enable atypical mycobacteria to proliferate. WGS is a promising adjunct for the investigation of outbreaks due to atypical mycobacteria.

Conflict of interest statement
None declared.

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The role of water in healthcare-associated infections

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Purpose of review
The aim is to discuss the epidemiology of infections that arise from contaminated water in healthcare settings, including Legionnaires' disease, other Gram-negative pathogens, nontuberculous mycobacteria, and fungi.

Recent findings
Legionella can colonize a hospital water system and infect patients despite use of preventive disinfectants. Evidence-based measures are available for secondary prevention. Vulnerable patients can develop healthcare-associated infections with waterborne organisms that are transmitted by colonization of plumbing systems, including sinks and their fixtures. Room humidifiers and decorative fountains have been implicated in serious outbreaks, and pose unwarranted risks in healthcare settings.

Summary
Design of hospital plumbing must be purposeful and thoughtful to avoid the features that foster growth and dissemination of *Legionella* and other pathogens. Exposure of patients who have central venous catheters and other invasive devices to tap water poses a risk for infection with waterborne pathogens. Healthcare facilities must conduct aggressive clinical surveillance for Legionnaires' disease and other waterborne infections in order to detect and remediate an outbreak promptly. Hand hygiene is the most important measure to prevent transmission of other Gram-negative waterborne pathogens in the healthcare setting.

Keywords
biofilm, healthcare-associated infection, Legionnaires' disease

INTRODUCTION

The complexity of modern healthcare facilities and increasing proportion of immunologically vulnerable patients make prevention of healthcare-associated waterborne infections a high priority. Several factors make hospital buildings suitable for colonization with bacteria and molds: large, complex water systems with areas of low flow predispose to stagnation and biofilm formation; water temperatures that are optimal for healthcare use may also be ideal for bacterial growth. Whereas these conditions exist in other buildings, the fragility of hospitalized patients and the presence of invasive devices put them at risk for infection with organisms that grow in hospital water. This article reviews the recent epidemiology of waterborne, healthcare-associated infections in the developed world.

LEGIONELLA

Legionnaires' disease is an important infection acquired from hospital water, and the one for which detection of a single nosocomial case should prompt an immediate investigation. The disease is typically transmitted to patients through aerosols of water that arise from showers, ice machines, decorative fountains, humidifiers, and other water sources in hospitals. The first documented nosocomial outbreak occurred nearly a decade before the discovery of the disease and its microbial cause. When McDade *et al.* [1] identified a fastidious thin-walled bacteria, *Legionella pneumophila,* as the cause of pneumonia among 182 people attending the 1976 American Legion Convention, the antibody test developed during the investigation was applied to serum specimens from a hospital outbreak. The

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KEY POINTS

- Healthcare facilities must conduct careful clinical surveillance for legionellosis, including diagnostic testing specific for *Legionella* in all patients who develop nosocomial pneumonia.
- Hospitalized patients who are highly immunocompromised or have invasive devices are most susceptible to infections with waterborne pathogens that can evade the body's normal defenses.
- Devices that aerosolize water in the presence of patients, such as room humidifiers and decorative fountains, pose a risk of infection with waterborne pathogens and are not recommended for use in hospitals.

1965 outbreak at a Washington, D.C. psychiatric facility comprised 81 cases of pneumonia of unknown cause [2]. Testing demonstrated antibody responses to *Legionella* in 21 out of 23 patient sera [1]. This hospital outbreak of Legionnaires' disease thus became the first of many documented over the past 50 years.

The incidence of Legionnaires' disease in the United States nearly tripled from 2000 to 2009, with only 4% of cases associated with a known cluster [3▪▪]. More than 80% of cases are attributable to *L. pneumophila,* and a large majority of those belong to serogroup 1 [4,5]. The urine antigen assay, which detects only serogroup 1, was responsible for 97% of diagnoses, whereas culture was performed in only 5% of cases [3▪▪]. The challenges of culturing the organism make identification of other serogroups and other species uncommon. Pontiac fever is a self-limited hypersensitivity illness that occurs in immunocompetent hosts who are exposed to *Legionella*-containing aerosols, and who can have positive urine antigen assays, but do not develop pneumonia [6].

Many components of water systems have been implicated in *Legionella* transmission, including cooling towers, evaporative condensers, water heaters, and the potable water distribution system. When *L. pneumophila* is present in a hospital water system, the patients who acquire the infection generally have medical conditions that contribute to infection susceptibility [7–9], including organ or stem cell transplantation [10], chronic obstructive pulmonary disease [11], and immunosuppressive therapy [e.g. corticosteroids and tumor necrosis factor (TNF) inhibitors] [10–12]. Healthcare personnel are exposed and may seroconvert, but do not usually become ill [13]. Acquiring *Legionella* pneumonia in the hospital conveys an increased mortality risk; the case fatality rate for nosocomial infections in Spain was 31.7% compared to 6.8% for community-acquired disease [14].

L. pneumophila organisms are well suited to the waterworks of hospitals. They multiply between 25 and 42°C and thrive at 35°C, a frequently occurring temperature in manmade systems [4]. They thrive in the stagnant water, scale, or sediment that is found in the dead legs of complex plumbing systems. They flourish in biofilms when a column of water stagnates, as when a hospital fountain is turned off for repairs [9], or when material provides contaminated biofilms with protection from water currents and decontamination measures [15▪]. Point-of-use plumbing fixture selection may affect risk for colonization; at some hospitals, hands-free faucets have been shown to have higher *Legionella* contamination rates than manual faucets, and may be more likely to fail disinfection attempts [16–18]. Immunosuppressed patients may acquire the bacteria from hospital water sources via exposure to aerosols from bathing [8,19–21], steam-heated towels [22], decorative hospital fountains [9,15▪,23], and possibly aspiration of contaminated water [7], among others. Even the distilled water system can become colonized with *Legionella*, as documented in a Quebec City outbreak of *L. dumoffii* acquired via respiratory therapy equipment and a room humidifier [24].

Although pediatric legionellosis is very uncommon, neonates have developed *Legionella* pneumonia from delivery in a hospital birthing pool [25] and, more recently, use of a cool mist humidifier filled with contaminated water in a newborn nursery [26]. An additional challenge with pediatric disease is the treatment delay and poor outcome that may result if clinicians do not suspect the infection in this patient population [25,26].

In nature, *Legionella* grows in association with protozoa, including *Acanthamoeba* spp., *Hartmannella* spp., and *Naegleria* spp., all commonly found in fresh water. Some have suggested that culturing for free-living amoebae from a suspected water source may increase the sensitivity of *Legionella* detection [27].

Early initiation of therapy for Legionnaires' disease is associated with improved survival, but physicians must consider the diagnosis in order to pursue appropriate empiric therapy [28]. Aggressive pursuit of diagnosis in patients who develop hospital-acquired pneumonia is essential for instituting appropriate treatment and recognizing a nosocomial cluster. As part of their evaluation, patients should undergo *Legionella* urine antigen testing, and, if negative, *Legionella* culture and molecular

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testing from respiratory specimens to detect infection with nonserogroup 1 *L. pneumophila* and less common *Legionella* species [4].

Because preventing and remediating *Legionella* colonization are of utmost concern, guidelines for hospital construction prioritize *Legionella* risk reduction [29,30]. Some hospitals use systemic disinfection measures such as copper–silver ionization, chlorine dioxide, or monochloramine. These disinfection systems are reviewed thoroughly by Lin *et al.* [31▪▪] and Stout *et al.* [32]. Of note, monochloramine use in municipal water has been shown to reduce *Legionella* infection risk in hospitals [33,34].

Breakthrough *Legionella* has been reported with every modality of disinfection. A recent outbreak involving 21 patients and 5 attributable deaths at the Veterans Affairs Pittsburgh Healthcare System was notable in that 29 out of 44 water samples (66%) were positive for *Legionella* [23]. This proportion far exceeded the 30% threshold of 'heavy colonization' proposed by Yu and colleagues above which nosocomial cases of Legionnaires' disease occur more frequently [35,36]. Some water isolates matched the outbreak strain, despite appropriate copper and silver levels [23]. A filter and ozone generator failed to prevent contamination of a decorative wall fountain that caused infection in stem cell transplant recipients [9]. A larger outbreak stemmed from contamination of another hospital fountain despite the presence of a regularly maintained copper–silver ionizer [15▪].

When a water system is already contaminated with *Legionella*, options include super-heating and flushing the system with or without shock chlorination [20]. These methods have been effective in terminating existing outbreaks [19,31▪▪,32]. Preventing back-flow of heated water into the cool water system limits the possibility of producing ideal temperature conditions for *Legionella* growth [20,37]. Hospitals that utilize a systemic disinfection modality should monitor the intervention (e.g., ion levels) and consider periodic cultures to establish its effectiveness [31▪▪].

Hospitals providing care for immunocompromised patients must conduct close clinical surveillance for Legionnaires' disease among that patient population [10,38]. The US Centers for Disease control (CDC) recommends that facilities that have had a nosocomial outbreak of Legionnaires' disease conduct ongoing microbiologic surveillance to detect recontamination of their water supply [10,38]. The use of environmental surveillance for primary prevention, when there has been no outbreak, remains an area of controversy [36].

OTHER GRAM-NEGATIVE BACTERIA

Several clinically important Gram-negative bacterial species are well adapted to colonize the biofilms of water systems, and their presence has been associated with sporadic infection and outbreaks in hospitalized patients. Many genera are associated with transmission via hospital water, including *Pseudomonas, Stenotrophomonas*, *Acinetobacter*, *Sphingomonas*, *Burkholderia*, and *Achromobacter*. Most Gram-negative waterborne infections likely go unrecognized unless they occur in a cluster.

Pseudomonas species are commonly associated with biofilms in hospital water sources [39]. Therapy pools, tubs, and daily bathing in bed can be sources of transmission [38,40–42]. *Stenotrophomonas*, *Chryseomonas*, and other waterborne bacteria have caused outbreaks in neonates with intravenous lines or other invasive devices who were bathed in tap water [43,44]. In one neonatal ICU in Belgium, pseudomonal infection and colonization in four newborns was linked to the thawing of frozen blood products in a contaminated water bath [45]. In the presence of surgical incisions, invasive devices, or significant immune compromise, an exposure that would normally be deflected by the body's surface defenses may cause invasive infection. In order to reduce the risk of transmission from these sources, sinks and wash basins should be cleaned and disinfected regularly as part of routine hospital environmental cleaning [38]. There are not yet data to support use of chlorhexidine baths to reduce the risk of infection with waterborne bacteria.

Hand hygiene of healthcare personnel is the most important measure to prevent Gram-negative hospital-acquired infections [38]. Ironically, transmission in the setting of appropriate hand hygiene may occur when hands become contaminated during hand-washing in a sink with a contaminated aerator, faucet, or drain. This method of transmission has been reported in several outbreaks [16,18,46–55]. A hospital in Toronto recently identified hand-washing sinks as a key reservoir for nosocomial transmission of multidrug-resistant *Klebsiella oxytoca* following an outbreak among 66 patients [56]. Hota *et al.* [57] reported contamination of an ICU sink with an outbreak strain of multidrug-resistant *Pseudomonas*; fluorescein injection into sink drains demonstrated splash-back up to 1 m from the sink when the water was running [57]. Remediation of outbreaks due to sink contamination may require disassembly and replacement of plumbing components [56], redirection of the faucet water jet [57,58], replacement of the sink [48], or rearrangement of the surrounding space [57]. Hospital waste water can also lead to outbreaks when blockages and

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leaks occur, as occurred in one hospital due in part to a sharp-angled pipe junction; splash-back from shower drains and toilets may have caused contamination of patient materials placed nearby [59].

Patients can acquire waterborne bacteria from healthcare devices that contain liquid but with which they do not have direct contact. Contamination of the water used in hemodialysis equipment has frequently been reported as a cause of bloodstream infections in dialysis patients [60]. A blood gas analyzer with a contaminated water reservoir was linked to a prolonged ICU outbreak of *Burkholderia cepacia* [61]. Room humidifiers have been implicated in transmission of Gram-negative organisms, in some cases despite use of sterile water. Colonization occurs after about 5 days of continuous use, possibly from room particles and from hand contamination during filling [62]. Cool mist humidifiers, which are difficult to clean and disinfect properly, have caused outbreaks of Legionnaires' disease [24,26], *Pseudomonas*, *Acinetobacter* [63,64], and other Gram-negative organisms, with little actual rise in room humidity [63]. The evidence suggests a highly unfavorable risk–benefit ratio of room air humidifier use in hospitals.

MYCOBACTERIA

Nontuberculous mycobacteria (NTM) are hardy organisms that are present in municipal water, survive in hot water systems, and resist chlorination [65,66]. Plumbing features that encourage the growth of *Legionella* species, such as dead legs, stagnation, and warm water, also foster proliferation of NTM. Because the organisms occur frequently in hospital tap water [67–70], many true outbreaks and several pseudo-outbreaks with NTM have been reported. Hospital-associated outbreaks and sporadic cases have included central line infections, sternal wound infections, cosmetic surgery-associated soft tissue infections, and bloodstream infections related to dialysis [71–80]. Most reported outbreaks involved exposure of invasive devices or nonintact skin to tap water. Wallace *et al.* [80] reported eight outbreaks involving 71 patients with NTM infections after cardiac bypass surgery. Eighty per cent of isolates were from southern US coastal states, where NTM infections have the highest incidence [81]. Sources of transmission included tap water used to cool the cardioplegia solution and ice machines; in both cases, contamination was thought to originate from the municipal water supply [80]. A cluster of 34 patients who underwent liposuction developed *Mycobacteria chelonae* cutaneous abscesses. Patient isolates matched those of bacteria detected in water pipes in the physician's office, and the investigation suggested that surgical instruments rinsed in that water were inadequately disinfected [78]. Five hemodialysis patients developed *M. chelonae-abscessus* infections linked to high-flux dialysis machines in a single center, where a contaminated water spray was used for reprocessing dialyzers and the disinfectant solution had inadequate germicidal activity against mycobacteria [77]. Pseudo-outbreaks with NTM are typically due to tap water rinsing or contamination of diagnostic testing equipment. In one hospital, the bronchoalveolar lavages of nine patients over a month grew *M. chelonae* in the absence of typical symptoms; investigation revealed that the incoming water line of an automated bronchoscope cleaner was the source of this pseudo-outbreak [74].

PROTOZOA

Nosocomial transmission of intestinal protozoa has become uncommon in developed countries with sanitary hospital water supplies. Poor sanitation increases risk of waterborne infection, but some organisms are hardy enough to survive even in the presence of disinfection [82]. An unusual outbreak of *Cyclospora cayetanensis* was traced to a contaminated rooftop water supply and caused diarrheal illnesses among 17 medical residents and three staff members in a Chicago hospital [83]. After *Cryptosporidium parvum* caused a massive community outbreak in Milwaukee, Wisconsin, that disproportionately affected immunocompromised persons [84], water treatment regulations implemented in the wake of that outbreak have successfully prevented further municipal water-related outbreaks in the United States [85]. *Cryptosporidium* can be spread in hospitals to elderly or immunocompromised patients through contaminated food or water, although a number of reports implicate transmission via contact [86]. In one outbreak in Denmark, a patient who had HIV/AIDS and *Cryptosporidium* infection contaminated a hospital ice machine, leading to 19 infections [87].

FUNGI

Fungal contamination of water in the healthcare environment is considered a potential source of nosocomial infection. The presence of opportunistic molds such as *Aspergillus* and *Fusarium* has been reported in hospital water and plumbing fixtures [88–90]. Although airborne spores are thought to be the primary mode of nosocomial transmission, those spores may derive in part from water sources within the hospital [91]. Molecular typing has

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been used to link waterborne isolates with patient infections in a few cases. An investigation of fusariosis in a Texas hospital demonstrated *Fusarium* species in a majority of environmental samples; two water isolates matched patient isolates, suggesting nosocomial acquisition from water or a plumbing fixture [89]. *Phialemonium* bloodstream infections in dialysis patients were linked to reflux of contaminated fluid from a waste water line into the patient dialysis circuit during priming [92], a mechanism that has also been implicated in bacterial bloodstream infections and transmission of hepatitis C in this population [93,94]. Because the role of water contamination with molds in the epidemiology of patient infections remains unclear, current guidelines do not recommend reducing exposure of vulnerable patients to hospital water, but rather focusing on using best practices in structural and engineering controls to limit transmission to patients [29,38,95].

CONCLUSION

No single approach guarantees that hospital water will be safe for vulnerable patients, but a combination of engineering and hygiene measures and clinical strategies can minimize the risk. Engineering measures in the built environment include avoidance of features in plumbing systems that predispose to stagnation, maintenance of separate cold and hot water systems until near the point of use, and thoughtful construction of wastewater pipes to avoid blockages. Decorative fountains should not be placed inside healthcare facilities [9,29]. Careful planning should be given to sink design, avoiding high flow over drains, proximity to critical patient care areas, and possibly hands-free faucets. Hygiene measures include routine cleaning and disinfection of sinks and plumbing fixtures, proper disinfection of equipment that is rinsed in tap water, and, most importantly, healthcare personnel hand hygiene to prevent transmission of pathogens derived from moist sources to patients. Clinical strategies include aggressive surveillance for nosocomial waterborne infection, including testing patients who develop nosocomial pneumonia for *Legionella* species, and conducting prompt investigations if a single hospital-acquired case is suspected. Protection of central venous catheter sites from exposure to tap water, as recommended by current guidelines [96▪], may prevent some bathing-related outbreaks. Water disinfection systems can be implemented as a primary or secondary preventive measure, but even expensive, potent systems have been documented to fail. Most essentially, infection control specialists should be quick to respond to increases in rates of known and emerging waterborne pathogens.

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Conflicts of interest

There are no conflicts of interest.

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Papers of particular interest, published within the annual period of review, have been highlighted as:
- ▪ of special interest
- ▪▪ of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (pp. 392–393).

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This document provides evidence-based recommendations for preventing bloodstream infections in patients who have central venous catheters. Adherence to these guidelines would prevent many infections with waterborne organisms.

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Bed-days and costs associated with the inpatient burden of healthcare-associated infection in the UK

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SUMMARY

Background: Healthcare-associated infection (HAI) is associated with increased morbidity and mortality resulting in excess costs.
Aim: To investigate the impact of all types of HAI on the inpatient cost of HAI using different approaches.
Methods: The incidence, types of HAI, and excess length of stay were estimated using data collected as part of the Evaluation of Cost of Nosocomial Infection (ECONI) study. Scottish NHS reference costs were used to estimate unit costs for bed-days. Variable (cash) costs associated with infection prevention and control (IPC) measures and treatment were calculated for each HAI type and overall. The inpatient cost of HAI is presented in terms of bed-days lost, bed-day costs, and cash costs.
Findings: In Scotland 58,010 (95% confidence interval: 41,730–74,840) bed-days were estimated to be lost to HAI during 2018/19, costing £46.4 million (19m–129m). The total annual cost in the UK is estimated to be £774 million (328m–2,192m). Bloodstream infection and pneumonia were the most costly HAI types per case. Cash costs are a small proportion of the total cost of HAI, contributing 2.4% of total costs.
Conclusion: Reliable estimates of the cost burden of HAI management are important for assessing the cost-effectiveness of IPC programmes. This unique study presents robust economic data, demonstrating that HAI remains a burden to the UK NHS and bed-days capture the majority of inpatient costs. These findings can be used to

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inform the economic evaluation and decision analytic modelling of competing IPC programmes at local and national level.

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Introduction

Healthcare-associated infection (HAI) represents a major issue for health services, patients, and public authorities [1]. These potentially avoidable events are associated with increased morbidity and mortality, resulting in excess management costs [1—3]. The Evaluation of Cost of Nosocomial Infection (ECONI) study estimated HAI incidence of 0.76% (95% confidence interval (CI): 0.72—0.81) with 7437 (7021—7849) HAI cases in teaching and large general hospitals in NHS Scotland in 2018/19 [4].

Many studies have examined the costs associated with HAIs but comparisons among estimates can be challenging due to the differences between settings, patient groups, and methods of attributing costs [5]. Few studies have examined the whole-hospital incidence and all HAI types. The last study to do this for the UK by Plowman *et al.* found HAI to be a considerable burden, equivalent of 9.1% of the total 1994/5 inpatient acute, obstetric, and geriatric programme budget in England [6]. These cost estimates arose from methods that did not account for the time-varying nature of HAI and are likely to have been overestimated [7]. In the intervening period the UK and other countries established national infection prevention and control (IPC) programmes focused on HAI prevention [8,9]. Since the 1990s there have been significant changes in the age and frailty of the hospital population, complexity of treatments, use of invasive devices, antimicrobial resistance (AMR) and targeted IPC measures, all of which have affected the incidence and impact of HAI. Accurate and current information is needed to optimize decision-making when selecting between competing IPC programmes to ensure the most efficient programmes are implemented [10,11].

The aim of this study was to estimate the costs of different types of HAI in acute hospitals in NHS Scotland using a variety of approaches, and to extrapolate to the whole of the UK. One of the major costs of HAI can be shown by the number of bed-days released by its prevention. Released hospital beds can be valued in monetary terms by examining how much they historically cost the hospital to supply, the accounting cost. Bed-days include a high proportion of fixed costs and some variable costs [11]. When HAI cases are prevented, releasing bed-days, resources represented by fixed costs can be redeployed for other uses but not recovered, whereas variable costs can be recovered as cash savings. The cost of HAI is presented as natural units of bed-days lost due to HAI and bed-days valued using accounting costs. The accounting costs represent valuations of resources for alternative uses. The cash or variable costs related to the treatment of HAI in NHS hospitals are also calculated separately. The cash costs of treating HAI represent potential savings if HAI cases were prevented [11].

This study presents new information for healthcare decision-makers which can inform economic decision-making for competing IPC programmes locally and nationally.

Methods

To estimate the inpatient cost of HAI on the health service, the incidence rates and estimates of excess length of stay (LOS) derived from the ECONI study were combined [4,12]. ECONI was a two-centre, prospective observational incidence study with a nested case—control study [13]. ECONI took place in one teaching hospital and one large general hospital in NHS Scotland in 2018/2019. The cost of HAI to the NHS acute care sector was estimated by taking the following steps. First, the expected number of annual HAI cases was estimated. Second, the extra resources used to treat the average case were identified. Third, those resources used for the treatment of HAI were valued in monetary terms. The costs from the ECONI study were extrapolated to produce an estimate for the UK.

Expected annual HAI cases

The expected number and types of annual HAIs were estimated using data collected as part of the ECONI study [4]. ECONI reported the incidence of HAI using standard case definitions of the European Centre for Disease Prevention and Control [13]. Incidence rates of HAI per 100,000 acute occupied bed-days (AOBD) in the study hospitals were used to estimate HAI incidence in NHS Scotland. National estimates of HAIs were derived by applying the incidence within each specialty group to the total annual overnight admissions within NHS Scotland [4]. The nested case—control sample included ~5% of the HAI cases and was used to calculate the cash cost of antibiotic treatment only (see Appendix) [14].

Resources used to manage the average HAI case

HAI cost is mainly driven by excess LOS in the hospital [15]. During these extra days in hospital, HAI patients consume a mix of resources represented by fixed and variable costs. Fixed costs do not change with the number of patients treated and, in the NHS, represent buildings and staff; variable costs change with the number of patients treated and include consumables such as drugs and disposable equipment. Estimates of excess LOS due to HAI were produced for each HAI type and all HAI using a multi-state modelling approach that took account of time-varying exposures and the competing risks of death and discharge [16,17]. The multi-state model estimated excess LOS, for each HAI type, that could have been spent in any clinical area inclusive of intensive care unit (ICU), high-dependency unit (HDU) or other wards. The methods and results for the multi-state model are described in detail elsewhere [12]. Estimates of annual bed-days lost to HAI depend on both estimated incidence and excess LOS due to HAI [4,12].

Table I
Bed-day unit costs (£)[a]

Unit cost	Mean	SD	Distribution
Bed-day total cost	799.17	535.37	Log–normal
Bed-day direct cost	519.38	344.27	Log–normal

SD, standard deviation.
[a] Source: Information Services Division (ISD) Scotland [26].

Valuing resources used in the treatment of HAI in monetary terms

To value bed-days lost due to HAI, the 'total' and 'direct' accounting unit costs were calculated. These are mostly fixed costs and are based on a top-down valuation approach with gross-costing methodology [18]. Total costs include capital, overheads, staff, pharmacy, and laboratory costs. The total and direct costs were calculated using routinely reported historical data from NHS Scotland [19]. Direct costs include staff and consumable costs outlined above and exclude capital and overhead costs. Direct costs can be directly attributed to patient care and have been used previously to estimate the costs of treating HAI [20–25]. Unit cost estimates were weighted by the total number of discharges across all specialties from April 2017 to March 2018 in Scottish teaching hospitals and large general hospitals (see Appendix). Unit costs were aggregated across ICUs, HDUs, and other wards to match the estimates of the multi-state model [12]. Unit cost raw data were assumed to be log–normally distributed. In cost estimation CIs were calculated by taking 5000 Monte Carlo draws from log–normal distributions fitted to the unit cost data. Bed-day unit costs were based on Scottish reference costs and are presented in Table I [26]. Standard deviations in Table I reflect the substantial variability in bed-day costs across specialties and hospitals in Scotland.

The excess variable or cash cost incurred for each type of HAI was also calculated separately. These cash costs excluded fixed staff costs and were grouped into diagnostic tests and IPC consumables (including cleaning materials and antibiotic drugs). Diagnostic tests were defined according to HAI type and causative organisms reported in the ECONI study [4]. IPC and cleaning consumable costs were calculated for each level of transmission-based precautions (TBP) required for treatment. This included mapping the proportion of each HAI type which required use of TBP based on the Scottish National IPC manual and consultation with IPC experts [27]. The unit costs of IPC consumables were based on a mix of existing literature and expert opinion (see Appendix for full details).

Data on antibiotic prescribing in hospital was collected from the nested case–control sample of the ECONI study. The British National Formulary was used to cost antibiotics [28]. The costs were recorded in the week after data collection had been completed. Cash costs were multiplied by the estimated annual number of HAIs to calculate cash treatment by HAI type and a total. All cash costs were calculated in 2019 pound sterling (£); further detail is presented in the Appendix.

UK extrapolation of bed-day HAI costs

The ECONI study estimated incidence 0.76% (95% CI: 0.72–0.81) was applied to the UK total elective and emergency patient admissions in the financial year April 2017 to March 2018 to produce national estimates of costs [29–32]. This extrapolation assumes that the two hospitals of the study were representative of other acute hospitals in Scotland and the UK in terms of specialties, excess LOS, and bed-day unit costs [19].

Estimation of lost bed-days and costs due to HAI

Estimates of annual bed-days lost, for each HAI type and overall HAI, along with bias-corrected confidence intervals, using 5000 non-parametric bootstrap samples, were based on incidence and excess LOS estimated elsewhere [4,12]. In this study the annual and per-case cost of HAI is defined as the product of vectors of unit costs and excess resources consumed due to HAI. Point estimates of annual and per-case bed-day costs, for each HAI type and overall HAI, were calculated using annual and per-case bed-days lost multiplied by bed-day unit costs and excess LOS multiplied by bed-day unit costs, respectively. To estimate 95% CIs of annual and per-case costs, 5000 Monte Carlo simulations were drawn from log–normal distributions fitted to the data shown in Table I [17].

Cash costs were calculated separately using a different analytical process (see Appendix). Due to the way cash costs were calculated, point estimates of the unit costs were used in the calculation of cash costs. Therefore, no CIs are provided for cash costs related to IPC and treatment of HAI.

Table II
Incidence, average excess LOS and bed-days lost by HAI type in Scotland

HAI	Incidence rates per 100,000 AOBD (95% CI)	Estimated annual number of HAI cases (95% CI)	Average excess LOS[a] per HAI (95% CI)	Total annual bed-days lost to HAI[b] (95% CI)
BSI	35.0 (31.3–39.5)	1389 (1245–1570)	11.4 (5.8–17.0)	15,830 (7550–23,950)
GI	31.6 (28.2–36.3)	1256 (1122–1440)	6.0 (−0.7 to 12.7)	7540 (0–16,100)
LRI	26.2 (3.6–30.7)	1041 (937–1218)	7.3 (1.8–12.7)	7600 (1300–13,540)
PN	15.9 (13.7–19.2)	630 (544–764)	16.3 (7.5–25.5)	10,270 (4170–16,380)
SSI	25.8 (22.8–30.5)	1023 (904–1210)	9.8 (4.5–15.0)	10,030 (4190–15,900)
UTI	41.0 (36.6–46.2)	1628 (1454–1836)	−1.0 (−4.3 to 2.3)	0 (0–4,180)
Other	12.0 (9.5–15.8)	475 (378–628)	14.0 (−3.9 to 31.8)	6650 (0–16,360)
All HAI	187.2 (176.8–197.6)	7437 (7021–7849)	7.8 (5.7–9.9)	58,010 (41,730–74,840)

LOS, length of stay; HAI, healthcare-associated infection; AOBD, acute occupied bed-days; CI, confidence interval; BSI, bloodstream infection; GI, gastrointestinal infection; LRI, lower respiratory tract infection; PN, pneumonia; SSI, surgical site infection; UTI, urinary tract infection; 'Other' includes: SST, skin soft tissue; BJ, bone and joint; CV, cardiovascular; EENT, eye, ear, nose, and throat; and SI, systemic infection.
[a] Excess LOS is expressed in additional days per case.
[b] NHS Scotland acute hospitals.

Ethics

This study was surveillance and therefore was confirmed as ineligible for ethical review (A. Bailey. Personal communication to S. Stewart, 2016, South East Scotland Research Ethics Service). The case–control study component of the study received a favourable ethical opinion from the Scotland A Research Ethics Committee on March 3rd, 2017 (Reference 16/SS/0199). It was approved by national information governance approvals: Public Benefit of Health and Social Care: Incidence study: 1617-0037.

Results

The incidence rate and average excess LOS from the ECONI study and total bed-days lost by HAI type for teaching and general hospitals in Scotland are shown in Table II. These are based on the total annual admissions to teaching and general hospitals in NHS Scotland in 2018/19.

Bloodstream infection (BSI) was the HAI type with the greatest total annual impact in terms of bed-days lost, followed by pneumonia and surgical site infection (SSI). Urinary tract infection (UTI) was shown to have a negative impact on LOS in the multi-state model. In practice this means that on average UTI did not increase LOS, and it was assumed that there were zero additional days for these patients. In total there were 58,010 bed-days (95% CI: 41,730–74,840) lost in a year due to all HAI types.

Cost per case and annual inpatient costs in Scotland are shown in Table III. The total cost attributable to HAI treatment annually in NHS Scotland is estimated to be £46.35 million (19.4m–128.8m). The direct cost due to HAI is estimated to be £30.11 million (14.1m–74.4m) per year.

The extrapolation of the costs for the whole of the UK is shown in Table IV. Total costs in the UK based on total admissions are estimated to be £774 million (328 million to 2.2 billion) annually. Direct costs are estimated to be £503 million (236 million to 1.2 billion) per year.

The costs of consumable items that could be saved in the short term are shown in Table V. The total cost of these items varies by HAI type. These costs are small in comparison to staff time and other fixed resources. The total annual estimate is approximately £1.1 million across acute hospitals in the Scottish NHS. Cash costs are ~2.4% of the estimated total cost of HAI and 3.7% of the direct cost of HAI in Scotland.

Table IV
Annual total inpatient cost of HAI in the UK[a]

Annual total cost in the UK (£ million per year)	Annual direct cost in the UK (£ million per year)
774 (328–2,192)	503 (236–1,217)

Annual UK total and direct costs are based on ECONI HAI incidence: 0.76% (0.72–0.81).
[a] Values are mean (95% confidence interval).

Discussion

The ECONI study is the first in the UK to report whole-hospital incidence of HAI since the study by Plowman *et al.*, which was based on data from more than 20 years ago [6]. It was estimated that in Scotland 58,010 (95% CI: 41,730–74,840) bed-days were lost due to HAI each year. These occupied beds are the main economic cost arising from HAI. The impact of lost bed-days in a system like the NHS results in an increase in waiting lists, which means that potential patients are delayed in accessing services. This size of the loss equates to 159 beds or a small general hospital of 180 beds (assuming average bed occupancy of 88%) being occupied for a whole year with HAI cases. Alternatively, the impact of HAI can be shown by the number of elective patients who could have been treated after a 10% reduction in HAI rates. Given that LOS for elective patients in NHS Scotland is on average 3.4 days, then 1700 additional elective patients could be treated annually if 10% of HAI is prevented [33]. Estimated lost bed-days represent the opportunity cost of HAI expressed in natural units. The opportunity cost of a bed-day can be defined as the forgone benefit of the best alternative use of the resource such as treating another patient. In the NHS high demand means that a released bed is very valuable since a new patient will always occupy it, but in situations of spare capacity the value would be lower if a bed remains empty. Bed-days are a unit of currency familiar to healthcare decision-makers who manage resources with a high proportion of fixed costs.

The total cost valuation of the lost bed-days due to HAI was £46.35 million (95% CI: 19m–129m) and the direct cost was £30.11 million (14m–75m). In 2018/19 the total acute inpatient expenditure in Scotland was about £4 billion [34]; this sets the total cost of HAI at ~1.1% of the total acute inpatient expenditure in NHS Scotland. These are mostly fixed costs that cannot be recovered as savings if HAI is prevented, since they are based

Table III
Cost per case for each HAI type and annual cost of HAI in NHS Scotland[a]

HAI	Cost per case for each HAI type and overall (£)		Annual cost in NHS Scotland (£ million)	
	Total cost per case	Direct cost per case	Total cost	Direct cost
BSI	9,109 (3,511–28,210)	5,917 (2,552–15,438)	12.65 (4.82–38.96)	8.22 (3.45–21.94)
GI	4,794 (445–19,835)	3,114 (192–10,401)	6.02 (0.52–24.83)	3.91 (0.24–14.11)
LRI	5,833 (1,729–20,019)	3,789 (1,234–11,684)	6.07 (1.66–21.25)	3.94 (1.17–11.84)
PN	13,024 (4,808–45,061)	8,460 (3,432–23,548)	8.20 (2.99–25.88)	5.33 (2.01–14.44)
SSI	7,830 (2,987–24,993)	5,086 (2,095–14,433)	8.01 (2.95–27.02)	5.20 (1.96–13.45)
UTI	0 (0–2,109)	0 (0–1,304)	0 (0–3.63)	0 (0–2.21)
Other	11,186 (0–45,319)	7,266 (0–26,523)	5.31 (0.05–24.45)	3.45 (0–12.77)
All HAI	6,232 (2,733–18,181)	4,048 (1,927–9,591)	46.35 (19.43–128.81)	30.11 (14.12–74.46)

HAI, healthcare-associated infection; CI, confidence interval; BSI, bloodstream infection; GI, gastrointestinal infection; LRI, lower respiratory tract infection; PN, pneumonia; SSI, surgical site infection; UTI, urinary tract infection; 'Other' includes: skin/soft tissue; bone and joint; cardiovascular; eye, ear, nose, and throat; and systemic infection.
[a] All values are mean (95% confidence interval).

Table V
Costs of annual IPC, laboratory materials, and antibiotics used in the treatment of HAI in Scotland

HAI	IPC and laboratory costs (£)				Antibiotic costs (£)[a]	
	Mean IPC cost per HAI case	Mean laboratory test cost per HAI case	Total IPC and laboratory cost per HAI case	Annual cost in Scotland	Cost of antibiotics per HAI case	Annual cost in Scotland
BSI	15.76	23.13	38.89	54,018	91	126,399
GI	67.10	65.52	132.62	166,571	43	54,008
LRI	22.53	39.10	61.63	64,157	125	130,125
PN	24.01	36.41	60.42	38,065	280	176,400
SSI	12.62	27.10	39.72	40,634	454	464,442
UTI	14.96	19.03	33.99	55,336	7	11,396
Other	8.44		8.44	4,009	4	1,900
All HAI				422,790	91	676,767

IPC, infection prevention and control; HAI, healthcare-associated infection; BSI, bloodstream infection; GI, gastrointestinal infection; LRI, lower respiratory tract infection; PN, pneumonia; SSI, surgical site infection; UTI, urinary tract infection; 'Other' includes: skin/soft tissue; bone and joint; cardiovascular; eye, ear, nose, and throat; and systemic infection.
[a] Antibiotic costs were calculated from the case–control sample and not directly comparable with other results presented in this study.

on historical accounting unit costs. However, it is still important to consider costs in this way so that comparisons can be made with other NHS spending that is reported in similar terms. These costs also represent a monetary valuation of benefits from alternative uses of these resources when HAI is prevented. Direct costs are a representation of staff and consumable resources that could have been used to treat other patients if HAI rates were reduced.

The top three HAI types which had the greatest cost impact were BSI, pneumonia, and SSI (Table III). HAI cost is estimated as a combination of incidence and excess LOS, and the rank order of HAI type changes according to the impact on either incidence or LOS. For example, according to ECONI incidence, UTIs are the most common infections in Scotland but these are usually easily treated and thus have minimal impact on inpatient resources. This does not mean that IPC teams should disinvest in UTI prevention since these high-incidence infections frequently require antibiotic treatment, thus contributing to AMR. UTIs were also found to be one of the most common primary infection types leading to secondary BSI [4]. BSI is the second most common HAI type and has a relatively large impact on LOS (11.4 additional days on average). BSI is very costly, and targeting investment in IPC measures to reduce this type of HAI is likely to be cost-effective. Pneumonias also have serious consequences for the patients and can be difficult to treat, increasing LOS by more than 16 days on average, but they were less frequent than other HAIs. Nevertheless, IPC measures to prevent pneumonias could represent a good use of resources given the high cost per case of these infections. Outbreaks that would cause an increase in viral respiratory tract infection can be very costly for the health service and vigilance against these is required. SSIs have a lower cost per case than pneumonias but are more frequent, making these the second most costly HAI type annually in Scotland.

The cost of HAI was extrapolated to the whole of the UK and is estimated to be at £774 million (95% CI: 328m to 2,192m) and direct costs at £503 million (236m–1,217m) annually. The total cost of HAI is estimated to be at 0.62% of the NHS total spending in the four UK nations in 2018 and is associated with ~968,000 lost bed-days annually. This is much lower than the 9.1% and 3.64 million lost bed-days estimated by Plowman *et al.* more than 20 years ago [6]. Since the 1990s, changes in the hospital population, treatments, use of devices, antimicrobial resistance and IPC measures have affected the incidence and impact of HAI on the health service. The extrapolation results in this study should be interpreted with caution since they assume a similar mix of hospitals, specialties, and severity of illness across the UK.

Whereas total costs may represent historical spending to supply these beds, they do not necessarily represent their value in terms of opportunity costs, especially in situations of spare capacity. Opportunity costs are a more useful measure for decision-making under conditions of scarce resources but estimating these accurately may be difficult [35]. There have been attempts to estimate the opportunity cost of a bed-day using willingness-to-pay (WTP) surveys in other countries [36,37]. For example, Page *et al.* estimated opportunity costs using a WTP survey, for bed-days released by IPC programmes, elicited from CEOs of acute hospitals in Australia [37]. These estimates suggest that the total accounting cost to opportunity cost ratio is approximately equal to 3.7, which would imply an economic value of £216 for each bed-day in this study. A bed-day cost at this level would result in yearly opportunity costs in Scotland of up to £16 million, falling at the lower end of the estimated direct cost confidence interval (95% CI: 14m–75m). The true economic value or opportunity cost of the occupied bed-day in teaching and general hospitals in the UK is unknown, and using WTP estimates from another country or other types of hospitals would introduce sources of uncertainty. WTP can over- or underestimate the cost depending on demand for hospital beds, and estimates would be much higher in an infection outbreak or pandemic. In a WTP study in European tertiary hospitals Stewardson *et al.* recognized that a limitation of this approach is that WTP measures purchase intention, not actual cost [36]. Additionally, they found that WTP values depended on the type of hospital reimbursement [36]. Other studies also found that the hospital remuneration pro-cess had implications in how hospital executives view infection prevention [38,39].

This study values resource lost to HAI in total costs and direct costs using estimates of HAI incidence and excess LOS that are based on methodologies that minimize bias [4,12]. Most UK hospitals are operating close to full capacity with long waiting lists, which suggests that, when HAI is prevented, resources could be readily redeployed to treat other patients [40,41]. This means that the valuation of HAI cost in this study

represents resources with alternative uses. In addition, this study allows a comparison of the cost of different HAI types, and at the same time contrasts incidence with resource use, which is relevant to IPC planning. Another strength of this study is the probabilistic methodology that combined estimates of HAI incidence, excess LOS, and bed-day unit costs, and accounted for all types of uncertainty in the parameters. Previously in this literature studies have reported costs without fully accounting for all sources of uncertainty [38,42–45].

This study has several limitations. It was not conducted using a bottom-up micro-costing approach [18]. An example of this method is the patient-level information costing system (PLICS) but this was not routinely available during the study period. PLICS is a patient-level approach that can be used to standardize the method of reporting cost information across the health service. PLICS has the potential to be more accurate than gross-costing methods but is still limited by unit costs that do not reflect opportunity costs, and staff costing may occasionally be based on averages resembling a gross-costing methodology. A study in an English NHS hospital using PLICS to report the economic burden of SSI reported an attributable cost of SSI of £5,239 (95% CI: 4,622–6,719) [38]. This study estimates that the attributable direct hospital cost of SSI was £5,086 (2,095–14,433). Another limitation of this study is that the multi-state model estimates of excess LOS do not distinguish between facilities that have completely different cost profiles. For example, if 10% of the excess LOS took place in an ICU bed, this would increase estimated costs by ~14%. Heister *et al*. in a study of *C. difficile* show that multi-state models may also underestimate excess LOS, which means that the results of this study could be a conservative estimate of the true cost of HAI [46]. Furthermore, since antibiotic costs are based on a smaller sample, these costs may not be directly comparable with the rest of the results.

Bed-day costs reported previously in the literature mostly relate to capital costs, overheads, and fixed contracts that do not change in the short term [11]. Since the cost of facilities and staff are fixed under normal circumstances there is small potential for any annual saving that could be achieved by preventing HAI. Any savings would relate to the consumable items that are purchased as they are consumed. Gastrointestinal infections (GIs) and pneumonias had the highest IPC and laboratory cash costs per case, with GIs having the greatest annual impact. This study shows that pneumonias are highly resource intensive, both in terms of fixed costs and variable costs. While the results of this study have shown that Scottish annual cash costs for all HAI types are relatively small at approximately £1.1 million per year, this money could eventually be reinvested if HAI cases were prevented. Plowman *et al*. suggested that cash costs are 11% of the total costs [6]. The results of this study suggested that cash costs are a much smaller proportion of costs at 2.4% of the total and 3.8% of direct costs. This means that any expected cash savings from HAI prevention would be very small. Preventing HAI may only release relatively small funds as cash savings, but there is an additional benefit – that is not included in these monetary valuations – of reducing antibiotic consumption [47]. The human cost of HAI should also be taken into account when evaluating HAI prevention since it is also not included in these monetary costs.

A recent meta-analysis concluded that HAI reduction of between 35% and 55% may be possible with the implementation of multi-faceted interventions [48]. However, preventable proportions of HAI may decrease over time as IPC initiatives are successfully implemented. Reductions shown in some of the earlier studies within this meta-analysis would not be achievable today, as many of the proposed interventions have been implemented in some way. It is likely that realistic reductions in overall HAI numbers in Scotland would be lower than Schreiber *et al*. reported, especially given the low proportion of surgical and device-related HAIs identified in the ECONI study [4,48]. Exaggerated estimates of the cost of HAI and the potential benefits from prevention of HAI may lead policy-makers to be disappointed when IPC programmes turn out to be less efficient than expected.

Although considerable progress has been made in evaluating IPC measures with cost-effectiveness modelling approaches, these analyses rely heavily on unbiased information [49]. When seeking funding, 'attention grabbing' costs are frequently quoted in order to convince policy-makers to invest in IPC measures among other interventions. Within the literature there are also attempts to compare the cost of HAI with other conditions, e.g. cancers, with the intention to focus policy-makers' attention on IPC and HAI prevention. However, as discussed elsewhere, it is patients with these conditions who are most at risk of developing HAI [50]. Rather than promoting such competition for resources among patient groups, studies should include integration of IPC measures in order to maximize the efficacy of existing treatments for those most at risk of developing HAI. This study reports the cost of HAI using a variety of measures that can reliably inform future economic evaluations of IPC programmes.

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Author contributions

S.M. contributed to aspects of the study design and led data collection for economic analysis, calculated the total and direct costs and prepared the manuscript. S.S. led the study design, wrote study protocols and ethics and Public Benefit and Privacy Panel approvals, patient-facing materials, contributed to the design of the collection tools, contributed to the statistical analysis, developed the manuscript and the cash treatment costs. N.G. prepared the manuscript and contributed to the study design. H.M. contributed to the study design, led on health economic aspects of the study design and contributed to the manuscript. C.R. contributed to the concept of the study, study design, statistical analysis plan and the manuscript. S.K., J.P. and K.K., undertook the statistical analysis and prepared results. L.H. contributed to the development of study design, protocol and data management and contributed to the final manuscript. M.A. contributed to the final manuscript. S.D. and B.C. are the Principal Investigators at the recruiting sites and contributed to the final

manuscript. J.R. conceived the study, is Chief Investigator for the study and contributed to the manuscript.

Non-author collaborators

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Conflict of interest statement

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2020.12.027.

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pathogens

MDPI

Review

Water as a Source of Antimicrobial Resistance and Healthcare-Associated Infections

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Abstract: Healthcare-associated infections (HAIs) are one of the most common patient complications, affecting 7% of patients in developed countries each year. The rise of antimicrobial resistant (AMR) bacteria has been identified as one of the biggest global health challenges, resulting in an estimated 23,000 deaths in the US annually. Environmental reservoirs for AMR bacteria such as bed rails, light switches and doorknobs have been identified in the past and addressed with infection prevention guidelines. However, water and water-related devices are often overlooked as potential sources of HAI outbreaks. This systematic review examines the role of water and water-related devices in the transmission of AMR bacteria responsible for HAIs, discussing common waterborne devices, pathogens, and surveillance strategies. AMR strains of previously described waterborne pathogens including *Pseudomonas aeruginosa, Mycobacterium* spp., and *Legionella* spp. were commonly isolated. However, methicillin-resistant *Staphylococcus aureus* and carbapenem-resistant Enterobacteriaceae that are not typically associated with water were also isolated. Biofilms were identified as a hot spot for the dissemination of genes responsible for survival functions. A limitation identified was a lack of consistency between environmental screening scope, isolation methodology, and antimicrobial resistance characterization. Broad universal environmental surveillance guidelines must be developed and adopted to monitor AMR pathogens, allowing prediction of future threats before waterborne infection outbreaks occur.

Keywords: antibiotic resistance; antimicrobial resistance; water; waterborne outbreak; healthcare associated infection; biofilm

1. Introduction

Healthcare-associated infections (HAIs) are defined as infections caused as a direct or indirect result of an individual receiving healthcare [1]. This may occur in hospitals, aged care facilities, dental clinics and long-term care facilities [2]. The United States (US) Centers for Disease Control and Prevention (CDC) have estimated that 1 in 25 hospital patients are diagnosed with a HAI each year [3]. Additionally, there are over 4 million HAIs in Europe, 1.7 million in the US and 165,000 in Australia annually [4]. HAIs result in unnecessary morbidity and mortality with estimates from the US indicating HAIs are responsible for approximately 99,000 unnecessary deaths every year [4]. Hospital patients and aged care residents are especially vulnerable to infection due to their potentially compromised immune systems [5]. HAIs are commonly associated with catheters, surgical sites and ventilators [6], where the causative organisms may originate from the patient's own microbial flora, other patients, staff or from the healthcare facilities physical environment [5]. The US CDC have identified a number of causative agents that pose serious threats to hospitalized patients including *Acinetobacter*

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spp., influenza, *Klebsiella* spp., methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile, Pseudomonas aeruginosa,* non-tuberculous mycobacteria (NTM) and norovirus [7]. The significance and severity of HAIs are increasing due to the rise in antimicrobial resistance and emergence of multidrug resistance (MDR) [8]. Thus, treatment for patients suffering HAIs resistant to traditional antibiotic therapies is more precarious, costly and, in the worst case scenario, unsuccessful [6]. The increase in antimicrobial resistance is driven, in part, by the inappropriate use of antibiotics and ineffective disinfectant protocols [9]. Understanding potential environmental reservoirs of infectious bacterial species is needed to develop and implement effective infection control [1]. Strategies for the prevention of person-to-person transmission are well defined, including disinfection procedures of dry surface fomites such as bed rails, doorknobs and light switches [1,10–12]. However, there are limited studies investigating the role of environmental microorganisms, including waterborne pathogens such as *Legionella* spp., *P. aeruginosa* and *Mycobacterium* spp. [13–27]. It has been estimated that 20% of nosocomial pneumonias are caused by waterborne *P. aeruginosa* in the US, resulting in a conservative annual mortality of approximately 1400 individuals [28]. An outbreak of *L. pneumophila* infection in the neonatal unit of a private hospital was linked to a cold-mist humidifier filled with contaminated tap water, resulting in nine infections and three deaths [29]. Transmission of these waterborne pathogens may occur via water related devices such as showers, drinking fountains, bathtubs, dental units, ice machine, humidifiers, sinks and toilets [27]. Notably, approximately 80% of chronic and recurrent microorganism infections are caused by biofilms [30], which are communities of microorganisms, providing protection from adverse environmental conditions and antimicrobial agents [30].

This systematic review examined the role of water in the transmission of AMR pathogens that are responsible for HAIs. Common waterborne devices, pathogens, and surveillance strategies are discussed. A greater understanding of the ecological niche of these pathogens is needed to develop improved management strategies for the prevention of waterborne HAIs.

2. Results

Two thousand, two hundred, and one papers were retrieved from SCOPUS and Web of Science using the search terms identified (Figure 1). After applying the inclusion and exclusion criteria described in Figure 1, a total of 88 papers were included for review. These were further divided such that 21 papers (presented in Table 1) described studies specifically investigating the presence of AMR bacteria in water and water-related devices including tap faucets, drains, showers, and baths. A further 67 papers that did not specifically investigate water but included some water sampling are presented in the Table S1. These include clinical outbreak investigations and other studies screening a range of environmental sources within healthcare facilities.

Table 1. Summary of reports and studies identifying antimicrobial resistant bacterial species within healthcare water sources and water-related devices.

Study Site	Reservoir	Organism	Country *	Bacterial Isolation Methods ◊	Antimicrobial Methods †	Antimicrobial Characteristics	Additional Comments ×	Reference
Hospital	Water	*Legionella* spp.	Greece *	ISO 11731 (filtration, untreated, heat and acid treatments) plated on GVPC agar	E-test strips	Five strains displayed low-level resistance to CIP and ERY	SGs 1–15 identified. Antibiotics tested: CIP, ERY	[31]
Hospital	Water	*Burkholderia cepacia* *Pseudomonas stutzeri* *Chryseobacterium meningosepticum* *Stenotrophomonas maltophilia* *Enterobacter cloacae* *Acinetobacter baumannii* *Escherichia coli* *Proteus mirabilis* *Alcaligenes xylosoxidans* *Pseudomonas aeruginosa* *Pseudomonas putida* *Serratia liquefaciens* *Moraxella osloensis* *Serratia plymuthica*	Greece	Membrane filtration and plated on m-endo medium and cetrimide agar	Agar dilution	*S. maltophila* isolate resistance: 37% resistant to CAZ 58% resistant to FEP 100% resistant to IPM *E. coli* isolates: 55% resistant to TIC *P. mirabilis*, *P. putida*, *S. liquefaciens*, *P. stutzeri* and *S. plymuthica* exhibited resistance to tetracycline 19% of the total enterobacteria and 35% of the total non-fermenting isolates were MDR	Antibiotics tested: AMK, CAZ, CIP, FEP, IPM, TET, TIC, SXT, TOB	[32]
Hospital	Water	*Acinetobacter haemolyticus* *B. cepacia* *Pseudomonas aeruginosa* *P. stutzeri*	Brazil	MPN, APHA 2000 plated on MacConkey agar	Disc diffusion	*B. cepacian* isolates showed resistance to 10/11 antibiotics *P. aeruginosa* isolates showed resistance to 11/11 antibiotics *A. haemolyticus* isolates showed resistance to 11/11 antibiotics *P. stutzeri* isolates showed resistance to 7/11 antibiotics	Antibiotics tested: AMK, CAZ, CCHL, CIP, FEP, GEN, IPM, TET, TMP, TOB, TZP	[33]
Hospital	Hot water system	*Legionella pneumophila*	Italy	Italian guidelines for prevention and control of Legionellosis	VITEK-2	MIC values of *L. pneumophila* SG 1 were higher than non-SG 1 isolates for AZI, CIP, LEV, MOX, and TIG No difference in MIC values between SGs for CEF, CLA, DOX, ERY, and RIF	Antibiotics tested: AZM, CIP, CLR, CTX, DOX, ERY, LVX, MXF, RIF, TGC	[34]

Table 1. *Cont.*

Study Site	Reservoir	Organism	Country *	Bacterial Isolation Methods ◊	Antimicrobial Methods †	Antimicrobial Characteristics	Additional Comments ×	Reference
Hospital	Water system	*Legionella* spp.	Turkey	Culture methods	Broth dilution	MICs: Greatest MIC to CLR	Antibiotics tested: AZM, CIP, CLR, LVX, RIF	[35]
Hospital	Water	*L. pneumophila*	Spain	UNE-ISO 11731:2007 (filtration: untreated, acid and heat treatments) plated on GVPC agar	E-test strips, Disc diffusion	E-test strips: Greatest average MIC resistance from CIP and DOX Lowest average MIC resistance from AMC and AZT Disc diffusion: Greatest average disc inhibition from AZT and AMC Lowest average disc inhibition from SXT and RIF	Antibiotics tested: E-test strips: AMC, AZM, CIP, CTX, DOX, ERY, LVX, MXF Disc diffusion: AMC, AZM, CIP, CTX, ERY, FOX, LVX, MXF, RIF, SXT	[36]
Hospital	Water	*Acinetobacter* spp. *Aeromonas* spp. *Citrobacter* spp. *Enterobacter* spp. *Escherichia coli* *Klebsiella oxytoca* *Klebsiella pneumoniaeLeclercia adocarboxylata* *Pseudomonas* spp. *Serratia* spp.	Turkey	Membrane filtration and inoculated in MacConkey broth and MacConkey agar	Disc diffusion PCR	*E. coli* isolates: 1 isolate resistant to CRO 5 isolates resistant to AMP 1 isolate resistant to PIP Other species: 3 *Pseudomonas* spp. isolates showed resistance to CAZ, IMP and GEN	Antibiotics tested: AMC, AMK, AMP, CAZ, CEF, CHL, CIP, CRO, FEP, FOX, GEN, IPM, MEM, PIP, TET, SXT, TZP	[37]
Hospital	Water	*P. aeruginosa*	France	Membrane filtration	Disc diffusion	Copper tolerant isolates.	Antibiotics tested: AMK, ATM, CAZ, CIP, FEP, FOF, IPM, MEM, TOB, TZP	[38]

Table 1. *Cont.*

Study Site	Reservoir	Organism	Country *	Bacterial Isolation Methods ◊	Antimicrobial Methods †	Antimicrobial Characteristics	Additional Comments ×	Reference
Hospital	Water	*P. aeruginosa*	India	Membrane filtration. Plated on R2A agar immediately and on either cetrimide, Columbia + 5% horse blood or R2A after 14 days	Disc diffusion	All isolates showed resistance to TET and PEN 2 isolates resistant to STR 4 isolates resistant to NET 5 isolates showed MDR	Antibiotics tested: NET, OFX, PEN, STR, TET	[39]
Hospital	Water	*P. aeruginosa*	Tanzania	Water sample inoculated directly in malachite-green broth then subcultured on blood and cetrimide agar	VITEK-2	Resistance (% of isolates): ETP (2.6%); IPM (2.6%); TZP (2.6%); TOB (5.1%); GEN (12.8%); CIP (15.4%); PIP (18%); FOF (61.5%); ATM (100%)	Antibiotics tested: AMK, ATM, CAZ, CIP, CST, ETP, FEP, FOF, GEN, IPM, MEM, PIP, TOB, TZP Two hospitals sampled; one received water from a deep drilled well and the other from Lake Victoria	[40]
Hospital Dental chair	Water	*Sphingomonadacae* spp.	Portugal *	Membrane filtration and plated on R2A, GSP, *Pseudomonas* isolation and tergitol-7 agar	ATB PSE EU system	Hospital taps resistance (% of isolates): TIM (2%); CIP (11%); MEM (17%); CAZ (21%); FEP (26%); TSU (30%); TIC (36%); TOB (36%); LVX (42%); FOS (42%); PIP (49%); TZP (36%); CST (94%) Dental chair resistance (% of isolates): TZP (17%); CAZ (17%); MEM (17%); TOB (17%); TSU (17%); FEP (33%); GEN (33%); CIP (33%); TIC (50%); PIC (67%); COL (83%)	Antibiotics tested: CAZ, CIP, CST, FEP, FOF, GEN, IPM, LVX, MEM, PIP, TIC, TIM, TOB, TSU, TZP	[41]

Table 1. *Cont.*

Study Site	Reservoir	Organism	Country *	Bacterial Isolation Methods ◊	Antimicrobial Methods †	Antimicrobial Characteristics	Additional Comments ×	Reference
Medical centre	Drain	*Achromobacter* spp. *Acinetobacter anitratus* *Acinetobacter lwoffi* *Aeromonas* spp. *Enterobacter agglomerans* *Enterobacter cloacae* *Flavobacterium* spp. *Moraxella* spp. *Pseudomonas acidovorans* *P. aeruginosa* *Pseudomonas* spp. *Pseudomonas cepacia* *Pseudomonas fluorescens* *Pseudomonas putida* *P. stutzeri* *Stenotrophomonas maltophila*	USA	Drains swabbed and plated on deoxycholate agar biplate with GEN and AMK	Selective media	Resistance (% of isolates): AMK (77%); GEN (88%)	Antibiotics tested: AMK, GEN	[42]
Hospital Residential care home	Taps Shower Drinking fountain	*P. aeruginosa*	Italy	UNI EN ISO 16266:2008. Membrane filtration and plated on Pseudomonas agar with CN supplement	Disc diffusion PCR DNA sequencing	7.72% resistant to imipenem. 13.2% resistant to >1 antibiotic	Antibiotics tested: AMK, ATM, CAZ, CIP, DOR, FEP, GEN, IPM, LVX, MEM, NET, PIP, TIC, TIM, TOB, TZP	[43]
Hospital Sanatorium	Water	*Legionella* spp.	Poland	Culture methods	E-test strips	*L. pneumophila* SG2-14 isolated from one sanatorium showed resistance to AZM	Antibiotics tested: AZM, CIP, RIF	[44]
Hospital	Shower head	*Erythrobacter* spp. *Mycobacterium* spp. *Novosphingobium* spp. *Sphingomonas* spp.	USA	Biofilm removed from inner surfaces and resuspended to be plated on R2A agar	High-throughput sequencing	Resistance genes found: *aac2ib* *aac2ic* *aph3ic* *baca* *bL2b* *ceob* *mfpa*	N/A	[45]

Table 1. *Cont.*

Study Site	Reservoir	Organism	Country *	Bacterial Isolation Methods ◊	Antimicrobial Methods †	Antimicrobial Characteristics	Additional Comments ×	Reference
Hospital	Tap water	*P. aeruginosa*	France *	Hospital standard—culture method	Disc diffusion PGFE	7 isolates have Opr-mediated resistance to IPM	Antibiotics tested: CAZ, IPM, PIP Samples taken before and after ICU move for comparison	[46]
Hospital	Haemodialysis water Tap water	*Enterococci* spp.	Greece	Membrane filtration	Agar diffusion	Resistance (% of isolates): RIF (43%) STR (60%) 1 isolate resistant to ERY	Antibiotics tested: AMC, AMP, CIP, ERY, GEN, RIF, STR, TMP, VAN	[47]
Hospital	Water	*P. aeruginosa*	France	Membrane filtration and plated on cetrimide agar	Disc diffusion	*P. aeruginosa* resistant to chlorine disinfection treatment	Antibiotics tested: AMK, CAZ, CTX, FOF, GEN, IPM, OFX, CIP, RIF, TIM, TOB	[48]
Hospital	Sink U-bend	*P. aeruginosa*	France	U-bend content collected and centrifuged pellet was streaked on cetrimide agar	Disc diffusion	Strains: ST1725 (2 MDR isolates) ST539 (100% resistant to IMI) ST1416 (2 MDR isolates) ST540 (1 MDR isolate) STI11 (100% resistant to IPM, 9 MDR isolates) ST622 (7 MDR isolates) ST520 (100% resistant to IPM, 1 MDR isolate)	Antibiotics tested: AMK, CAZ, CIP, FEP, GEN, IPM, MEM, TIC, TOB, TZP	[49]

Table 1. *Cont.*

Study Site	Reservoir	Organism	Country *	Bacterial Isolation Methods ◊	Antimicrobial Methods †	Antimicrobial Characteristics	Additional Comments ×	Reference
Hospital	Tap water	*P. aeruginosa* *P. fluorescens* *Ralstonia picketti* *S. maltophila*	Italy	Membrane filtration and placed on cetrimide agar	ATB PSE 5	*P. aeruginosa:* 17 strains non-MDR 4 MDR 3 XDR *S. maltophila:* 1 strain non-MDR 8 strains MDR *P. fluorescens:* 1 MDR strain	Antibiotics tested: AMK, AMP + SUL, CAZ, CIP, CST, FEP, FOF, GEN, IPM, MEM, SXT, TIM, TOB, TZP	[50]
Hospital	Bathtub Tap water	*Citrobacter diversus* *Citrobacter freundiii* *Enterobacter aerogenes* *E. cloacae* *E. coli* *K. pneumoniae* *Pantoea agglomerans* *P. aeruginosa* *Serratia marcescens* *Staphylococcus aureus*	Zambia	Swabs of bathtub and cultured on agar	PCR	MRSA found on bathtubs	Comparison of clinical isolates collected at the same time	[51]

* In countries where the study location was not specified in the article, it was assumed that the country of origin was denoted by the country of the authors. ◊ Abbreviations: American Public Health Association, APHA; Glycine Vancomycin Polymyxin Cycloheximide agar, GVPC; International Organization for Standardization, ISO; most probable number, MPN; Spanish Organization for Standardization, UNE ISO. † Abbreviations: BioMerieux susceptibility test, ATB-PSE-EU; polymerase chain reaction, PCR; pulse gel field electrophoresis, PGFE; BioMerieux identification and antibiotic susceptibility testing instrument, VITEK-2. × Abbreviations: extended-spectrum beta-lactamase, ESBL; multidrug resistant, MDR; minimum inhibitory concentration, MIC; methicillin-resistant *Staphylococcus aureus,* MRSA; serogroup, SG; extensively drug resistant, XDR. Antimicrobial abbreviations: AMK, amikacin; amoxicillin-clavulanic acid, AMC; ampicillin, AMP; azithromycin, AZZM; aztreonam, AZM; aztreonam, ATM; cefepime, FEP; cefotaxime, CTX; cefoxitin, FOX; ceftazidime, CAZ; ceftriaxone, CRO; cephalothin, CEF; chloramphenicol, CHL; ciprofloxacin, CIP; clarithromycin, CLR; colistin, CST; doripenem, DOR; doxycycline, DOX; ertapenem, ETP; erythromycin, ERY; fosfomycin, FOF; fusidic acid, FA; gentamicin, GEN; imipenem, IPM; levofloxacin, LVX; meropenem, MEM; methicillin, MET; moxifloxacin, MXF; neomycin, NEO; netilmicin, NET; ofloxacin, OFX; penicillin, PEN; piperacillin, PIP; piperacillin-tazobactam, TZP; rifampin, RIF; streptomycin, STR; tetracycline, TET; ticarcillin, TIC; ticarcillin-clavulanic acid, TIM; tigecycline, TGC; tobramycin, TOB; trimethoprim, TMP; trimethoprim-sulfamethoxazole, SXT; vancomycin, VAN; sulbactam, SUL; methylisothiazolinone, MIT; tributyl tetradecyl phosphonium chloride, TTPC; didecyldimethylammonium chloride, DDAC; 2,2-dibromo-3-nitrilopropionamide, DBNPA; hydrogen peroxide + silver nitrate, H_2O_2 + $AgNO_3$; tetrakis (hydroxymethyl)phosphonium sulfate, THPS; sodium hypochlorite, NaOCl; benzalkonium chloride, BZK; cotrimoxazole, TSU; mupirocin, MUP.

2.1. Study Sites

Of the 21 papers that specifically investigated the presence of pathogens associated with HAIs in water sources (Table 1), 15 studies were from Europe, 3 from North and South America, 2 from Africa and 1 from Asia. Seventeen studies sampled water sources from hospitals, one from a residential care home, one from dental chair units, one from a medical center and another from a sanatorium. AMR bacterial species were found in potable water samples (15 studies), followed by showers (2 studies) and building water distribution systems (2 studies), sinks (1 study), baths (1 study), haemodialysis water (1 study) and drains (1 study).

In those clinical outbreak investigations and studies examining a range of environmental sources (Table S1), there were 27 reports from Europe, 22 from Asia, 11 from the Americas, 6 from Africa and 1 published from Oceania. Of these studies, 30/67 found AMR bacterial contamination within a water source, including tap water, hydrotherapy pool water, nasogastric water, and incubator water. Taps and tap components such as aeration grids, tap handles, and hands-free taps had AMR bacterial contamination in 18/67 studies. Sink and sink components such as drain holes, sink surfaces, drainpipe leaks and sink traps were found to have multidrug resistant (MDR) bacterial contamination resistant to two or more antimicrobials in 45/67 studies (Table S1). Shower components such as the shower hoses, showerhead and outlets were contaminated with AMR bacteria in 11/67 studies. Baths were found to have MDR bacterial contamination in 4 studies and bath toys were identified as a source of contamination in 1 study [14,16,52–54].

2.2. Identified Pathogens Associated with HAIs

Seven of the studies used culture-based techniques to investigate the bacterial diversity in the water sources in healthcare facilities. The pathogens identified are detailed in Table 1 and include *Achromobacter* spp., *Acinetobacter* spp., *Acinetobacter anitratus, Acinetobacter baumannii, Acinetobacter haemolyticus, Acinetobacter lwoffi., Aeromonas* spp., *Alcaligenes xylosoxidans, Burkholderia cepacia, Chryseobacterium meningosepticum, Citrobacter* spp., *Citrobacter diversus, Citrobacter freundii, Enterobacter* spp., *Enterobacter aerogenes, Enterobacter agglomerans, Enterobacter cloacae, Erythrobacter* spp., *Escherichia coli, Flavobacterium* spp., *Klebsiella oxytoca, Klebsiella pneumoniae, Leclercia adocarboxylata, Moraxella* spp., *Moraxella osloensis, Mycobacterium* spp., *Novosphingobium* spp., *Pantoea agglomerans, Proteus mirabilis, Pseudomonas* spp., *Pseudomonas acidovorans, P. aeruginosa, Pseudomonas cepacia, Pseudomonas fluorescens, Pseudomonas putida, Pseudomonas stutzeri, Ralstonia picketti, Serratia* spp., *Serratia liquefaciens, Serratia marcescens, Serratia plymuthica, Sphingomonas* spp., *S. aureus,* and *Stenotrophomonas maltophila.*

Fourteen studies investigated the presence of one specific bacterial species or genus that may cause HAIs in water and water-related devices. Of these, seven papers investigated *P. aeruginosa* exclusively, three investigated *Legionella* spp. and two papers focused specifically on *L. pneumophila*. One paper focused on *Enterococci* spp. and another focused on *Sphingomonadacae* spp. (Table 1).

Twenty studies undertook comprehensive environmental bacterial screens of the study sites. These studies included additional pathogens such as *Acidovorax* spp., *Acinetobacter johnsonii, Aeromonas caviae, Aeromonas hydrophila, Alkaligenes faecalis, Bosea* spp., *Chryseobacterium* spp., *Chryseobacterium indologenes, Elizabethkingia meningoseptica, Enterobacter asburiae, Enterococci* spp., *Klebsiella ozenae, Methylobacterium* spp., *Mycobacterium chelonae, Pantoea calida, Proteus* spp., *Proteus vulgaris, Providencia stuartii, Raoultella ornithinolytica, Raoultella planticola, Sphingomonas paucimobilis, Staphylococcus citrus, Staphylococcus epidermidis* and *Staphylococcus* spp., as shown in Table S1. However, due to the design of some studies, it was not always clear whether these bacterial species were isolated from the water samples taken or from other environmental sources.

Thirty-five of 67 (Table S1) investigated bacterial clinical outbreaks in one or more healthcare facilities identified contamination of water and/or a water related device as the likely source of transmission via strain comparison. This included HAI outbreaks of *Achromobacter bacteraemia, Achromobacter denitrificans, Achromobacter xylosoxidans, Acinetobacter bereziniae, A. hydrophila,* carbapenem-resistant *Enterobacteriaceae* (CRE), carbapenem-resistant *E. coli, Citrobacter amalonaticus,*

C. freundii, Collinsella aerofaciens, Comamonas testosterone, E. cloacae complex, *Klebsiella* spp., *Pseudomonas medocina, Pseudomonas nitroreducens, Pseudomonas oleovorans* and *P. putida*. A surveillance review of waterborne diseases in the US from 2013 to 2014 found that there were 42 outbreaks from drinking water, resulting in 13 deaths all caused by *Legionella* spp. [55].

Nine studies compared clinical bacterial isolates and environmental isolates, including those from water samples for molecular epidemiology in non-outbreak settings. These studies included bacterial species such as *Aeromonas spp., Burkholderia spp., Klebsiella quasipneumoniae, P. aeruginosa* and *S. maltophila*, as shown in Table S1.

2.3. Antimicrobial Resistance of Identified Strains

Several AMR pathogens of concern, as classified by the US CDC, were identified by studies included in this review (Table 1 and Table S1). Specifically, three studies detected CRE, one from a plumbing fixture, one from a water sample and one sample site was unspecified [21,52,56]. MDR *P. aeruginosa* strains were also found in 12 studies, most commonly from potable water samples (7 studies), sinks (3 studies) and faucets (2 studies) [14–16,33,39,40,43,49,50,57–59]. Eight studies reported AMR *Acinetobacter* spp. of which five reported MDR isolates and one study identified the resistance genes *tetG, ermX* and *ermF* in bacteria within a biofilm sample [32,37,42]. Additionally, the resistance gene OXA-23 was found in *A. baumannii* sampled from hospital water which has been linked to β-lactam antibiotic resistance [60]. Specific genetic elements such as Opr protein-mediated resistance to fluoroquinolone antibiotics was also found in *P. aeruginosa* isolates [37]. MRSA was detected in every bathroom sink tap that was tested in a UK hospital. However, it is unclear which antibiotics this specific environmental isolate was resistant to [61]. Sixteen studies that investigated water and water-related devices found bacterial isolates that were resistant to two or more of the antibiotics that were tested (Table 1). One study investigating *P. aeruginosa, P. stutzeri, B. cepacian* and *A. haemolyticus* in hospital water samples found that all isolates were resistant to seven or more of the 11 antibiotics that were tested, including amikacin, ceftazidime, chloramphenicol, ciprofloxacin, cefepime, gentamicin, imipenem, tetracycline, trimethoprim, tobramycin and piperacillin-tazobactam [33]. One study into the presence of *L. pneumophila* in a hospital hot water system found that the minimum inhibitory concentration (MIC) values were higher in serogroup 1 isolates compared to non-serogroup 1 isolates for the antibiotics azithromycin, ciprofloxacin, levofloxacin, moxalactam and tigecycline [34]. Resistance to β-lactamase inhibitors such as tazobactam and clavulanic acid was identified in *K. oxytoca, P. calida, R. ornithinolytica* and *P. aeruginosa* isolated from hospital sinks, drains, shower heads, water and aerators [15,25,62]. Biofilm samples taken from hospital shower heads contained *Erythrobacter* spp., *Mycobacterium* spp., *Novosphingobium* spp. and *Sphingomonas* spp. isolates that carried the resistance genes *aac2Ib, aac2Ic, aph3Ic, bacA, bL2b, ceoB* and *mfpA* that have been linked to biofilm formation, virulence, peroxide resistance, DNA repair, antibiotic resistance, and antigenic variation traits [45].

2.4. Detection Methods

There was significant variation in the methods used for detecting bacterial species from the environment. Fifteen studies (Table 1) examined water using culture techniques. Specifically, eleven studies performed membrane filtration followed by plating onto selective agar media, nine of these studies used 0.45 µm pore diameter filters and two did not specify (Table 1). Of those that specifically investigated *Legionella* spp., two studies referenced the International Organization for Standardization (ISO) 11731—water quality enumeration of *Legionella* [31,36]. One study investigating *L. pneumophila* followed Italian guidelines for prevention and the control of legionellosis [34] and two studies used other culturing techniques [35,44]. Of the studies investigating *P. aeruginosa,* four papers used membrane filtration methods followed by plating onto selective media such as R2A, cetrimide, and Columbia with horse blood, one of which referenced the ISO 16266:2008—detection and enumeration of *P. aeruginosa* specifically [38,39,43,48]. One paper alternatively inoculated malachite-green broth with the individual environmental water sample and subcultured onto cetrimide agar to isolate *P. aeruginosa* [40]. Bacterial

species from biofilm and swab samples taken from water-related devices were isolated using a variety of methods including direct inoculation onto cetrimide, MacConkey, tegritol-7, or deoxycholate agar, and centrifugation to resuspend a pellet for inoculation onto selective agar, as shown in Table 1 [33,37,42,45,49]. Five studies used additional methods such as polymerase chain reaction (PCR), matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF), VITEK-2, multiplex PCR and 16S gene sequencing to identify isolated bacterial species (Table S1) [63–65].

2.5. Antimicrobial Resistance Characterization Methods

A range of methods were used to determine the antimicrobial resistance characteristics of isolated strains. Seventy-one of 88 studies (Table 1 and Table S1) used traditional microbiological methods including disc diffusion (56 studies), agar dilution (4 studies), broth microdilution (5 studies) and E-test strips (6 studies). Other approaches for characterizing antimicrobial resistance included PCR (17 studies) and comparison to known AMR strains using VITEK-2 system (5 studies), pulse field gel electrophoresis (PFGE) (3 studies), microscan (2 studies), microarray (1 study) and multilocus sequencing typing (MLST) (1 study).

Comparing the antimicrobial resistance is challenging due to the varying approaches used in the different studies. A joint initiative by the European CDC and US CDC provided definitions for the terms MDR and XDR to standardize international terminology. To facilitate these definitions, lists of antimicrobial categories and breakpoints were developed from the Clinical Laboratory Standards Institute (CLSI), the European Committee on Antimicrobial Susceptibility Testing (EUCAST) and the United States Food and Drug Administration (FDA). MDR was defined as acquired non-susceptibility to at least one agent in three or more antimicrobial categories. XDR was defined as non-susceptibility to at least one agent in all but two antimicrobial categories [66]. The terms MDR and extensively drug resistant (XDR) were used by five studies and the terminology has been reported as stated in the papers (Table 1 and Table S1); however, it was unclear what specific antibiotics the isolates were resistant to [32,39,49,50,58]. Of the studies detailed in Table S1, 20/67 studies reported the environmental isolates as a whole data set rather than describing the phenotypes of each individual strain.

3. Discussion

3.1. Water as a Source of HAIs

Water sources and water-related devices are often contaminated with pathogens responsible for HAIs. This may occur when microorganisms survive treatment protocols or via end point contamination [67]. The design of a hospital or healthcare facility's water system can influence the risk of microbial contamination [68]. Complex infrastructure may have points of heat transfer and stagnation which can promote biofilm formation, microbial growth and the rise or transfer of antimicrobial resistance [69]. The CDC Antibiotic Resistance Threats Report estimated that there are more than 2.8 million AMR infections each year in the US resulting in approximately 35,000 deaths [8]. This review identified that water and water-related devices play a significant role in the transmission of AMR HAIs with subsequently an economic and health imperative to improve the control of hospital and healthcare water sources.

This review identified a range of waterborne pathogens present in the potable water supply and plumbing surfaces (such as drains and tap faucets). However, pathogens not typically considered waterborne were also detected, including *S. aureus*, *Moraxella* spp. and *E. aerogenes* [32,42,51,54,70–73]. For example, AMR pathogens of concern, extended-spectrum beta-lactamase-producing Enterobacteriaceae and MRSA, were located in a hospital sink bowl, hospital bathroom sink taps and a hospital bathtub [51,61,74]. This raises the hypothesis that end point contamination may be occurring from patient-to-water source. A study examining the influence of contaminated splash backs when handwashing in twenty faucet/sinks in hospital intensive care units found that the faucet spouts were more contaminated than the sink bowl and drains. Flawed sink design such as shallow bowls

enable splashing contaminated sink contents onto patient care items, healthcare workers hands and the patients' broader environment [75].

Numerous approaches are taken to ensure a facility's potable water supply is suitable for human use and consumption. The Healthcare Infection Control Practices Advisory Committee (HICPAC) has published guidelines to prevent the growth of bacterial species such as *Legionella* spp. [69]. This includes recommendations such as maintaining adequate water pressure, temperature and preventing stagnation. Some older healthcare facilities, built prior to such guidelines, often have plumbing infrastructure that doesn't meet these requirements. If infrastructure recommendations can't be met, additional measures such as chlorine treatment, copper-silver ionization or ultraviolet light can be used to ensure water quality [76]. As municipal water passes through the distribution network, the amount of residual disinfection agent can vary. If the facility is far away from the point of disinfection, the water the building receives may have disinfectant levels lower than the effective concentration [69]. The success of disinfection approaches may also be impacted by resistant species. For example, copper resistant *P. aeruginosa* was isolated from a French water system and tap aeration grids, and hydrogen peroxide and silver nitrate resistant *Legionella* spp. were isolated from a hospital's water supply [57,77]. Future work is needed to inform and improve HAI guidelines regarding the use of water and prevent the spread of AMR pathogens.

3.2. Biofilm Formation and Antimicrobial Resistance

Biofilms are secure, often heterogeneous, communities of microorganisms which colonize and grow on surfaces of medical implants, plumbing infrastructure and on patients [30]. They are comprised of dense microbial populations immobilized by an extracellular matrix comprised of bacterial secreted polymers such as exopolysaccharides (EPS), extracellular DNA and proteins [30]. Recently, point of use filters have been implemented in healthcare facilities as an additional form of protection from bacteria present in the water supply [78]. Even though *P. aeruginosa* and *Legionella* spp. were eliminated from taps in an intensive care unit in Hungary when point of use filters were installed, decreasing cases of infection to zero [79], they have been found to facilitate biofilm formation inside the filter when not maintained correctly, directly affecting the bacterial load in the water over time [78,80]. Within hospital water distribution systems and plumbing fixtures, biofilms provide a source of nutrients and protection from disinfection processes [30]. Biofilm growth is promoted in areas of low flow rate and stagnation which allows for bacterial attachment to the infrastructure surface [81].

The metabolic activity of the bacterial biofilm communities is different compared to planktonic bacteria, such as increased rates of EPS production, activation or inhibition of genes associated with biofilm formation and decreased growth rate [30]. The role of EPS has been linked to conferring tolerance to aminoglycosides by quenching their activity via a diffusion reaction inhibition [82]. An outbreak strain of aminoglycoside resistant *P. aeruginosa* was found on a contaminated bath toy in an Australian hospital [16]. Biofilm production confers protection to the microorganism communities from harmful pH, osmolarity, nutrient scarcity and shear forces [30]. Bacteria in biofilms are also more resistant to antimicrobial exposure by blocking the access of antibiotics, increasing the resistance by up to 1000-fold when compared to planktonic bacteria [45]. Once a biofilm community has reached maturation, species such as *L. pneumophila* may enter a viable non-culturable (VBNC) stationary phase as a way of surviving antibiotic stress [30,83]. Recent data suggests that hot water flushing and chlorination are not effective in eliminating *Legionella* spp. from plumbing systems over long periods of time [76,84]. This may be due to in part to bacterial species such as *Legionella* spp. being intracellular parasites of free living amoeba, resulting in conferred protection from disinfection by techniques when phagocytized [76].

One of the predominant mechanisms for acquiring antimicrobial resistance is uptake of resistance genes by horizontal gene transfer (HGT) [82]. The high cell density and presence of genetic elements from a highly heterogeneous community promotes this transfer via mechanisms such as conjugation, transformation or transduction [82]. Antimicrobial resistance may also be acquired via a mutation event in a bacterial chromosome [85]. Once the resistance mutation has stabilized in a generation,

it will be directly transmitted to all descendant cells by mitosis [86]. This process is known as vertical transmission. Under antimicrobial stress, resistance may arise via a combination of both HGT and vertical transmission. These genetic elements may enhance antimicrobial defense strategies by restricting drug entry via modifications to the cell wall, pumping the drug out of the cell, enzymatic degradation of the drug or deleting or decreasing the affinity of the involved target [87]. Exposure to chlorine can also stimulate the expression of efflux pumps and drug resistance operons, as well as induce mutations in some genes leading to increased antimicrobial resistance [45]. Some antibiotic gene profiles observed in hospital shower hose metagenomes have been reported to be triggered by biocide exposure [45,88,89]. These include commonly used antibiotics such as chloramphenicol, kanamycin, and penicillin. Species such as *Mycobacterium* spp. are commonly found in biofilm communities [45]. This may be because of physiochemical properties such as plumbing pipes being galvanized or made of copper, the disinfectant use and low organic carbon content of the water selectively favoring the growth of some *Mycobacterium* spp. [45]. When exposed to stress conditions, *Mycobacterium* spp. can modify the cell membrane fatty acid composition producing an altered permeability to biocide and antibiotic compounds [45,90,91]. The biofilm-forming capacity of pathogens such as *P. aeruginosa*, *Mycobacterium* spp. and *S. maltophilia* can promote the attachment of other pathogens such as *Salmonella* spp., *Campylobacter* spp. and *S. aureus* that are typically found in the wider hospital environment [92].

3.3. Detection Methods

3.3.1. Outbreak Investigations

Environmental screening typically takes place in response to an outbreak rather than as routine sampling, which leads to inconsistencies between the types of samples taken, isolation methods and antimicrobial resistance reporting. Thirty-five of 88 papers included in this review explored clinical outbreaks and sampled water and/or water related devices as a part of the investigation (Table S1). In contrast, 20/88 papers conducted broad screens of the facilities' environment in a non-outbreak setting. The Australian Guidelines for the Prevention and Control of Infection in Healthcare suggest that environmental testing should be carried out to identify risk factors [1]. However, it is not clear what sampling techniques are to be used and which samples should be taken [1]. Similarly, in the UK, there is guidance available from The National Specifications for Cleanliness in the NHS for monitoring the hospital environment. However, there was no indication of microbiological screening [93,94]. The absence of a standard approach for when environmental sampling should occur and what samples should be taken limits data comparisons that can be made and potentially overlooks reservoirs such as water and water-related devices.

3.3.2. Pathogen Detection from Environmental Sources

International standards have been published for the processing of environmental water samples for organisms such as *Legionella* spp., *P. aeruginosa* and *E. coli*. However, of the publications reviewed in this study, only three referenced a specific ISO standard [31,36,43]. There was significant variation between sampling techniques and selective growth media used in publications that investigated water-related surfaces such as tap faucets and drain holes [32,33,39–41,43,47,48,50,51]. Traditional microbial culturing techniques used for waterborne pathogens such as *Legionella* spp. has presented challenges for some environmental samples as VBNC cells and result in false negative results [83,95]. Furthermore, environmental waterborne pathogens often adapt to environments that are nutrient poor, which may be difficult to culture on nutrient-rich media types. Using nutritionally reduced media types such as R2A agar for longer incubation periods (14–28 days) may enhance the recovery of chlorine damaged and stressed bacteria [76]. Environmental water samples are often passed through membrane filters to concentrate and isolate any bacterial cells present in the sample. The pore diameter in these membrane filters typically ranges from 01 to 0.45 µm depending on the intended use [96]. The size, shape and biovolume of bacteria may influence the filterability of a sample and

potentially lead to inaccurate findings, particularly if multiple species of bacteria are being investigated using the one pore diameter [96]. Alternative molecular techniques for bacterial detection such as qPCR and whole-genome sequencing (WGS) have been employed by 27 studies included in this review [13,14,17,18,20,25,26,34,37,40,43,45,46,51,52,56,57,59,60,63–65,97–101]. Molecular techniques have significant advantages such as rapid turnaround times and detection of non-culturable cells [102]. However, limitations such as environmental inhibitors and potential overestimation of bacterial presence due to the amplification of non-viable cells needs to be considered [103]. For some bacteria, PCR-based techniques have been developed to differentiate viable cells from dead cells. For example, ethidium monoazide bromide viability staining can be used in conjunction with qPCR to enumerate viable cells (such as *L. pneumophila)* [102]. In order to implement effective surveillance programs, detailed and consistent sampling techniques and detection methods are essential.

3.3.3. Characterizing AMR

International standards for antimicrobial susceptibility testing have been jointly published by the Clinical and Laboratory Standards Institute and the European Centre for Disease Prevention and Control and the US CDC [104]. These standards include antibiotics to be tested against species that have commonly been associated with HAIs including *Acinetobacter* spp., *P. aeruginosa*, and *S. aureus* as well as breakpoints to determine an isolate's resistance to each antibiotic. Irrespectively, the reporting of resistant species remains inconsistent. When papers report the resistance profiles of an AMR isolate using differing units such as µg/mL or mg/mL MICs, percentage of isolates resistant or as specific resistance genes, the comparisons that can be made between studies are limited to broad comments rather than quantifiable data trends.

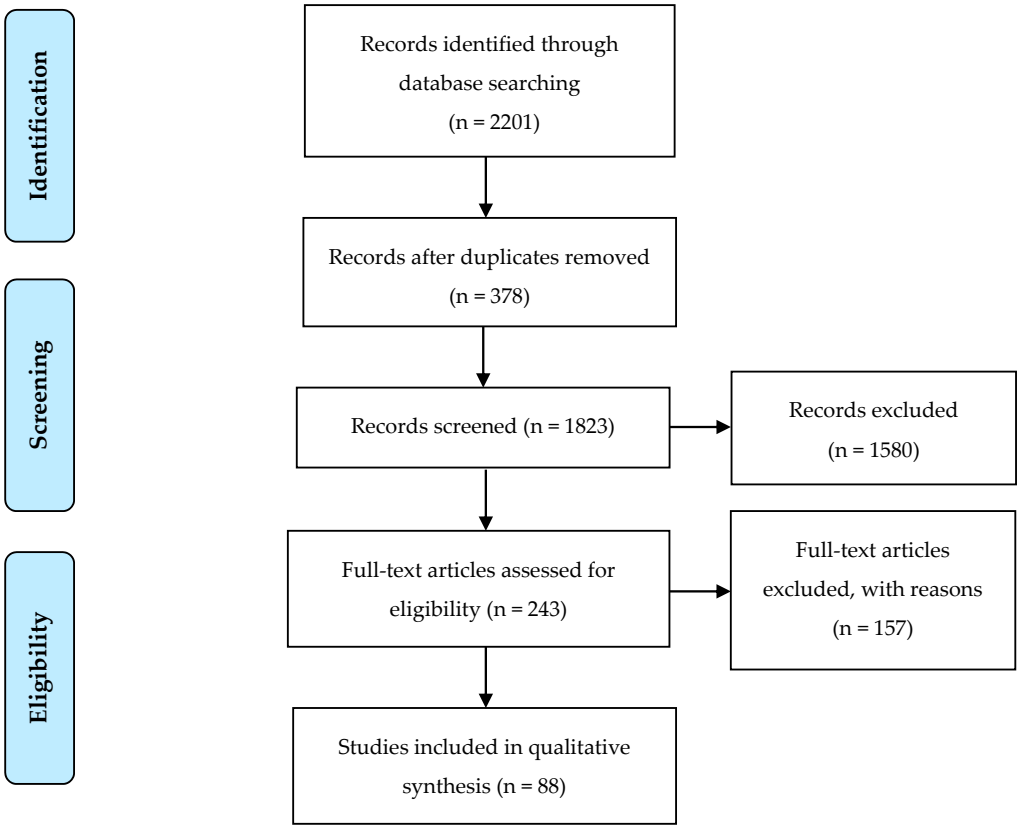

Figure 1. Flow diagram presenting the search strategies used, based on the PRISMA statement reporting guidelines for systematic literature reviews [105].

Figure 1. Flow diagram presenting the search strategies used, based on the PRISMA statement reporting guidelines for systematic literature reviews [105].

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4. Materials and Methods

This systematic literature review is based on an adapted version of the PRISMA statement [105], presented in Figure 1. This tool is an evidence-based system for evaluating and reporting evidence. A systematic search of the SCOPUS and Web of Science databases was performed, and all literature published prior to 2020 was included. Keywords used in this search are presented in Table 2. A detailed search strategy was established to ensure a comprehensive literature review of all identified antimicrobial resistance bacteria in healthcare water environments was achieved.

Table 2. Complete search strategy and all keywords used to identify relevant literature.

Search Terms Employed to Identify Relevant Literature
"antibiotic resistance *"OR "antimicrobial resistance *" OR disinfectant * OR AMR AND Water OR potable OR drinking OR taps OR faucet OR bath OR shower OR drain OR bathroom OR sink AND Hospital OR healthcare OR "aged care" OR ICU OR "intensive care unit" OR nosocomial OR HCAI OR "healthcare acquired infection" OR HAI OR "hospital acquired infection" OR "hospital associated infection" OR "healthcare associated infection"

'*' Indicates wildcard symbol used to when variations of the search term may be possible.

All titles and abstracts of published literature were manually reviewed to ensure that they reported antimicrobial resistant bacteria to the genus level. The paper must also have reported this presence in a healthcare setting water source or water-related device. Papers were excluded if they were not written in English, reviews, reports of human clinical infection with no mention of a contributing water source, laboratory setting experiments and wastewater investigations. All relevant papers had key points taken and recorded including the study site, water source, country, species of organism, isolation method used, antimicrobial method used, and relevant characteristics.

5. Conclusions

Although environmental reservoirs such as dry surface fomites have been identified as potential sources of HAIs, water and water-related devices are often overlooked. Understanding the role that water and water-related devices play as reservoirs for AMR bacteria is imperative to prevent transmission pathways that may cause HAIs. Water sources contaminated with AMR pathogens provide unique environments for the dissemination of antimicrobial resistance genes that are often unaffected by commonly employed disinfection strategies. Sinks, tap faucets, drains, bathtubs, drinking water fountains, aeration grids, showers and haemodialysis water have all been identified as contaminated with one or more species of AMR bacteria capable of causing HAIs. Broad universal environmental surveillance guidelines must be developed, including sampling locations, methodology and resistance reporting, to monitor resistant pathogens and predict future threats before infection outbreaks occur. By understanding how water and water related devices may harbor AMR species, better environmental controls can be implemented to significantly reduce the rates of waterborne HAIs.

Supplementary Materials: The following are available online at http://www.mdpi.com/2076-0817/9/8/667/s1, Table S1: Summary of reports and studies identifying AMR bacterial species within healthcare water sources and water-related devices during outbreak investigation, environmental screening, and molecular epidemiology.

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Investigation of healthcare infection risks from water-related organisms: Summary of CDC consultations, 2014—2017

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Abstract

Objective: Water exposures in healthcare settings and during healthcare delivery can place patients at risk for infection with water-related organisms and can potentially lead to outbreaks. We aimed to describe Centers for Disease Control and Prevention (CDC) consultations involving water-related organisms leading to healthcare-associated infections (HAIs).

Design: Retrospective observational study.

Methods: We reviewed internal CDC records from January 1, 2014, through December 31, 2017, using water-related terms and organisms, excluding *Legionella*, to identify consultations that involved potential or confirmed transmission of water-related organisms in healthcare. We determined plausible exposure pathways and routes of transmission when possible.

Results: Of 620 consultations during the study period, we identified 134 consultations (21.6%), with 1,380 patients, that involved the investigation of potential water-related HAIs or infection control lapses with the potential for water-related HAIs. Nontuberculous mycobacteria were involved in the greatest number of investigations (n = 40, 29.9%). Most frequently, investigations involved medical products (n = 48, 35.8%), and most of these products were medical devices (n = 40, 83.3%). We identified a variety of plausible water-exposure pathways, including medication preparation near water splash zones and water contamination at the manufacturing sites of medications and medical devices.

Conclusions: Water-related investigations represent a substantial proportion of CDC HAI consultations and likely represent only a fraction of all water-related HAI investigations and outbreaks occurring in US healthcare facilities. Water-related HAI investigations should consider all potential pathways of water exposure. Finally, healthcare facilities should develop and implement water management programs to limit the growth and spread of water-related organisms.

Water that is used in health care can harbor pathogenic organisms that can threaten patient safety.[1–3] Patients may be exposed to water sources and so-called “opportunistic pathogens of premise plumbing” through a variety of means.[4] In healthcare facilities, water systems often have complex distribution pathways with areas of stagnation, exposure to a variety of

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plumbing materials, and wide variability in temperature, pH, and disinfectant types and levels. These conditions can promote the development of biofilms and the growth of environmental opportunistic pathogens (eg, *Legionella*, nontuberculous mycobacteria (NTM), and *Pseudomonas* species). These organisms can be transmitted to patients, directly or indirectly, through typical water uses involving showers, sinks, and toilets. Moreover, water is widely used in clinical care, often in association with medical devices; it is also a key component in many drug or medication formulations. Patient susceptibility to opportunistic pathogens found in water may be increased by morbidities such as non-intact skin, open wounds, immunocompromising conditions, or the presence of invasive devices. Furthermore, hospital wastewater plumbing, including sink drains, can harbor multidrug-resistant organisms (MDROs), such as carbapenemase-producing *Enterobacteriaceae* (CRE), and may be a source of transmission to patients and a cause of clusters of healthcare-associated infections (HAIs).[5–7]

Outbreaks related to these organisms can be challenging to identify, investigate, and resolve. A high level of suspicion is typically needed to recognize that an infection or cluster of infections might be related to some form of water exposure associated with healthcare delivery. Interruption of transmission may require multidisciplinary interventions, often involving public utilities, health authorities, and consultants with expertise in water and environmental health. *Legionella* is a well-described cause of water-related HAIs, and these outbreaks can be associated with considerable patient harm and costs.[8] However, the occurrence of clusters of other water-related pathogens in healthcare has been less well described. In this report, we present a summary of Centers for Disease Control and Prevention (CDC) consultation experiences that have involved evaluating potential or confirmed transmission of water-related organisms, exclusive of *Legionella*. We describe the distribution of organisms, settings, and potential routes of transmission.

Methods

The Division of Healthcare Quality Promotion (DHQP) at CDC assists health departments and healthcare facilities with investigations of potential outbreaks involving the provision of health care. We reviewed our internal investigation consultation records from January 1, 2014, through December 31, 2017, using a query that involved a predefined set of water-related terms and list of water-related organisms (Table 1).

Investigations were excluded if (1) the consultation was for laboratory referencing testing only; (2) the infections were likely community acquired; (3) the organism in question was not a water-related opportunistic pathogen[3]; (4) an alternate transmission pathway was determined; or (5) the infections occurred outside the United States among non-US patients. Infections or outbreaks occurring abroad among non-US patients residing outside of the United States were excluded, whereas infections or outbreaks related to medical tourism where US patients travel abroad for medical care and acquire infections while abroad were included. Consultations involving *Legionella* infections and outbreaks were excluded because they have been summarized elsewhere.[8,9] Multistate investigations (which may have involved individual consultations with multiple health departments) were analyzed and counted as a single investigation.

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We compiled the following information for each investigation identified: (1) number of patients infected or colonized; (2) organism(s) identified, including multidrug-resistant designation;(3) classification as confirmed or pseudo-outbreak (ie, increase in positive cultures without evidence of disease in patients);(4) whether pediatric patients were involved; (5) type of healthcare facility (ie, inpatient, outpatient, long-term care); (6) whether hemodialysis was an exposure of interest; (7) whether surgery was an exposure of interest; and (8) details regarding medical product exposures. Information regarding the types of infections (eg, disseminated, respiratory) was not available for many consultations and was therefore not reported.

We classified investigations as medical-product related if the use of a medical device or medication was an exposure of interest. Medical devices included central venous catheters, injections, endoscopes, ventilators, and other types of medical devices. We classified investigations that implicated compounded or manufactured medication products as involving either intrinsic contamination (eg, medication supplied in a contaminated state due to a manufacturing error) or extrinsic contamination (eg, medication became contaminated at the point of care). Categories were not mutually exclusive. Although routes of transmission for patient colonization or infection were not always confirmed or documented for each investigation, we determined plausible exposure pathways and routes of transmission based on available epidemiologic and laboratory information. We also identified pathways associated with >1 investigation. Molecular typing methods are increasingly used to help determine potential transmission pathways in HAI investigations, but we did not have consistent or systematic information on molecular typing results for all consultations included in this analysis.

Two authors (K.M.P. and S.C.R.) reviewed a sample of 30% of the investigations to ensure agreement that all investigations met the inclusion criteria and agreement on investigation characteristics and classification. One author (K.M.P.) reviewed the remaining investigations.

Results

We provided consultation support for 620 investigations between 2014 and 2017. Of those, 134 (21.6%) consultations met our criteria (Table 2). These investigations involved 1,380 patients, with an average of 10.3 affected patients per investigation (range, 0–163). Pediatric patients were involved in 21.6% of investigations. More than 20 different organisms were identified as the pathogen of concern (Table 2). Investigations involving NTM accounted for the greatest number of investigations (n = 40, 29.9%) and patients affected (n = 549, 39.8%). *Pseudomonas* spp accounted for the next greatest number of investigations (n = 25, 18.7%; patients: n = 152,11.0%). *Burkholderia* spp accounted for 10.4% of all water-related investigations but represented 26.2% of patients. Some water-related investigations included >1 organism (n = 10, 7.5%). One-third of investigations included pathogens that were multidrug-resistant, excluding NTM (n = 45, 33.6%).

Consultations involved a variety of healthcare settings. Although most occurred in inpatient facilities (n = 94, 70.1%), many also occurred in outpatient (n = 26, 19.4%) and long-term

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care (n = 20, 14.9%) facilities. Surgery was an exposure of interest among 24 investigations (17.9%) and included cardiothoracic (n = 8), cosmetic (n = 5), and orthopedic (n = 3) surgeries among others. Medical products were involved in >35% of investigations, with medical devices representing the majority (n = 40, 83.3%). Medical device investigations involved 654 infected or colonized patients and included heater-cooler devices (n = 8), broncho-scopes (n = 5), other endoscopes (n = 3), and ventilators (n = 3), among others. Contaminated medications represented 9.7% of all investigations, with most involving probable intrinsic medication contamination (n = 10, 76.9%) and the remainder involving probable extrinsic medication contamination (n = 4, 30.8%).

As noted, NTM were involved in more investigations than any other bacterial pathogen. Of investigations involving NTM, most were *Mycobacterium abscessus* only (n = 10, 25.0%) or included multiple species of NTM (n = 11, 27.5%). Other NTM species included *M. fortuitum, M. chelonae, M. avium* complex, *M. goodii*, and *M. mucogenicum*, among others. NTM water-related investigations often involved a medical device (n = 20, 50.0%) or surgery (n = 21, 52.5%).

Table 3 lists examples of exposure pathways and routes of transmission for the investigations included in this study such as medication and nutrition preparation near the splash zones of sinks, contaminated water from operating room and patient care sinks, and poor practices in the reprocessing of reusable medical equipment, among others. Most exposure pathways and routes of transmission were identified in >1 investigation.

Discussion

Water-related opportunistic pathogens appear to contribute in important ways to the US HAI burden. Investigations involving non-*Legionella* water-related organisms or water exposures accounted for more than one-fifth of HAI consultations supported by CDC/DHQP from 2014 to 2017. These involved >1,300 patients, both adult and pediatric. Additionally, these water-related investigations span the spectrum of healthcare settings, including inpatient, outpatient, and long-term care settings. Table 4 provides descriptions of selected examples of water-related investigation consultations that occurred during the study period and represent a variety of healthcare settings and patient populations.

Our review may not represent the full spectrum of non-*Legionella*, water-related HAI investigations because we included only investigations in which CDC/DHQP provided consultation and assistance. The investigations summarized in our review likely represent more complex outbreaks and scenarios than those to which healthcare facilities and health departments might respond without consultation. Although CDC/DHQP tracks its response consultation activities, this does not constitute formal surveillance and final or complete information is lacking for many investigations. Therefore, information such as total number of patients infected or colonized reported in this review are likely underestimates. The number of patients not clinically infected or colonized by water-related organisms but *affected* by water-related outbreaks (eg, by patient notifications of exposed patients) is likely greater.[13] Additionally, as described in the Methods section, multistate outbreaks were counted as a single consultation, thereby underestimating the total number of consultations.

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For example, CDC/DHQP involvement in the multistate outbreak of *Mycobacterium chimaera* infections following cardiac surgery associated with contaminated heater-cooler devices was counted as a single investigation, despite more than a dozen individual consultations with various states across the United States.[14]

In our review, a large proportion of water-related HAI investigations involved surgery (17.9%) or a medical device (29.9%). In the presence of surgical incisions, injections, and invasive devices, normal surface and mucosal host defenses are breached, potentially leading to invasive infections.[18,19] As more invasive medical procedures are transitioned from the inpatient to the outpatient setting, patients at risk for becoming infected with water-related organisms are increasingly being exposed in ambulatory settings. Although more than two-thirds of water-related investigations occurred in the inpatient setting, we found that 20% occurred in outpatient settings. In recent years, increasing attention has focused on adherence to standard infection control practices in the outpatient setting because this setting has been identified as an area with limited to no regulatory oversight.[20] Infection control issues related to water-related HAIs in ambulatory settings pose a special challenge because freestanding outpatient facilities may have little awareness or monitoring of their water quality and of the pathways through which water-related organisms can be transmitted to patients.

Medical products featured prominently in more than one-third of the investigations on which we consulted, with medical devices representing the majority. Transmission pathways from medical devices to patients should always be considered for any device that utilizes water. Water contamination of medical products can occur through local exposures at the facility-level or further upstream at the site of manufacture. Both points of contamination should be considered at the start of an investigation, but when the latter is suspected, CDC and the Food and Drug Administration (FDA) should be alerted early in the investigation because point-source contamination can manifest as sporadic cases across multiple institutions and can be challenging to detect. As the development of new medical devices evolves and the use of established medical devices continues to increase in the delivery of patient care, special attention to the potential introduction of water-related organisms is needed at the point of manufacture.[16,17,15,21–23]

The global outbreak of *Mycobacterium chimaera* infections associated with contaminated heater-cooler devices used during cardiothoracic surgery is a prime example of a medical device that uses water but had not been historically considered to have a water-transmission pathway from device to patient. During this global outbreak, heater-cooler devices were discovered to generate bioaer-osols that were transmitted into the operating room environment, exposing patients to NTM and the risk of infection.[15,23] Prior to the outbreak, heater-cooler devices had been used for years during cardiothoracic surgery without an appreciation of this water-related risk. This example highlights the potential for widespread harm associated with contamination of a medication or device during production and the need for additional safeguards to protect against the introduction of water-related organisms at the site of manufacture. Nonetheless, the introduction of water-related organisms to medical products often occurs proximal to patient care. Examples include the preparation of

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injections near water sources such as sinks and the use of tap water in reprocessing reusable medical equipment (Table 3).

Nontuberculous mycobacteria featured prominently in our review as the single most common source of water-related organism infections and consultation requests during the study period. Surgery and medical devices were each involved in half of NTM water-related investigations. This finding is consistent with a systematic review of water-related infections of NTM in healthcare facilities, which found that the most common route of NTM infection transmission was through the use of nonsterile water during medical procedures, such as insertion of central venous catheters or with the use of tap water to rinse medical equipment.[24] The presence of NTMs in municipal water systems, their habitation in biofilms, and their relative chlorine resistance makes these organisms especially difficult to control or eradicate.[4,18,19] Given that NTM infections are often marked by long incubation periods, nonspecific symptomatology, and severe clinical impact, standard case reporting and public health surveillance for extrapulmonary NTM have been recommended; these measures could facilitate more timely identification of clusters and outbreaks.[25–27]

More than one-third of our water-related investigation consultations included an MDRO (not including NTM, which are intrinsically resistant to many antibiotics). Many of these MDROs were *Enterobacteriaceae* and other gram-negative organisms, for which routes of transmission other than water, such as person-to-person transmission, may play a significant role. Although incoming healthcare-facility water is often hypothesized as the ultimate source of infections with water-related organisms, MDROs have been identified in healthcare wastewater plumbing, such as sink drains and toilets, and these water reservoirs have been linked to patient transmission events.[5–7] When investigating a cluster of these water-related MDROs, potential transmission from wastewater plumbing should especially be considered.

Water is increasingly recognized as a source of HAIs.[28] A 2016 review of published literature of healthcare outbreaks associated with water reservoirs revealed a wide variety of pathogens and infection types, including bloodstream infections, pneumonia, and disseminated disease.[1] Reservoirs implicated in these outbreaks included potable water, bathing, decorative water fountains, faucets, ice machines, and hospital wastewater systems, among others, and they were consistent with many of the exposure pathways and transmission routes identified in our study (Table 3). CDC and the Centers for Medicare and Medicaid Services (CMS) encourage hospitals and nursing homes to establish water management programs to prevent water-related HAIs.[8,29] CMS recently clarified a memorandum requiring “all hospitals, critical access hospitals and long-term care facilities to develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduces the risk of growth and spread of *Legionella* and other opportunistic pathogens in water.”[29] However, water management programs should go beyond mitigating the risk of *Legionella* and the traditional routes of spread; they should explore other pathways of transmission, such as those described in this report. CDC’s “Tap Water Quality and Infrastructure Discussion Guide for Investigation of Potential Water-Associated Infections in Healthcare Facilities” is available to assist healthcare facilities identify areas of concern.[3] Water management programs should also maintain awareness of

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the risks and benefits of water conservation efforts, such as those associated with green water systems.[30]

In summary, our review highlights the contribution of water-related organisms to healthcare outbreaks and transmission and helps illustrate some of the challenges surrounding their investigation and prevention. Modern healthcare facilities have large, complex water systems that predispose them to biofilm formation and bacterial growth if not properly maintained.[18] For this reason, it is essential that healthcare facilities devise and implement a water management program that is effective in limiting water-related organisms from growing and spreading in their facility. Patient safety depends on assuring that water entering a healthcare facility meets all applicable quality standards and that the premise plumbing within the healthcare facility is designed and maintained in a way that minimizes growth and spread of water-related pathogens. Additionally, careful consideration should be taken of all potential pathways of water transmission to patients within a facility during patient care to minimize the risk of infection from water exposure.[3] Finally, because the potential exposure pathways for water-related organisms are numerous and extend from points of production to distribution, use, and disposal, primary prevention may never be absolute. Robust systems are needed, bridging healthcare and public health, to actively monitor and identify evidence of patient harms involving water-related organisms and to support timely investigation and effective interventions. This review highlights a wide variety of healthcare exposures and pathways that inform investigation and prevention of water-related healthcare-associated infections.

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Table 1.

Search Terms Used to Query Division of Healthcare Quality Promotion Records to Identify Water-Related Investigations, CDC, United States, 2014–2017

Aerator	*Burkholderia cepacia*
Aerosol	*Chronobacter* spp
Aerosolization	*Cupriavidus pauculus*
Bath tub	*Elizabethkingia anopheles*
Bidet	*Elizabethkingia meningoseptica*
Burn unit	*Enterobacter cloacae*
Drain	*Methylobacterium* spp
Faucet	*Pantoea agglomerans*
Ice machine	*Pseudomonas aeruginosa*
Splash	*Pseudomonas fluorescens*
Splash zone	*Pseudomonas putida*
Sink	*Ralstonia pickettii*
Water	*Ralstonia mannitolytica*
Waterborne	*Segniliparus* spp
Waterlines	*Serratia marcescens*
Mycobacterium	*Serratia liquefaciens*
Acinetobacter baumannii	*Sphingomonas paucimobilis*
Aeromonas hydrophila	*Stenotrophomonas maltophilia*

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Table 2.

Characteristics of Water-Related Investigations, Division of Healthcare Quality Promotion, CDC, United States, 2014–2017

Characteristic	Investigations (n = 134),[a,b] No. (%)	Patients (n = 1,380), No. (%)
Organism		
Achromobacter spp	1 (0.7)	2 (0.1)
Acinetobacter baumanii	8 (6.0)	40 (2.9)
Aspergillus niger	1 (0.7)	22 (1.6)
Burkholderia spp	14 (10.4)	361 (26.2)
Candida parapsilosis	1 (0.7)	4 (0.3)
Chronobacter sakazakii	1 (0.7)	1 (0.1)
CRE unspecified	1 (0.7)	1 (0.1)
Elizabethkingia spp	7 (5.2)	31 (2.2)
Enterobacter spp	11 (8.2)	38 (2.8)
Klebsiella spp	3 (2.2)	35 (2.5)
Malassezia spp	1 (0.7)	4 (0.3)
Methylobacterium thiocyanatum	1 (0.7)	1 (0.1)
Nontuberculous mycobacteria	40 (29.9)	549 (39.8)
Pseudomonas spp	25 (18.7)	152 (11.0)
Serratia spp	6 (4.5)	49 (3.6)
Stenotrophomonas spp	1 (0.7)	4 (0.3)
Multiple	10 (7.5)	85 (6.2)
Investigation characteristics[b,c]	**Investigations (n = 134), No. (%)**	
Multidrug-resistant organisms	45 (33.6)	
Pseudo-outbreak	7 (5.2)	
Pediatric	29 (21.6)	
Facility type		
Inpatient	94 (70.1)	
Outpatient	26 (19.4)	
Long-term care	20 (14.9)	
Dialysis	7 (5.2)	
Surgery related	24 (17.9)	
Medical product related	48 (35.8)	
Devices	40 (29.9)	
Medications	13 (9.7)	
Intrinsic contamination	10 (7.5)	
Extrinsic contamination	4 (3.0)	

[a] 2 investigations involved water-related infection control issues without an identified organism of concern or confirmed patient infection at the time of consultation with CDC/DHQP.

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[b] As described in the Methods section, multistate outbreak investigations were counted as a single consultation, such as the multistate investigation of *Mycobacterium chimaera* associated with contaminated heater-cooler devices.

[c] Categories are not mutually exclusive.

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Table 3.

Possible Exposure Pathways and Routes of Transmission Involved in Water-Related Investigations, Division of Healthcare Quality Promotion, CDC, United States, 2014–2017

Injection/medication preparation near sink[a]
Nutrition (including breast milk and infant formula) preparation near sink[a]
Patient care supplies stored by sinks and toilets in intensive care unit[a]
Contaminated compounded nasal spray used prior to laryngoscopy
Contaminated water from neonatal intensive care unit (NICU) sinks[a]
Contaminated water from operating room scrub sinks[a]
Contaminated sink drains[a]
Contaminated dialysis wall boxes[a]
Use of nonsterile ice for patient care among immunocompromised patients[a]
Use of contaminated water in dental water lines[10,11,a]
Water introduction during respiratory therapy[a]
Use of tap water during bronchoscopy procedures[a]
Use of nonsterile water for humidification reservoirs of infant incubators in NICU[a]
Use of consumer-grade humidifier in operating room during LASIK procedures[12]
Use of nonsterile water and inadequate disinfection of heater-cooler devices used during cardiac surgery[13–15,a]
Intrinsic contamination of medical products due to water contamination at production site[16–17,a]
Poor medical device reprocessing procedures[a]
Contaminated automated endoscope reprocessors
Poor cleaning and disinfection of hydrotherapy rooms and equipment[a]
Water from contaminated shower heads[a]
Improperly cleaned mobile shower trolleys
Hot tub use by surgical personnel[a]
Water contamination of specimens/reagents in the laboratory[a]
Building water leaks in patient care areas

[a]Indicates a potential exposure pathway or route of transmission that was documented as the possible source of infection in two or more investigations.

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Table 4.

Selected Examples of Water-Related Investigations, Division of Healthcare Quality Promotion, CDC, United States, 2014–2017

Year	Healthcare Setting	Description
2015	Outpatient dental clinic	• 24 children with odontogenic infections with *Mycobacterium abscessus* after undergoing pulpotomy procedures • All children required hospitalization and surgical intervention. • Water samples from dental station waterlines were positive for *M. abscessus* with laboratory typing showing matching strains to patient isolates. • Likely mode of transmission was the use of water from dental waterlines during pulpotomy procedures without water quality monitoring or disinfection of the waterlines.[10–11]
2016	Neonatal intensive care unit (NICU)	• 8 infants colonized or infected with *Pseudomonas aeruginosa* • Tap water and surface samples from sinks and expressed breast milk in the NICU were positive for *P. aeruginosa.* • Concern for multiple water transmission routes, including preparation of breast milk and infant formula near sinks, suboptimal cleaning of breast pump equipment, and use of tap water for filling humidifier reservoirs of infant incubators
2016–2017	Skilled nursing facilities	• 163 bloodstream infections of *Burkholderia cepacia* complex among patients from 59 nursing facilities across 5 states • Isolates from manufactured prefilled saline flush syringes were positive for *B. cepacia* complex with laboratory typing showing closely-related strains to patient isolates. • Nationwide recall of the contaminated saline flush syringes issued • Inspection of manufacturing facility identified deficiencies that could have contributed to contamination[16]
2017	Burn unit	• 5 infections of multidrug-resistant *P. aeruginosa* among patients in burn unit • Water samples from hydrotherapy room notable for heterotrophic plate count of >1 million colony-forming units/mL • Samples from family handwashing sinks and counters, hydrotherapy room equipment, and various sink drains were positive for *P. aeruginosa* of multiple different strains on molecular typing. • Likely modes of transmission included insufficient cleaning of hydrotherapy equipment and poor environmental cleaning practices.

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Clinical Infectious Diseases

INVITED ARTICLE

HEALTHCARE EPIDEMIOLOGY: Robert A. Weinstein, Section Editor

Healthcare Outbreaks Associated With a Water Reservoir and Infection Prevention Strategies

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Hospital water may serve as a reservoir of healthcare-associated pathogens, and contaminated water can lead to outbreaks and severe infections. The clinical features of waterborne outbreaks and infections as well as prevention strategies and control measures are reviewed. The common waterborne pathogens were bacteria, including *Legionella* and other gram-negative bacteria, and nontuberculous mycobacteria, although fungi and viruses were occasionally described. These pathogens caused a variety of infections, including bacteremia and invasive and disseminated diseases, particularly among immunocompromised hosts and critically ill adults as well as neonates. Waterborne outbreaks occurred in healthcare settings with emergence of new reported reservoirs, including electronic faucets (*Pseudomonas aeruginosa* and *Legionella*), decorative water wall fountains (*Legionella*), and heater-cooler devices used in cardiac surgery (*Mycobacterium chimaera*). Advanced molecular techniques are useful for achieving a better understanding of reservoirs and transmission pathways of waterborne pathogens. Developing prevention strategies based on water reservoirs provides a practical approach for healthcare personnel.

Keywords. waterborne outbreaks; healthcare-associated infections; water; outbreaks.

Hospital water and water-related devices as well as moist environments and aqueous solutions can serve as a reservoir of waterborne pathogens in healthcare settings [1, 2]. The hospital environment may allow contamination by waterborne pathogens, in part because water temperatures are suitable for bacterial growth, and the complex structure of hospital water systems often leads to stagnation, corrosion, and biofilm formation [3]. A variety of water reservoirs have been linked to nosocomial outbreaks including potable water, sinks, faucet aerators, showers, tub immersion, toilets, dialysis water, ice and ice machines, water baths, flower vases, eyewash stations, and dental-unit water stations [4]. Waterborne pathogens have included *Legionella*, other gram-negative bacilli, nontuberculous mycobacteria (NTM), fungi, protozoa, and viruses [3–5]. Transmission of these pathogens from a water reservoir may occur by direct and indirect contact, ingestion and aspiration of contaminated water, or inhalation of aerosols [1, 2]. Waterborne outbreaks caused by these pathogens and reservoirs have occurred among patients in healthcare settings and have been a serious threat to high-risk patients, especially critically ill patients and immunocompromised hosts, leading to substantial morbidity and mortality [3–5].

The aim of this review article was to (1) review healthcare-associated outbreaks and infections associated with a water reservoir from the published literature, and (2) provide infection prevention strategies and control measures by water reservoirs based on the published scientific evidence and available guidelines.

SEARCH AND SELECTION CRITERIA FOR REVIEWING THE LITERATURE

We searched the published literature via PubMed using the following Medical Subject Headings (MeSH) and keywords: (hospital OR hospitals OR hospital units OR nursing homes OR ambulatory care facilities OR ambulatory care OR dental facilities OR assisted living facilities OR healthcare settings OR patient) AND (waterborne pathogens OR *Legionella* OR Legionnaires' disease OR bacterial infections OR *Mycobacterium* infections OR fungal infections OR mycoses OR protozoan infections OR healthcare-acquired infection OR nosocomial OR cross infection OR outbreak) AND (hospital water OR drinking water OR potable water OR ice OR sink OR faucet OR faucet aerator OR shower OR tub or toilet OR water fountain OR water bath OR dialysis water OR decorative fountain OR ice machine OR air conditioning OR heater-cooler unit OR water microbiology OR disease reservoirs).

From January 1967 to July 2015, 2445 publications were identified as a result of our search and were reduced to 1746 by filters of availability in English and abstracts. The 1189 references (January 1997–July 2015) were screened using titles and abstracts, then selected articles were carefully reviewed. For the references published before 1997, we cited a previous review

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article [4] because of limited numbers of citable references. We excluded articles without abstracts, non-English-language articles, articles that were unavailable in PubMed, reported cases of contaminations or pseudo-outbreaks, and articles that did not include human infections. We identified 179 references by our initial screening process, and then prioritized listed citations to include at least 1 article from each reservoir and organism. Finally, 73 original articles [6–78] were selected and data were retrieved for further analysis. Table 1 provides the features of waterborne healthcare-associated outbreaks and infections by each category, including author, publication year, reservoir, organism, transmission, patient population, infection type, molecular typing, and study type.

HEALTHCARE-ASSOCIATED OUTBREAKS AND INFECTIONS CAUSED BY WATERBORNE PATHOGENS

A review of the literature revealed multiple outbreaks in healthcare facilities due to a variety of pathogens associated with a water reservoir (Table 1). Infections included bloodstream infections, pneumonia, and disseminated diseases (Table 1). Patient populations at risk for waterborne outbreaks and infections included those with hematological and other malignancies or stem cell transplants, immunocompromised patients, location in an intensive care unit (ICU), premature infants in a neonatal intensive care unit (NICU), burn patients, and patients during/after surgery (Table 1).

Causative pathogens included bacteria (*Legionella*, *Pseudomonas*, *Acinetobacter*, *Serratia*, *Stenotrophomonas*, *Enterobacter*, *Klebsiella*, *Alcaligenes*, *Burkholderia*, *Chryseobacterium*, *Elizabethkingia*, *Halomonas*, *Ochrobactrum*, *Sphingomonas*, NTM), fungi (*Aspergillus*, *Mucor*, *Trichosporon*, *Fusarium*, *Exophiala*), and viruses (norovirus) (Table 1). Details of overall waterborne pathogens in healthcare-associated infections [3, 5, 79–82], and specifically *Legionella* [83–86], *Pseudomonas aeruginosa* [87, 88], *Aspergillus* [89], and NTM [90], have been previously reviewed. *Legionella* and NTM can reside in hospital water distribution systems, while other gram-negative bacteria and fungi can form biofilms [3, 79]. We briefly updated key points from recent literature on healthcare-associated pathogens in waterborne outbreaks and infections as described below.

Legionella

Legionella can be detected in most water sources at low levels [91]. The level of contamination of *Legionella* in hospital water systems associated with disease remains unclear. A large healthcare-associated *Legionella* outbreak occurred at a Pennsylvania hospital despite implementing a *Legionella* disinfection program with a copper-silver ionization system of hospital water [40]. In this outbreak, a link between clinical isolates of *Legionella* and hospital environmental samples was confirmed by molecular typing, and *Legionella* was viable and transmissible despite the presence of copper and silver ion concentrations within the manufacturer's recommended range [40].

Multidrug-Resistant Gram-Negative Bacteria

As antimicrobial resistance in bacteria has become a global concern, multidrug-resistant gram-negative bacteria (*Klebsiella*, *Enterobacter*, *Pseudomonas*, *Acinetobacter*), including bacteria producing extended-spectrum β-lactamases or carbapenemases (eg, *Klebsiella pneumoniae* carbapenemase [KPC] and New Delhi metallo-β-lactamase), were described as waterborne pathogens causing healthcare-associated infections [19, 21, 22, 48, 50, 52, 54, 55, 57–59, 70, 71]. Multidrug-resistant organisms were most commonly linked to contaminated sinks as a reservoir (Table 1). Notably, an outbreak of 6 infections due to KPC-2–producing *Klebsiella oxytoca* in patients with hematological malignancies was linked to contaminated handwashing sinks [57].

Nontuberculous Mycobacteria

Our review found that a variety of NTM, including both rapid-growing and slow-growing species, has led to waterborne healthcare-associated outbreaks and infections as follows: *Mycobacterium abscessus* with tap water, *Mycobacterium avium* with potable water, *Mycobacterium chelonae* with ice and ice machines, *Mycobacterium chimaera* with heater-cooler units, *Mycobacterium fortuitum* with hospital water systems and showers, *Mycobacterium genavense* with tap water, *Mycobacterium mucogenicum* with bathing and tub immersion, electronic faucets, sinks, showers, and hospital water systems, *Mycobacterium neoaurum* with hospital water systems, *Mycobacterium phocaicum* with showers, *Mycobacterium porcinum* with ice and ice machines and tap water, and *Mycobacterium simiae* with tap water [7, 13, 20, 27, 28, 31, 34, 35, 37, 41, 45, 51, 60, 62, 66]. NTM can be present in municipal water systems and is relatively resistant to chlorination as well as being difficult to eradicate from contaminated water systems [3].

Fungi

Waterborne fungal outbreaks and infections occurred among patients with hematological malignancies or stem cell transplantation. *Aspergillus* can be detected from hospital water samples and has been reported to cause invasive aspergillosis [25, 43, 68, 89]. However, there are no criteria for contamination levels of hospital water associated with fungal infections. Furthermore, whether *Aspergillus* can cause waterborne healthcare-associated infections via aerosols generated from contaminated hospital water remains controversial [92]. Other fungal outbreaks associated with water reservoirs included *Mucor* with water-damaged plaster, *Trichosporon asahii* with wash basins, *Fusarium* with showers and sinks in a hospital water distribution system, and *Exophiala jeanselmei* with deionized water from the hospital pharmacy [11, 24, 74, 78].

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Table 1. Characteristics of Waterborne Outbreaks and Infections in Healthcare Settings, 1997 January–2015 June

Reservoir	Organism(s)	Transmission	Patient Population	Type of Infection	Molecular Typing	Study Type	First Author, Year
Bathing and tub immersion (bathing tub drain)	*Pseudomonas aeruginosa*	Tub immersion water contaminated from drain when whirlpool bathtub filled	Patients with hematological malignancies (leukemia)	Bloodstream infection, pneumonia, UTI	PFGE	Outbreak – strong causation	Berrouane, 2000 [6]
Bathing and tub immersion (showering)	*Mycobacterium mucogenicum*	Water contamination of CVCs during bathing or showering	BMT and oncology patients	Bacteremia	RAPD	Outbreak – strong causation	Kline, 2004 [7]
Bathing and tub immersion	*Legionella pneumophila*	24 h bath water contaminated	An elderly patient with dementia admitted to a nursing home	Pneumonia	PFGE	Case report (single) – strong causation	Mineshita, 2005 [8]
Bathing and tub immersion (bathing mattress)	*Alcaligenes xylosoxidans*	Bathing procedures and hydrotherapy in burn unit	Burn patients	Cholecystitis, meningitis	PFGE	Case report (single) – strong causation	Fujioka, 2008 [9]
Decorative water fountain	*Legionella pneumophila*	Exposure to contaminated water from decorative fountain	Allogeneic stem cell transplant patients	Pneumonia	PFGE	Outbreak – strong causation	Palmore, 2009 [10]
Deionized water from the hospital pharmacy	*Exophiala jeanselmei*	Contaminated deionized water solution that was used to prepare antiseptic solutions	Hematological malignancies	Fungemia	RAPD	Outbreak – strong causation	Nucci, 2002 [11]
Dialysis water supply	*Burkholderia cepacia*	Inadequate cleaning and a leak in the reverse osmosis tubing connection	Hemodialysis patients	Bacteremia	RAPD	Outbreak – strong causation	Souza, 2004 [12]
Electronic faucet	*Mycobacterium mucogenicum*	Exposure of CVC sites to contaminated water during bathing	Cancer patients (leukemia, rhabdomyosarcoma, neuroblastoma)	Catheter-associated BSI	RAPD	Outbreak – strong causation	Livni, 2008 [13]
Electronic faucet	*Pseudomonas aeruginosa*	Contamination of outlet, magnetic valve, and mixing device of the electric faucets	Patients in NICU	Bloodstream infection, ventilator-associated pneumonia	PFGE	Outbreak – strong causation	Yapicioglu, 2012 [14]
Faucet (aerator)	*Stenotrophomonas maltophilia*	Contaminated water after aeration	Patients in surgical ICU	Pneumonia, peritonitis, bacteremia, UTI	PFGE	Outbreak – strong causation	Weber, 1999 [15]
Faucet	*Pseudomonas aeruginosa*	Contaminated faucets	Patients in ICU	*P. aeruginosa* infection	PFGE	Case series (multiple) – strong causation	Blanc, 2004 [16]
Faucet	Nonfermentative gram-negative bacilli (eg, *Chryseobacterium meningosepticum*)	Unknown	Patients in ICU	Nosocomial infections	PFGE	Case series (multiple) – strong causation	Wang, 2009 [17]
Faucet (outlet)	*Pseudomonas aeruginosa*	Potential transmission from contaminated flow straighteners in the water outlets	Neonates in NICU	Bacteremia	VNTR	Case series (multiple) – strong causation	Walker, 2014 [18]
Faucet (water-saving device)	MDR-*Pseudomonas aeruginosa*	Water-saving device (aerator) in a staff hand basin and biofilm in the basin's plumbing contaminated	Patients in high dependency units	Nosocomial infection	PFGE	Case series (multiple) – strong causation	Inglis, 2010 [19]
Heater-cooler unit for cardiac surgery	*Mycobacterium chimaera*	Airborne transmission from contaminated heater-cooler unit water tanks	Patients who received open-chest heart surgery	Endocarditis, bloodstream infection, vascular graft infection	RAPD	Outbreak – strong causation	Sax, 2015 [20]

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Table 1 continued.

Reservoir	Organism(s)	Transmission	Patient Population	Type of Infection	Molecular Typing	Study Type	First Author, Year
Hospital waste water system	MDR *Pseudomonas aeruginosa*	Contaminated hospital waste water systems (sink, shower, and toilet)	Patients in ICU and hematology units	Bacteremia	PFGE, VNTR	Outbreak – strong causation	Breathnach, 2012 [21]
Hospital waste water system	IMP-type metallo-β-lactamase-producing *Klebsiella oxytoca*	Contaminated water	Patients in medical and surgical ICU	Bacteremia, ventilator-associated pneumonia, UTI, peritonitis	PFGE	Outbreak – strong causation	Vergara-Lopez, 2013 [22]
Hospital water system	*Legionella pneumophila*	Contaminated water supply	Immunocompromised patients	Pneumonia	PFGE	Case series (multiple) – strong causation	Rangel-Frausto, 1999 [23]
Hospital water system	*Fusarium*	Aerosols from showers and sinks	Patients with leukemia, neutropenia, BMT or stem cell transplant	Invasive fusariosis	RAPD, RFLP, IR-PCR	Case series (multiple) – strong causation	Anaissie, 2001 [24]
Hospital water system	*Aspergillus fumigatus*	Unknown	BMT patients	Invasive pulmonary aspergillosis	AFLP	Case series (multiple) – strong causation	Warris, 2003 [25]
Hospital water system	Amoeba-associated bacteria (mainly *Legionella anisa, Bosea massiliensis*)	Unknown	Patients receiving mechanical ventilation in ICU	Ventilator-associated pneumonia	Seroconversion	Case series (multiple)	La Scola, 2003 [26]
Hospital water system	*Mycobacterium avium* complex	Contaminated hospital hot water system	Hospitalized patients	NTM pulmonary disease	PFGE	Case series (multiple) – strong causation	Tobin-D'Angelo, 2004 [27]
Hospital water system	NTM (*Mycobacterium mucogenicum, Mycobacterium neoaurum*)	Exposure of CVC sites to contaminated water during showering	Patients with hematological malignancies	Bacteremia	NA	Outbreak	Baird, 2011 [28]
Hospital water system	Rapidly growing mycobacteria (eg, *Mycobacterium chelonae*)	Contaminated water and ice machines	Hematopoietic cell transplant patients	Mycobacterial infection	NA	Outbreak	Iroh Tam, 2014 [29]
Hospital water system	*Pseudomonas aeruginosa*	Contaminated water outlet and shower hydrotherapy	Burn patients	Nosocomial infection	Whole-genome sequencing	Case series (multiple) – strong causation	Quick, 2014 [30]
Hospital water system	*Mycobacterium fortuitum*	Contaminated shower water	A postoperative patient with breast cancer	Breast infection	Repetitive extragenic palindromic PCR	Case report (single) – strong causation	Jaubert, 2015 [31]
Ice and ice machine	*Legionella pneumophila*	Microaspiration of ice or ice water	A patient with interstitial pneumonia and mechanical ventilation treated with steroids	Respiratory tract infection	NA	Case report (single)	Graman, 1997 [32]
Ice and ice machine	*Enterobacter cloacae*	Contaminated ice used for cardioplegia in cardiac surgery	Patients who received coronary artery bypass grafting	Postoperative wound infection	PFGE	Outbreak – strong causation	Breathnach, 2006 [33]
Ice and ice machine/ tap water	*Mycobacterium chelonae*	Application of contaminated nonsterile ice to the skin	Patients after cosmetic dermal filter injections at a plastic surgery clinic	Cutaneous infection	PFGE	Case series (multiple) – strong causation	Rodriguez, 2013 [34]
Ice and ice machine/ tap water	*Mycobacterium porcinum*	Contaminated water	Patients with pulmonary disease or extrapulmonary disease	Pulmonary infection, localized abscess, infected port, peritonitis	PFGE	Case series (multiple) – strong causation	Brown-Elliott, 2011 [35]
Ice bath	*Pseudomonas fluorescens*	Contaminated ice bath used for cardiac output infusion	Patients with cardiac diseases in a CCU	Bacteremia	PFGE	Outbreak – strong causation	Benito, 2012 [36]
Potable water	*Mycobacterium avium*	Contaminated water	Patients with AIDS and non-AIDS	Disseminated infection	PFGE	Outbreak – strong causation	Aronson, 1999 [37]

Table 1 continued.

Reservoir	Organism(s)	Transmission	Patient Population	Type of Infection	Molecular Typing	Study Type	First Author, Year
Potable water	*Pseudomonas fluorescens*	Contaminated water dispenser that supplied bottled water in a BMT unit	Patients with hematological malignancies	Nosocomial infection and febrile neutropenia	RAPD, PFGE	Outbreak – strong causation	Wong, 2011 [38]
Potable water	*Stenotrophomonas maltophilia*	Contaminated drinking water of the cooling unit in the ICU kitchen and mouth care to patients	Patients in ICU	Pneumonia	PFGE	Outbreak – strong causation	Guyot, 2013 [39]
Potable water	*Legionella pneumophila*	Unknown	Patients with Legionnaires' disease	Healthcare-associated Legionnaires' disease	Sequencing	Outbreak – strong causation	Demirjian, 2015 [40]
Shower	*Mycobacterium fortuitum*	Showerhead used by patients	A neutropenic patient with leukemia	Disseminated infection	AP-PCR typing	Case report (single) – strong causation	Kauppinen, 1999 [41]
Shower	*Pseudomonas aeruginosa*	Potential transmission via hand shower contaminated	Patients in a BMT ward	Bacteremia	PFGE	Outbreak – strong causation	Lyytikainen, 2001 [42]
Shower (wall)	*Aspergillus*	Potential aerosolization of fungal propagules	Patients in BMT units	Aspergillosis	RAPD	Case report (single) – strong causation	Anaissie, 2002 [43]
Shower (hot water supply)	*Legionella* spp (mainly *Legionella pneumophila*)	Inhalation of shower aerosols	Older people in nursing homes	Pontiac fever	NA	Case series (multiple)	Bauer, 2008 [44]
Shower	*Mycobacterium mucogenicum, Mycobacterium phocaicum*	Exposure to contaminated water via hand shower	Oncology patients	Catheter-associated BSI	Repetitive element PCR, RAPD, PFGE	Outbreak – strong causation	Cooksey, 2008 [45]
Shower	*Acinetobacter ursingii*	Unknown	Immunocompetent pregnant patients in an obstetrics ward	Bloodstream infection	PFGE (unrelated)	Case series (multiple)	Horii, 2011 [46]
Sink	*Serratia marcescens*	Soap and soap bottles contaminated	Infants in NICU	Multiple (eye, respiratory, blood, urine, wound, rectum)	PFGE	Outbreak – strong causation	Archibald, 1997 [47]
Sink / Faucet	MDR *Pseudomonas aeruginosa*	Contamination of water basin sinks and water taps (potential)	Patients who received invasive treatment (surgery, cancer therapy)	Pneumonia, UTI	PFGE	Case series (multiple) – strong causation	Pitten, 2001 [48]
Sink	*Enterobacter*	Unknown	Patients in ICU	Pneumonia	PFGE	Case report (single) – strong causation	Wagenlehner, 2002 [49]
Sink (trap)	MDR *Acinetobacter baumannii*	Unknown	Patients in medical/surgical ICU	Respiratory tract infection, ventilator-associated pneumonia, bloodstream infection, abscess, wound infection	Restriction endonuclease analysis	Outbreak – strong causation	La Forgia, 2010 [50]
Sink	*Mycobacterium mucogenicum*	Probable exposure when intravenous medication was prepared near the sink and implanted ports were accessed	Patients with sickle cell disease in an outpatient clinic	Bloodstream infection	Repetitive-sequence-based PCR	Outbreak – strong causation	Ashraf, 2012 [51]
Sink	KPC-producing *Klebsiella pneumoniae*	Sinks contaminated from waste water	Patients in surgical/medical ICU	Bacteremia	PFGE, MLST	Outbreak – strong causation	Tofteland, 2013 [52]
Sink	*Elizabethkingia meningoseptica*	Contaminated handwash sink and water	Bedside hemodialysis patients on mechanical ventilation in ICU	Bacteremia, lower respiratory tract infection, ventilator-associated pneumonia	NA	Case series (multiple)	Ratnamani, 2013 [53]
Sink	ESBL-producing *Enterobacter cloacae*	Contaminated sink	Patients in ICU	Pneumonia	AFLP	Outbreak – strong causation	Wolf, 2014 [54]

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Table 1 continued.

Reservoir	Organism(s)	Transmission	Patient Population	Type of Infection	Molecular Typing	Study Type	First Author, Year
Sink	GIM-producing *Pseudomonas aeruginosa*	Inappropriate use of surface areas around washbasins as placement of clean items	Patients in a tertiary care hospital	*P. aeruginosa* infection	PFGE, MLST	Outbreak – strong causation	Wendel, 2015 [55]
Sink	*Pseudomonas aeruginosa*	Contaminated water from sink	Infants in NICU	Pneumonia	Whole-genome sequencing, ERIC-PCR typing	Outbreak – strong causation	Davis, 2015 [56]
Sink	KPC-producing *Klebsiella oxytoca*	Contaminated handwashing sink	Patients with hematological malignancies	Pneumonia, abdominal wall abscess	Repetitive-sequence-based PCR, MLST	Outbreak – strong causation	Leitner, 2015 [57]
Sink / Shower	NDM-producing *Klebsiella pneumoniae*	Interhospital transfer of patients and contaminated sink trap	Older or chronically ill patients	*K. pneumoniae* infection	PFGE, MLST	Outbreak – strong causation	Seara, 2015 [58]
Sink / Tap water	MDR *Pseudomonas aeruginosa*	Contaminated water or patient-to-patient transmission	Patients in a neurosurgery ICU	Multiple (urinary infection, pneumonia, sinusitis)	PFGE	Outbreak – strong causation	Bert, 1998 [59]
Tap water	*Mycobacterium abscessus*	Inadequate sterilization of surgical instruments	Postsurgical patients	Wound infection	NA	Outbreak	Chadha, 1998 [60]
Tap water	Small round structured viruses	Transient contamination of the taps	Patients in a reeducation ward	Gastroenteritis	Sequencing	Outbreak – strong causation	Schvoerer, 1999 [61]
Tap water	*Mycobacterium genavense*	Ingestion of contaminated water	HIV-infected patients treated with HAART	Disseminated mycobacteriosis	NA	Case series (multiple)	Hillebrand-Haverkort, 1999 [62]
Tap water	*Ochrobactrum anthropi*	Unknown	Immunocompromised patients (leukemia) in hematology unit	Bacteremia	PFGE (unrelated)	Case series (multiple)	Deliere, 2000 [63]
Tap water	*Chryseobacterium* (*Flavobacterium*) *meningosepticum*	Contaminated sink drain and biofilm inside the sink tap	Neonates in NICU	Pneumonia, meningitis with septicemia	PFGE	Outbreak – strong causation	Hoque, 2001 [64]
Tap water	*Sphingomonas paucimobilis*	Contaminated taps and showers used in a hematology ward	A neutropenic patient with leukemia	Bacteremia	RAPD	Case report (single) – strong causation	Perola, 2002 [65]
Tap water	*Mycobacterium simiae*	Potential transmission via showering	Pulmonary cancer, chronic pulmonary disease	Pulmonary infection	PFGE	Outbreak – strong causation	Conger, 2004 [66]
Tap water	*Burkholderia cepacia*	Alcohol skin antiseptic diluted by contaminated tap water that was applied to intravenous catheter site	Patients with cardiovascular disease or cancer	Bacteremia	RFLP	Outbreak – strong causation	Nasser, 2004 [67]
Tap water	*Aspergillus flavus*	Contamination of hospital environment (air, tap water, surface)	Patients in BMTU, ICU, and NICU	Invasive aspergillosis	RAPD	Case report (single) – strong causation	Ao, 2014 [68]
Tap water	*Pseudomonas aeruginosa*	Contaminated tap water	Patients in ICU	Nosocomial infection	NA	Case series (multiple)	Venier, 2014 [69]
Tap water / Wash basin	MDR *Pseudomonas aeruginosa*	Contaminated water taps and wash basins	Patients receiving mechanical ventilation in ICU	Lower respiratory infection and bloodstream infection	AFLP	Outbreak – strong causation	Bukholm, 2002 [70]
Toilet	MDR *Pseudomonas aeruginosa*	Potential cross transmission via toilet brush	Hospitalized patients	Nosocomial infection	PFGE	Case series (multiple) – strong causation	Kouda, 2011 [71]
Toilet / Shower	Norovirus	Possible transmission via hand contact and contaminated items within toilets and the bedside environment	Hospitalized patients with symptoms of gastroenteritis	Gastroenteritis	RT-PCR	Case series (multiple)	Morter, 2011 [72]

Table 1 continued.

Reservoir	Organism(s)	Transmission	Patient Population	Type of Infection	Molecular Typing	Study Type	First Author, Year
Wash basin / Potable water	*Legionella pneumophila*	Contaminated water in wash basins	A patient with leukemia	Pneumonia	PFGE	Case report (single) – strong causation	Brulet, 2008 [73]
Wash basin / Sink	*Trichosporon asahii*	Contaminated wash basins	Patients with malignancies, burns, and surgery in ICU	Disseminated infection	Sequencing	Case series (multiple) – strong causation	Fanfair, 2013 [74]
Water bath	*Pseudomonas aeruginosa*	Transfusion of contaminated fresh frozen plasma or human albumin	Infants in NICU	Bloodstream infection	RAPD	Outbreak – strong causation	Muyldermans, 1998 [75]
Water bath	*Halomonas phocaeensis* sp nov	Administration of fresh frozen plasma warmed by contaminated water baths	Neonates in NICU	Bacteremia	16S rRNA gene sequencing	Outbreak	Berger, 2007 [76]
Water birthing	*Legionella pneumophila*	Aspiration of pool water contaminated	A neonate	Pneumonia	NA	Case report (single)	Franzin, 2001 [77]
Water-damaged plaster	*Rhizomucor pusillius*	Water damage in a linen room and parents' shower room	Patients with leukemia	Rhinocerebral mucormycosis	NA	Outbreak	Garner, 2008 [78]

In study type, each article's definition of "case series (multiple)" or "outbreak" was used. "Case series (multiple)" or "case report (single)" was determined based on the number of human infections linked to a water reservoir. "Strong causation" was added when at least 1 molecular typing method indicated relatedness to a water reservoir.

Abbreviations: AFLP, amplified fragment length polymorphism; AP-PCR, arbitrarily primed polymerase chain reaction; BMT, bone marrow transplant; BMTU, bone marrow transplant unit; BSI, bloodstream infection; CCU, coronary care unit; CVC, central venous catheter; ERIC-PCR, enterobacterial repetitive intergenic consensus polymerase chain reaction; ESBL, extended-spectrum β-lactamase; GIM, German imipenemase; HAART, highly active antiretroviral therapy; HIV, human immunodeficiency virus; ICU, intensive care unit; IMP, imipenem; IR-PCR, interrepeat polymerase chain reaction; KPC, *Klebsiella pneumoniae* carbapenemase; MDR, multidrug resistant; MLST, multilocus sequence typing; NA, not applicable; NDM, New Delhi metallo-β-lactamase; NICU, neonatal intensive care unit; NTM, nontuberculous mycobacteria; PCR, polymerase chain reaction; PFGE, pulsed-field gel electrophoresis; RAPD, random amplification of polymorphic DNA; RFLP, restriction fragment length polymorphism; rRNA, ribosomal RNA; RT-PCR, reverse transcription polymerase chain reaction; UTI, urinary tract infection; VNTR, variable number tandem repeat.

RESERVOIRS AND TRANSMISSION ROUTES OF WATERBORNE PATHOGENS AND INFECTION PREVENTION STRATEGIES AGAINST WATERBORNE OUTBREAKS IN HEALTHCARE SETTINGS

All water with the exception of sterile water and filtered water is contaminated with microbes (eg, potable water, tap water, showers, and ice). In healthy persons, contact or ingestion of such water rarely leads to infection. However, contact or ingestion of such water may cause infection in immunocompromised persons or when applied to nonintact skin. Water-related reservoirs in healthcare settings during 1997–2015 were as follows: bathing and tub immersion, decorative water fountains, deionized water, dialysis water, electronic faucets, faucets, heater-cooler units, hospital wastewater systems, hospital water systems, ice and ice machines, ice baths, potable water, showers, sinks, tap water, toilets, wash basins, water baths, water birth, water-damaged plaster, and water-saving devices (Table 1). Transmission routes were primarily direct contact with contaminated water and water-related devices/activities or inhalation via aerosols generated from the contaminated water (Table 1). Waterborne healthcare-associated outbreaks and infections continue to occur and were mostly associated with well-recognized water reservoirs as previously described [4]. Moreover, recent studies document electronic faucets (*P. aeruginosa*, *Legionella*, *M. mucogenicum*) [13, 14, 93–95], decorative water wall fountains (*Legionella*) [10, 91], and heater-cooler devices used for cardiac surgery (*M. chimaera*) [20, 96] as water reservoirs. Infection prevention and control measures by each reservoir category are summarized in Table 2. The Centers for Disease Control and Prevention (CDC) has published recommendations of infection prevention and management for hospital water [1, 2].

Potable Water, Tap Water, and Hospital Water Systems

Various healthcare-associated infections were linked to contaminated potable/tap water and hospital water systems, especially among immunocompromised and severely ill patients [21–26, 28, 29, 37–39, 62–65, 68–70]. The common pathogens included gram-negative bacilli (eg, *Pseudomonas*, *Stenotrophomonas*) [21, 30, 38, 39, 69, 70], *Legionella* [23, 40], and NTM [27–29, 31, 37, 60, 62, 66]. Waterborne organisms may exist in potable water at acceptable levels of coliform bacteria (<1 coliform bacterium/100 mL) [4]. Standards for potable water should adhere to public health guidelines, and hot water temperature at the outlet should be maintained at the highest temperature allowable [1, 2].

Sinks

Some studies demonstrated a transmission link between sinks colonized with a pathogen and patients using molecular typing methods [47–52, 54–59]. The most frequent pathogens associated with sinks were gram-negative bacilli (eg, *Pseudomonas*, *Acinetobacter*, *Serratia*), as gram-negative bacilli can survive in wet

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Table 2. Summary of Key Issues and Infection Prevention Strategies Against Waterborne Outbreaks by Major Water Reservoir in Healthcare Settings

Reservoir	Key Issues	Infection Prevention Strategies
Potable water, tap water, and hospital water systems	Potable water is not sterile, and pathogenic waterborne organisms may exist in potable water at acceptable levels of coliform bacteria (<1 coliform bacterium/100 mL). Healthcare-associated outbreaks have been linked to contaminated potable water. Semicritical devices are often rinsed with potable water, which may lead to contamination of the equipment and subsequent healthcare-associated infections. Common pathogens include nonenteric gram-negative bacilli (eg, *Pseudomonas aeruginosa*), *Legionella*, NTM.	Follow public health guidelines. Hot water temperature at the outlet at the highest temperature allowable, preferably >51°C. Water disruptions: post signs and do not drink tap water. Maintain standards for potable water (<1 coliform bacterium/100 mL). Rinse semicritical equipment with sterile water, filtered water, or tap water followed by alcohol rinse. Some experts have recommended periodic monitoring of water samples for growth of *Legionella*. *Legionella* eradication can be technically difficult, temporary, and expensive. Potential methods of eradication include filtration, ultraviolet, ozonization, heat inactivation (>60°C), hyperchlorination, and copper-silver ionization (>0.4 ppm and >0.04 ppm, respectively).
Sinks	Colonization of sinks with gram-negative bacilli has been reported. Some studies demonstrate a transmission link between a colonized sink and infected patients. Some studies describe that multidrug-resistant gram-negative bacilli are associated with contaminated sinks. Gram-negative bacilli can survive wet environments, including sinks, for a long time (>250 d) Transmission can be caused by splashing of water droplet from contaminated sinks to hands of healthcare personnel, followed by transient colonization of hands. Common pathogens include gram-negative bacilli (eg, *Pseudomonas*, *Acinetobacter*, *Serratia*).	Use separate sinks for handwashing and disposal of contaminated fluids. Decontaminate or eliminate sinks as a reservoir if epidemic spread of gram-negative bacteria via sinks is suspected.
Faucet aerators	Faucet aerators may serve as a platform for accumulation of waterborne pathogens. Potential pathogens include *Pseudomonas*, *Stenotrophomonas*, and *Legionella*.	Routine screening and disinfection or permanent removal of all aerators are not warranted at present. No precautions necessary at present. For *Legionella* outbreaks, clean and disinfect faucet aerators in high-risk patient areas periodically, or consider removing them in the case of additional infections.
Showers	Some outbreaks are linked to contaminated shower heads or inhalation of aerosols. Potential pathogens include *Legionella*, *Pseudomonas*, NTM, group A *Streptococcus*, and *Aspergillus*.	Prohibit use of showers in neutropenic patients. Control *Legionella* colonization of potable water.
Ice and ice machines	Patients can acquire pathogens by sucking on ice, ingesting iced drinks, or use of contaminated ices for cooling medical procedure and patients' skin. Large outbreaks occurred when ice machines have become contaminated and ice used for cooling drinking water. Common pathogens include *Pseudomonas*, *Enterobacter*, *Legionella*, NTM, and *Cryptosporidium*.	Do not handle ice by hand. Do not store pharmaceuticals or medical solutions on ice for consumption. Use automatic dispenser rather than open chest storage compartments in patient areas. Clean and disinfect ice-storage chests regularly. Meaningful microbial standards for ice and ice machines do not exist. Routine culturing of ice machines are not recommended. A regular disinfection program for ice machines is recommended.
Eyewash stations	Stationary and portable eyewash stations may not be used for months or years. The water source may stand in the incoming pipes at room temperature for a long period. Pathogens, including *Pseudomonas*, *Legionella*, amoebae, and fungi, could be transmitted.	Use sterile water for eye flush or regularly (eg, monthly) flush eyewash stations.
Dental-unit water systems	Potable water usually supplies dental units. Water delivered to dental devices (eg, dental handpieces and air/water syringes) as well as dental unit water lines may be contaminated. Immunocompromised patients may be at risk for infection. Pathogens, including *Sphingomonas*, *Pseudomonas*, *Acinetobacter*, *Legionella*, and NTM, have been recovered from water supplies in dental units.	Clean dental water systems. Flush with water and disinfectant solution, or use of clean-water systems that put sterile water into the dental unit. Flush dental instruments with water and air for 20–30 sec from any dental device connected to the dental water system that enters the patient's mouth (eg, handpieces). Ensure that water in dental unit meets standards (<500 CFU/mL).
Dialysis water	Excessive levels of gram-negative bacilli in the dialysate were responsible for pyrogenic reactions in patients or bacteremia, which was caused by bacteria or endotoxin entry into the blood from the contaminated dialysate.	Follow AAMI standards for quality assurance performance of dialysis devices. Disinfect water distribution system on a regular basis. Perform microbiological testing and endotoxin testing for water in dialysis settings regularly. Maintain dialysis water (input) <200 CFU/mL and dialysate (output) <200 CFU/mL per CMS.
Water and ice baths	Contaminated water baths were used to thaw or warm blood products (fresh plasma, cryoprecipitate) or peritoneal dialysate bottles, followed by contamination of the infusates occurred during preparation. Contaminated ice baths were used to cool syringes or bottles of saline in measuring cardiac output. Potential pathogens include *Pseudomonas*, *Acinetobacter*, *Burkholderia*, *Staphylococcus*, and *Ewingella*.	Consider routine cleaning, disinfection, and changing of water in water baths. Add germicide to water bath or use plastic overwrap of blood products and keep the surfaces dry. Use sterile water in ice baths (or at room temperature) used for thermodilution catheters.

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Table 2 continued.

Reservoir	Key Issues	Infection Prevention Strategies
Bathing, tub immersion, and hydrotherapy	Tub immersion used in hospitals for physical hydrotherapy and for cleaning of burn wounds can cause cross-transmission, transmission from environmental reservoirs, or autotransmission. Skin infections such as folliculitis and cellulitis occurred related to water immersion. Water contamination of central venous catheters during bathing was related to bloodstream infection. Potential pathogens include *Pseudomonas*, *Enterobacter*, *Citrobacter*, *Acinetobacter*, *Legionella*, *Alcaligenes*, and NTM.	Adhere strictly to proper disinfection of tub between patients. Drain and clean tanks and tubs after use of each patient, and disinfect surfaces and components according to the manufacturer's instructions. Add disinfectant to the water: 15 ppm in small hydrotherapy tanks and 2–5 ppm in whirlpools per CDC. Disinfect after using tub liners. Cover catheter sites with transparent occlusive dressing.
Toilets	Transmission can be caused by aerosolization of fecal bacteria via flushing or surface contamination by fecal bacteria. Transmission could happen in healthcare facilities caring for mentally or neurologically impaired patients, or children. Potential pathogens include enteric bacteria, *Pseudomonas*, *Clostridium difficile*, and norovirus.	Facilitate good handwashing practices. Maintain clean surfaces with disinfectants. Clean bowl with a scouring powder and a brush. No reason to pour disinfectant into bowl. Separate toilet bowl from clean hospital surfaces.
Flowers and vases	Flower vases and potted plants are heavily colonized with potential pathogens, including *Acinetobacter*, *Klebsiella*, *Enterobacter*, *Pseudomonas*, *Serratia*, *Burkholderia cepacia*, *Aeromonas hydrophila*, and *Flavobacterium*. No healthcare-associated outbreaks directly linked to flower vases or potted plants have been reported.	Prohibit fresh flowers and potted plants in the rooms of immunocompromised and ICU patients. Or add antimicrobial agent to vase water and disinfect vases after use.
Electronic faucets	Electronic faucets were likely to be contaminated by several waterborne pathogens than handle-operated faucets. Issues associated with electronic faucets include a longer distance between the valve and the tap, resulting in a longer column of stagnant, warm water, which favors production of biofilms; reduced water flow; reduced flushing effect (growth favored); valves and pipes made of plastic (enhances adhesion of *P. aeruginosa*).	Electronic faucets need to be designed so that they do not promote the growth of microorganisms. No guideline (but some authors have recommended) to remove electronic faucets from high-risk patient care areas [eg, BMTU]). Some have recommended periodic monitoring of water samples for growth of *Legionella*.
Decorative water wall fountains	*Legionella* pneumonia cases associated with decorative water fountain were reported. There is an unacceptable risk in hospitals serving immunocompromised patients (even with standard maintenance and sanitizing methods).	Avoid installation, especially in healthcare facilities serving immunocompromised patients or in areas caring for high-risk patients. Perform maintenance regularly and monitor water safety strictly unless removed.
Heater-cooler units	Healthcare-associated *Mycobacterium chimaera* outbreak due to heater-cooler units during cardiac surgeries as a water source has been recently reported. Airborne transmission from contaminated heater-cooler unit water tanks.	Ensure that heater-cooler units are safe and properly maintained according to the manufacturer's instructions. Enhance vigilance for NTM infections in patients after cardiac surgeries using heater-cooler devices. If NTM infections are suspected, review microbiology database (NTM-positive cultures) and medical records of surgical procedures within several years after cardiac surgeries.
Miscellaneous	Potential reservoirs include distilled water or containers (outbreaks with *Enterobacter cloacae* and *B. cepacia*), wash basins (*Salmonella urbana* infection, *Trichosporon asahii* infection, *Legionella* pneumonia), intraaortic balloon pump (*B. cepacia* bacteremia), humidifier water in ventilator systems (*Acremonium kiliense* postoperative endophthalmitis), water cooler (gastrointestinal illness), holy water (*Acinetobacter baumannii* infection), deionized water (*Exophiala jeanselmei* fungemia), water-damaged plaster (mucormycosis), water birth (*Legionella* pneumonia), water-saving device (*P. aeruginosa* infection), rinse water during endoscope reprocessing (gram-negative bacteria).	Consider control measures based on risk assessment by each reservoir when available.

The information used in this table is based on references in this review. The infection prevention and control section was updated from our previous review [4] and recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee [1, 2].

Abbreviations: AAMI, Association for the Advancement of Medical Instrumentation; BMTU, bone marrow transplant unit; CDC, Centers for Disease Control and Prevention; CFU, colony-forming unit; CMS, Centers for Medicare and Medicaid Services; ICU, intensive care unit; NTM, nontuberculous mycobacteria; ppm, parts per million.

environments, including sinks, for a long time [4]. Sinks should be decontaminated if epidemic spread of gram-negative bacteria via sinks is suspected [4]. Further, multidrug-resistant gram-negative bacilli have been linked to contaminated sinks and healthcare-associated infections as stated above [48, 50, 52, 54, 55, 57–59]. Although hand hygiene is an essential precaution against healthcare-associated infections in healthcare personnel, transmission from contaminated sinks to their hands during hand washing can occur [3]. Separate sinks should be used for handwashing and disposal of contaminated fluids [1, 4].

Showers

Healthcare-associated infections have been linked to use of contaminated showers or inhalation of aerosols by immunocompromised patients [41–43, 45]. Potential pathogens related to showers were *Legionella*, *Pseudomonas*, NTM, and *Aspergillus* [41–45]. The use of showers in immunocompromised patients (eg, neutropenic patients) should be avoided [4].

Bathing and Tub Immersion

Tub immersion used in hospitals for physical hydrotherapy and for cleaning of burn wounds can cause cross-transmission and

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transmission from environmental reservoirs [4]. Water contamination of central venous catheters during bathing was linked to bloodstream infection [7]; therefore, catheter sites should be covered with transparent occlusive dressing. Pathogens associated with bathing and tub immersion were *Pseudomonas*, *Legionella*, *Alcaligenes*, and NTM [6–9]. Tubs should be drained and cleaned after use of each patient, and strict adherence to proper disinfection of tubs between patients is essential [1, 4].

Electronic Faucets

Electronic faucets have been introduced in healthcare facilities, mainly to save water consumption and costs and avoid healthcare personnel's hands from being contaminated by touching the handle [93]. However, several studies have revealed that water samples from electronic faucets were heavily or frequently contaminated by *P. aeruginosa* and/or *Legionella*, compared with handle-operated faucets [93–95], and a *P. aeruginosa* outbreak due to electronic faucets among immunocompromised patients in a NICU has been reported [14]. Electronic faucets are more likely to be colonized because of low amounts of water flow, more favorable conditions for growth of waterborne pathogens (temperature of about 35°C in the column; materials made of rubber, plastic, and polyvinylchloride), and less flushing. Although the degree of risk posed by electronic faucets has not been quantified and there is no guideline for the water quality of electronic faucets, some authors have recommended monitoring water samples periodically from electronic faucets as well as removing electronic faucets from high-risk patient areas (eg, stem cell transplant units), given the difficulty of decontamination even with hyperchlorination [14, 93–95].

Decorative Water Wall Fountains

Two immunocompromised patients were exposed to a decorative water fountain in radiation oncology, which was heavily contaminated despite standard maintenance and disinfection (ozone generator, filter, and weekly cleaning), and developed *Legionella* pneumonia [10]. Another study described laboratory-confirmed Legionnaires' disease (pneumonia) in 8 patients, 6 of whom had exposure to a decorative fountain near the main hospital entrance; high counts of *Legionella* were detected from foam materials on the fountain despite routine maintenance [91]. A fountain's water has a closed recirculating system that can stagnate, and the spraying function may generate aerosols [91]. The results from both studies suggested that decorative water fountains can pose a risk for transmission of waterborne pathogens and should not be installed in healthcare facilities serving immunocompromised patients, even with standard cleaning, disinfection, and maintenance; at a minimum, water safety should be strictly monitored [10, 91].

Heater-Cooler Units

Heater-cooler devices are frequently used in cardiopulmonary bypass during cardiac surgeries to warm and cool patients' blood [97]. A *M. chimaera* outbreak associated with heater-cooler units during cardiac surgeries as a water source has been recently documented [20, 96]. Patient infections included prosthetic valve endocarditis, bloodstream infection, and vascular graft infection. The transmission was potentially caused by aerosols generated from stirred water in contaminated heater-cooler unit water tanks. In a report of surgical site infections due to *Mycobacterium wolinskyi*, a cold-air blaster and a self-contained water system in a heater-cooler unit was identified as a potential reservoir [98]. The CDC's recommendations for healthcare facilities are as follows: (1) ensure that heater-cooler units are safe and properly maintained according to the manufacturer's instructions; (2) enhance vigilance for NTM infections in patients after cardiac surgeries using heater-cooler devices; and (3) if NTM infections are suspected, review microbiology data (NTM-positive cultures) and medical records of surgical procedures within 4 years after cardiac surgeries [97]. The US Food and Drug Administration recommended the following maintenance of heater-cooler units: (1) use sterile water or filtered water (≤0.22 μm) to rinse or fill water tanks or when making ice for cooling patients during a surgical procedure (avoid using tap water); (2) monitor cleaning, disinfection, and maintenance for heater-cooler units regularly with written documentations of the quality control program; and (3) avoid using heater-cooler units with cloudiness or discoloration in the fluid lines or circuits (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm).

WATER SAMPLING AND MOLECULAR STRAIN TYPING IN OUTBREAK INVESTIGATION OF WATERBORNE HEALTHCARE-ASSOCIATED INFECTIONS

Infectious disease physicians and infection preventionists should recognize the emergence of waterborne healthcare-associated pathogens and the unusual change of these rates, and begin an initial investigation if waterborne healthcare-associated cases are suspected [3]. Microbiologic sampling can be considered to enhance epidemiological investigations and to develop infection prevention and control measures. Microbiologic water sampling is not routinely recommended, but can be performed in the following situations: support of outbreak investigations, research purposes, evaluation of a potentially hazardous environmental situation, and quality assurance (eg, biological monitoring of dialysis water or assessment of infection control measures) [1, 2]. Established water sampling methods (eg, volume, media, and incubation temperature) should be utilized to ensure recovery of waterborne pathogens; water samples should be filtered before culturing when low counts are expected and large volumes are needed (>100 mL) [1].

Molecular typing has been increasingly applied to outbreak investigations in healthcare settings, and the advantages as well as disadvantages of molecular methods have been described by other authors [99–101]. In our review, molecular

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typing methods used for waterborne healthcare-associated pathogens when applicable were mostly pulsed-field gel electrophoresis, followed by random amplification of polymorphic DNA (Table 1). Recent studies using whole-genome sequencing demonstrated more powerful evidence of water reservoirs in transmission dynamics of waterborne pathogens, including an outbreak of *P. aeruginosa* (1 pneumonia/17 colonizations) from contaminated water via sinks among infants in a NICU; transmission of *P. aeruginosa* from contaminated water outlets and a thermostatic mixer valve among burn patients receiving hydrotherapy even in plumbing of a new hospital; and 2 healthcare-associated cases of pneumonia caused by *Legionella pneumophila* serogroup 1 from a contaminated hospital water distribution system [30, 56, 102]. Thus, whole-genome sequencing is now promising for genomic comparative analysis in investigations of waterborne healthcare-associated outbreaks and can provide more accurate and informative strain typing to assess the relatedness of pathogens isolated from clinical and environmental water sources.

CONCLUSIONS

We reviewed waterborne healthcare-associated outbreaks and infections and summarized current infection prevention and control. With emergence of reservoirs and pathogens that have been unrecognized so far, waterborne healthcare-associated outbreaks and infections continue to occur and affect patients' health and safety, underscoring the significant role of water as a reservoir for healthcare-associated infections. Water contamination can cause pseudo-outbreaks [3, 80] as well as outbreaks/infections, both of which require substantial efforts and resources for investigation and control. Waterborne healthcare-associated infections are preventable for some pathogens and reservoirs, but eliminating contamination of waterborne pathogens as natural inhabitants of water systems may be difficult in healthcare settings. It is essential for healthcare personnel to understand reservoirs and transmission pathways of waterborne pathogens for developing prevention strategies and control measures of healthcare-associated infections. Multiple approaches of engineering and hygiene measures as well as surveillance and clinical management for hospital water can reduce the risk for contracting waterborne healthcare-associated infections [3]. Advancement of pathogen identification and molecular typing methods has enhanced outbreak investigations as well as provided better understanding of reservoirs and transmission routes of waterborne pathogens. The safe level of microbial water contamination, which would preclude healthcare-associated infections for any waterborne pathogen in susceptible patients, remains to be determined. Further scientific and practical evidence on hospital water reservoirs, pathogens, and healthcare-associated infections is needed to address unresolved issues on infection prevention and control.

Notes

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Water Safety Plan Manual

Step-by-step risk management for drinking-water suppliers

World Health Organization

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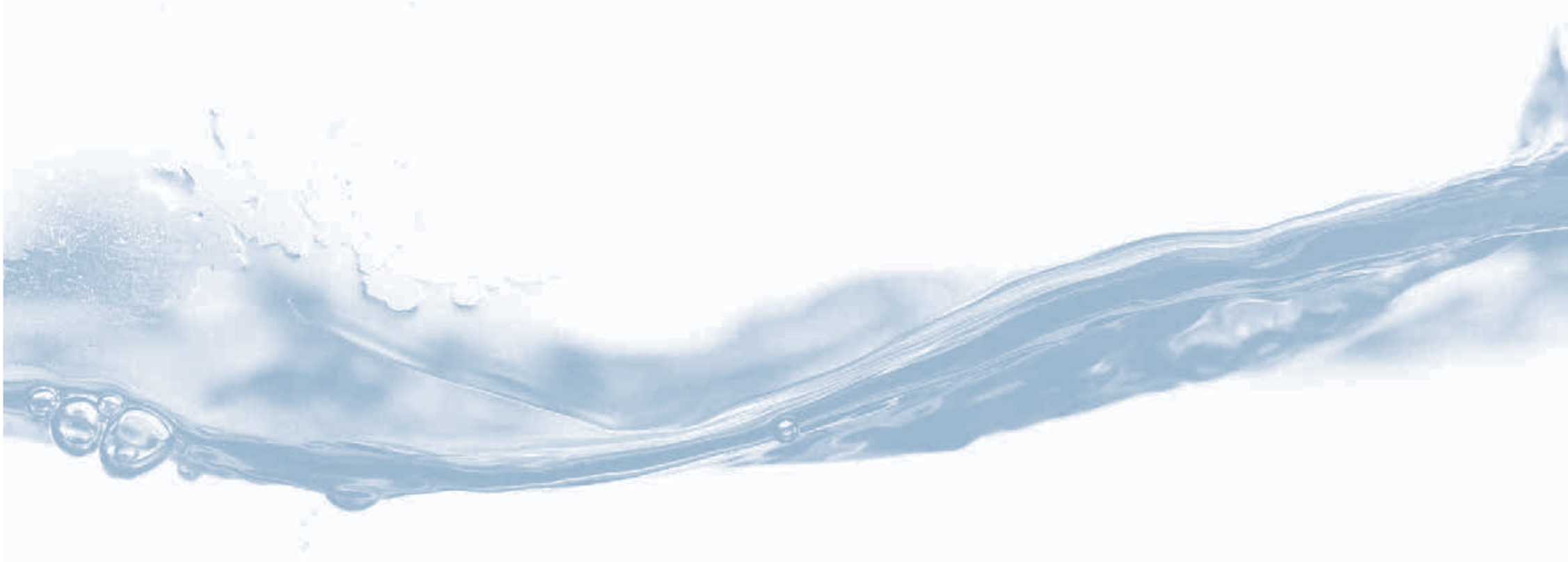
International Water Association (IWA)

The International Water Association (IWA), a global network of water professionals, is a Non-Government Organization (NGO) in Official Relations with WHO. WHO's network of NGOs in Official Relations contributes to promote the policies, strategies and programmes derived from the decisions of the Organization's governing bodies. IWA's role as an NGO in Official Relations with WHO focuses on supporting countries to implement intersectoral policies and interventions for protecting health from immediate and longer-term environmental threats. A long history of cooperation exists, built on previous joint activities between WHO and IWA's predecessors, the International Water Supply Association and the International Water Quality Association. A key area of cooperation is on drinking-water safety.

IWA's Bonn Charter for Safe Drinking Water promotes the application of Water Safety Plans (WSPs) as expressed in the WHO Guidelines for Drinking-water Quality. (Revisions to the WHO Guidelines will be taken as revisions to the Bonn Charter in as much as the Bonn Charter refers to the Guidelines). IWA promotes WSPs with WHO through a formal project collaboration agreement and associated programme of work lasting through 2015, and through its membership of water utilities, research institutes, industry, and individual professionals. IWA's work spans the continuum between research and practice, covering all facets of the water cycle. IWA is a registered charity in England (Company registered in England No. 3597005 Registered Charity (England) No. 1076690).



Water Safety Plan Manual

Step-by-step risk management for drinking-water suppliers

World Health Organization

International Water Association

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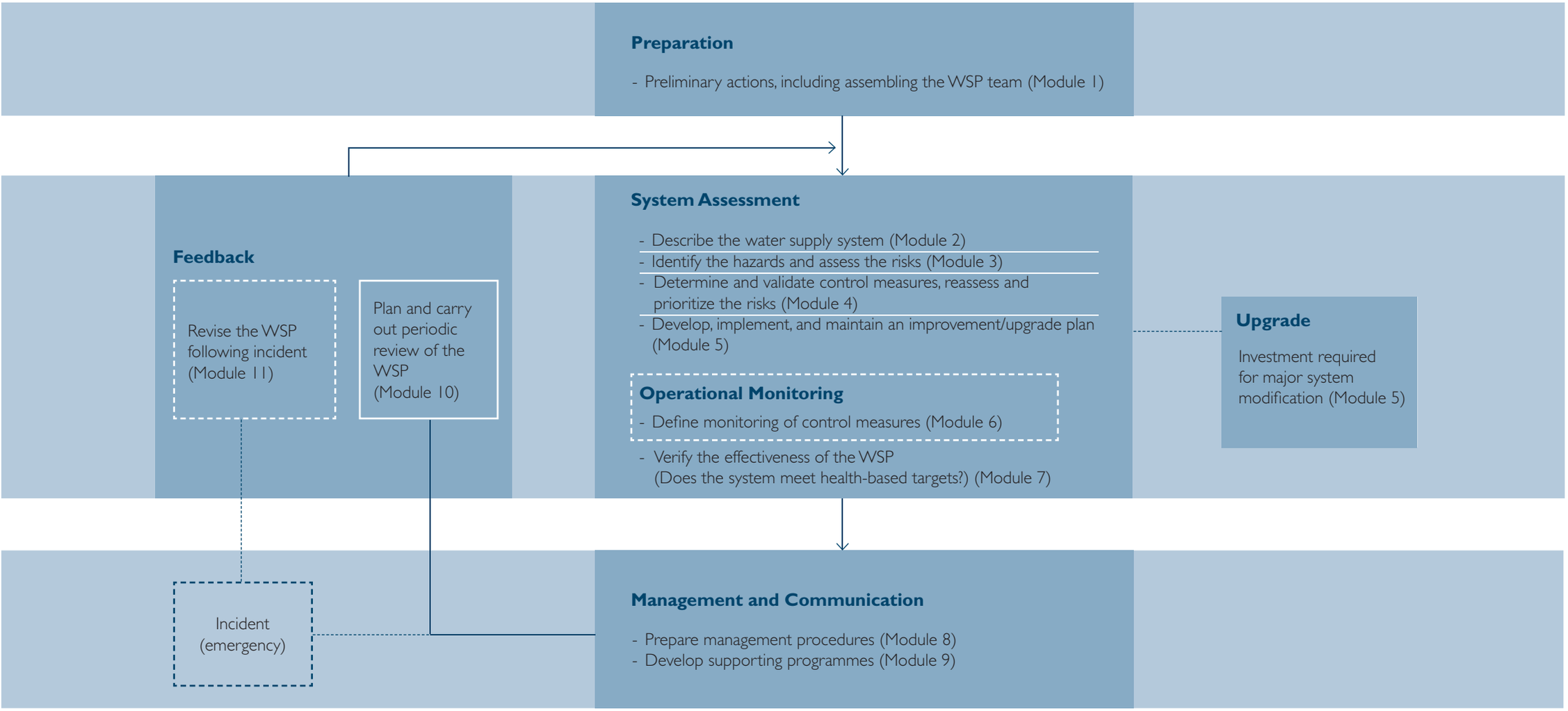
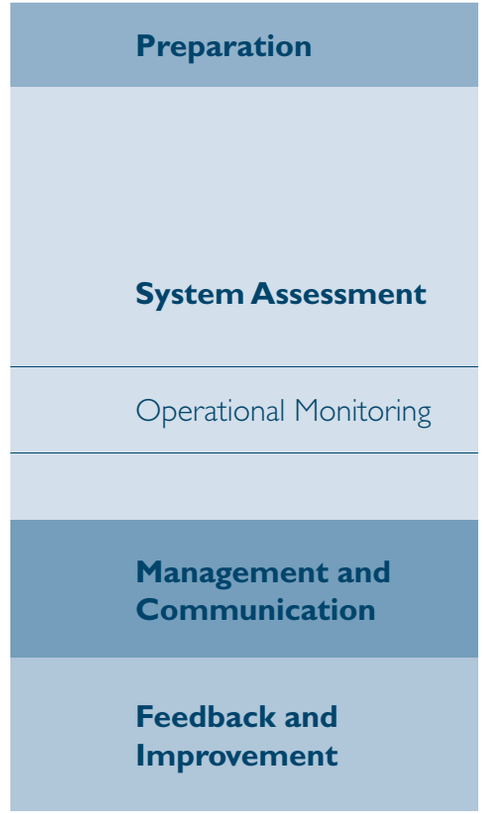
How to develop and implement a Water Safety Plan

A step-by-step approach using 11 learning modules





Contents

Introduction

"The most effective means of consistently ensuring the safety of a drinking-water supply is through the use of a comprehensive risk assessment and risk management approach that encompasses all steps in water supply from catchment to consumer. In these Guidelines, such approaches are called water safety plans (WSPs)".

Purpose of the Manual

The words above open Chapter 4 of the Third Edition of the WHO Guidelines for Drinking-water Quality (2004) and capture the philosophy of the WSP approach. The chapter describes the principles of the WSP approach rather than being a guide to their practical application. The aim of this Manual is to provide that practical guidance to facilitate WSP development focusing particularly on organized water supplies managed by a water utility or similar entity.

Points to consider when developing and implementing a WSP

The aim of a WSP is very straightforward:
To consistently ensure the safety and acceptability of a drinking-water supply.

The development and implementation of the WSP approach for each drinking-water supply is as follows:

- Set up a team and decide a methodology by which a WSP will be developed;
- Identify all the hazards and hazardous events that can affect the safety of a water supply from the catchment, through treatment and distribution to the consumers' point of use;
- Assess the risk presented by each hazard and hazardous event;
- Consider if controls or barriers are in place for each significant risk and if these are effective;
- Validate the effectiveness of controls and barriers;
- Implement an improvement plan where necessary;
- Demonstrate that the system is consistently safe;
- Regularly review the hazards, risks and controls;
- Keep accurate records for transparency and justification of outcomes.

This systematic nature of the WSP strategy should never be lost or forgotten during implementation. The great advantage of the WSP strategy is that it is applicable to ensuring the safety of water in all types and sizes of water supply systems no matter how simple or complex.

The WSP approach should be considered as a risk management strategy or umbrella which will influence a water utility's whole way of working towards the continuing supply of safe water. Significant risks that are not currently controlled need to be mitigated. This may involve short-, medium- or long-term steps for improvement. **The WSP approach should be dynamic and practical and not merely another operating procedure.** It should not be viewed as a vehicle for generating bureaucracy and paperwork. If it just ends up as a rarely-used folder labelled 'WSP' on a shelf, it is almost certainly not an effective approach.

There is no one way to undertake the WSP approach. The text in this Manual shows how the strategy can be implemented, with examples showing what has been effective for some water utilities. What is important is that the WSP approach fits in with the way a utility is organized and operates, otherwise it will not be accepted within the organization. Developing the WSP approach may show that certain ways of working introduce, or do not properly control risks, in which case the utility should alter its way of working. It should not alter its way of working just to comply with a recommendation from a manual or to reflect another utility's methodology.

Implementation of the WSP approach requires both financial support and encouragement from senior management within a utility. There will be financial and resource requirements and these need to be addressed at the outset but there should also

be the understanding that proper implementation of the **WSP approach can save money** and better target resources in the longer term.

It is important that the WSP team has adequate experience and expertise to understand water abstraction, treatment and distribution and the hazards that can affect safety through the supply system. For small utilities, additional external expertise may be helpful. The team is vital to getting the WSP approach understood and accepted by everyone connected with water safety in the utility and those outside.

A WSP cannot be done solely as a desk study. It must involve site visits to confirm the knowledge, information and schematics available to the utility. Site visits need to include input from those who work at the sites or within catchments and have detailed local knowledge that may not have been captured within the utility's records. Assessment, updating, compiling or rewriting standard operating procedures is an integral part of the WSP strategy. Ideally, all procedures should be labelled as part of the WSP strategy or way of working which helps to gain recognition and acceptance across the utility.

The water utility will take the lead in the WSP approach but it should not do this in isolation. It is a prime purpose of the WSP approach to identify that others have responsibilities towards ensuring the safety of water and for them to work with the water utility on risk reduction. Examples are agriculture and forestry workers, landowners, industry, transport, other utilities, local government and consumers. It is probably not necessary for representatives of all organizations to be included in the WSP team but they should be part of a communication network and aware of the impact of their contributions to the WSP effort. It is important that the WSP is subject to regular external independent audit. This will retain the confidence of all stakeholders.

There can be a tendency for the identification of hazards to be limited to thinking about those direct inputs to the water supply system impacting microbial and chemical parameters, as these are important in terms of compliance with water quality standards. However, the approach to ensure safe water must go much wider, with consideration of aspects such as potential for flood damage, sufficiency of source water and alternative supplies, availability and reliability of power supplies, the quality of treatment chemicals and materials, training programmes, the availability of trained staff, service reservoir cleaning, knowledge of the distribution system, security, emergency procedures, reliability of communication systems and availability of laboratory facilities all requiring risk assessment. This list is by no means exhaustive. **If a water utility considers that some of these areas fall outside of its WSP approach, then it does not have a comprehensive WSP strategy and has not fully understood the concept.**

The obvious controls for identified risks are physical barriers or processes within water treatment plants such as filtration and disinfection, but consideration and assessment of controls needs to be much wider. Agreements with farmers and industry on chemical usage, livestock controls, use only of trained staff, pumping regimes, visual inspection, auto-shutdown or turnout, audit of, or quality agreements with, chemical suppliers and plant manufacturers, could all be considered controls as long as they can be validated as effective and monitored to demonstrate that they continue to provide protection. Again, this list is by no means exhaustive. **Starting out on the implementation of the WSP approach does not mean that every existing control has to be re-validated but it does require the robustness of existing data and reports to be evaluated.**

It is important to assess risk before and after its control (or mitigation) where this exists because this will demonstrate that each hazard has been recognized and its control assessed for

effectiveness. The risk assessment is likely to highlight a great many risks that are not considered significant to the safety of the water supply system. It is important, though, that all risks are clearly documented and understood by the utility. Even **more important is the need to prioritize and quickly put in place an improvement programme** where significant risks are identified.

Not all risks can be easily assessed using a methodology (e.g. a 'semi-quantitative' risk matrix), where a risk is estimated in terms of likelihood of the hazard occurring, and severity of the consequence should the hazard occur. Some risks do not lend themselves to be assessed via narrow definitions of likelihood (e.g. estimated occurrence is 'monthly') or consequence (e.g. estimated severity is 'moderate' public health impact). For example, potential negative feedback from consumers regarding issues that may not have a significant impact on health may be viewed as a significant risk to a utility's reputation and therefore should be addressed for the WSP. Sometimes, it may be more appropriate to assess risk in a simplified format (e.g. 'significant', 'non-significant' or 'uncertain') based on a group decision. **Whatever method is used, it is imperative that the risk assessment methodology is sufficiently clear and detailed to allow consistency.** This is a particular concern for a large utility, where the risk assessment is likely to be undertaken by many different people.

The complexity of the risk assessment depends on the complexity of the water supply system. Sophisticated water treatment equipment and processes viewed as controls for safe water production introduce their own potential hazards to a water supply system which will require detailed risk assessment. For example, an ozone and granular activated carbon system introduced as a control for organic contamination could generate hazards such as ozone emissions, bromate formation, biofilm growth, taste problems and contamination after regeneration. **The WSP approach needs to be included from the planning stage of any improvements or new arrangements for a water supply system.**

Compliance monitoring is an important part of the verification process to show that the WSP is working. It will show whether water at the point of compliance, which is often the consumers' tap, is meeting water quality standards; it does not make the water safe because by the time the results of compliance monitoring are available the water will have been drunk and used for other domestic purposes. Validation, to show that controls are capable of mitigating risks, and operational monitoring, to demonstrate that they continue to work effectively, are much more important tools in ensuring the safety of water because they focus on the processes that make water safe. **Operational monitoring is an integral part of the WSP approach.**

Overcoming complacency

Many elements of the WSP approach are already incorporated in existing water utility good operating practice. However, fully implementing the WSP will require all utilities to take a fresh look at everything that can affect the safety of water. **Nothing should be taken for granted.** If barriers are in place and producing water of acceptable quality, is this because they are robust or through luck? The water utility that has no incidents or near misses and consumers that are happy with their safe water supplies is fortunate indeed, or maybe it is lacking the procedures and assessment it needs to identify problems. Open and transparent implementation of the WSP approach will increase the confidence of consumers and all other stakeholders in the safety of water supplies. Developing a WSP is not an end in itself, but a means to an end. A WSP is only useful if it is implemented and revised.

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Overview of the modules

Points to consider when using the Manual

The Manual is divided into 11 Modules, each representing a key step in the WSP development and implementation process. Every Module is divided into three sections: 'Overview', 'Examples and Tools', and 'Case Studies', as described below.

Overview

The overview section provides a brief introduction to the Module, including why it is important and how it fits into the overall WSP development and implementation process. It outlines key activities that should be carried out, lists typical challenges that may be encountered, and summarizes the essential outputs to be produced.

Examples and Tools

The examples and tools section provides resources which could be adapted to support the development and implementation of WSPs. These resources include example tables and checklists, template forms, diagrams, or practical tips to help a WSP team address specific challenges. These are often example outputs and methodologies adapted from recent WSP experiences.

Case Studies

Case studies present lessons-learned from real-life experiences. They are intended to make WSP concepts more concrete and to help readers anticipate issues and challenges that may arise. The descriptions were drawn from WSP initiatives in Australia, the Latin American and the Caribbean region (LAC), and the United Kingdom. These experiences are presented as three distinct case studies. The insights gained through the development of these 'composite' WSPs are likely to apply to other water systems that share a similar profile. A general description of the water supplier and the context within which the WSP was developed and implemented is provided in the following pages.

CASE STUDY 1: AUSTRALIA

Profile
Organized urban piped water supply systems in Australia.

Introduction
These WSPs were undertaken almost entirely by the urban water utilities themselves without significant external agency support. Most water utility employees were familiar with the use of systematic risk assessment and management systems, and of management systems generally, due to previous requirements to implement occupational health and safety and environmental management systems. In addition to this, most utilities had some kind of generic management system in place, such as ISO 9001. The WSPs drew to varying degrees on these management systems in place, and on food safety management systems, such as HACCP and ISO 22000. The WSPs were driven initially by a desire by utilities to adopt good practice, and more recently by a desire to conform to the Australian version of the WHO WSP, being the Framework for Management of Drinking Water Quality (Australian Drinking Water Guidelines 2004).

Population served
The populations served ranged from around 50,000 to over 4 million.

Water sources
Water was supplied from a combination of surface and groundwater sources. In most cases, there was considerable unregulated low intensity agricultural activity within the catchment, such as cattle grazing; there was also rural residential habitation. Sewage systems existed in some catchments and others included on-site sanitation with varying degrees of oversight.

Treatment processes
Treatment processes typically consisted either of chlorine disinfection only, or of direct or conventional filtration and chlorination. Surface water sources from protected catchments were typically treated by chlorination only and those from impacted catchments by conventional coagulation/flocculation/sedimentation, filtration and chlorination. Chloramination was commonly applied to maintain residual in many systems. Groundwater sources were typically treated by aeration and chlorination. Treatment processes were well-operated.

Delivery point
Households received water directly to their homes through internal plumbing systems. The cities were predominantly connected to the municipal water system with reliable continuous pressurization so that storage in household tanks was virtually absent.

Water quality standards
Water quality standards were set out in the Australian Drinking Water Guidelines, which are very similar to the WHO Guidelines for Drinking-water Quality. Testing and reporting against guidelines was well established, particularly for *E. coli* or thermotolerant coliforms.

Quality of service
Water service to taps was continuous and water quality standards were met almost continually. There were no recorded waterborne disease incidents during the period of WSP development and implementation. Point-of-use treatment was not required, although this was sometimes used by consumers for aesthetic reasons to remove chlorinous tastes and odours.

Resource constraints
Systems were operating on full cost recovery with government dividends being paid. The utility recovered all costs associated with maintaining water quality and quantity.

Condition of infrastructure
The systems described were well maintained with low leakage rates reflecting the focus on water savings in these relatively dry Australian settings. Systematic asset management systems were in place to repair and replace assets to keep failure rates under control.

CASE STUDY 2: LATIN AMERICA AND THE CARIBBEAN (LAC)

Profile
Organized piped water supplies operating under significant resource constraints in Latin America and the Caribbean.

Introduction
These WSPs were initiated as part of a multi-agency effort for which external technical advice and seed funding were provided to promote WSP demonstration projects in the LAC region. Project site selections were made by drinking-water utility managers and senior government officials, primarily within the Ministry of Health. Although some water utility employees were familiar with the WSP approach, they did not have a formal process of preventive risk management and believed that they did not have the expertise or resources to carry out the process.

Population served
The populations served by the utilities ranged from 30,000 to 120,000.

Water sources
Water was supplied from a combination of surface and groundwater sources. In all cases, there was considerable unregulated industrial activity within the watershed, such as mining, forestry, or road construction. Municipal sewerage systems did not exist; hence excreta was treated in poorly maintained septic systems or deposited directly into source waters.

Treatment processes
Between one and five treatment plants served each community. Surface water sources were treated by conventional treatment techniques: coagulation/flocculation/sedimentation, filtration and chlorination. Groundwater sources were treated by aeration, filtration and chlorination, or in some cases, chlorination alone. In all cases, treatment processes were not operated optimally due to poorly trained operators and financial constraints.

Delivery point
Most households received water directly to their homes. Others had yard taps, and some used shared community taps or storage sites. In each case, there were parts of the city that were not connected to the municipal water system, or had unauthorized and clandestine connections. Storage in household storage tanks was common due to inconsistent service.

Water quality standards
Water quality standards were often poorly defined, or were inconsistent, with some agencies using environmentally-based targets and others using health-based targets for the same system. In some cases, WHO's health-based guidelines were adopted without adaptation to local conditions and constraints, making standards unrealistic and therefore of little value. In all cases, there were no active enforcement programmes.

Quality of service
Water service to taps was intermittent. In some areas, households routinely experienced eight hours or more per day without service and periods of low pressure were the norm in a majority of homes. Water quality was consistently out of compliance with regulatory standards; secondary treatment within the home was common.

Resource constraints
Systems were not operating at cost recovery even with government subsidies. The utilities could therefore not afford to maintain a sufficient supply of chemicals, adequate equipment maintenance, or the high energy cost of pumping 24 hours a day.

Condition of infrastructure
The systems described were characterized by aging treatment infrastructure, leaking distribution system pipes with as much as 70% loss, and decrepit storage tanks in the distribution system that had been taken off-line, affecting pressure and ability to meet demand. In all cases, capital improvements were needed in order to achieve desired water quality and consistency of service.

CASE STUDY 3: UNITED KINGDOM (ENGLAND AND WALES)

Profile
Privately-operated organized piped water supplies in England and Wales.

Introduction
This case study, written by a regulator of drinking-water quality, describes some of the benefits and challenges faced by private water suppliers introducing WSPs in England and Wales. The regulator encouraged water companies to implement WSPs following the publication of the third edition of the WHO Guidelines for Drinking-water Quality in 2004, with its advocacy of the WSP approach. Impetus for WSP implementation was given by the regulator stating that drinking-water improvement schemes for the next five year investment programme would only receive regulator support if they were identified through WSP methodology.

The case study focuses on areas where the regulator viewed WSP methodology as weak or incomplete, in order to be most helpful to suppliers starting out on WSP implementation. Experiences should not be taken to reflect the experiences of all suppliers, as some companies developed good WSP methodologies from the outset.

For the first three years of WSP implementation the regulator gave guidance and advice on development. The regulator made a point of not specifying detailed WSP methodology, in order to ensure that companies developed their WSPs in a way that fitted in with how each company operated, an important consideration given the diversity in water companies under the regulations.

Compliance monitoring was initially viewed as the main WSP verification stage. However, additionally from the beginning of 2008, the hazard identification and risk assessment elements of the WSP framework were made regulatory requirements and WSPs began to feature in the regulator's audit programme.

Population served
The populations served by individual utilities ranged from 2,500 to 8.5 million consumers.

Water sources
Approximately 70% of supplies originated from surface water sources, 30% from groundwater sources. Twenty-six water companies supplied 15,750 million litres a day of mains water to a population of 53.6 million people through a distribution network of 338,500 km. There were 4,520 service reservoirs and 1,690 water supply zones.

Treatment processes
The case study covered 1,220 water treatment works, with a range of processes, encompassing conventional coagulation/flocculation/sedimentation, filtration and chlorination, and increasingly, technologies such as GAC (granular activated carbon), membranes, ozonation and UV light, to deal with emerging risks. Many groundwater sources were still treated by disinfection only.

Delivery point
Households received water directly to their homes through internal plumbing systems, connected to the companies' water system with reliable continuous pressurization. Despite this, plumbed-in water storage within premises was common in England and Wales.

Water quality standards
Water quality regulations were set out for England and Wales, in line with the European Union's Drinking Water Directive, which in turn reflect the WHO Guidelines for Drinking-water Quality. Water suppliers were subject to firm regulation from financial, drinking-water quality, and environmental regulators.

Quality of service
Treated water quality as a whole was very good, generally 99.9% in compliance with European and national standards for drinking-water quality.

Resource constraints
The water industry in England and Wales was privatized in 1989, which has resulted in improved investment by the water suppliers. It is a technically sophisticated and advanced industry.

Condition of infrastructure
The systems described were well maintained, but leakage rates from the network are still a problem in some areas with aging mains.

Module 1

Assemble the WSP team

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Introduction

Establishment of a qualified, dedicated team is a prerequisite to securing the technical expertise needed to develop a Water Safety Plan (WSP). This step involves assembling a team of individuals from the utility, and also in some cases, from a wider group of stakeholders, with the collective responsibility for understanding the water supply system and identifying hazards that can affect water quality and safety throughout the water supply chain. The team will be responsible for developing, implementing and maintaining the WSP as a core part of their day-to-day roles. It is essential that all involved play an active role in the development of the WSP and support the WSP approach. It is important that the WSP team has adequate experience and expertise to understand water abstraction, treatment and distribution and the hazards that can affect safety through the supply system from the catchment to the point of consumption. For small utilities, additional external expertise may be helpful. The team is vital to getting the WSP approach understood and accepted by everyone connected with water safety within and outside the utility. Therefore, an inclusive team that works with everyone within a utility and outside is likely to be far more effective than an exclusive team who impose their WSP approach on the utility. A vital early task of the team is to set out how the WSP approach is to be implemented and the methodology that will be used, particularly in assessing risk.

Key actions

Engage senior management, and secure fi nancial and resource support

For successful implementation of the WSP, it is important that senior management support the process. This support is crucial to obtain support for changes in working practices, to ensure sufficient fi nancial resources are available and to actively promote water safety as a goal of the organization. A clear case is needed to show that the adoption of a WSP is important and advantageous to the organization.

Identify the required expertise and appropriate size of the team

Involving operational staff on the team will contribute to the success of the plan through facilitating its ownership and implementation. However, depending on the size of the utility, most members of the team will not be 100% committed to WSP duties, but will also continue with their normal duties. Team members need to collectively possess the skills required to identify hazards as well as to understand how the associated risks may be controlled. The team needs to have the authority to enable implementation of the recommendations stemming from the WSP.

Appoint a team leader

A team leader should be appointed to drive the project and ensure focus. This person should have the authority and organizational and interpersonal skills to ensure the project can be implemented. In situations where required skills are unavailable locally, the team leader should explore opportunities for external support.

This can include use of benchmarking or partnering arrangements with other organizations, national or international assistance programmes and resources, such as the internet.

Define and record the roles and responsibilities of the individuals on the team

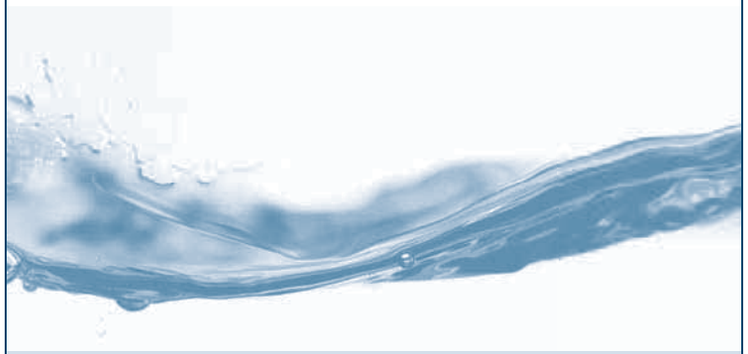
It is important to divide responsibilities among the team members at the start of the process and clearly defi ne and record their roles. For large teams it is often helpful to put together a table outlining WSP-related activities along with who will be responsible for carrying these out.

Define the time frame to develop the WSP

The initial development of a WSP requires considerable time input. WSPs will increase the amount of time staff spend in the fi eld inspecting the system yet reduce the reliance on the results of routine laboratory tests. The WSP approach enables the operators to get to know their system more effectively as they spend more time identifying and controlling risks instead of just analyzing risks. Once the WSP is established and the organization becomes familiar with the system the time input will decrease.

Typical challenges

- Finding skilled personnel;
- Organizing the workload of the WSP team to fit in with the existing organizational structure and roles;
- Identifying and engaging external stakeholders;
- Keeping the team together;
- Getting the team to communicate effectively with the rest of the utility and other stakeholders.



Outputs

Establishment of an experienced, multidisciplinary team that understands the components of the system, and is well-placed to assess the risks that may be associated with each component of the system. The team needs to understand the health and other targets which have to be achieved; and have the expertise to confi rm, following an assessment, whether the system can meet the relevant water quality standards.

Example/tool 1.1: Checklist of skills to be considered when identifying the required expertise for a large WSP team

- ☑ Technical expertise and operational system-specific experience;
- ☑ Capacity and availability to undertake the WSP development, implementation and maintenance;
- ☑ Organizational authority to report through to the relevant controlling authorities, such as the executive of an organization, or leaders of a community;
- ☑ Understanding of the management systems including emergency procedures;
- ☑ Understanding of the processes used to obtain and communicate the results of monitoring and reporting;
- ☑ Understanding the water quality targets to be met;
- ☑ Appreciation of the water quality needs of the users;
- ☑ Understanding of the practical aspects of implementing WSPs in the appropriate operational context;
- ☑ Understanding the impact of proposed water quality controls on the environment;
- ☑ Familiarity with training and awareness programmes.

Example/tool 1.2: WSP team composition (from Melbourne Water, a large utility supplying water to 3.5 million people through separate retail companies)

Job title	Work team	Expertise
Team Leader / Senior Engineer	Water Quality Planning	Water quality engineering
Water Supply Operator	Water Harvesting Team	Operations – Upper Yarra
Process Support – Service Delivery	Operations – North Area	Water treatment specialist
Water Supply Operator	Westernport Area Team	Operations – distribution/treatment
Section Leader Water Treatment	Treatment Systems	Treatment plant asset management
Operations Contractor	Operations – South Area	Water supply engineering
Water Supply Operator	Thomson Reservoir Team	Operations – Thomson Reservoir
Process Engineer	Operations – North Area	Water supply engineering
Water Supply Operator	Silvan Reservoir Team	Treatment plant operations
Water Supply Operator	Maroondah-Winneke Reservoir Team	Sugarloaf Reservoir, Winneke Treatment Plant and Maroondah Reservoir area
Principal Scientist	Water Quality Planning	Microbiology
Section Leader Headworks	Operations	Catchment operations
Scientist from retail water company	Retail Water Company	Water quality specialist/chemist
Engineer from retail water company	Retail Water Company	Water quality engineering (distribution)
Engineering Manager from retail water company	Retail Water Company	Water quality planning

Example/tool 1.3: Different WSP team building approaches for larger and smaller systems

Depending on the size of the water supply organization, and where organizations are responsible for multiple systems, it may be necessary to have more than one WSP working group, which report to a central team. The usefulness of this arrangement needs to be assessed at the commencement of the process, but may include: a core team; subordinate working groups that undertake particular aspects of the WSP (e.g. on 'catchment', 'source water', 'treatment' and 'distribution system'); and external team members and reviewers, which may comprise government agencies and independent experts. It is essential that each team uses the same methodology, particularly for assessing risks and is aware of what the other teams are doing.

Small utilities may often not have in-house water quality experts. However, such utilities should at least have the operators and management on the team and bring in health and water quality expertise from external sources. External sources could include agencies (e.g. the department of health, engineering and sanitation or natural resources) or consultants.

Examples of forms that can be used to record essential information when assembling the WSP team and starting the initial stages of the WSP are listed in Example/tool 1.4, 1.5 and 1.6.

Example/tool 1.4: WSP team details form

The details of the WSP team and any subordinate teams should be documented as part of a utility's WSP methodology. This needs to be kept up to date as personnel and contact details change.

Name	Affiliation	Title	Role in team	Contact Information
Sam Kariuke	Blue Water Supply	Water Supply Operator	Catchment Liaison Officer	234-5678 kariuke@bluewater.com
Etc. ↴				

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Example/tool 1.5: WSP resourcing plan form (example for a large utility)

While outsourcing work may be necessary when there is limited in-house expertise or capacity, it should be minimized as much as possible as in-house knowledge development will be impeded.

Activity	Activity budget	Aspects sourced within the utility	Aspects sourced from outside the utility	Staff budget
Establishment of WSP team	US $5,000	Project management and delivery	Facilitation and review	1.5 Full-time equivalents (FTE) during development and implementation 0.5 FTE for ongoing maintenance
WSP working group(s)	US $30,000 each	Project management Stakeholder liaison Integration with existing systems	Technical support Data assembly Data analysis and presentation	3 FTE during development and implementation 1 FTE for ongoing maintenance
Etc. ↴				

Example/tool 1.6: WSP stakeholder identification form

Stakeholder name	Relationship to drinking-water supply issues	Key point	Point of contact in WSP team	Stakeholder point of contact	Interaction mechanism	Reference to contact details and record of interaction
Environment Protection Authority (EPA)	Regulate large polluting facilities	Affects catchment protection	Regulatory Liaison Officer	Regional Manager	Annual meeting	EPA file
Farming organization with land adjacent to catchment	Livestock raising and agricultural chemical use	Minimizes the introduction of microbial and chemical hazards to catchment	Catchment Protection Liaison Officer	Manager of Operations	Informal and scheduled meetings	Catchment stakeholder file
Chemical manufacturing plant	Point-source discharges to catchment	Adheres to industrial effluent standards	Regulatory Liaison Officer	Plant Manager	Annual meeting	Catchment stakeholder file
Etc.						

Example/tool 1.7: Understanding the WSP commitment

A WSP represents a significant responsibility that is shared by all relevant employees within a water supply organization. Development and implementation is time consuming and requires significant resources. Implementation requires commitment at all levels within the organization. Maintenance of the WSP requires ongoing management attention to reinforce a culture of compliance with the requirements of a WSP. It may take several years to see all the benefits of WSP implementation, but experience has shown that the input and commitment is rewarded as the WSP leads to efficiencies and better understanding of the water supply system, including producing water of a quality that consistently meets the health-based targets.

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Case study 1: Australia

Field Experience 1.1 – roles of the WSP team

The WSP team was typically set up and led by a dedicated utility coordinating person. This person was usually a graduate engineer or scientist with several years or more experience working in water quality management. The coordinating person typically had titles such as 'Water Quality Manager', or 'Water Quality Coordinator', or more recently, the title 'Product Quality Coordinator' has been used to reflect an extension of their role to cover recycled water. Typically the WSP coordinating team was small, made up of just the coordinator, or the coordinator and one or a few support staff, being almost solely dedicated to creating and maintaining the WSP. The coverage of the full team extended to a dozen or more staff which typically included staff from operations, field maintenance and water supply planning who contributed to the work of the WSP team as a small part of their overall role.

Field Experience 1.2 – external parties

One or more stakeholders usually contributed to the WSP efforts. In most cases, the health authority that regulated the utility was involved in risk assessment workshops and in reviewing the plan. Often local government and catchment management agencies were involved in the plan. Bulk water suppliers, or retail utilities, were often involved in WSP development, represented by their retail customers or wholesale suppliers, respectively. Contractors, such as treatment or operations and maintenance contractors, were also typically involved in the utility's WSP development. However, the involvement of these external stakeholders and contractors was usually limited to review and workshop participation. Sometimes professional facilitators were contracted to help support the development of the plans, acting as coaches or mentors and providing technical support to the WSP coordinator, and general support to run workshops and help complete documentation.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 1.1 – roles of the WSP team

A small 'initiating' group comprising external experts and a senior utility manager discussed the objectives and composition of the WSP team and agreed that it should serve two key functions. The first was to bring together people with expertise in water supply (e.g. abstraction, treatment and distribution), health, and environmental issues, to develop the WSP. Thus, a multidisciplinary Task Force was formed to provide this on-the-ground role. The second purpose of the team was to provide the political support and authority necessary to enable implementation of the recommendations that followed from the WSP. To this end, a Steering Committee comprising senior officials of the water utility, the Ministry of Health, and the regional Environmental Protection Agencies was formed to oversee and support the activities of the Task Force. Engaging senior officials from the start of the project proved essential for generating support to carry out tasks that required managerial or political authority, such as establishing water quality standards, introducing regulatory requirements, and dedicating financial or personnel resources.

Field Experience 1.2 – designating a WSP writer/coordinator

While the role of the WSP coordinator is ideally filled by water utility personnel, the utility was unable to commit full-time personnel to this time-intensive task due to resource constraints. Therefore the WSP team decided to engage a consultant to assume the role of the WSP coordinator, which involved planning and facilitating Task Force meetings, liaising with Task Force and Steering Committee members, identifying information gaps, providing technical expertise in water quality assessment, and writing the WSP document. A number of problems soon presented themselves, including the utility's hesitation to share potentially sensitive information about their operations; concerns about conflicts of interests in a small country where considerable overlap in professional spheres exists; and a reduced sense of utility investment and engagement in the WSP.

Personality conflicts also contributed to an ineffective team dynamic and progress was significantly hindered. A second consultant was ultimately engaged to replace the first and a senior utility manager assumed additional responsibility for WSP development. The increased role of the utility manager required relieving her of some other duties for the duration of the WSP development process, but it proved essential to increasing interagency collaboration and project momentum. The second arrangement was successful and underscored the importance of giving careful consideration to the designation of a WSP coordinator to avoid conflicts of interest and to ensure team cohesion.

Case study 3: United Kingdom (England and Wales)

Field Experience 1.1 – gaining commitment to adopt the WSP approach

Enthusiasm for the WSP approach was initially not universal within the industry and in some companies there was scepticism of its additional value to an advanced, well performing industry. However, other companies immediately viewed the approach as developing what they were already doing in risk assessment and risk management.

Some companies were uncomfortable using the term 'safety' in Water Safety Plan, because they felt consumers might perceive that the water may be unsafe. Therefore, these companies preferred to label their WSPs as 'Risk Management Plans' or similar, terms which the regulator viewed as appropriate alternatives, provided that the content was consistent with a WSP.

A short document explaining WSP methodology, how they were going to be implemented and what was expected to be achieved was seen as a necessary starting point to obtain board and senior management approval which was essential for the success of the project. A common experience among almost all water companies was that the time required for WSP implementation was significantly underestimated.

Paper-based WSPs restricted access within the company and therefore did not encourage staff ownership. For large water companies computer-based systems available to all staff through an intranet was much more successful. Such systems usually had the basic elements of the WSP for each water supply system laid out in a conventional manner and included links to all the associated procedures and other material. The best plans identified everything as part of the WSP. Issues with sensitive and security related matters were overcome by having restricted levels of access.

Field Experience 1.2 – expanding the WSP team

In most companies, teams expanded from an initial small core group as appreciation of how wide the WSP approach covered was fully understood. In very large companies that covered a wide geographical area, sub-teams were set up that liaised with a central team. This worked well in getting company wide involvement.

External stakeholders have not yet been generally included as members of the WSP team. This probably results from understandable reticence about making sensitive information too readily available.

Field Experience 1.3 – valuing WSP team members with fresh perspectives

Early in the implementation process, in some companies, responsibility for WSP development was given solely to the water quality manager or similar post. This meant that the water supply system was considered only by someone who thought they were already fully familiar with it and aware of all the hazards, risks and weaknesses so the fresh WSP approach was lost. Such individuals also tended to limit their thinking to hazards relating to compliance parameters (although this was not a problem confined to individuals) as this was their main area of experience. This meant that the wide umbrella WSP approach was missing from the beginning.

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Module 2

Describe the water supply system

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Introduction

The first task of the WSP team is to fully describe the water supply. Where utilities do not already have documentation of the water system, it is essential that field investigations are conducted. The objective is to ensure that subsequent documentation of the nature of the raw, interim, and finished water quality, and of the system used to produce water of that quality is accurate to allow risks to be adequately assessed and managed. While it is accepted that there may be some room for a generic approach to be taken where works are very similar, or where liaison with outside bodies remains the same for a number of water supplies, each supply must be assessed in detail on its own. Data should be gathered specifically for that supply, and all other steps taken leading to a WSP should be exclusive to that particular supply. Many utilities will already have extensive experience of their water system and hold relevant documentation. In this case, the WSP will simply require this to be systematically reviewed to ensure it is up to date and complete and checked for accuracy by a site visit.

Key actions

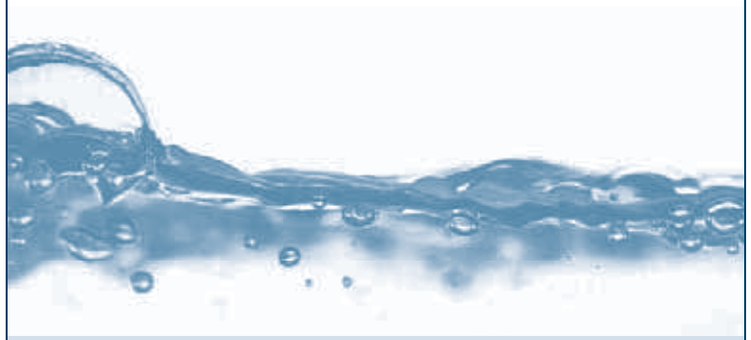
A detailed description of the water supply system is required to support the subsequent risk assessment process. It should provide suffi cient information to identify where the system is vulnerable to hazardous events, relevant types of hazards, and control measures. The following should be included in the description but it is not an exhaustive list, nor is every point relevant for each water supply system:

- Relevant water quality standards;
- The source(s) of water including the runoff and/or recharge processes, and if applicable, alternative sources in case of incident;
- Known or suspected changes in source water quality relating to weather or other conditions;
- Any interconnectivity of sources and conditions;
- Details of the land use in the catchment;
- The abstraction point;
- Information relating to the storage of water;
- Information relating to the treatment of the water, including the processes and chemicals or materials that are added to the water;
- Details of how the water is distributed including network, storage and tankers;
- Description of the materials in contact with water;
- Identification of the users and uses of the water;
- Availability of trained staff;
- How well existing procedures are documented.

A fl ow diagram should be developed which captures all the elements of the water supply system in suffi cient detail. The fl ow diagram should be validated through on-site field checking and then used in the risk assessment process. Cross reference should be made to other documentation showing details such as maps with property boundaries, sewage treatment plants, septic tanks, industry and other potential sources of risk. A map of the supply areas should be checked. Referenced and dated copies of the validated flow diagram should be retained as part of the WSP. Not all process steps are the responsibility of the water supply organization. However, it is important to record who has primary responsibility as this information will impact on the choice and effi cacy of control measures. For simple systems, showing the order of each step is suffi cient to indicate the direction of water fl ow through the system. However, for more complex systems it may be necessary to indicate the water direction with the use of arrows.

Typical challenges

- Lack of accurate maps showing distribution systems;
- Lack of knowledge of land use / management in catchments;
- Lack of knowledge of industry and risks;
- Finding all government and local agencies with potential information or a role to play;
- Time required by staff to undertake fieldwork;
- Out-of-date procedures and documentation.



Outputs

1. A detailed up-to-date description of the water supply system, including a fl ow diagram.
2. An understanding of water quality currently being provided by the utility.
3. Identifi cation of the users and uses of the water.

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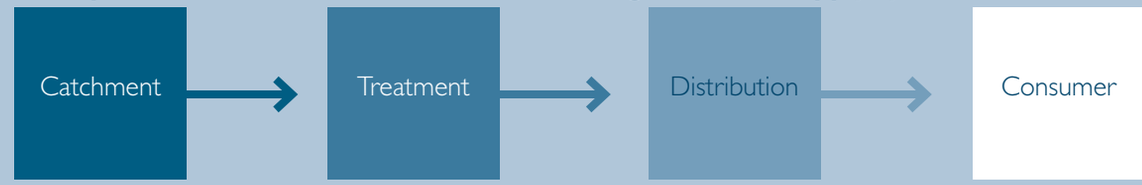
Example/tool 2.1: Consider the basic arrangements of the water supply system to be assessed

The description should cover the whole system from the source to the end point of supply. Staff should be prepared to spend considerable time on this step. For example, undertaking the field assessment of a large water distribution system of more than 800 km of pipeline in Kampala, Uganda took 40 person days, while the assessment of a smaller network of 600 km took 15 days.

Example/tool 2.2: Basic elements for describing the water supply system



Several other formats for a supply system are possible, for example, more than one source catchment feeding a treatment works; a distribution area receiving water from more than one treatment works; further dividing distribution into trunk main, service reservoir and network elements; and separately considering consumers as industrial and domestic users. The basic system must document all inputs and outputs even if they do not operate all the time.

Example/tool 2.3: A good water system flow diagram

An accurate flow diagram of the water supply system from catchment to point-of-use greatly helps the identification of hazards, risks and current controls. It will help identify how risks can be transferred to consumers and where they are or can be controlled. It is vital to take the flow diagram out on site to check its accuracy and local knowledge is an important input. For simplicity and consistency, standard engineering flow diagram symbols can be used (see Example/tool 2.5). For large systems it may be helpful to divide the flow diagram for each or some of the basic elements (catchment, treatment, distribution, and consumer) into discrete sections. Discrete flow diagrams could be produced, for example for more than one source in the catchment, for different treatment streams and service reservoirs, and trunk mains and network mains in distribution.

Example/tool 2.4: Intended uses and users of the water

Suitable uses may be specified in regulations. For example, the European Drinking Water Directive covers water intended for human consumption which is defined as water intended for drinking, cooking, food preparation and food production.

Intended use	Intended users
The water supplied is intended for general consumption, personal hygiene and clothes washing. Foodstuffs may be prepared from the water.	Water is provided to the general population. The intended consumers do not include those who are significantly immunocompromised or industries with special water quality needs. These groups are advised to provide additional points-of-use treatment.

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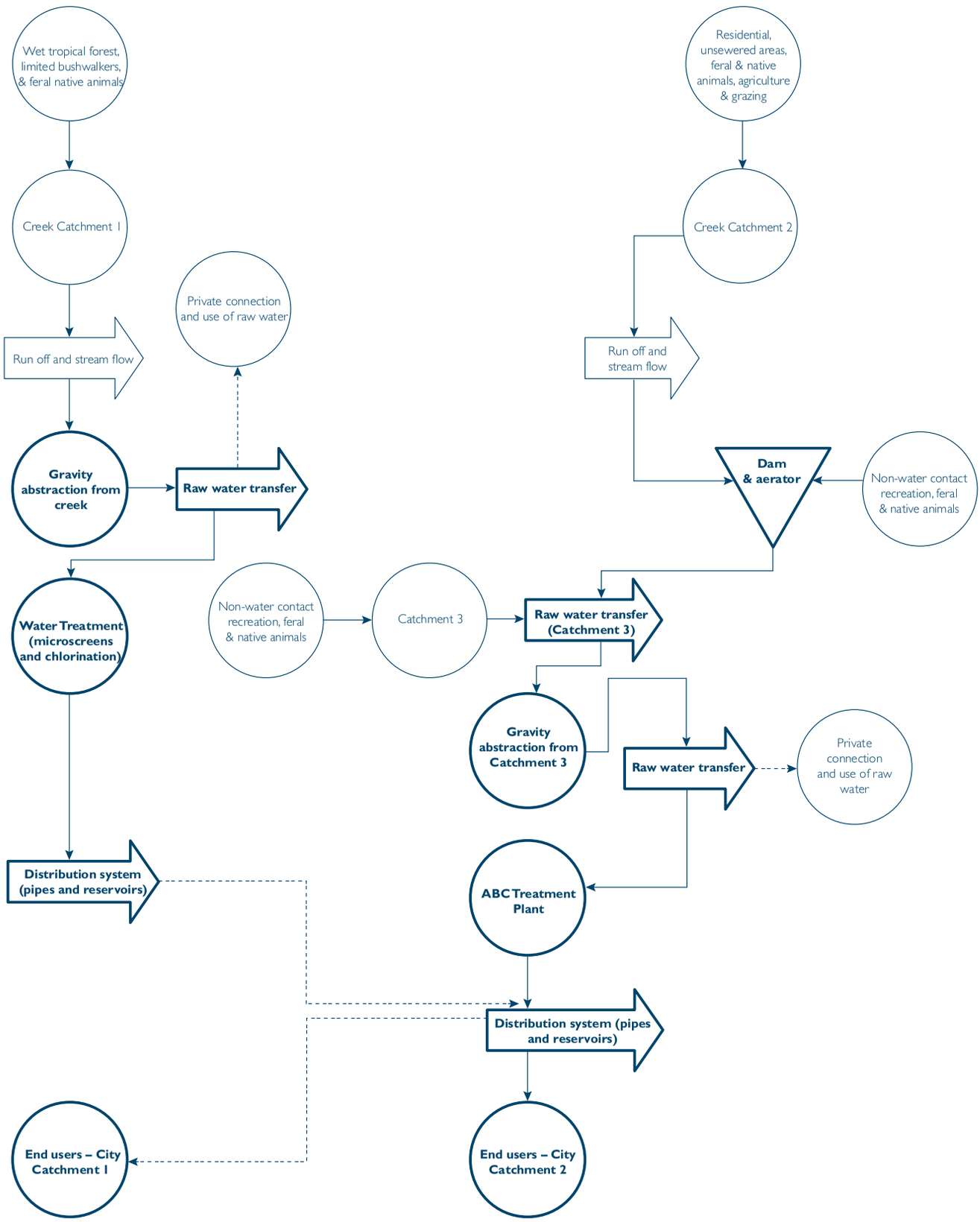
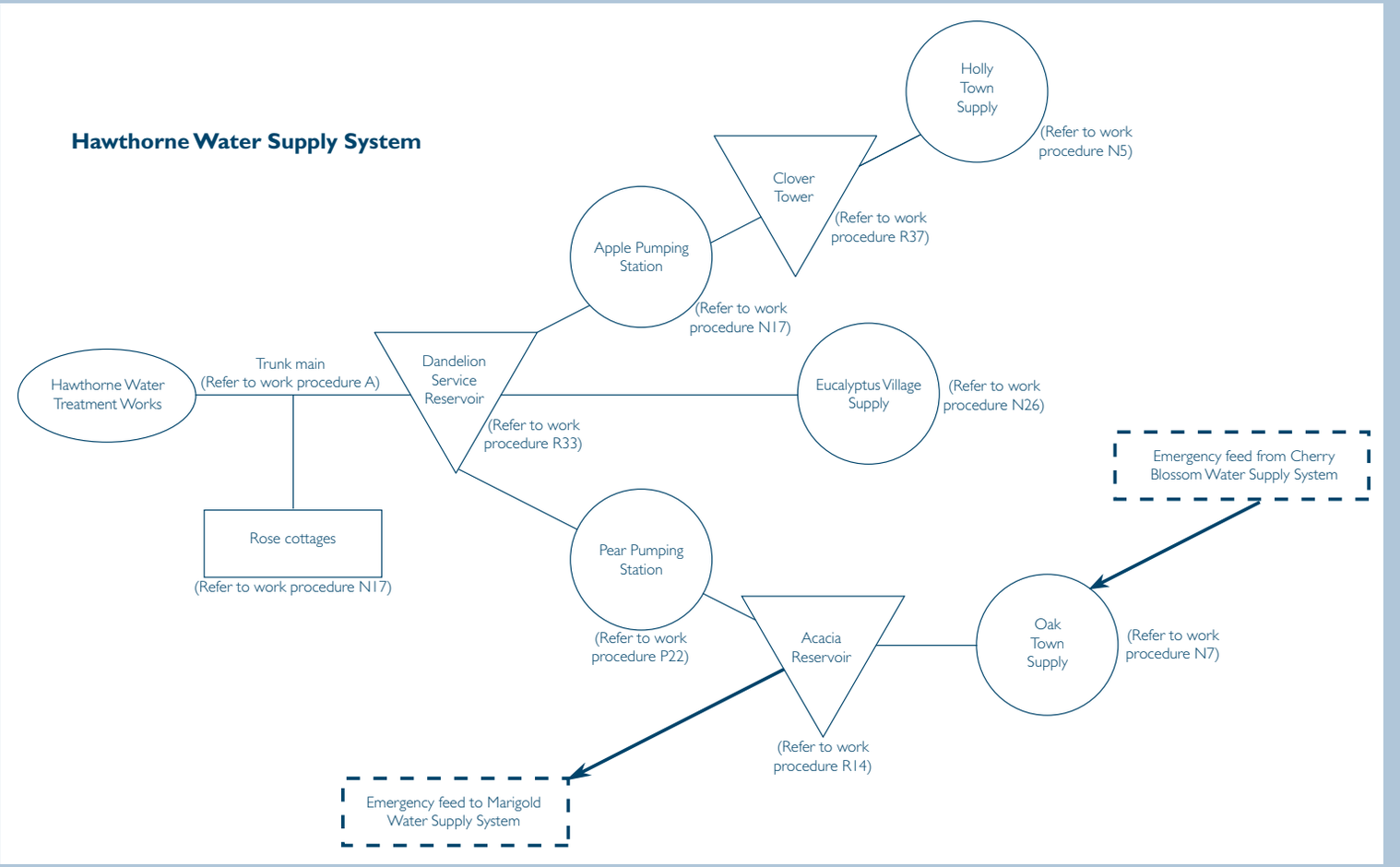
Example/tool 2.5: Checked system process flow diagram. Note that a separate flow diagram would be produced for the water treatment plant to show the steps involved in treatment (e.g. coagulation, flocculation, sedimentation, filtration, clearwell storage, and chemical addition points such as alum and pH adjusters, any upfront oxidants, chlorine for primary disinfection, and if necessary, additional chlorine for desired residual, finished water pH adjustment, etc.).



Example/tool 2.6: Basic distribution system diagram, referencing more detailed procedures and diagrams as necessary



Case study 1: Australia

Field Experience 2.1 – the flow diagram

Most utilities already had extensive system diagrams including geographic information system (GIS) data for their catchments, asset locations and distribution network. Most utilities also had process flow and hydraulic system diagrams for their assets. However, few had the type of theoretical flow diagram typically used for WSPs. Therefore, most utilities developed one or more additional flow diagrams to support their WSPs. Most utilities developed one overarching flow diagram and many then developed specific flow diagrams for each treatment plant and for each distinct water supply system. The flow diagrams were generally developed using common generic software, but many also used specialized flow diagram software.

Field Experience 2.2 – describing current water quality

Most utilities undertook water quality data analysis as part of the risk assessment phase of their WSP development. Water quality was typically plotted showing time series graphs of results against date, usually illustrating guideline values on the plots. Tables were usually prepared to summarize water quality statistics and compared with guideline values. This data was used to help inform the utility of what hazards might be present at levels of concern. Additional, or special water quality testing was usually not required to complete the WSP, although investigative sampling was often flagged as an action for improvement in the future.

Field Experience 2.3 – describing the system

System descriptions were typically brief and summary in nature. Detailed system descriptions, such as reports used for design and operation, were referenced for full details, with the WSP just providing summary details. As a result, the WSP system descriptions were usually quite brief and were aimed at the key audience: the WSP team.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 2.1 – the flow diagram

The WSP team found the flow diagram to be a useful tool for describing the system and referred to it frequently throughout the WSP development process. Rather than using the standard engineering flow diagram symbols, the team opted for an alternative schematic to represent the water supply system in an intuitive way because these were seen to be more easily interpreted and user friendly. The schematic showed all surface and groundwater sources and a detailed description of treatment processes, including coagulation/flocculation/sedimentation, filtration, clearwell storage and all chemical addition points, and directional arrows with pipe diameters to indicate flow through the distribution system. This level of detail made the diagram a useful tool to facilitate understanding and discussion of the system being assessed. Additional maps of the watershed and distribution network were also useful visual guides.

Field Experience 2.2 – describing current water quality

A key component of the system description is an assessment of the current quality of treated and delivered water. Water quality testing and a review of monitoring records collected by the water utility and the health department showed that finished water was consistently not meeting water quality standards, revealing discrepancies between perceived and actual water quality. These discrepancies were particularly important to consider when evaluating the effectiveness of existing control measures and in assessing the risk presented by the identified hazards (Module 4). For example, if the belief that chlorination at the water treatment plant was sufficient to maintain water quality throughout the distribution network had not been disproven through a current water quality assessment, increased chlorine dosing would not have been identified as a critical corrective action to prevent microbial contamination. Because subsequent steps of the WSP rely and build upon information gathered in the system description, it was important that the system description accurately reflected current conditions.

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Field Experience 2.3 – conducting a household survey

Problems with inconsistent service and uncertainty about water quality led many community residents to store or treat water in the home. To better understand the impact of point-of-use practices, a Household Water Use and Health Survey was conducted that included questions about household water sources, household storage and treatment practices, consumer perceptions, satisfaction and health concerns. Water from household taps was tested for chlorine residual and some samples were also tested for microbial contaminants. The household survey found that storing water in household tanks and drinking-water containers was associated with increased contamination; identified areas with inconsistent or no service; found that most water reaching the taps was not chlorinated; and revealed that water-associated health impacts and costs were major community concerns. Such information served to inform the water utility about consumers' experiences and priorities and informed the Ministry of Health of health concerns and the need for public education.

Field Experience 2.4 – selecting appropriate regulatory standards

In order to determine whether regulatory standards for chemicals and disinfection were being met, it was first necessary that all agencies involved in monitoring agree upon which standards should be targeted. At the start of the WSP process, target levels for some chemicals were set so low that they could not be expected to be reached even within an optimized system. Agencies differed on whether they used the environmentally-based EPA, European Union or national standards, or WHO health-based standards. The agencies represented on the WSP team agreed to adopt a consistent set of criteria that ensured drinking-water safety and was also achievable given system capabilities. In the case of turbidity, the team determined that the system could not be expected to consistently reach the indicated target until considerable system improvements were made. Rather than remain in continual non-compliance, a step-wise approach was taken, in which intermediate targets were set with the understanding that standards would be modified in subsequent WSP revisions as improvements were made. This incremental approach to reaching target turbidity levels represented a realistic and proactive way of dealing with certain limitations within the system and provided a long-term plan for reaching compliance for this parameter.

Case study 3: United Kingdom (England and Wales)

Field Experience 2.1 – field checking system descriptions

The water treatment works and distribution systems were already reasonably well documented using flow and engineering diagrams. A lot of information was already available on catchments, from companies' own investigations and regulatory requirements in respect of pesticides, nitrate and *Cryptosporidium*. The main challenge was the time and workload required to take existing and desk reviewed system diagrams out on site to check their accuracy and obtain input from catchment and site technicians and operators. This exercise paid dividends in that the review often revealed small errors or provided information previously not available centrally.

Field Experience 2.2 – incorporating existing water supply data into the WSP

Generally companies had very good information on their distribution systems and maintained sophisticated GIS systems and records of large industrial users and sensitive users such as hospitals and schools. Such systems and records, being already in place were not always immediately included in WSP development.

Module 3

Identify hazards and hazardous events and assess the risks

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Introduction

In practice this Module, together with Module 4 (determine and validate control measures, reassess and prioritize the risks), and Module 5 (develop, implement and maintain an improvement/upgrade plan), are usually carried out concurrently. For clarity, each of these is being presented as a separate step as they involve a number of activities. In essence these steps constitute the system assessment which identifies the potential hazards and hazardous events in each part of the water supply chain, the level of risk presented by each hazard and hazardous event, the appropriate measures to control the identified risks, and confirmation that standards and targets are met.

Module 3, the first step in this process, should:

- Identify all potential biological, physical and chemical hazards associated with each step in the drinking-water supply that can affect the safety of the water;
- Identify all hazards and hazardous events that could result in the water supply being, or becoming, contaminated, compromised or interrupted;
- Evaluate the risks identified at each point in the flow diagram previously prepared.

Key actions

Identify the hazards and hazardous events

For each step of the validated process flow diagram, the WSP team is required to assess what could go wrong at what point in the water supply system in terms of hazards and hazardous events. Hazard identification involves site visits as well as desk studies. Visual inspection of aspects such as the area surrounding abstraction points and elements of treatment may reveal hazards that would not have been identified through desk studies alone. Hazard identification also requires assessment of historic information and events, as well as predictive information based on utility data and knowledge of particular aspects of the treatment and supply systems. The team should consider factors that could introduce risks that are not readily obvious, for example the siting of a water treatment works in a flood plain (where there was no record of flooding) or the age of pipes in a distribution system (old pipes could be more susceptible to pressure fluctuations than new ones). Identification of 'influencing' factors like these will require the WSP team to think laterally and widely. A number of hazards and hazardous events may occur at any step in the water supply system.

Assessment of risk

The risk associated with each hazard may be described by identifying the likelihood of occurrence (e.g. 'certain', 'possible', 'rare') and evaluating the severity of consequences if the hazard occurred (e.g. 'insignificant', 'major', 'catastrophic'). The potential impact on public health is the most important consideration, but other factors such as aesthetic effects, continuity and adequacy of supplies, and utility reputation should also be considered.

The aim should be to distinguish between significant and less significant risks. The best way of carrying this out is to draw up a simple table in order to systematically record all potential hazardous events and associated hazards, together with an estimation of the magnitude of risk (see Example/tool 3.8). When starting the risk assessment process, utilities should draw up detailed definitions of what they mean by 'possible', 'rare', 'insignificant', 'major' etc. These definitions should enable the risk assessment to avoid being too subjective. Of crucial importance is the need to define in advance the definition or risk matrix score that identifies 'significant' risk. The information that will inform the risk assessment will come from the experience, knowledge and judgment of the utility and the individual team members, industry good practice and technical literature. When data is insufficient to determine whether a risk is high or low, risks should be considered significant until further investigations clarify the assessment.
The risk assessment should be specific for each drinking-water system because each system is unique.

Hazards and hazardous events
Hazards are defined as: Physical, biological, chemical or radiological agents that can cause harm to public health. Hazardous events are defined as: An event that introduces hazards to, or fails to remove them from, the water supply. For example, heavy rainfall (hazardous event) may promote the introduction of microbial pathogens (hazards) into source water.

Typical challenges

- The possibility of missing new hazards and hazardous events. Since a risk assessment provides a 'point in time' picture of the system, the risk assessment should be reviewed on a regular basis in order not to miss new hazards and hazardous events.
- Uncertainty in assessment of risks due to unavailability of data, poor knowledge of activities within the water supply chain and their relative contribution to the risk generated by the hazard or hazardous event.
- Properly defining likelihood and consequence with sufficient detail to avoid subjective assessments and to enable consistency.

Outputs

1. Description of what could go wrong and where in terms of hazards and hazardous events.
2. Assessment of risks expressed in an interpretable and comparable manner, such that more significant risks are clearly distinguished from less significant risks.

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Example/tool 3.1: Typical hazards affecting a catchment

Hazardous event (source of hazard)	Associated hazards (and issues to consider)
Meteorology and weather patterns	Flooding, rapid changes in source water quality
Seasonal variations	Changes in source water quality
Geology	Arsenic, fluoride, lead, uranium, radon Swallow holes (surface water ingress)
Agriculture	Microbial contamination, pesticides, nitrate Slurry and dung spreading Disposal of dead animals
Forestry	Pesticides, PAHs - polyaromatic hydrocarbons (fires)
Industry (including abandoned and former industrial sites)	Chemical and microbial contamination Potential loss of source water due to contamination
Mining (including abandoned mines)	Chemical contamination
Transport – roads	Pesticides, chemicals (road traffic accidents)
Transport – railways	Pesticides
Transport – airports (including abandoned airfields)	Organic chemicals
Development	Run-off
Housing – septic tanks	Microbial contamination
Abattoirs	Organic and microbial contamination
Wildlife	Microbial contamination
Recreational use	Microbial contamination
Competing water uses	Sufficiency
Raw water storage	Algal blooms and toxins Stratification
Unconfined aquifer	Water quality subject to unexpected change
Well / borehole headworks not watertight	Surface water intrusion
Borehole casing corroded or incomplete	Surface water intrusion
Flooding	Quality and sufficiency of raw water

Example/tool 3.2: Typical hazards associated with treatment

Hazardous event (source of hazard)	Associated hazards (and issues to consider)
Any hazard not controlled / mitigated within the catchment	As identified in catchment
Power supplies	Interrupted treatment / loss of disinfection
Capacity of treatment works	Overloading treatment
Disinfection	Reliability Disinfection by-products
By-pass facility	Inadequate treatment
Treatment failure	Untreated water
Unapproved treatment chemicals and materials	Contamination of water supply
Contaminated treatment chemicals	Contamination of water supply
Blocked filters	Inadequate particle removal
Inadequate filter media depth	Inadequate particle removal
Security / vandalism	Contamination / loss of supply
Instrumentation failure	Loss of control
Telemetry	Communication failure
Flooding	Loss or restriction of treatment works
Fire / explosion	Loss or restriction of treatment works

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Example/tool 3.3: Typical hazards within a distribution network

Hazardous event (source of hazard)	Associated hazards (and issues to consider)
Any hazard not controlled / mitigated within treatment	As identified in treatment
Mains burst	Ingress of contamination
Pressure fluctuations	Ingress of contamination
Intermittent supply	Ingress of contamination
Opening / closing valves	Reversed or changed flow disturbing deposits Introduction of stale water
Use of unapproved materials	Contamination of water supply
Third party access to hydrants	Contamination by backflow Increased flow disturbing deposits
Unauthorized connections	Contamination by backflow
Open service reservoir	Contamination by wildlife
Leaking service reservoir	Ingress of contamination
Unprotected service reservoir access	Contamination
Security / vandalism	Contamination
Contaminated land	Contamination of water supply through wrong pipe type

Example/tool 3.4: Typical hazards affecting consumer premises

Hazardous event (source of hazard)	Associated hazards (and issues to consider)
Any hazard not controlled / mitigated within distribution	As identified in distribution
Unauthorized connections	Contamination by backflow
Lead pipes	Lead contamination
Plastic service pipes	Contamination from oil or solvent spillage

Example/tool 3.5: Deciding which method of risk assessment is most appropriate

The risk assessment process can involve a quantitative or semi-quantitative approach, comprising estimation of likelihood/frequency and severity/consequence (see Example/tool 3.6, 3.7 and 3.8), or a simplified qualitative approach based on expert judgment of the WSP team (see Example/tool 3.9 and 3.10). A small water supply system may only require a team decision, whereas a more complex system may benefit from a semi-quantitative risk prioritization approach. In any case, it is beneficial to record the basis of the decision to act as a reminder to the team and/or auditor or reviewer as to why the decision was taken.

Example/tool 3.6: Semi-quantitative risk matrix approach (from Deere et al., 2001)

		Severity or consequence				
		Insignificant or no impact - Rating: 1	**Minor compliance impact - Rating: 2**	**Moderate aesthetic impact - Rating: 3**	**Major regulatory impact - Rating: 4**	**Catastrophic public health impact - Rating: 5**
Likelihood or frequency	**Almost certain / Once a day - Rating: 5**	5	10	15	20	25
	Likely / Once a week - Rating: 4	4	8	12	16	20
	Moderate / Once a month - Rating: 3	3	6	9	12	15
	Unlikely / Once a year - Rating: 2	2	4	6	8	10
	Rare / Once every 5 years - Rating: 1	1	2	3	4	5
Risk score		<6	6-9	10-15	>15	
Risk rating		Low	Medium	High	Very high	

All risks should be documented in the WSP and be subject to regular review even when the likelihood is rare and the risk rating is low. This avoids risks being forgotten or overlooked and provides the water utility with a record of due diligence should incidents occur.

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Example/tool 3.7: How to calculate the risk using the matrix

Event	Loss of network integrity through illegal connections results in the ingress of pathogens.
Severity of event and basis for score	5 – Public health impact including disease and potentially death.
Likelihood of event and basis of score	2 – Plumbing controls are in place, but are ineffective - at least two outbreaks have occurred from illegal connections in the past 5 years.
Score	5 x 2 = 10 high risk
Outcome	Risk requires prioritizing for action, including reviewing the current controls and whether new control(s) could be implemented (see Module 5).

Example/tool 3.8: Output of hazard assessment and risk assessment using semi-quantitative approach

Process step	Hazardous event (source of hazard)	Hazard type	Likeli-hood	Severity	Score	Risk rating (before consideration of controls)	Basis
Source (groundwater)	Cattle defecation in vicinity of unfenced wellhead causing source of potential pathogen ingress in wet weather	Microbial	3	5	15	High	Potential illness from pathogens from cattle, such as *Cryptosporidium*
Source	Cocktail of pesticides from agricultural uses	Chemical	2	4	8	Medium	Potential introduction of toxic chemicals which could lead to concentrations in finished water above national standards and WHO Guideline values
Source	Potential for informal solid waste disposal	Microbial and chemical	1	1	1	Low	Potential for hazardous waste plus rainfall event causing contamination to water supply is low
Storage tank	Unroofed reservoir allows birds to congregate and defecate in treated water	Microbial	2	5	10	High	Potential illness from pathogens such as *Salmonella* and *Campylobacter*
Treatment	No back-up power supply	Microbial and chemical	2	5	10	High	Potential loss of treatment and pumps/pressure
Distribution	Leaks on trunk main and distribution system	Microbial	5	3	15	High	Leaks are a potential source of microbial pathogens and contribute to high % of unaccounted for water

Example/tool 3.9: Simplified risk assessment based on expert judgment of the WSP team

An alternative to scoring risks based on the likelihood and severity of consequences model, is to undertake a simplified risk assessment process, drawing on the team's judgment. Risks may be ranked as 'significant', 'uncertain', or 'insignificant', based on an assessment of the hazards/hazardous events at each step in the process. Following this, and as explained in Module 4 and 5, it will be necessary to determine whether risks are under control, through which control measures, and when necessary, identify and put in place an improvement programme, which may require short-, medium- and long-term mitigation measures. It is critical to document which events need urgent attention. The NZ MoH (2005) defines 'urgent attention' as those things that can happen frequently and/or could cause significant illness. The descriptors below can be used to capture this information.

Example/tool 3.10: Definition of descriptors for use in simple risk prioritization

Descriptor	Meaning	Notes
Significant	Clearly a priority	The risk should be considered further to determine whether additional control measures are required and whether a particular process step should be elevated to a key control point in the system. It is necessary to validate existing control measures before defining whether additional control measures are required.
Uncertain	Unsure if the event is or is not a significant risk	The risk may require further studies to understand if the event is really a significant risk or not.
Insignificant	Clearly not a priority	Note that the risk will be described and documented and will be revisited in future years as part of the WSP rolling review.

Example/tool 3.11: Prioritizing and documenting risks for urgent action or regular review

Any hazard scored for risk as 'high' or 'very high' or 'significant', should have in place, or requires urgently, validated controls (or mitigation measures). Where controls are not in place, an improvement programme should be drawn up. Any hazard classified as 'moderate' or 'low risk' should be documented and kept under regular review. Controls for 'high' or 'very high' risks may also mitigate other risks.

Example/tool 3.12: The necessity of working with stakeholders

Identification of a hazard does not mean the water company is responsible for the cause. Many hazards are naturally occurring or the result of agricultural or industrial activity. The WSP approach requires water utilities to work with other stakeholders to make them aware of their responsibilities and the impact that their actions have on the utility's ability to supply safe drinking-water. The WSP approach promotes dialogue, education and collaborative action to remove or minimize risks.

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Case study 1: Australia

Field Experience 3.1 – identifying threats to water quality

Usually two-day workshops were convened for each major water supply system and involved the full WSP team with one or more external experts, stakeholders and facilitators. The process of hazard identification and risk assessment was usually carried out on day one. Control point determination and specification was usually carried out on day two. Hazardous events were typically listed for each process step identified in the flow diagram. For each hazardous event, the hazards arising were considered and risks were scored against two factors: likelihood and consequence. Likelihood was usually expressed as a frequency of anticipated occurrence. Consequence was usually expressed in terms of population size (small-large) and severity of effect (operational-aesthetic-health). The workshops typically involved brainstorming exercises, review of water quality data and consideration of a range of what-if scenarios. Most utilities assessed risks assuming that the current control measures were in place and working normally. Some utilities assessed each risk twice: both with and without considering the effect of the current controls in place. Most utilities used a risk assessment ranking matrix that was based on their corporate risk assessment system which was often used for environmental, occupational health and safety and other types of risk assessment, too.

Field Experience 3.2 – limitations of the semi-quantitative approach to risk assessment

The semi-quantitative approach was relatively easy to apply in Australia because it formed the basis of the Australian and New Zealand Risk Management Standard (1995, 1999, 2004) and was very familiar to most industry professionals. However, there was always difficulty forming agreement on risks. In particular, it was common for the same stated risk to have more than one connotation: a low likelihood of a severe consequence and a high likelihood of a minor consequence. For instance, the risk of dirty water contamination was both likely but minor (sporadic dirty water complaints with no health implications are quite common) and rare but severe (major dirty water events that compromise disinfection are serious but not common). Therefore, it was necessary to set out very clearly what each risk was. Another limitation of the scoring system was that health consequences were typically not differentiated between short-term acute and established effects, such as pathogen infections, and long-term theoretical effects, such as disinfection by-product effects. Therefore, the risk ranking tended to overstate the importance of some chemical related health risks of relatively low or even questionable significance as compared with microbial risks.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 3.1 – identifying threats to water quality

A two-day workshop was convened to carry out the process of hazard identification and risk assessment. Hazards in the watershed, treatment process, distribution system, and household were identified by Task Force members through brainstorming exercises and through a review of water quality monitoring site visits and household survey reports. The most critical threats identified were institutional, including a lack of operator training, a lack of system accountability to ensure routine monitoring and a lack of standard operating procedures. Physical hazards identified through brainstorming, such as the introduction of sewage and gasoline, while important, were found to be largely hypothetical. The more critical physical threats, such as a lack of chlorine and the presence of thermotolerant coliforms in delivered water,

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were identified through a review of the monitoring and survey reports of existing conditions and practices.

Because of the range of possible hazards at each step of the water supply chain, the multiple factors considered in assigning risk, and the relative and subjective nature of the scoring process, the input of stakeholders with varied expertise and experience was important for minimizing bias by any single agency perspective. It also improved the accountability of those agencies and facilitated the appropriate assignment of responsibility for corrective actions identified to address the risks.

Field Experience 3.2 – limitations of the semi-quantitative approach to risk assessment

Initially a semi-quantitative approach following WHO's WSP risk scoring matrix (chapter 4 of the Guidelines) was employed. Considerable confusion and disagreement arose, however, over some hazards that did not always lend themselves to quantitative ranking and led to time-consuming discussions of hypothetical situations. In many cases, assignment of severity and likelihood was inconsistent. The severity of sewage effluent from cesspool emptying, for example, was ranked high, while the severity of sewage effluent from on-site absorption pits was ranked low, resulting in vastly different priority assignments, even though likelihood was ranked the same. Participants also found it difficult to exclude consideration of existing control measures when assessing risk, further contributing to frustration in the preliminary ranking process. WSP team members found that the resulting rankings did not reflect priorities and therefore decided to switch to a more intuitive approach and to delay priority ranking of risks until after control measures had been considered (see LAC Field Experience 4.1).

Case study 3: United Kingdom (England and Wales)

Field Experience 3.1 – broadening the application of risk assessment

The initial process for many companies was to restrict hazard identification and risk analysis to those that related directly to compliance parameters. Issues such as flooding, power supplies, security, emergency responses, telemetry, communications and IT systems, although well documented within company procedures, were not considered as part of the WSP, often because they were not under the direct control of the WSP team lead or members (usually from the operations or scientific divisions of a company). Gradual development of the WSP approach demonstrated the need for wider application but this area remains a problem.

Many companies had applied risk assessment techniques to their operations, assets and financial systems for many years and had risk registers. Sometimes ownership of the risk register was not covered by the WSP team so that, for example, a waterborne outbreak of illness did not feature in the WSP because it already featured in the company's risk register. Widening WSP application is still a challenge in some companies.

Field Experience 3.2 – tailoring the risk scoring matrix to fit the supplier

Most companies found the 5x5 risk matrix from Chapter 4 of the third edition of the Guidelines useful for scoring and prioritizing risks. Some changed the scoring ratio because they considered it was easier to separate high, medium and low risks. The use of a basic non-scoring 3x3 risk matrix (high, medium and low) was not found to be very helpful because most risks ended up in the medium category and then had to be reprioritized. Many companies found it useful to supplement the basic definitions in the Guidelines with further explanations to help with consistent

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assessment, particularly where more than one team was carrying out assessments. An example is shown below but it is important that each company works out its own methodology rather than copy other examples.

High risk ≥20 Medium risk 10-19 Low risk <10				Consequence				
				Wholesome water Insignificant 1	Short term or localised, not health related non compliance or aesthetic Minor 2	Widespread aesthetic issues or long term non compliance not heath related Moderate 4	Potential long term heath effects Major 8	Potential illness Catastrophic 16
Likelihood	Has not happened in the past and it is highly improbable that it will happen in the future	Most unlikely	1	1	2	4	8	16
	Is possible and cannot be ruled out completely	Unlikely	2	2	4	8	16	32
	Is possible and under certain circumstances could happen	Forseeable	3	3	6	12	24	48
	Has occurred in the past and has the potential to happen again	Very likely	4	4	8	16	32	64
	Has occurred in the past and could happen again	Almost certain	5	5	10	20	40	80

Field Experience 3.3 – addressing risks within consumer premises

It was noticeable that many WSPs did not identify consumers or consumer organizations as WSP stakeholders. Hazard identification and risk assessment of consumer premises was a weak area in most WSPs and it is true that there is a limit to what water companies can achieve although they do have powers of inspection. Water storage within premises is common in England and Wales and is a source of hazards but is an area where water companies have little control. A good example of co-operation within the water industry was an education package for consumers setting out what they can do to protect the safety of their water supplies in areas such as hygiene, plumbing and preventing back syphonage. Companies were aware that this is an area that requires handling carefully as there is a danger of scaring consumers away from drinking tap water.

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Module 4

Determine and validate control measures, reassess and prioritize the risks

Introduction

Concurrently with identifying the hazards and evaluating the risks, the WSP team should document existing and potential control measures. In this regard, the team should consider whether the existing controls are effective. Depending on the type of control, this could be done by site inspection, manufacturer's specification, or monitoring data. The risks should then be recalculated in terms of likelihood and consequence, taking into account all existing control measures. The reduction in risk achieved by each control measure will be an indication of its effectiveness. If the effectiveness of the control is not known at the time of the initial risk assessment, the risk should be calculated as though the control was not working. Any remaining risks after all the control measures have been taken into account, and which the WSP team consider unacceptable, should be investigated in terms of additional corrective actions.

Control measures (also referred to as 'barriers' or 'mitigation measures') are steps in the drinking-water supply that directly affect drinking-water quality and ensure the water consistently meets water quality targets. They are activities and processes applied to reduce or mitigate risks.

Key actions

Identify the controls

Existing control measures should be determined for each of the identified hazards and hazardous events. Missing controls (i.e. those that are needed, but are not in place to mitigate hazards) need to be clearly documented and addressed, as explained below.

Validate the effectiveness of the controls

Validation is the process of obtaining evidence on the performance of control measures. For many controls validation will require an intensive programme of monitoring to demonstrate the performance of a control under normal and exceptional circumstances. This should not be confused with operational monitoring, which shows that the validated control continues to work effectively. The efficacy of each control measure should be determined at its point in the water supply system rather than in isolation as the performance of one control can influence the performance of subsequent controls. If a control has been in place for some time, a utility may have sufficient operating data to give it confidence that further validation monitoring is not required.

Technical data from scientific literature or data from studies at pilot drinking-water treatment plants may be helpful in the validation process, but care must be taken to check that the circumstances described or piloted are the same or very similar to the risks that have been identified as requiring controls. Validation may also be carried out by seeding challenge organisms or chemicals and determining the effectiveness of removal or inactivation, although this is not a procedure that should be used when water is going into supply. Validation of controls will involve a variety of methodologies. For example, validating buffer distances and fencing in a catchment may be carried out through catchment sanitary surveys to ensure minimal risk of microbial pathogens entering a water intake; and an alternative power source, supplied through an on-site emergency generator, may be validated by demonstrating that it switches on when power is lost, and that it has sufficient power output to run the required process.

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During operations, it is critical to monitor the effectiveness of validated controls against pre-determined targets or 'critical limits' (see Module 6 on operational monitoring). These targets may be expressed as upper and/or lower limits. For example, if a control measure is 'maintenance of continuous chlorine residual', a critical limit might be expressed as water meeting a 0.2-0.5 mg/l residual chlorine level, pH 6.5-7 and turbidity <1 NTU.

Reassess risks, taking into account the effectiveness of controls

The risks should be recalculated in terms of likelihood and consequences taking into account the effectiveness of each control. Control measures must be considered not only for their longer-term average performance, but also in light of their potential to fail or be ineffective over a short space of time. It is important that significant risks that do not have controls are highlighted as remaining significant risks in that water supply system. The determination of the appropriate missing controls is critical and is discussed in Module 5.

Prioritize all the identified risks

Risks should be prioritized in terms of their likely impact on the capacity of the system to deliver safe water. High priority risks may require system modification or upgrade to achieve the water quality targets. Lower priority risks can often be minimized as part of routine good practice activities.

As per Module 5, an upgrade or improvement plan should be developed to address all uncontrolled and prioritized risks. Upgrade plans should identify who is responsible for the improvements, together with an appropriate time frame for implementation of these controls.

Examples of controls include short-term mitigation measures (e.g. advice notices and restricting output or not using a particular source); and medium- and long-term mitigation measures (e.g. improving community consultation activities; catchment measures, such as covering of water storages; treatment improvements, such as enhanced coagulation and filtration; and other capital investment projects).

Typical challenges

- Identifying staff responsibilities in terms of who will undertake the field work to identify the hazards and determine the control measures;
- Ensuring appropriate controls are identified that are cost-effective and sustainable;
- Uncertainty in prioritizing the risks due to unavailability of data; poor knowledge of activities within the water supply chain and their relative contribution to the hazard type generated by the hazardous event as well as the risk score of the event.

Outputs

1. Identification of the controls.
2. Validation of the effectiveness of the controls.
3. Identification and prioritization of insufficiently controlled risks.

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Example/tool 4.1: Typical control measures associated with hazards at a catchment

Restricted access to catchments
Water utility ownership and control of catchment land
Stock fencing
Moving stock away from river access at calving / lambing times
Codes of practice on agricultural chemical use and slurry spreading
Moving farm operations away from sensitive locations
Planning controls
Agreements and communication with transport organizations
Communication and education of catchment stakeholders
Industrial effluent standards and volume controls
Raw water storage
Ability to close intakes (time of travel information)
River biology – indicator of diffuse or point source contamination
Covering and protecting springs
Ability to use good alternative water sources when hazards affect one source
Continuous monitoring of intake and river
Site inspections
Regular internal inspections of wells and boreholes

Example/tool 4.2: Typical control measures associated with hazards at treatment

Validated treatment processes
Alarmed operating limits
Stand-by generator
Automatic shut-down
Continuous monitoring with alarms
Trained staff (operator competency)
Purchasing policy and procedure
Fencing, locked premises, intruder alarms
Communications back-up

Example/tool 4.3: Typical control measures associated with hazards at a distribution network

Regular reservoir inspections (external and internal)
Cover open service reservoirs
Up-to-date network maps
Known valve status
Purchasing policy and procedure
Mains repair procedures
Trained staff (operator competency)
Hygiene procedures
Hydrant security
Non-return valves
Pressure monitoring and recording
Protected pipes
Fencing, locked hatches, intruder alarms for service reservoirs and towers

Example/tool 4.4: Typical control measures associated with hazards at consumer premises

Property inspections
Consumer education
Plumbosolvency control
Non-return valves
Advice to boil / not use the water

Example/tool 4.5: Critical limits and actions relating to microbial hazards

Hazards and hazardous events	Examples of control measures	Critical limit target	Critical limit trigger for action
Microbial hazards from contamination of a service reservoir	Ensure inspection covers remain in place Ensure ventilators and cable ducts are secured against vermin entry	Inspection covers locked in place and vermin-proofing intact	Inspection covers not in place or unlocked or damage to vermin-proofing
Microbial hazards from contamination of a source water reservoir	Protection of catchments from stock and human habitation Fencing stock from catchment streams and watercourses	Only permitted development or activity in catchment and stock fencing intact	Any non-permitted development or activity in catchment and any damage to stock fencing
Chemical, microbial and physical hazards overwhelming treatment capability	Cessation of source water abstraction during high contamination periods, e.g. after storms	Rain event, flow rate and turbidity monitoring within normal range	Rain event, flow rate and turbidity monitoring outside of specified range
Chemical cyanotoxin hazards from algal bloom in source water reservoir	Mixing of storages to reduce cyanobacteria	Mixing system operating when required	Failure of mixing system and stratification forming

Example/tool 4.6: Validation information capture format

Item validated	Validation	Reference
Chlorine residual critical limit values	Australian Drinking Water Guidelines state that a Ct of 15 is required to control bacterial pathogens which require the minimum specific chlorine concentrations at the specified measurement points in peak day demand flows.	*Australian Drinking Water Guidelines* (1996 and 2004). National Health and Medical Research Council.
Filtered effluent critical limit values	Systems that filter must ensure that the turbidity goes no higher than 1 NTU and 0.3 NTU for conventional or direct filtration in at least 95% of the daily samples in any month.	US EPA National Primary Drinking Water Regulations (2002)
Critical limits for underground travel time in riverbank filtration	Site and depth of wells should ensure minimal travel times of the water in the ground of 30 days (as shown from a two year observation programme run with a sequence of observation wells) to ensure elimination to < 1 µg/L of toxins even during prolonged cyanobacterial blooms with > 1000 µg/L of toxins in the river.	Internal report documenting analysis of two years' worth of data in observation and production wells.
Critical limit for turbidity at outlet of each single rapid filtration unit	Research programme run by five utilities over a two year period showed *Cryptosporidia* oocysts to remain below detection limit if the filters are operated to meet this critical limit for turbidity.	Project report of joint research programme. Analytical method had to meet performance target for result to be accepted.

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Example/tool 4.7: Validate controls before prioritizing risks for mitigation

Risks can only be reassessed and prioritized following validation of control measures. Initial validation of controls can be carried out through intensive monitoring, unless controls have proved their effectiveness over time. If it is clear that the system needs to be improved to achieve the relevant water quality objectives, an upgrade/improvement plan should be developed and implemented.

Example/tool 4.8: Maintaining consistency in reassessing and prioritizing risks

- ☑ Decide on a consistent risk assessment methodology upfront, as done in Module 3;
- ☑ Be specific about what the hazard is in terms of:
  - Likelihood of the hazard occurring, taking into account effectiveness of controls;
  - Consequence of the hazard occurring;
  - Probability that it will affect the safety of the water supply; and
  - Where and when it can occur.

Example/tool 4.9: Establishing cut-off points to prioritize risks

The WSP team needs to establish a cut-off point, above which the reassessed risks will require further action and below which they will be kept under review. In Example/tool 3.6, a score of 6 is taken as the cut-off point, but in addition, any risk that includes a catastrophic consequence rating should be documented and kept under review even if the likelihood is rare. Classifying the risk from low to very high can be rather subjective but should help to prioritize where the most urgent action is required.

Example/tool 4.10: Output of hazard assessment and determination and validation of control measures

Hazardous event	Hazard type	Likelihood	Severity	Risk	Control measure	Efficacy of control measure	Basis
Cattle defecation followed by rainfall	Microbial (pathogens)	3	5	15	Filtration of water Boil water advisory if filtration fails (corrective action)	Protozoa controlled by filtration validated by manufacturer's data on pore size and testing for oocysts	Waterborne disease outbreaks seen in similar situations
Etc. ↴							

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Example/tool 4.11: Dealing with uncertainty in scoring of risks

The uncertainty of risk scoring for each of the hazards and hazardous events can be addressed by further investigations which can be added to the WSP.

Step	Catchment
Event	Leaching from sites such as disused cattle, landfill or contaminated sites and run-off of water soluble compounds (e.g. pesticides) into the source water.
Basis	While the dilution factors are significant, there is no monitoring data available and no barriers in place for this hazard. If pesticides are present in high concentrations, there could be potential health risk.
Possible investigations to reduce uncertainty	1. Undertake a sanitary survey with special focus on pesticide usage and dip site locations, particularly those in the proximity of spray from pesticides. 2. Undertake pesticide monitoring at the source intake during normal and event conditions.
Practicality of investigation	1. High practicality but low cost and could be combined with other studies being undertaken by other stakeholders. 2. High practicality but high cost.
Output	The WSP team recommends which of the above options to undertake, by whom, at what time, and at what cost.

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Example/tool 4.12: Risk prioritization and reassessment

Hazard	Hazardous event (source of hazard)	Likelihood	Severity	Score	Risk rating (see table 3.6)	Example control measure	Validation of control measure	Reassessment of risk post-control
Microbial	Inadequate disinfection method	3	4	12	High	Improve disinfection method (longer-term). Minimizing ingress of contamination to system and lengthening reservoir detention times (short-term). Fitting alarms triggered by low disinfectant level.	Alarms effective and demonstration of consistent removal of indicator organisms under range of operating conditions.	Low with appropriate operational monitoring.
Chemical	Formation of disinfection by-products at levels that exceed Guideline values	3	3	9	Medium	Reducing water age through tanks downstream where possible in periods of low water demand.	Consistent reduction in disinfection by-products under range of operating conditions.	Low with appropriate operational monitoring.
Microbial	Less effective disinfection due to elevated turbidity	4	4	16	Very high	Improve clarification and filtration processes (longer-term). Fitting alarms triggered by low disinfectant level.	Alarms effective and demonstration of consistent removal of indicator organisms under range of operating conditions.	Low with appropriate operational monitoring.
Microbial	Major malfunction/ failure of disinfection plant	2	5	10	High	Chlorination plants refitted for equipment and process reliability of 99.5%. Fitting alarms triggered by low disinfectant level.	Alarms effective and demonstration of consistent removal of indicator organisms under range of operating conditions.	Low with appropriate operational monitoring.
Microbial	Reliability of disinfection plant less than target level of 99.5%	3	4	12	High	Defined band widths for chlorine dosing linked to alarms.	Alarms effective and demonstration of consistent removal of indicator organisms under range of operating conditions.	Low with appropriate operational monitoring.
Microbial	Failure of UV disinfection plants	3	4	12	High	Alarms in place for power outages.	Alarms triggered under a range of operating conditions.	Low with appropriate operational monitoring.

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Hazard	Hazardous event (source of hazard)	Likelihood	Severity	Score	Risk rating (see table 3.6)	Example control measure	Validation of control measure	Reassessment of risk post-control
Microbial	Low chlorine residual in distribution and reticulation systems	4	4	16	Very high	Set point designed to achieve established target chlorine residual to achieve microbial standards at consumer premises linked to alarms.	Alarms effective and demonstration of consistent removal of indicator organisms under range of operating conditions.	Low with appropriate operational monitoring.
Microbial	Power failure to disinfection plant	2	5	10	High	Dual power source.	Supplies confirmed to come from different generating sources. Automatic switching shown to be triggered under a range of operating conditions.	Low with appropriate operational monitoring.
Physical, chemical, microbial	Contamination of dosing chemicals or wrong chemical supplied and dosed	2	4	8	Medium	On-line monitoring controls. Laboratory analysis certificate from supplier.	Intensive audit of suppliers. Alarms triggered under a range of operating conditions.	Low with appropriate operational monitoring.
Chemical	Over or under dosing from fluoridation plants	3	3	9	Medium	Plants have alarms on high and low levels with dosing cut-offs on high levels.	Alarms triggered under a range of operating conditions.	Low with appropriate operational monitoring.
Chemical, physical	Over or under dosing of lime for pH correction	3	3	9	Medium	Plants have alarms on high and low pH with dosing cut-offs on high pH.	Alarms triggered under a range of operating conditions.	Low with appropriate operational monitoring.
Physical	Failure of pumps	4	3	12	High	Pressure measurement triggering back-up pumps. (Not in place.)	No controls in place.	High - priority for mitigation.
Chemical	Nitrate exceeds compliance standards	3	2	6	Medium	Blending with low-nitrate source from another water supply. (Alternative source itself has rising levels of nitrate and is subject to other demands.)	Unreliable long-term control.	Medium - keep trend under regular review and propose alternative mitigation scheme.

Case study 1: Australia

Field Experience 4.1 – using a qualitative approach to assessing controls

In most cases, actual performance of controls in the removal of contaminants, and actual source water concentrations of hazards, were not defined. Rather, a qualitative, 'gut feel' approach was used to rate the adequacy of controls based on operator experience. Reliable, telemetered, automated engineered controls, such as treatment plants, were often classified as critical control points. Less directly controlled control measures, such as backflow prevention strategies and catchment management actions, were sometimes classified as critical control points but were more usually classified as supporting programmes or just control points. There was often great difficulty in coming to agreement as to what should constitute a critical control point rather than a control point and some utilities did not use the term critical control point at all (consistent with WHO WSP and NZ MoH guidance). In general, however, there was good agreement as to which controls were important and needed to be actively managed.

Field Experience 4.2 – areas of uncertainty

There were significant uncertainties in estimating the effectiveness and value of some catchment and distribution system controls. There was often a reluctance to rely on catchment controls due to difficulties with measuring and enforcing controls in practice. There was also difficulty in having confidence as to the effectiveness of catchment controls, other than total exclusion of people, agriculture, industry and development, which was practiced in some catchments. In general, if activities were allowed in the catchments, it was assumed that treatment was required regardless of the way that the activities were managed. A good example of this was that many source waters that feed disinfection-only treatment systems prohibit recreational activity in catchments and dams because there is not confidence that these activities can be managed to low enough levels to avoid excessive contamination. Another area of concern was disinfectant residual maintenance in distribution systems. Most utilities targeted residual maintenance to water tanks, which are obvious points of possible ingress, but most did not target residual disinfection to all taps, relying instead on low leakage rates and reliable pressurization combined with sanitary repair procedures.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 4.1 – using qualitative operator knowledge and experience to inform risk assessment

Through discussion of the hazards, existing control measures, the effectiveness of the control measures, and 'gut feelings' about the relative importance of the hazards, the team came to consensus on the prioritization of risks. Because the water supply system was recognized as 'risky' a comprehensive pre-control risk assessment was not done. Postponing assessment of risk until after consideration of existing control measures and their effectiveness reduced the time spent on evaluating the risk of hazards for which good control measures were in place and allowed for the inclusion of additional variables, such as the feasibility of preventing the hazard. For example, theft of chlorine tanks resulting in no chlorination, which had occurred in the past, was ranked low in the semi-quantitative approach, while contamination due to residential and industrial activities along the 13-mile intake canal was ranked high. The qualitative approach considered the ease with which the problem of stolen tanks could be corrected (lock boxes), and thus ranked it higher than addressing the multitude of threats that existed along the expanse of the intake canal. This showed that prioritization of risks can be easily influenced by how readily they are mitigated. In this example, although locking the boxes was

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obviously an improvement, the much higher risk of the quality of the source water should have still remained a top priority.

Field Experience 4.2 – considering the effectiveness of control measures

In preparing the system description, the WSP team found that there were standards and protocols that were not always carried out as indicated. For example, chlorination was described as part of the standard operations for the water treatment plant; but at the time of the WSP development, a chlorinator had not yet been connected. Routine water quality monitoring was carried out as indicated, but there was no system of review or communication of results. Thus, even though control measures were indicated, they were shown to be minimally or not effective. The evaluation of current system operations as described in LAC Field Experience 2.2 proved helpful for understanding the effectiveness of the control measures and instances in which revising existing control measures or establishing new control measures were needed.

Case study 3: United Kingdom (England and Wales)

Field Experience 4.1 – assessing risk before and after controls

An area that the regulator has encouraged, which had been included in some but not all methodology, is the assessment of risks before and after controls. The reason for this is that it is important to know how many risks can affect the water supply system if no controls were in place. This in turn leads to the clear consideration of the effectiveness of each control under normal and abnormal conditions. Having to prove the reasons for the reduction in risk pre- and post-control is a powerful tool for confirming the validity of risk assessment criteria, scoring and effectiveness of controls.

Field Experience 4.2 – validating control measures

For a mature industry, identification and validation of controls was sometimes seen as a less important step because companies considered that they had so much data and information that the effectiveness of controls was self evident. However the WSP approach does encourage re-evaluation of the use of such data.

Validation of catchment initiatives such as animal management and pesticides and fertilizer usage is a challenge because it is not always a clear measurement and they require the involvement of catchment stakeholders as well as the water company.

The effectiveness of the WSP approach is now seen to be in the interest of the industry and regulator. For example, the WSP approach was effective in validating UV disinfection units, which have recently been allowed for use as a treatment measure for *Cryptosporidium*.

There was confusion about the meaning of the terms validation and verification and these sometimes appeared interchangeable although understanding has improved as the WSP approach has become more widely implemented.

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Module 5

Develop, implement and maintain an improvement/upgrade plan

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Introduction

If the previous step identifies significant risks to the safety of water and demonstrates that existing controls are not effective or are absent, then an improvement/upgrade plan should be drawn up. Each identified improvement needs an 'owner' to take responsibility for implementation and a target implementation date. The assessment may not automatically result in the need for new capital investment. In some instances, all that may be needed is to review, document and formalize the practices that are not working and address any areas where improvements are needed. In other cases, new or improved controls or a major infrastructure change may be needed.

Improvement/upgrade plans can include short-, medium- or long-term programmes. Significant resources may be needed and therefore a detailed analysis and careful prioritization should be made in accordance with the system assessment. It may be that improvements need to be prioritized and phased in.

Implementation of improvement/upgrade plans should be monitored to confi rm improvements have been made and are effective and that the WSP has been updated accordingly. It should be taken into consideration that the introduction of new controls could introduce new risks to the system.

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Key actions

Draw up an improvement/upgrade plan

Identify in the improvement/upgrade plan short-, medium- or long-term mitigation or controls for each significant risk, recognizing that other less significant risks can also be controlled by these measures.

Implement the improvement/upgrade plan

Update the WSP, including recalculating risks taking into account the new control(s).

Typical challenges

- Ensuring the WSP is kept up to date;
- Securing financial resources;
- Lack of human resources, including technical expertise, to plan and implement needed upgrades;
- Ensuring new risks are not introduced by the improvement programme.

Outputs

1. Development of a prioritized improvement/upgrade plan for each significant uncontrolled risk.
2. Implementation of the improvement plan according to the planned schedule of short-, medium- or long-term activities.
3. Monitoring the implementation of the improvement/upgrade plan.

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Example/tool 5.1: A checklist of issues to be considered when developing an improvement/upgrade plan

- ☑ Options for mitigating risks
- ☑ Responsibility for improvement programme (process owner)
- ☑ Financing
- ☑ Capital works
- ☑ Training
- ☑ Enhanced operational procedures
- ☑ Community consultation programmes
- ☑ Research and development
- ☑ Developing incident protocols
- ☑ Communication and reporting

Example/tool 5.2: Drinking-water quality improvement/upgrade plan actions and accountabilities

Action	Arising from	Identified specific improvement plan	Accountabilities	Due	Status
Implement measures to control *Cryptosporidium*-related risks.	*Cryptosporidium* has been identified as an uncontrolled risk. Cattle defecation in vicinity of unfenced wellhead is a potential source of pathogen ingress, including *Cryptosporidium*, in wet weather. Currently there is no confidence that these risks are adequately controlled.	Install and validate ultraviolet light treatment. Validation includes comparing theoretical treatment performance against that required to inactivate *Cryptosporidium* infectivity.	e.g. Engineer	e.g. Date the action should be completed by.	e.g. Ongoing, not started, etc.
Implement measures to control risks arising from agricultural pesticides introduced into the water supply.	Risk assessment process has identified a cocktail of pesticides from agricultural uses. Currently there is no confidence that these risks are adequately controlled.	Install ozone and granular activated carbon filtration within the water treatment plant. These controls should be validated through intensive monitoring and shown to continue to work through operational monitoring.	e.g. Engineer	e.g. Date the action should be completed by.	e.g. Ongoing, not started, etc.
Review the need for, and if required, the options for, reducing the risks from viral and protozoan water quality contamination from sewage systems to reduce risks to acceptable levels.	Risk assessment process for pathogens risks arising from sewage systems. Currently there is no confidence that these risks are adequately maintained to acceptable levels by the control measures in place.	Develop additional sewage disinfection and downstream water treatment, including avoidance strategies as warranted.	e.g. Water quality officer	e.g. Date the action should be completed by.	e.g. Ongoing, not started, etc.
Etc. ↴					

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Case study 1: Australia

Field Experience 5.1 – corrective actions to address inadequate chlorine dosing

In general, corrective actions in the event of critical limits being exceeded involved shutting down supplies until problems were fixed. Most systems had enough treated water in storage or alternative supply options, that it was possible to do this. However, some systems that would have difficulty shutting off supply had installed multiple duty and standby systems with automatic changeover to reduce the risk of untreated water being supplied. In general, treatment failure followed by an inability to provide an alternative supply or rely on stored treated water resulted in the issue of precautionary boil water advisories.

Field Experience 5.2 – revising the capital improvement plan

Most WSPs identified the need for capital works to improve the reliability of systems and address vulnerabilities. Generally the Australian water supplies were able, under normal circumstances, to provide safe water, so most capital upgrades were aimed at reducing risks of process failures and improving overall system reliability. One of the major benefits of a WSP was the identified capital improvements, using the evidence obtained through the WSP as the driver, had a very high probability of being funded and given a priority. Prior to the use of WSPs there was often less clarity as to the real priority needs of the water quality investments. Furthermore, the WSP provided a justification for capital improvements to improve theoretical reliability and reduce risk. In the past there was more reliance on reacting only to the adverse events that actually occurred. Therefore, the WSP has helped to drive more proactive, preventive water quality planning.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 5.1 – corrective actions to address inadequate chlorine dosing

Several of the hazards identified through the household survey and the monitoring records led to a lack of chlorine residual in the distribution system. The risk associated with this was high and therefore corrective actions to optimize chlorine dosing were ranked among the highest priorities. The insufficient chlorine was associated with a lack of operator knowledge about appropriate dosing, a lack of routine monitoring of chlorine in the distribution system, a lack of communication of monitoring results to operators, and the perception that one source was clean and therefore required only minimal treatment. Corrective actions were proposed to address each of these contributing factors: a training programme for plant operators was developed (see LAC Field Experience 9.1); a schedule was developed and sites were selected for routine monitoring along the distribution system (LAC Field Experience 7.1); a protocol for communicating monitoring results to plant operators was developed (LAC Field Experience 7.1); and water quality test results were presented to address misperceptions about the safety of water sources (LAC Field Experience 2.2). Corrective actions were highly detailed, and included responsible parties (process owners), specific tasks and target completion dates.

Field Experience 5.2 – developing a consumer education programme

The household survey revealed that a perception existed in the community that springs and a creek supplied water of high quality and could therefore be consumed directly, while water quality testing found the sources to be microbially contaminated. It also showed a lack of knowledge about effective point-of-use treatment and household storage methods to prevent

contamination in the home. Corrective actions to address these hazards focused on designing and carrying out a consumer education programme. Appropriate medias for communicating different messages, including radio and television public service announcements and posters, were developed jointly by the water utility and the Ministry of Health. Again, detailed action plans identified responsible parties, specific tasks and target completion dates.

Field Experience 5.3 – revising the capital improvement plan

Some capital improvement needs were identified through the system and hazard review. At the time of the WSP development, a plan for capital improvements, developed by the utility and sponsored by an outside donor, had already been proposed. The WSP team found that the improvements proposed by the plan did not necessarily reflect the priorities identified through the WSP process and were not based on a thorough needs assessment and risk analysis; thus, the plan had some important deficiencies. Identifying priority needs through the WSP allowed the team to provide input to the plan, to which the donor was responsive due to the team's ability to justify the proposed changes. The existing capital improvement plan was modified to address the priorities identified by the team, increasing its potential impact by making it an informed and recipient-driven process.

Case study 3: United Kingdom (England and Wales)

Field Experience 5.1 – targeting investment programmes

The financial regulatory regime in place requires five-year investment programmes, with potential support from the regulator provided that investments were identified through WSP methodology. Implementation of WSPs provides the opportunity for a comprehensive risk based prioritized investment programme. Some companies were reluctant at first to share the outputs of risk analysis with the regulator even on an informal basis but this tendency has reduced with the need for the water quality regulator to approve improvement programmes to be put forward for funding. Risk assessment also highlights the need for good maintenance of assets, an area that has previously been difficult to justify for proper funding. There were a few examples of companies already being aware of investment requirements and trying to work these backwards into the risk assessment process. External audit of the improvement programmes should be able to identify flawed risk assessments.

Field Experience 5.2 – prioritizing catchment initiatives

Over the years water treatment has become more sophisticated and complex to deal with contaminated water sources. With little control over many catchments, water companies had little alternative. However, the WSP approach is now starting to give more priority to catchment initiatives with collaboration between water companies and catchment stakeholders. Such initiatives also require a more flexible approach from regulators because benefits are likely to take longer to achieve than through installing water treatment but they are likely to be more sustainable and have a lower carbon footprint.

Many companies had done a lot of liaison work in this area and some companies had very good links and communications with the environmental regulator which had a lot of information on catchments; in other cases these links were weaker but as a result of the WSP approach, were improving. Many companies had also undertaken initiatives with other catchment stakeholders, particularly with agriculture in respect to pesticides and fertilizer usage and animal grazing and breeding. In some cases these

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initiatives had lost impetus and the WSP approach was a way of re-invigorating them. For example, re-organization of the rail network had meant that some previous understandings on pesticides usage near water sources needed reinforcing. The WSP approach is helping involvement from other catchment stakeholders such as industry, forestry, road, rail and airport authorities but this is an area that water companies have found often requires a lot of work to raise stakeholder awareness and interest.

Module 6

Define monitoring of the control measures

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Introduction

Operational monitoring includes defi ning and validating the monitoring of control measures and establishing procedures to demonstrate that the controls continue to work. These actions should be documented in the management procedures.

Defining the monitoring of the control measures also requires inclusion of the corrective actions necessary when operational targets are not met.

Key actions

The number and type of control measures will vary for each system and will be determined by the type and frequency of hazards and hazardous events associated with the system. Monitoring of control points is essential for supporting risk management by demonstrating that the control measure is effective and that, if a deviation is detected, actions can be taken in a timely manner to prevent water quality targets from being compromised.

Effective monitoring relies on establishing:

- What will be monitored
- How it will be monitored
- The timing or frequency of monitoring
- Where it will be monitored
- Who will do the monitoring
- Who will do the analysis
- Who receives the results for action?

Examples of operational monitoring parameters

Measurable: Chlorine residuals; pH; turbidity.

Observable: Integrity of fences or vermin-proofing screens; stock density on farms in catchments.

Routine monitoring is usually based on simple observations and tests, such as turbidity or structural integrity, rather than complex microbial or chemical tests. For some control measures, it may be necessary to define 'critical limits' outside of which confidence in water safety would diminish. Deviations from these critical limits usually require urgent action and may involve immediate notifi cation of the local health authority and/or the application of a contingency plan for an alternative supply of water. Monitoring and corrective actions form the control loop to ensure that unsafe drinking-water is not consumed. Corrective actions should be specifi c and predetermined where possible to enable their rapid

implementation. Monitoring data provide important feedback on how the water supply system is working and should be frequently assessed.

Regularly assessed monitoring records are a necessary element of the WSP as they can be reviewed, through external and internal audit, to identify whether the controls are adequate and also to demonstrate adherence of the water system to the water quality targets.

Typical challenges

- Lack of sufficient human resources to carry out monitoring and analysis;
- Financial implications of increased monitoring, particularly on-line monitoring;
- Inadequate or absent evaluation of data;
- Changing the attitude of staff members who are used to monitoring in a certain way;
- Ensuring that resources are available to the operations department to carry out corrective actions.

Outputs

1. An assessment of the performance of control measures at appropriate time intervals.
2. Establishment of corrective actions for deviations that may occur.

Example/tool 6.1: Checklist of factors to be considered when establishing a monitoring programme for the control measures

- ☑ Who will do the monitoring?
- ☑ How frequently will the monitoring be done?
- ☑ Who will analyse the samples?
- ☑ Who will interpret the results?
- ☑ Can the results be easily interpreted at the time of monitoring or observation?
- ☑ Can corrective actions be implemented in response to the detected deviations?
- ☑ Has the list of hazardous events and hazards been checked against monitoring or other appropriate criteria to ensure that all significant risks can be controlled?

* Note: often verification monitoring (see Module 7) will be the compliance monitoring required by regulatory or government bodies in which case parameters and monitoring frequencies will be specified as part of compliance.

Example/tool 6.2: Corrective actions

A corrective action(s) should be identified for each control that will prevent contaminated water being supplied if monitoring shows that the critical limit has been exceeded. Such events may be: non-compliance with operational monitoring criteria, inadequate performance of a sewage treatment plant discharging to source water, extreme rainfall in a catchment, or spillage of a hazardous substance. Examples of corrective actions include the use of alarms and auto-shutdown mechanisms, or switching to an alternative water source during a period of non-compliance (allowing the operator time to bring the supply back into compliance). Risks associated with use of the alternative source should be identified and addressed within the overall WSP framework.

Example/tool 6.3: Checklist of issues to consider for devising corrective actions

- ☑ Have corrective actions been documented properly, including assigning responsibilities for carrying out the actions?
- ☑ Are people correctly trained and appropriately authorised to carry out corrective actions?
- ☑ How effective are the corrective actions?
- ☑ Is there a review process in place for analysing actions to prevent recurrence of the need for a corrective action?

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Example/tool 6.4: Long- and short-term monitoring requirements and corrective actions

Process step/Control measure	Critical limit	What	Where	When	How	Who	Corrective action
Source: Control of development in catchment (example of long-term monitoring)	<1 septic tank per 40 ha and none within 30 m of watercourse	Council planning approvals	Council offices Site inspection	Annually	On site at council	Catchment/ Watershed Liaison Officer	Seek removal of septic system through planning tribunal
	Fencing out of all juvenile cattle from riparian or unfenced paddocks	Farm management practice audits	Dept of Agriculture Site Inspection	Annually	On site at Dept of Agriculture	Catchment/ Watershed Liaison Officer	Meet with landholder in breach and discuss incentive programme
Treatment: Chlorination at water treatment plant (example of short-term monitoring)	Chlorine concentration leaving plant must be >0.5 and <1.5 mg/l	Disinfectant residual	At entry point to distribution system	On-line	Chlorine analyser	Water Quality Officer	Activate chlorine non-compliance protocol
Etc. ↴							

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Case study 1: Australia

Field Experience 6.1 – identifying and monitoring critical control measures

Most control measures identified as 'critical' were assigned as 'critical control points' and were monitored against 'critical limit' criteria. In most cases, critical limits were monitored on-line with automated control in response to adverse results, and/or telemetry alarms being sent to 24-hour call centres and duty operators. In most cases such systems were in place prior to the use of WSPs, but WSPs provided a forum to review and upgrade these systems. Typically, the critical limits set related to filtered water turbidity, chlorine residual, post primary disinfection and maintenance of water pressure in distribution as measured indirectly by tank levels and pump pressures. In addition, many utilities formalized scheduled monitoring and inspection procedures for source waters and for assets such as water tanks. Procedures for sanitary working practices when repairing and installing water mains were often captured as key control measures and were sometimes classified as critical control points. Backflow prevention systems were usually given a renewed priority with WSPs and most utilities with WSPs had active programmes to enforce backflow prevention with various standards depending on the risk posed by the site being served with water.

Field Experience 6.2 – operational monitoring of treatment processes

Operational monitoring of treatment processes was usually fully instrumented using on-line calibrated instruments linked to SCADA systems (a computer system used to monitor and control a process). Alarm levels were typically set to provide an early warning as well as an emergency trigger. Alarms usually called system operators to attend the plant and often started automated processes to stop supplying water into the treated water storage. In practice, the automated monitoring systems required a lot of work due to problems with selecting reliable instruments and reliable control systems. However, most utilities persevered until the systems were sufficiently reliable and are continuing to improve these systems into the future as their WSPs mature. Most systems were designed to have multiple triggers to avoid ever supplying untreated water. For instance, systems often automatically shut down or switched to standby systems, and usually there were early warning alarms that would provide time for problems to be fixed before they affected the customers.

Field Experience 6.3 – operational monitoring along the distribution network

The process of maintaining continuous and quite high pressure to the whole distribution system at all times is well-established in Australian urban centres. Although taken for granted, the maintenance of positive pressure provides a highly effective water quality control which is monitored through water tank level sensors and pressure transducers at key points in the distribution network. Most systems have exceptionally reliable pressurization throughout the network with telemetered, SCADA linked alarms to alert system operators if pressures at any pump station or water levels at any service reservoir start to drop below critical levels. If areas of low pressure are identified through customer notifications, engineering or operational solutions are implemented as low or no pressure at customer supply points is not tolerated. In some isolated areas drought-related water restrictions led to unprecedented peak flows and low pressure events in elevated areas when all properties watered their gardens at once during restricted watering hours. Alternate odd and even property number watering arrangements have been used to alleviate this effect. Legally, the maintenance of sufficient pressure at all times

is a service standard requirement of all large urban Australian water suppliers. Water tanks and pump stations are typically monitored regularly and are usually fully enclosed, roofed, secured and vermin-proofed. Disinfectant residual monitoring within the network is increasingly being automated but is not as reliably maintained and managed as pressure. Most distribution systems have significant proportions of the system that are routinely without an effective disinfectant residual. However, the reliable pressurization means that in most cases this is not considered a health issue and the situation is widely tolerated. Some systems with WSPs do not even provide a disinfectant residual and use UV-only disinfection. In very warm climates with long pipelines, disinfectant residuals are routinely monitored and maintained to prevent bacterial growth in the distribution systems. Testable backflow prevention devices that protect water supplies from high and medium hazard connections are usually tested annually and the utility usually keeps records of these tests and actively follows up failure to report successful test results.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 6.1 – identifying and monitoring critical control measures

For the key control measures that addressed the hazards identified in Module 3, a monitoring plan was established that indicated an acceptable operational range for each parameter, designated appropriate monitoring locations, established a schedule for frequency of monitoring, and assigned responsible parties. Corrective actions to be taken in the event that monitoring reveals a parameter to be outside of the acceptable range were also established. The monitoring of critical control measures (operational monitoring) facilitated the identification by plant operators and managers of probable causes of non-compliance that may be identified through compliance monitoring.

Field Experience 6.2 – operational monitoring of treatment processes

The WSP team identified coagulation/flocculation/sedimentation, filtration and chlorination as critical control measures to be monitored. To gauge coagulation efficacy, regular measurement of turbidity at the outlet of the sedimentation basin was established. To monitor the efficacy of filtration, turbidity was again measured after filtration; and to gauge chlorine dosing efficacy, chlorine residual was measured at the point of entry to the distribution system. Monitoring at the plant was done by the utility plant operators and results were shared monthly with the utility managers, or immediately if found to be outside of established parameters. Prior to the WSP, these critical control measures were rarely measured or recorded. Because records were not reviewed and plant operators did not receive feedback, they saw little value in maintaining and submitting monitoring records. A schedule for distributing reports of utility operations from each of the treatment plants was established. Providing feedback increased plant operator accountability and adherence to protocol and informed them of any changes or concerns related to water quality.

Field Experience 6.3 – operational monitoring along the distribution network

Insufficient water pressure within the distribution system caused by leaky pipes and unauthorized connections, led to inconsistent water service and the introduction of microbial and chemical contamination. Maintaining water pressure was therefore identified as a critical control measure. Pressure gauges were installed at strategic points along the distribution network, an

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operator monitoring and recording plan was established, and monitoring records were reviewed monthly by utility managers. This system of increased operator awareness and supervisory oversight improved accountability and adherence to protocol and ensured that operators were better informed of pressure conditions that required immediate corrective action.

Case study 3: United Kingdom (England and Wales)

Field Experience 6.1 – developing a clear operational monitoring strategy

Operational monitoring was a normal and extensive part of the water companies' procedures and had been generally included and reviewed as part of the WSP implementation. A benefit of WSPs is that the methodology requires a clear operational monitoring strategy with defined responsibilities to consider its relevance to the safe production and distribution of drinking-water and for how it is programmed and assessed. This overcomes the tendency to carry out irrelevant tests.

Module 7

Verify the effectiveness of the WSP

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Introduction

Having a formal process for verification and auditing of the WSP ensures that it is working properly. Verification involves three activities which are undertaken together to provide evidence that the WSP is working effectively. These are:

- Compliance monitoring;
- Internal and external auditing of operational activities;
- Consumer satisfaction.

Verifi cation should provide the evidence that the overall system design and operation is capable of consistently delivering water of the specified quality to meet the health-based targets. If it does not, the upgrade/improvement plan should be revised and implemented.

Key actions

Compliance monitoring

All the control measures should have a clearly defi ned monitoring regime validating effectiveness and monitoring performance against set limits. The water supply organization should expect to fi nd results from verifi cation monitoring that are consistent with the water quality targets. Corrective action plans need to be developed to respond to, and understand the reasons for, any unexpected results. Verification monitoring frequencies will depend on the level of confidence required by the water supply organization and its regulatory authorities. The monitoring regime should include a review at intervals and at times of planned or unplanned changes in the supply system.

Internal and external auditing of operational activities

Rigorous audits help to maintain the practical implementation of a WSP, ensuring that water quality and risks are controlled. Audits may involve internal review and external review by regulatory authorities or by qualified independent auditors. Auditing can have both an assessment and a compliance-checking role. The frequency of audits for verifi cation will depend on the level of confi dence required by the water supply organization and its regulatory authorities. Audits should be undertaken regularly.

Consumer satisfaction

Verification includes checking that consumers are satisfied with the water supplied. If they are not, there is a risk that they will use less safe alternatives.

Typical challenges

- Lack of capable external auditors for WSPs;
- Lack of qualified laboratories to process and analyse samples;
- Lack of human and financial resources;
- Lack of knowledge of consumer satisfaction or complaints.

Outputs

1. Confirmation that the WSP itself is sound and appropriate.
2. Evidence that the WSP is being implemented in practice as intended, and working effectively.
3. Confirmation that water quality meets defined targets.

Example/tool 7.1: Parameters that might be included in routine verification monitoring programmes

For microbial water quality verification, indicator organisms are generally monitored. The most widely used verification system is to use the faecal indicator bacteria *E. coli* or thermotolerant coliforms at representative points in the water supply system. Other indicators may be more appropriate to verify that water is free from viral or protozoan faecal pathogens. Use of other tools, such as heterotropic plate counts, or *Clostridium perfringens* may be used for operational and investigative monitoring in order to better understand the water supply system.

Verification for chemical parameters is carried out by their direct measurement, rather than through the use of an indicator. Most chemical hazards are unlikely to occur at acutely hazardous concentrations and verification frequencies (often quarterly or sometimes biennially) might be less than those used for microorganisms.

Quantitative and qualitative taste and odour may be monitored to ensure the condition of the distribution network and consumer installations.

Example/tool 7.2: Checklist of factors to be considered when establishing a routine verification monitoring programme. (A utility-led verification programme can provide an additional level of confidence, supplementing regulations which specify monitoring parameters and frequencies.)

- ☑ Where appropriate, draw up a verification monitoring programme in accordance with regulatory requirements;
- ☑ Identify appropriate personnel to perform monitoring functions;
- ☑ Establish a system of communication between monitoring staff;
- ☑ Identify appropriate analysts;
- ☑ Ensure appropriate monitoring points are chosen;
- ☑ Ensure monitoring frequency is appropriate;
- ☑ Ensure results are interpreted and unusual or failing results are investigated;
- ☑ Establish a system to ensure the routine reporting of results to the appropriate regulator.

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Example/tool 7.3: Auditing the WSP itself and the implementation of the WSP

In addition to analysis of the water quality, verification should also include an audit of the WSP and of the operational practice to show good practice and compliance. Auditors will identify opportunities for improvement such as areas where procedures are not being followed properly, resources are insufficient, planned improvements are impractical, or where training or motivational support is required for staff.

When conducting audits, it is essential that the auditor has a detailed knowledge of the delivery of drinking-water and that procedures, not just records, are witnessed in person. Records may not always be factually correct and in some cases, equipment that has been shown to be working through the records may not be working in practice and can lead to unsafe water and waterborne disease outbreak.

Example/tool 7.4: Checklist of factors to consider to ensure all appropriate information is obtained during an audit

- ☑ All feasible hazards/events are taken into account;
- ☑ Appropriate control measures have been identified for each event;
- ☑ Appropriate monitoring procedures have been established;
- ☑ Critical limits for each control measure are set;
- ☑ Corrective actions have been identified;
- ☑ A system of verification has been established.

Example/tool 7.5: Operational monitoring and verification monitoring plan (from Jinga, Uganda)

Unit process	Operational monitoring (see Module 6)			Verification monitoring		
	What	When	Who	What	When	Who
Treatment works	On-line measurement – pH – Chlorine	Daily	Water treatment operators / Analyst	*E. coli*	Weekly	Analyst
				Enterococci	Weekly	
				Record audit	Monthly	
	Jar testing records	Weekly				
	Turbidity	Daily				
	Dosing records	Monthly				
Distribution system	pH	Weekly		*E. coli*	Monthly	
	Turbidity	Weekly				
	Chlorine	Weekly		Turbidity	Monthly	
	Sanitary inspection	Weekly		Enterococci	Monthly	
Etc. ↴						

Case study 1: Australia

Field Experience 7.1 – compliance monitoring

Water utilities had typically made no significant changes to their verification monitoring as part of the introduction of WSPs. In general, this area was a strong focus of regulation in water supply for many decades prior to the advent of WSPs. Both monitoring of customer satisfaction and water quality testing were already well established processes, with data being publicly reported. WSPs have changed the focus to prevention and improved operational monitoring, but have not significantly affected verification monitoring. The major change has been to reposition customer complaint monitoring and water quality testing as 'verification monitoring'. Another effect of WSPs has been to recast verification testing as after-the-fact confirmation whereas in the past verification activities were often the focus of water quality management.

Field Experience 7.2 – creating systems for internal and external auditing

One of the major changes introduced with WSPs has been the auditing of water quality management. Internal, and increasingly external, auditing is becoming commonplace with most Australian water utilities now being audited at roughly annual intervals by external auditors. Within the past year a new drinking-water quality management auditing system had been set up, together with a growing pool of specialist auditors. There has been some opposition to external auditing from many utilities but regulators are increasingly requiring it as part of their oversight roles.

Field Experience 7.3 – selecting appropriate regulatory standards

Each jurisdiction (state and territory) has introduced or is developing a requirement for its major public water utilities to have WSPs. Victoria was the first through its Safe Drinking Water Act 2003 and other states have introduced or are introducing the same requirements through acts, regulations or licences. It is likely that by 2015 all public urban water utilities in all states and territories of Australia will have implemented WSPs that are subject to regulatory audit. The first regulatory audits took place in Victoria in 2008, allowing some time between the Act and the point at which compliance was required. Other states and territories are following this lead.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 7.1 – developing a compliance monitoring plan

When the utility's water quality monitoring records were collected and reviewed to assess the current state of the piped water supply (see LAC Field Experience 2.2), it became clear that the utility's protocol for testing, recording and reporting finished water quality was not consistently followed by operators. Lapses in data collection were common and the body of data that did exist had never been systematically compiled and reviewed to ensure compliance with water quality standards and to inform operational decisions. Additionally, the majority of samples had been processed at a remote laboratory and the results were never reported back to operators, denying them important feedback on plant operations. These deviations from protocol were attributed to the limited availability of personnel to perform the testing and analyse results; the cost of transporting samples to the remote laboratory; a shortage of necessary testing reagents; and a lack of accountability (both internal and external). The WSP team agreed that addressing these barriers should be given top priority as knowledge of the quality of water being produced is fundamental to safe water provision. The compliance monitoring plan was revised to include detailed guidance on data collection, recording, compilation and analysis, and operator feedback reporting. The revised monitoring plan also describes internal actions to be taken when results indicate non-compliance with water quality standards.

Field Experience 7.2 – creating systems for internal and external auditing

When the WSP process began, there was no formal system in place for internal and external auditing of water quality or utility operations and management practices. The result was a lack of accountability within the utility and routine disregard for established procedures. To address these issues, the utility developed a plan to submit monthly water quality reports (created as part of the compliance monitoring plan described in LAC Field Experience 7.1) to senior management within the utility and to the Ministry of Health. This internal and external reporting of water quality records is expected to encourage consistent compliance monitoring and to facilitate regulatory oversight. In order to ensure that the other key procedures outlined in the WSP are also consistently followed, the utility worked with the Ministry of Health to develop an additional, more comprehensive internal and external WSP auditing plan. The more comprehensive plan involves semi-annual internal reviews with senior utility management and annual external reviews with the Ministry of Health. While the entire WSP is subject to review during these audits, the key focus areas are the standard operating procedures (including operational monitoring and compliance monitoring plans), operator training programmes, and action plans to address high-priority hazards. In addition to improving adherence to established plans and procedures, these audits are expected to improve communication both within the utility and between the utility and the regulatory body.

Case study 3: United Kingdom (England and Wales)

Field Experience 7.1 – verification through compliance and audits

Generally, verification of the effectiveness of the WSP approach is through compliance with regulatory requirements for drinking-water quality, treatment and use of chemicals and materials.

The regulator of drinking-water quality will be the WSP external auditor. It does not anticipate normally auditing a company's WSPs in their entirety but particular elements of the WSP will feature in its other audits including compliance assessment, sample audit trails, incident investigations, site inspections, consumer complaints and stakeholder liaison.

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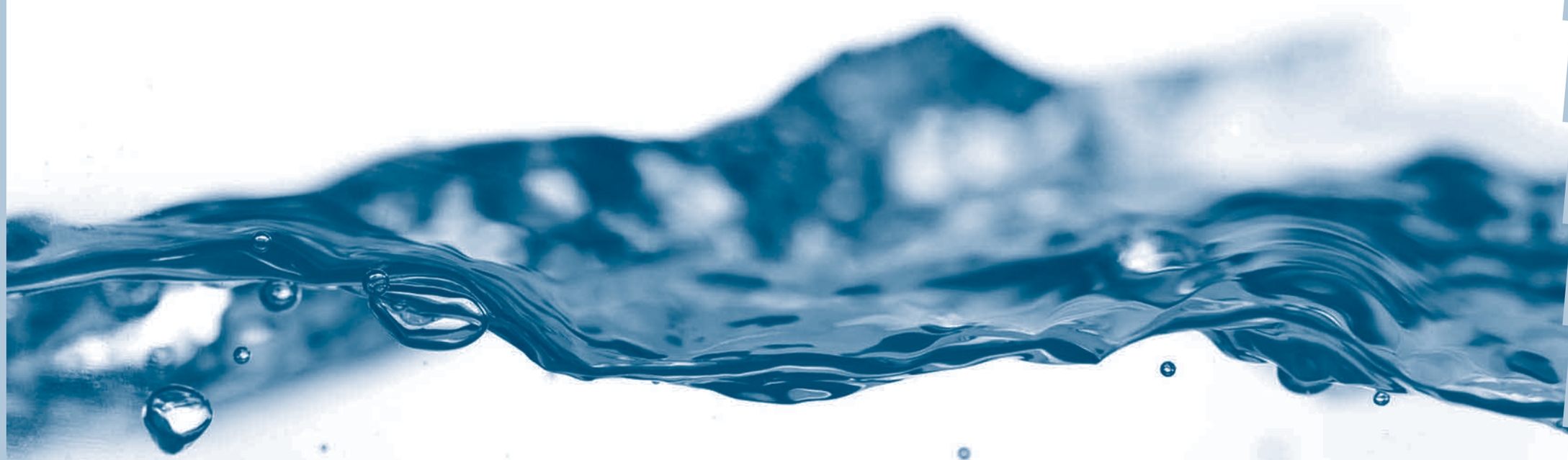

Module 8

Prepare management procedures

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Introduction

Clear management procedures documenting actions to be taken when the system is operating under normal conditions (Standard Operating Procedures or SOPs) and when the system is operating in 'incident' situations (corrective actions) are an integral part of the WSP. The procedures should be written by experienced staff and should be updated as necessary, particularly in light of implementation of the improvement/upgrade plan and reviews of incidents, emergencies and near misses. It is preferable to interview staff and ensure their activities are captured in the documentation. This also helps to foster ownership and eventual implementation of the procedures.

Key actions

Documentation of all aspects of the WSP is essential. Management procedures are the actions to be taken during normal operational conditions, and detail the steps to follow in specific 'incident' situations where a loss of control of the system may occur. Management staff have a responsibility to ensure procedures are kept up to date and in place to keep operators and management staff connected and involved, to make it easy for people to 'do the right thing', to provide adequate resources and to ensure that people are willing to come forward instead of withholding information for fear of reprisals. An effi cient, regular review and updating cycle is also important.

If monitoring detects that a process is operating outside of the specifi cations of the critical or operational limits, there is a need to act to restore the operation by correcting the deviation. An important part of the WSP is the development of corrective actions which identify the specific operational response required following deviations from the set limits.

Unforeseen events/incidents or deviations may occur for which there are no corrective actions in place. In this case, a generic emergency plan should be followed. This would have a protocol for situation assessment and identification of situations that require activation of the emergency response plan. It is also important that near misses are assessed as they could be an indicator of a likely future emergency.

Following an emergency, an investigation should be undertaken involving all staff to discuss performance, assess if current procedures are adequate, and address any issues or concerns. Appropriate documentation and reporting of the emergency should also be established. Review of the cause of the emergency or near miss and the response to it may indicate that amendments to existing protocols, risk assessments and the WSP are necessary (see Module 11).

Typical challenges

- Keeping the procedures up to date;
- Ensuring that staff are aware of changes;
- Obtaining information on near misses.

Example/tool 8.1 gives a general outline that can be used to start the development of a list of SOPs that would be typical for a water utility operation. It is impossible to list all the SOPs a facility would require due to the varying nature of the processes at each facility. The SOPs can be prioritized and once documented, additional SOPs can be developed as needed and added to the documentation. The SOP should be developed in a way that allows for revisions as required.

Outputs

Management procedures for normal and incident/emergency conditions which address:

- Response actions;
- Operational monitoring;
- Responsibilities of the utility and other stakeholders;
- Communication protocols and strategies, including notifi cation procedures and staff contact details;
- Responsibilities for coordinating measures to be taken in an emergency;
- A communication plan to alert and inform users of the supply and other stakeholders (e.g. emergency services);
- A programme to review and revise documentation as required;
- Plans for providing and distributing emergency supplies of water.

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Example/tool 8.1: Typical Standard Operating Procedures for a water utility

Category	Sub-category	Standard Operating Procedure
Facility operations overview	General tasks/information	Daily rounds Site security Record keeping Reporting procedures Cross contamination prevention for operators
	Sampling	Sampling procedure
	Emergency response	Power failure
Intake and pre-treatment	Raw water	Valve operation Screening
	Flow measurement	Meter calibration
	Pump operation	Switching duty pump operation Increasing/decreasing pumping operation
Dosing procedure		
Disinfection procedure		
Etc.		

If monitoring detects that there is a deviation from an operational or critical limit, corrective actions need to be applied.

Example/tool 8.2: Checklist of management procedures (or corrective actions) to deal with incidents

- ☑ Accountabilities and contact details for key personnel and other stakeholders;
- ☑ Clear description of the actions required in the event of a deviation;
- ☑ Location and identity of the SOPs and required equipment;
- ☑ Location of back-up equipment;
- ☑ Relevant logistical and technical information.

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Quality control procedures should also be recorded for as many aspects of the WSP as possible. All measurements of control measures, for example, should be subject to appropriate quality control procedures, such as internal and external analytical control within laboratories. (Note that this could also be dealt with as a 'supporting programme'.)

Example/tool 8.3: Checklist of characteristics and systems relating to people management which will facilitate ongoing success of the WSP

- ☑ Choosing meaningful parameters on which to report;
- ☑ Having a well-defined and efficient failure reporting system;
- ☑ Including higher-level management in reporting so they are involved in events;
- ☑ Designing 'respected' audits that target likely areas of complacency that lead to adverse consequences;
- ☑ Observing the 'no blame' model where failure is shared by system participants;
- ☑ Having a widely accessible mechanism for presenting improvement opportunities, risk analysis and interpretation and for challenging existing practices;
- ☑ Ensure that all procedures are signed off at senior level. This is an important part of the continuous improvement mechanism.

Example/tool 8.4: Emergency management procedures

During an emergency it may be necessary either to modify the treatment of existing sources or temporarily use an alternative water source. It may be necessary to increase disinfection at the source or to additionally disinfect (e.g. rechlorinate) during distribution. Procedures for such an emergency situation should be documented.

Example/tool 8.5: Checklist of key areas to be addressed in emergency management procedures

- ☑ Response actions, including increased monitoring;
- ☑ Responsibilities and authorities internal and external to the organization;
- ☑ Plans for emergency water supplies;
- ☑ Communication protocols and strategies, including notification procedures (internal, regulatory body, media and public);
- ☑ Mechanisms for increased public health surveillance;
- ☑ Emergency procedure should be practiced regularly.

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Case study 1: Australia

Field Experience 8.1 – developing standard operating procedures (SOPs)

In general, the Australian water supply industry was fairly informal with limited formal procedures and documentation. Therefore, most WSPs include some associated additional documentation. The lack of formality partly reflected the long careers and extensive experience of most water supply operators, making written procedures less important than the body of experience and hands-on training. In general, the procedures that have been developed for the Australian WSPs are concise statements of what is required to be achieved rather than detailed procedures for how to achieve those objectives. Generally, there is a reliance on training and operator experience and discretion rather than on following documented procedures. However, where large parts of utility operations are outsourced to contractors, most authorities have developed detailed procedures against which contractor activity can be measured and assessed.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 8.1 – developing standard operating procedures (SOPs)

The WSP team agreed that SOPs would be a critical focus area during the development of the WSP. The treatment plant operators and distribution system maintenance personnel had no reference document to inform and guide day-to-day operations. Operational guidance took the form of verbal instruction from supervisors and was often incomplete and poorly understood. The lack of thorough, clearly defined operating procedures was recognized as a major barrier to safe water provision and was also believed to adversely impact engagement and morale among utility personnel. Considerable time and energy was therefore invested in the development of SOPs. The utility's system-specific SOPs were created by adapting SOPs for another system in the region to the utility's own infrastructure, institutional framework, priorities and constraints. The SOPs contain information on key physical, chemical and microbial contaminants of concern and the role of each treatment process in their removal or inactivation. The SOPs also contain guidance on the optimization of treatment plant operations, such as determining the most effective pH and aluminum sulfate dose for coagulation; recognizing filter backwash and media replacement indicators; and ensuring sufficient chlorine dose and contact time for pathogen destruction. The control measure monitoring plan and the compliance monitoring plan (see LAC Field Experience 6.1 and 7.1) are also important components of the SOPs.

Field Experience 8.2 – delaying emergency response plans due to resource constraints

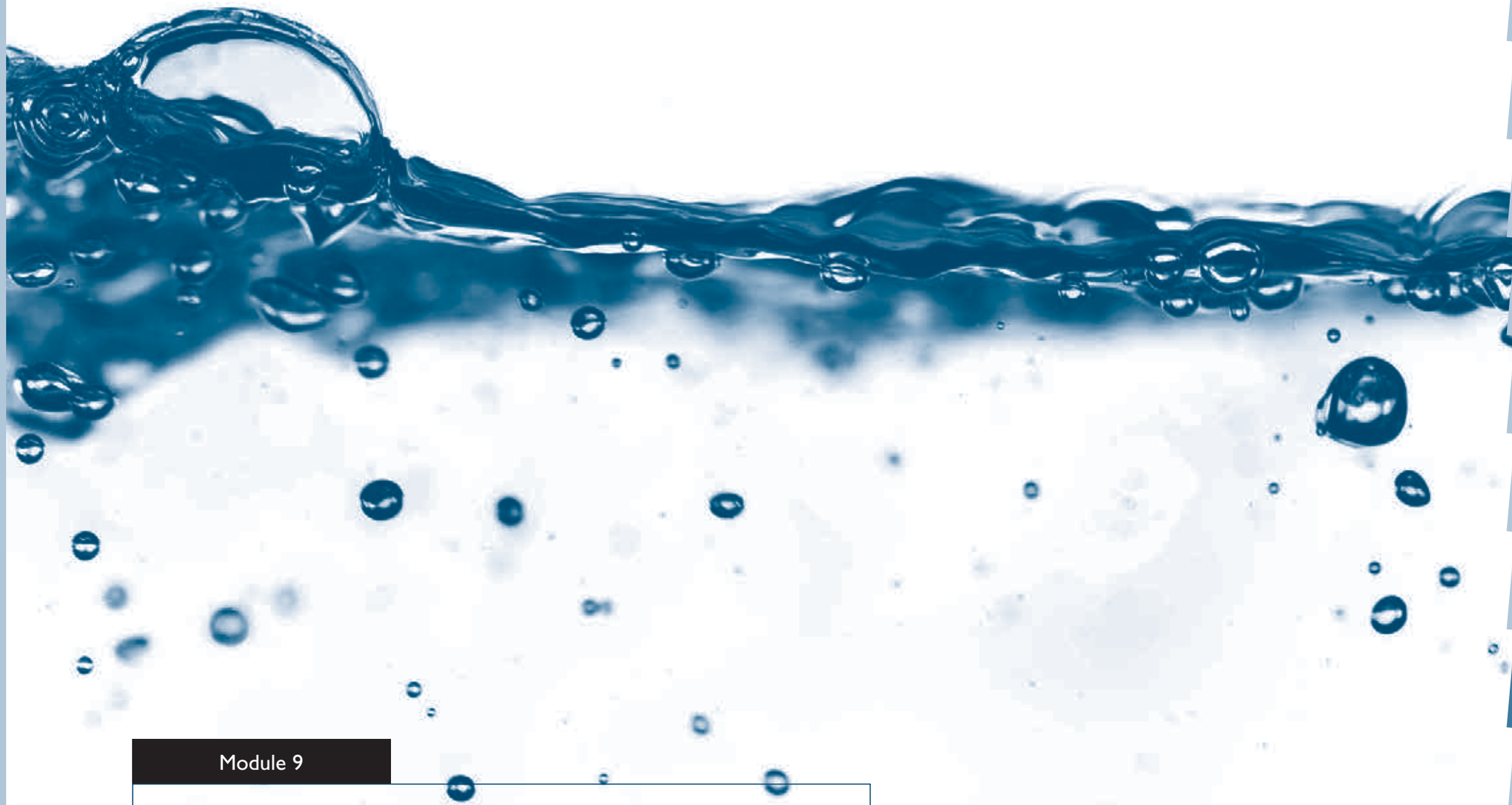
The WSP team made the decision not to develop a formal incident/emergency response plan during the first iteration of WSP development in favor of focusing efforts elsewhere. Team members simply did not have sufficient time in their schedules to address each task recommended in the Manual in a meaningful way, so prioritization was necessary. Because the utility's operations were such that noncompliance with most water quality standards was the rule rather than the exception, the water system was effectively in a constant state of emergency. Consumers were under a continuous boil-water advisory and a system was in place to reinforce the ongoing advisory with additional public service announcements by the Ministry of Health whenever sampling revealed particularly poor water quality. While the WSP team members recognized opportunities to enhance the basic response plan, they determined that the water system would be best served by focusing limited resources on improving water quality.

As improvements to water quality are realized through WSP interventions and further experience, the utility will address gaps in the response plan during subsequent revisions of the WSP (see LAC Field Experience 10.1).

Case study 3: United Kingdom (England and Wales)

Field Experience 8.1 – revising procedures to incorporate WSP outputs

Water companies already had good management and SOPs. The challenge was to modify these in line with the outputs of the WSP and to consider such procedures as part of the WSP.



Module 9

Develop supporting programmes

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Introduction

Supporting programmes are activities that support the development of people's skills and knowledge, commitment to the WSP approach, and capacity to manage systems to deliver safe water. Programmes frequently relate to training, research and development. Supporting programmes may also entail activities that indirectly support water safety, for example those that lead to the optimization of processes, like improving quality control in a laboratory. Programmes may already be in place, but are often forgotten or overlooked as important elements of the WSP. Examples of other activities include continuing education courses, calibration of equipment, preventive maintenance, hygiene and sanitation, as well as legal aspects such as a programme for understanding the organization's compliance obligations. It is essential that organizations understand their liabilities and have programmes in place to deal with these issues.

Key actions

- Identify the supporting programmes needed for implementing the WSP approach;
- Review, and as necessary, revise existing supporting programmes;
- Develop additional supporting programmes to address gaps in staff knowledge or skills that may impede the timely implementation of the WSP.

Typical challenges

- Human resources;
- Equipment;
- Financial resources;
- Support of management;
- Not identifying procedures and processes as part of the WSP.

Outputs

Programmes and activities that ensure that the WSP approach is embedded in the water utility's operations.

Supporting programmes include training of appropriate staff in all aspects of preparing and implementing the WSP, quality control procedures such as internal and external analytical quality control within laboratories, and research and development programmes to support long-term solutions.

Example/tool 9.1: Reviewing existing programmes

In developing supporting programmes, it may not always be necessary to develop new programmes. Organizations should assess the programmes that are currently in place to identify any gaps that need to be addressed including updates of existing programmes.

All procedures should be documented and dated to ensure that staff follow the most recent version.

Example/tool 9.2: Types of supporting programmes that could be included in the WSP

Programme	Purpose	Examples
Training and awareness	To ensure organization (and contractor) personnel understand water safety and the influence of their actions.	WSP training Competency requirements Induction training Hygiene procedures
Research and development	To support decisions made to improve or maintain water quality.	Understanding potential hazards Research into better indicators of contamination
Calibration	To ensure that critical limit monitoring is reliable and of acceptable accuracy.	Calibration schedules Self-calibrating equipment
Customer complaint protocol	To ensure that customers are responded to if water quality questions are raised.	Call centre Complaints training
Etc. ↴		

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Case study 1: Australia

Field Experience 9.1 – operator training programmes

In the past there have been limited formal training opportunities and requirements for water supply system operators and managers with most training being provided on the job. However, at present, regulators are driving more formalized training, competency assessments and qualifications and are working on developing training and assessment packages for the Australian water industry. WSPs invariably place a high prominence on training and experience as a supporting programme, but to date, this has been typically relatively informal.

Field Experience 9.2 – calibration and maintenance

Asset management programmes were typically well established within Australian urban water utilities. In general, key civil assets were well maintained and assessed. One area that has improved with the advent of WSPs is the maintenance of process assets and calibration of monitoring equipment. WSPs have driven more detailed review and often resulted in upgrades of how process assets are maintained and of how monitoring devices are calibrated and maintained.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 9.1 – developing an operator training programme

The utility did not have a formal operator training programme and poorly trained operators were considered among the highest-priority threats to water quality. Training had not been offered in many years and considerable operator turnover had taken place since. Further, past training sessions had been conducted by external experts and in-house capacity had not been developed to address future training needs. The WSP team therefore developed an operator training programme with a focus on sustainability. A senior utility manager was identified as the training lead and a number of utility personnel were selected as trainers. The training lead designed and conducted a 'training of trainers' course, drawing heavily from the material contained in the SOPs (see LAC Field Experience 8.1). An external consultant contributed additional expertise on optimizing system operations and effective troubleshooting techniques. The consultation and the utility's subsequent hands-on experience are expected to build sufficient capacity within the utility to preclude the need for external support in the future. Upon completion of the 'training of trainers' course, the trainers and the training lead designed the operator training course. The full operator training course will be held every three years and each time there is operator turnover. A simplified refresher course will be held annually.

Field Experience 9.2 – improving surveillance monitoring

The WSP team identified surveillance monitoring as an important factor in safe water provision as it provides public assurance and demonstrates due diligence. A review of multiple years of surveillance monitoring records (performed as part of the existing conditions assessment described in LAC Field Experience 2.2) revealed that the Ministry of Health had not consistently performed monthly water quality sampling in the distribution system as required by protocol. On occasions when surveillance monitoring was carried out, findings were not shared with the utility. Instead, utility personnel learned of unacceptable surveillance results alongside their consumer base via public service announcements. The WSP team also learned that surveillance officers had never been formally trained in appropriate microbial sampling techniques, causing the utility to routinely challenge the validity of surveillance results and further contributing to poor

relations between the utility and surveillance officers. To address these concerns, the surveillance monitoring plan was enhanced to include a system of timely communication of results with the utility as well as surveillance officer training on sampling techniques, appropriate sampling locations and key parameters of interest. Senior officials within the Ministry of Health were engaged in the surveillance plan improvement process to ensure follow-through and accountability.

Field Experience 9.3 – increasing cost recovery

Cost recovery was identified as a critical WSP focus area given that effective utility operation is contingent upon a sufficient revenue stream. Existing revenue was well below full cost recovery and even with government subsidies the utility did not have adequate funds to meet basic operational needs such as staffing, purchasing treatment chemicals and testing reagents, replacing filter media, and maintaining equipment. The utility was also unable to afford the high cost of pumping 24 hours a day – a constraint with major implications for water quality and consumer health. Daily breaks in service of eight hours or more made the water supply vulnerable to recontamination by creating routine low-pressure conditions in the distribution network and by giving consumers no option but to store water at home. Poor cost recovery was attributed in part to an ineffective system of billing and collections. Additionally, poor water quality and intermittent service affected consumers' willingness to pay for water (as evidenced by the household survey findings discussed in LAC Field Experience 2.3). The WSP team developed a plan to expedite the utility's ongoing efforts to revamp the billing system and created a public relations strategy to improve consumer-utility relations and increase willingness to pay.

Case study 3: United Kingdom (England and Wales)

Field Experience 9.1 – revising supporting programmes to incorporate WSP outputs

This area was not a significant challenge for water companies as they already had good supporting programmes such as training programmes, hygiene procedures, ISO quality systems, accredited laboratories with internal and external quality control programmes and company and collaborative industry research and development. The challenge was to consider and include such supporting programmes as part of the WSP.

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Module 10

Plan and carry out periodic review of the WSP

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Introduction

The WSP team should periodically meet and review the overall plan and learn from experiences and new procedures (in addition to regularly reviewing the WSP through analysis of the data collected as part of the monitoring process). The review process is critical to the overall implementation of the WSP and provides the basis from which future assessments can be made. Following an emergency, incident or near miss, risk should be reassessed and may need to be fed into the improvement/upgrade plan.

Key actions

Keep the WSP up to date

Regularly reviewing and revising the WSP ensures that new risks threatening the production and distribution of safe water are regularly assessed and addressed. An updated, relevant WSP will maintain the confidence and support of staff and stakeholders in the WSP approach.

A WSP can quickly become of out of date through:

- Catchment, treatment and distribution changes and improvement programmes, which can impact on process diagrams and risk assessments;
- Revised procedures;
- Staff changes;
- Stakeholder contact changes.

Convene regular WSP review meetings

The WSP team should agree to meet regularly to review all aspects of the WSP to ensure that they are still accurate. Local operator input or site visits may also be required as part of the review. Operational monitoring results and trends should be assessed. In addition to the regular planned review, the WSP should also be reviewed when, for example, a new water source is developed, major treatment improvements are planned and brought into use, or after a major water quality incident (see also Module 11). During the regular review meeting, the date of the next review should be established.

Typical challenges

- Reconvening the WSP team;
- Ensuring continued support for the WSP process;
- Ensuring that where original staff have left the utility, their duties are maintained by others;
- Keeping records of changes;
- Keeping in contact with stakeholders.

Outputs

A WSP that is up to date and continues to be appropriate to the needs of the water utility and stakeholders.

Example/tool 10.1: When to review the WSP

A WSP should be reviewed immediately when there is a significant change of circumstances or a problem within the water supply chain. A WSP should also be reviewed from time to time, particularly taking into account the results of implementing the WSP. Any change made to the WSP as a result of a review should be documented.

Example/tool 10.2: Example checklist for WSP review

- ☑ Notes of last review meeting;
- ☑ Notes of any interim review;
- ☑ Changes to membership of the WSP team;
- ☑ Changes in catchment, treatment, distribution;
- ☑ Review of operational data trends;
- ☑ Validation of new controls;
- ☑ Review of verification;
- ☑ Internal and external audit reports;
- ☑ Stakeholders communication;
- ☑ Date of next review meeting.

Example/tool 10.3: Changes that can affect the WSP

A housing development increased demand for water within the Hawthorne Water Supply System. This led to a proposal that water from the Dahlia Water Supply System should be fed into the area. Yet the materials used in the piped distribution system of the Hawthorne System could not cope with the more aggressive water chemistry of the Dahlia Supply, leading to corrosion and leaching of metals. This situation could have been avoided if the WSP team had assessed the risks of such a change beforehand. The team would have needed to ensure that the process diagram for the 'joined-up' water supply system had been updated, and whether the risk assessment from the other water supplier was adequate, including data from operational monitoring, and consumer complaints.

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Case study 1: Australia

Field Experience 10.1 – executive review of the WSP

Most Australian urban water utilities have at least one executive level water quality champion and they report on WSP implementation and outputs at the executive level. Audits of WSPs are typically reported to the utility executive. The WSP provides a useful framework for organizing and presenting water quality management actions in a form that assists executives to make strategic decisions on water quality management.

Field Experience 10.2 – revising the WSP

Australian utilities maintain their WSPs as 'living documents' that are subject to ongoing change to capture improvements. Most WSPs are in fact version-controlled by having an intranet-based electronic version live on the web rather than a hard copy version. The WSPs typically undergo a major revision every couple of years with ad hoc revisions usually scheduled to coincide with audits or other milestones or major asset changes.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 10.1 – establishing a review committee for the WSP

The WSP team felt that a formal process of WSP review and revision needed to be established to ensure that the WSP is kept current and effective. Owing to the busy schedules of Task Force and Steering Committee members, long-term maintenance of the WSP was considered unrealistic without a clear plan outlining major review activities and identifying responsible parties. A Review Committee was formed and agreed to meet biennially following WSP development to revise the WSP to reflect progress on prescribed corrective actions and to address any shortcomings identified. In addition to scheduled biennial reviews, the Review Committee agreed to meet following any drinking-water-related incidents to revise the WSP as necessary to prevent recurrence.

Field Experience 10.2 – revising the WSP following capital improvements

Several capital improvements were proposed as a result of the WSP. Structural or operational changes to the system can introduce additional risks, such as a lack of knowledge about operating new equipment or changing levels of disinfectants for a modified system. The Review Committee will revisit the WSP following structural improvements to assess and address any unforeseen hazards and update the WSP accordingly following any changes that are implemented. Similarly, as the capacity for improved water quality is realized through capital and operational improvements, standards will be revisited and may need to be modified, such as the step-wise standards established for turbidity, as discussed in LAC Field Experience 7.3.

Case study 3: United Kingdom (England and Wales)

Field Experience 10.1 – staying committed to the WSP approach

Companies that had many paper-based WSPs were challenged by the workload requirements to keep them up to date particularly where many improvements had been identified and implemented. Keeping the WSP initiative embedded in company operations was likely to be a challenge before the WSP risk assessment and risk management approach was made a regulatory requirement.

Module 11

Revise the WSP following an incident

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Introduction

As outlined previously, to ensure that a WSP covers emerging hazards and issues, it should be reviewed periodically by the WSP team. A particular benefit of implementing the WSP framework is a likely reduction in the number and severity of incidents, emergencies or near misses affecting or potentially affecting drinking-water quality. However, such events may still occur. In addition to the periodic review, it is important that the WSP is reviewed following every emergency, incident or unforeseen event irrespective of whether new hazards were identified to ensure that, if possible, the situation does not recur and determine whether the response was sufficient or could have been handled better. A post-incident review is always likely to identify areas for improvement whether it is a new hazard or revised risk for the risk assessment, a revision for an operating procedure, a training issue or a communication issue, and the WSP must be revised to reflect the changes. In many cases, it will be necessary to include other stakeholders in the review. It is important that water suppliers, within their WSP, have procedures in place to ensure that the WSP team is made aware of the circumstances and details of all incidents, emergencies, and near misses.

Key actions

- Review the WSP following an incident, emergency or near miss;
- Determine the cause of the incident, emergency or near miss and sufficiency of the response;
- Revise the WSP as necessary, including updates to supporting programmes.

Typical challenges

- An open and honest appraisal of the causes, chain of events, and factors influencing the emergency, incident or near miss situation;
- Focusing and acting on the positive lessons learned, rather than apportioning blame.

Outputs

1. Comprehensive and transparent review of why the incident occurred and the adequacy of the utility's response.
2. Incorporation of the lessons learned into WSP documentation and procedures.

Example/tool 11.1: A checklist of questions to be asked following an emergency, incident or near miss includes

- ☑ What was the cause of the problem?
- ☑ Was the cause a hazard already identified in the WSP risk assessment?
- ☑ How was the problem first identified or recognized?
- ☑ What were the most essential actions required and were they carried out?
- ☑ If relevant, was appropriate and timely action taken to warn consumers and protect their health?
- ☑ What communication problems arose and how were they addressed?
- ☑ What were the immediate and longer-term consequences of the emergency?
- ☑ How can risk assessment / procedures / training / communications be improved?
- ☑ How well did the emergency response plan function?

Example/tool 11.2: Following an incident, emergency or near miss the following checklist may be useful to revise the WSP

- ☑ Accountabilities and contact details for key personnel, usually including other stakeholders and individuals, are clearly stated;
- ☑ Clear definition of trigger levels for incidents including a scale of alert levels (e.g. when an incident is elevated to a boil water alert);
- ☑ Review whether the management procedures were appropriate for the incident and if not, revise accordingly;
- ☑ Standard operating procedures and required equipment, including back-up equipment, are readily available, and relevant;
- ☑ Relevant logistical and technical information is in hand and up to date;
- ☑ Checklists and quick reference guides have been prepared and are up to date;
- ☑ Does the risk assessment need revising?
- ☑ Do procedures/ training / communications need improving?
- ☑ Has the incident shown the need for an improvement programme?

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Case study 1: Australia

Field Experience 11.1 – defining 'incident' and planning review and revision

Even prior to developing WSPs, Australian water utilities typically had incident and emergency response plans. Major water quality problems or threats to water quality typically constituted an 'incident', which was the term used to describe a major event. Agreed criteria were used to mark the start of an incident whereupon an incident management team was formed. The incident management team then managed the incident to minimize harm caused during the event and to return to normal operations as soon as possible. Most water quality incidents involved responding urgently to early warning and mobilizing sufficient resources to ensure that customers were not affected. Such incidents were usually managed internally by the utility. In a few cases, contaminated or inadequately treated water may reach customers. If contaminated or inadequately treated water reaches customers, then typically the incident involves the health department and customers are advised not to drink that water, or to boil the water. Water supplies are not usually shut off even if they may be contaminated. Water is required for sanitation and hygiene purposes, and most contamination events are not so severe that water supply should be terminated. Rather, water supply continues and people are asked to avoid or boil water before use, as a precaution. As a matter of course, following an incident there is a 'debrief' process in which the root cause of the problem is identified and the WSP changed to prevent a recurrence, if possible.

Field Experience 11.2 – post-incident assessment

As an example, many WSPs triggered incidents due to disinfection system failures in their early stages. Prior to WSPs there was not necessarily a critical limit value set below which disinfection was considered suspect. However, with the advent of WSPs, disinfection critical limit values were set and these were breached from time to time. As a result of the root cause analysis following the incidents, many utilities changed their disinfection practices. Utilities introduced full or partial (focusing on vulnerable components) duty and standby systems to allow a change to the standby system in the event of a failure of the duty system. In some suppliers that desire high reliability, there are two independent standby systems to provide further back-up with one system at an independent downstream location. In many systems, automation was introduced to allow switchover to back-up systems and to provide an alert to operators. Treated water storage was augmented in many cases to allow systems to shut down and provide a window of a day or more to repair the systems without affecting customers. Utilities that would experience multiple incidents in the first years of the WSP implementation gradually moved to less than one incident per year through this improvement process.

Case study 2: Latin America and the Caribbean (LAC)

Field Experience 11.1 – defining 'incident' and planning review and revision

The WSP team defined an 'incident' as a violation of water quality that poses an acute or immediate threat to public health. At the time of WSP development, issues potentially satisfying this definition, such as microbial contamination in the distribution system, were commonplace and were largely the motivating factors for initially undertaking the WSP. Hazards such as these were identified as part of Module 3 and 4. The implementation of corrective actions, such as increased chlorine dosing and improved monitoring practices, are expected to address those problems. If post-implementation monitoring reveals recurrent

microbial contamination, the Review Committee will meet to address weaknesses in the plan.

Field Experience 11.2 – post-incident assessment

During the course of WSP development, an incident occurred in which chlorine gas was released into a residential area. Several failings in emergency mitigation and response procedures were identified, including a lack of monitoring of chlorine gas transfer; an unmanned duty station, which caused the leak to go unnoticed by the utility; a lack of prompt reporting to appropriate parties within the utility, to the EPA and to residents; a failure to evacuate appropriately; and a lack of provision of health officers to evaluate the incident. A post-incident evaluation by the utility and the EPA was subsequently conducted that addressed each of the failings and introduced protocol and enforcement procedures to the WSP to prevent the recurrence of such incidents.

Case study 3: United Kingdom (England and Wales)

Field Experience 11.1 – keeping emergency plans up to date

Water companies already had good emergency plans which are tested and kept up to date as part of normal procedures. Again, with such well established procedures, the challenge was to consider these as coming under the WSP umbrella.

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Glossary

The following represents terms used in GDWQ and other documents such as Codex Alimentarius and other guiding materials used throughout this Manual.

Term	Definition
Control (noun) (for instance control of water safety):	The state wherein correct procedures are being followed and criteria are being met.
Control (verb) (for instance control of a hazard):	To take all necessary actions to ensure and maintain compliance with criteria established in the WSP.
Control Measure:	Any action and activity that can be used to prevent or eliminate a water safety hazard or reduce it to an acceptable level.
Control Point:	A step at which control can be applied to prevent or eliminate a water safety hazard or reduce it to an acceptable level. Some plans contain *key* control points at which control might be essential to prevent or eliminate a water safety hazard.
Corrective Action:	Any action to be taken when the results of monitoring at the control point indicate a loss of control.
Critical Limit:	A criterion which separates acceptability from unacceptability.
Deviation:	Failure to meet a critical limit.
Flow Diagram:	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular water item.
HACCP:	Hazard Analysis and Critical Control Point.
Hazard Analysis:	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for water safety and therefore should be addressed in the WSP.
Hazard:	A biological, chemical, physical or radiological agent in, or condition of water, with the potential to cause an adverse health effect. Another word for hazard includes "contaminant".
Hazardous Event:	A process whereby a hazard/contaminant is introduced into a water supply.
Monitor:	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control point is under control or whether the water meets quality criteria.
Risk Assessment:	For the purposes of this Manual, risk assessment has the same meaning as hazard analysis.
Risk Score:	The score assigned to a hazard based on the risk analysis process.
Step:	A point, procedure, operation or stage in the water supply chain including raw materials, from primary production to final exposure.
Supporting Programmes/ Supporting Requirements:	The foundation activities required to ensure safe water including training, raw material specifications and general good water management practices. These programmes can be just as important as control points in controlling water quality risks but are used where application tends to cover long timeframes and/or broader organizational or geographic areas. Includes general organizational supporting programmes as well as specific programmes targeted to particular risks.
Validation:	Obtaining evidence that the elements of the WSP can effectively meet the water quality targets.
Verification:	The application of methods, procedures, tests and other evaluations, to determine compliance with the WSP, i.e. checking whether the system is delivering water of the desired quality and whether the WSP is being implemented in practice.
WHO:	World Health Organization.
WSP:	Water Safety Plan.

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Design: www.paprika-annecy.com Photos: © Horst Brandt - zanfr - Andrzej Szoblik - Robert Creigh - 2jenn - Fotolia

The most effective means of consistently ensuring the safety of a drinking-water supply is through the use of a comprehensive risk assessment and risk management approach that encompasses all steps in water supply from catchment to consumer. In these Guidelines, such approaches are called water safety plans (WSPs).

WHO Guidelines for Drinking-water Quality, 3rd Edition, 2004

9 789241 562638

World Health Organization

International Water Association

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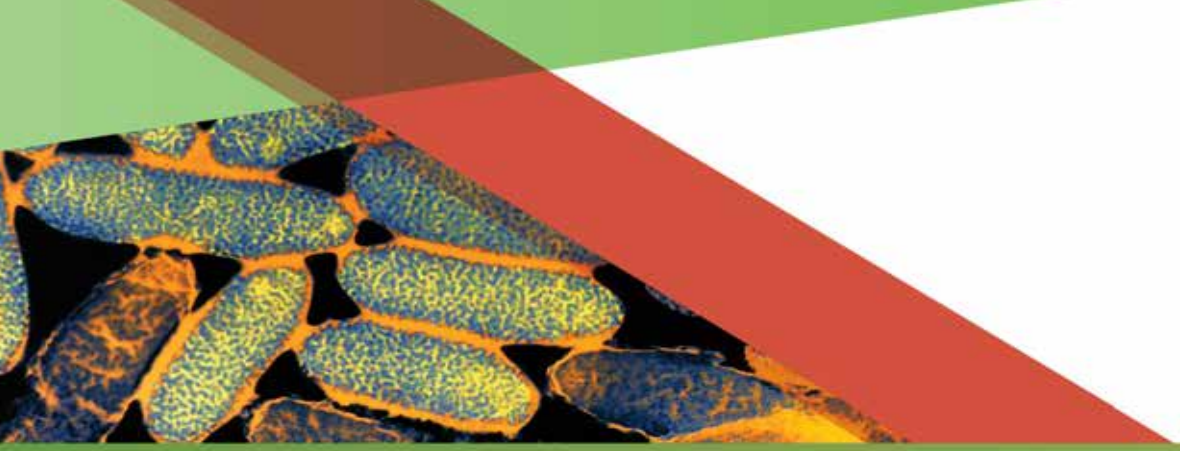


SURVEILLANCE REPORT

Legionnaires' disease

Annual Epidemiological Report for 2019

Key facts

- Legionnaires' disease remains an uncommon and mainly sporadic respiratory infection with an overall notification rate in 2019 for the EU/EEA of 2.2 cases per 100 000 population.
- There is heterogeneity in notification rates between EU/EEA countries, with the highest rate reported by Slovenia (9.4 cases per 100 000 population).
- The annual notification rate increased in recent years, from 1.4 in 2015 to 2.2 cases per 100 000 population in 2019.
- There was a marginal decrease of less than 1% in the number of reported cases in 2019, compared with 2018.
- Four countries (France, Germany, Italy, and Spain) accounted for 71% of all notified cases in 2019.
- Males aged 65 years and above were most affected (8.4 cases per 100 000 population).
- Only 10% of cases were culture-confirmed (10%) probably meaning that disease caused by *Legionella* species other than *Legionella pneumophila* is under-estimated.

Methods

This report is based on data for 2019 retrieved from The European Surveillance System (TESSy) on 12 January 2021. TESSy is a system for the collection, analysis and dissemination of data on communicable diseases.

The methods used to produce this report are published online by ECDC [1] together with an overview of the national surveillance systems [2]. A subset of the data used for this report is available through ECDC's online *Surveillance atlas of infectious diseases* [3].

The surveillance data were collected through three different schemes:

- annual retrospective data collection of Legionnaires' disease (LD) cases reported in EU Member States, Iceland and Norway;
- annual retrospective data collection of outbreak events detected and reported in EU Member States, Iceland and Norway. The following thresholds for reporting outbreaks are used:
  - ≥ five cases, if these cases were not exposed in same building, there is no evidence of exposure to the same aerosol-producing installation/device, or microbiological evidence of linked cases;
  - ≥ three cases, if these cases were exposed in the same building, or if there is evidence of exposure to the same aerosol-producing installation/device, or if there is microbiological evidence of linked cases;
- near-real-time reporting of travel-associated cases of Legionnaires' disease (TALD) through the European Legionnaires' disease surveillance network (ELDSNet) [4], including reports from countries outside the EU/EEA. This scheme aims primarily to identify clusters of cases that may otherwise not be detected at national level, in order to quickly investigate them and take control measures at the implicated tourist accommodation sites to prevent further infections.

Legionnaires' disease cases should be reported to these surveillance schemes in accordance with the 2018 EU/EEA case definition for confirmed cases or probable cases, which includes at least one positive laboratory test.

Annual case surveillance

Epidemiology

In 2019, 28 countries reported 11 298 cases (Table 1), of which 10 636 (94%) were classified as confirmed. The number of notifications per 100 000 population remained stable at 2.2, being the highest notification rate ever observed for the EU/EEA. In the last five years, the notification rates have nearly doubled in the EU/EEA, from 1.4 in 2015 to 2.2 per 100 000 population. Four countries, France, Germany, Italy and Spain, accounted for 71% of all notified cases, although their combined populations only represent approximately 50% of the EU/EEA population.

Table 1. Distribution of Legionnaires' disease cases and rates per 100 000 population by country and year, EU/EEA, 2015–2019

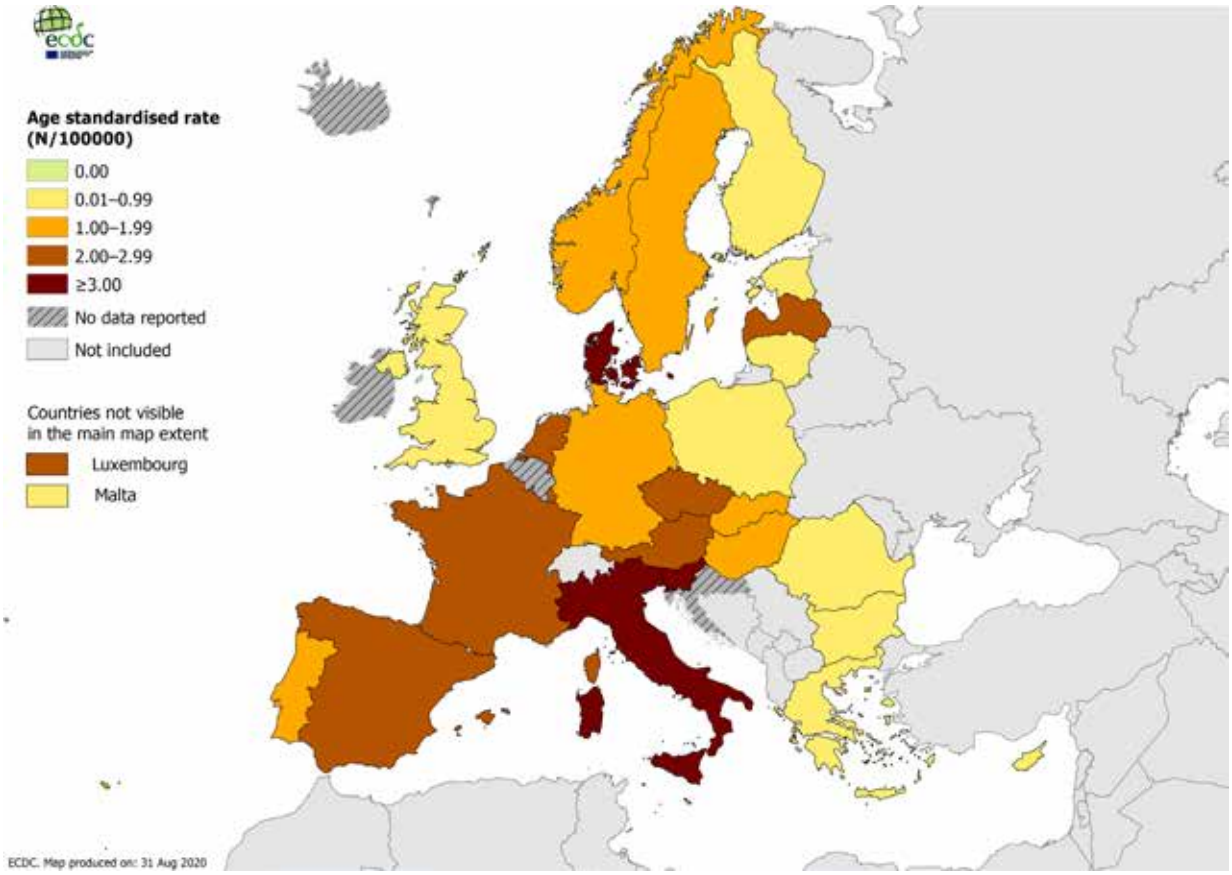
Country	2015		2016		2017		2018		2019		
	Number	Rate	Number	Rate	Number	Rate	Number	Rate	Number	Rate	ASR
Austria	160	1.9	161	1.9	219	2.5	237	2.7	255	2.9	2.6
Belgium	118	1.1	157	1.4	235	2.1	270	2.4	224	2.0	1.8
Bulgaria	1	0.0	0	0.0	2	0.0	11	0.2	5	0.1	0.1
Croatia	48	1.1	31	0.7	33	0.8	43	1.0	-	-	-
Cyprus	2	0.2	3	0.4	1	0.1	5	0.6	4	0.5	0.5
Czechia	120	1.1	147	1.4	217	2.1	231	2.2	277	2.6	2.3
Denmark	185	3.3	170	3.0	278	4.8	264	4.6	270	4.7	4.2
Estonia	6	0.5	14	1.1	16	1.2	18	1.4	12	0.9	0.8
Finland	17	0.3	15	0.3	27	0.5	24	0.4	44	0.8	0.7
France	1389	2.1	1218	1.8	1630	2.4	2133	3.2	1816	2.7	2.5
Germany	842	1.0	974	1.2	1278	1.5	1446	1.7	1545	1.9	1.6
Greece	29	0.3	31	0.3	43	0.4	65	0.6	45	0.4	0.4
Hungary	58	0.6	66	0.7	62	0.6	74	0.8	113	1.2	1.1
Iceland	1	0.3	3	0.9	3	0.9	5	1.4	-	-	-
Ireland	11	0.2	10	0.2	25	0.5	25	0.5	21	0.4	0.5
Italy	1572	2.6	1733	2.9	2037	3.4	3018	5.0	3143	5.2	4.2
Latvia	22	1.1	24	1.2	31	1.6	37	1.9	42	2.2	2.1
Liechtenstein	.	.	.	.	.	.	.	.	.	.	.
Lithuania	7	0.2	11	0.4	14	0.5	21	0.7	17	0.6	0.6
Luxembourg	5	0.9	3	0.5	9	1.5	10	1.7	14	2.3	2.3
Malta	6	1.4	8	1.8	11	2.4	13	2.7	5	1.0	0.8
Netherlands	419	2.5	454	2.7	561	3.3	584	3.4	566	3.3	3.0
Norway	60	1.2	43	0.8	52	1.0	69	1.3	65	1.2	1.2
Poland	23	0.1	24	0.1	38	0.1	70	0.2	74	0.2	0.2
Portugal	145	1.4	197	1.9	232	2.3	211	2.1	201	2.0	1.7
Romania	3	0.0	2	0.0	19	0.1	62	0.3	19	0.1	0.1
Slovakia	14	0.3	14	0.3	14	0.3	54	1.0	85	1.6	1.6
Slovenia	106	5.1	93	4.5	117	5.7	160	7.7	195	9.4	8.3
Spain	1024	2.2	951	2.0	1363	2.9	1513	3.2	1542	3.3	2.9
Sweden	142	1.5	145	1.5	189	1.9	198	2.0	182	1.8	1.6
United Kingdom	412	0.6	383	0.6	504	0.8	532	0.8	517	0.8	0.7
EU-EEA	**6947**	**1.4**	**7085**	**1.4**	**9260**	**1.8**	**11403**	**2.2**	**11298**	**2.2**	**1.9**

Source: Country reports.
ASR: age-standardised rate.
.: no data reported.
-: no rate calculated.

Of 8 458 cases with known outcome, 630 (7%) were reported to have been fatal.

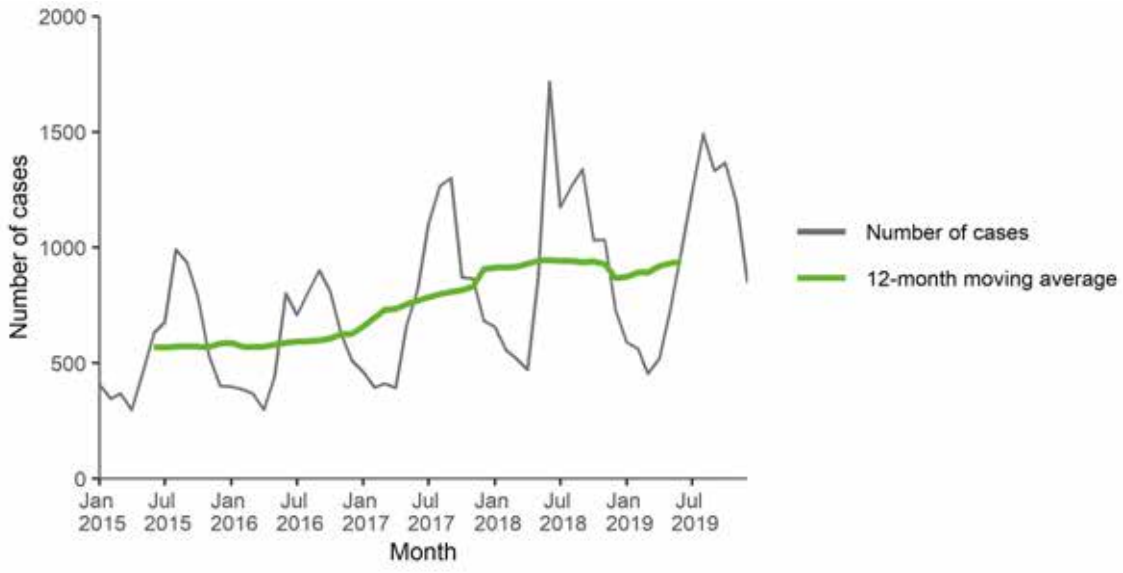
Notification rates ranged from less than 1.0 cases per 100 000 population in 10 countries (Bulgaria, Cyprus, Estonia, Finland, Greece, Ireland, Lithuania, Poland, Romania and the United Kingdom) to 3.0 cases per 100 000 population or more in six countries (Denmark, France, Italy, the Netherlands, Slovenia and Spain); see Table 1 and Figure 1.

Figure 1. Distribution of Legionnaires' disease cases per 100 000 population by country, EU/EEA, 2019



During the period 2015−2019, the number of reported cases increased by 65% from 6 947 to 11 298 showing an increasing trend in recent years (Table 1; Figure 2).

Figure 2. Distribution of Legionnaires' disease cases by month, EU/EEA, 2015−2019

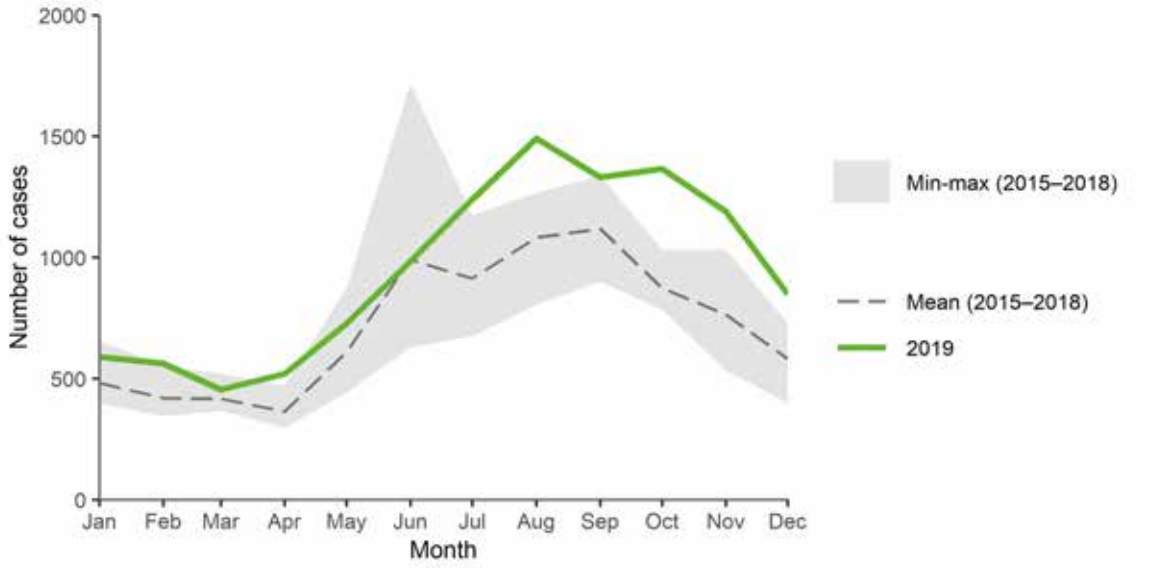


Source: Country reports from Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom.

The distribution of cases by month of reporting shows that the majority (57%) occurred between June and October, similar to previous years (Figure 3). An increase in cases compared to the maximum in previous years (2015–2018) was observed for every month during the period July to December. The peak of 1 743 cases in June

2018 was the highest monthly number recorded to date under EU/EEA surveillance and was not reached again in 2019. No community outbreaks were reported by any EU/EEA country that could explain the shifted seasonal curve to the later summer and autumn period.

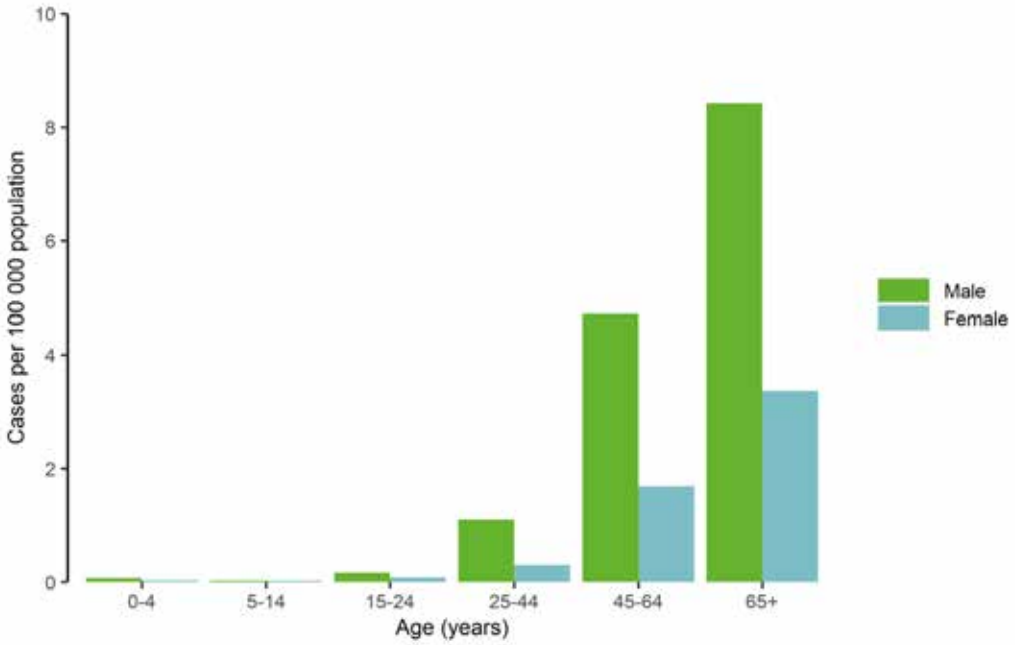
Figure 3. Distribution of Legionnaires' disease cases by month, EU/EEA, 2019 and 2015–2018



Source: Country reports from Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom

In 2019, people aged 45 years and older accounted for 10 236 of 11 279 cases with known age (91%). The notification rate increased with age, from ≤0.1 cases per 100 000 population in those under 25 years of age to 5.6 cases per 100 000 population in those aged 65 years and above (8.4 cases per 100 000 population in males and 3.4 in females, Figure 4). The overall male-to-female ratio remained unchanged compared to 2018 at 2.3:1.

Figure 4. Distribution of Legionnaires' disease cases per 100 000 population, by age and gender, EU/EEA, 2019



The vast majority of cases in 2019 (90%) were reported using the laboratory method of urine antigen tests (UAT). This was similar to the range of 88−90% cases with UAT testing reported since 2012. In comparison, few cases were reported with a culture test (1 148 cases; 10%) and use of polymerase chain reaction (PCR) method tests was reported for 1 024 cases (9%).

This continues the low-level use of culture as a reported method observed during the same period. Among culture-confirmed cases (1 148) a total of 35 *Legionella* non-pneumophila species were reported: *L. anisa* (1), *L. bozemanii* (2), *L. dumoffi* (1), *L. jordanis* (1), *L. longbeachae* (15), *L. micdadei* (2) and *Legionella* other species (13). As illustrated in Table 2, although *Legionella pneumophila* isolates of all serogroups are detected and reported annually among culture-confirmed cases, over 80% are reported as serogroup 1.

Table 2. Serogroups reported for culture-confirmed cases of *L. pneumophila*, EU/EEA, 2018–2019

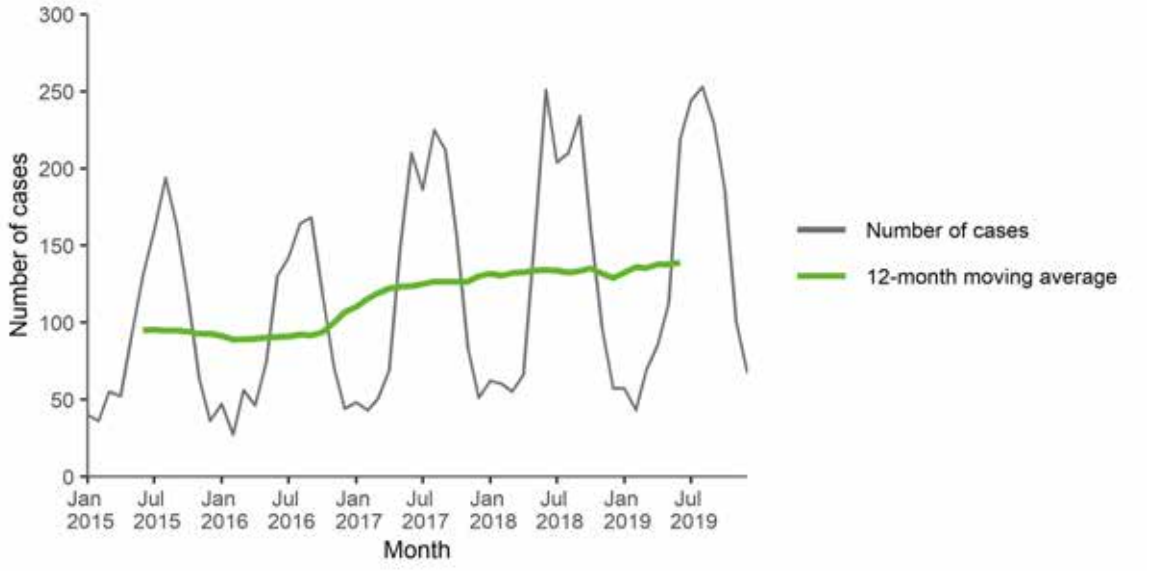
Serogroup (SG)	2018		2019	
	Number	%	Number	%
1	909	85	923	83
2	3	<1	9	<1
3	32	3	35	3
4	7	<1	2	<1
5	7	<1	8	<1
6	16	1	17	2
7	0	-	5	<1
8	3	<1	6	<1
9	0	<1	1	<1
10	2	<1	9	<1
11	0	-	0	-
12	2	<1	0	-
13	2	<1	1	<1
14	1	<1	1	<1
15	0	<1	3	<1
L. pneumophila non serogroup 1	7	<1	7	<1
L. pneumophila serogroup mixed	11	1	3	<1
L. pneumophila serogroup unknown	71	7	76	7
TOTAL	**1 073**		**1 106**	

Travel-associated Legionnaires' disease (TALD)

TALD case reports

ELDSNet received reports of 1 657 cases of TALD with date of onset in 2019, 2% more cases than in 2018, and the highest annual number of TALD cases ever reported to the network (Figure 5).

Figure 5. Distribution of travel-associated cases of Legionnaires' disease by month, EU/EEA, 2015–2019

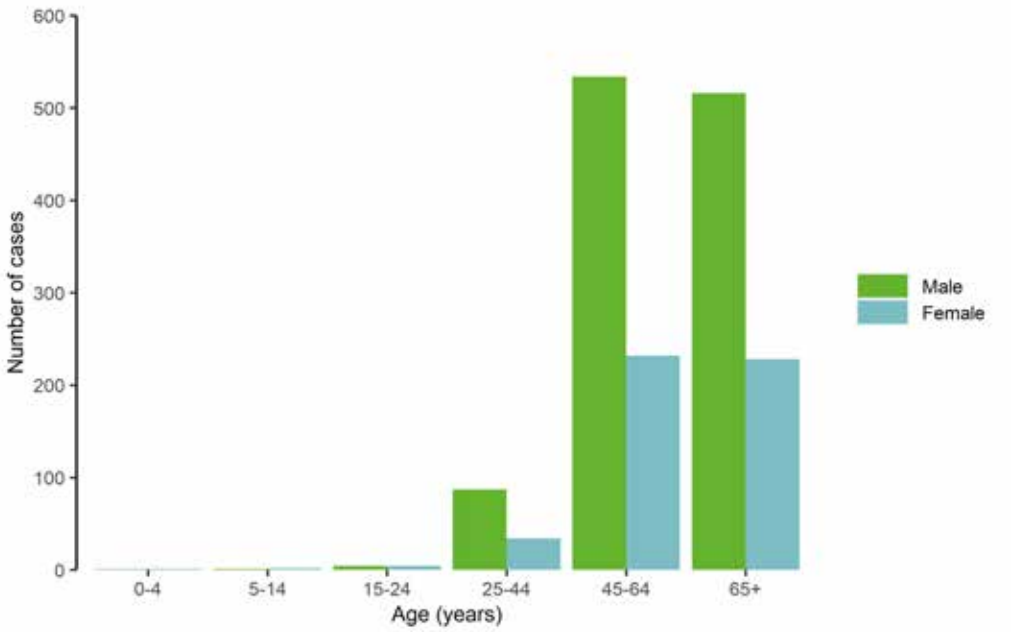


Source: Country reports from Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, the United Kingdom.

Cases were reported from 28 countries: 26 EU/EEA Member States and two non-EU/EEA countries: Switzerland (32 cases) and the USA (19 cases). Three quarters (76.7 %) of all TALD cases were reported by only five countries: Italy, Germany, France, the United Kingdom, and the Netherlands.

Similar to previous years, and the overall distribution for Legionnaires' disease, over two thirds (69%) of reported TALD cases were male. Cases had a median age of 63 years (IQR 55-71, range 7-99); 83% of cases occurred in people 50 years and older (Figure 6).

Figure 6. Distribution of travel-associated cases of Legionnaires' disease by age and gender, 2019

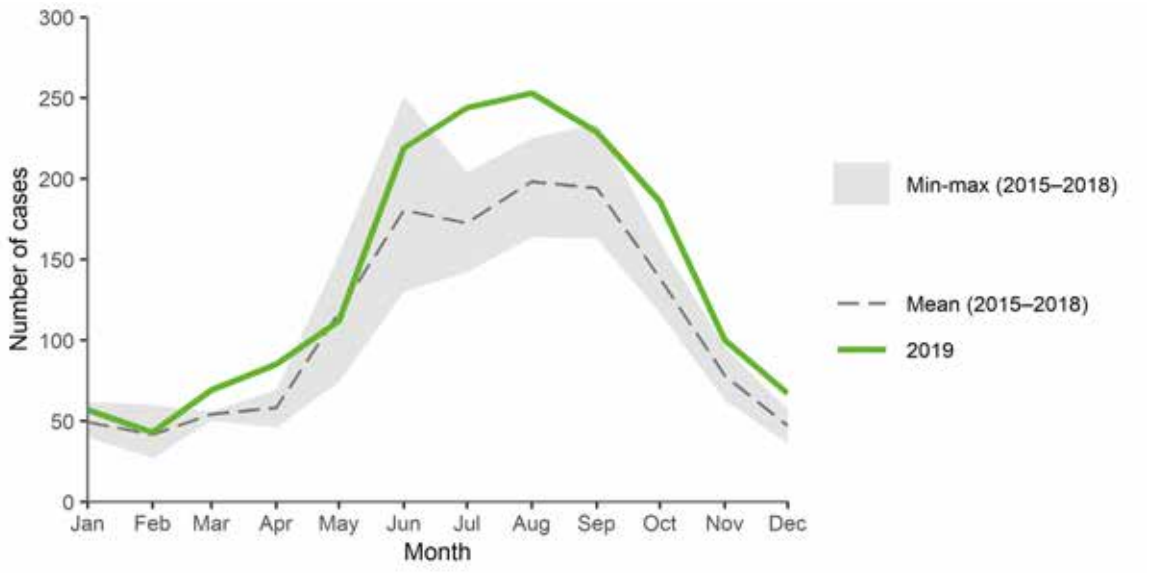


The reported TALD cases were resident in 35 countries. The majority of cases resided in those countries that reported the most cases, but 78 (4.7%) of cases were non-EU/EEA residents, from Switzerland (34), the USA (25), Australia (eight), Canada (four), China (three), Brazil (two), Mexico (one) and New Zealand (one).

The median time from date of onset to reporting to ELDSNet was 18 days, ranging from a minimum of 10−12 days (Latvia, France, Ireland and Norway) to a maximum of 50−53 days (Poland, Hungary and Portugal).

In 2019, two thirds of TALD cases fell ill between June and October, which is in line with the known seasonality for Legionnaires' disease (Figure 7).

Figure 7. Distribution of travel-associated cases of Legionnaires' disease by month, EU/EEA, 2019 and 2015−2018



Source: Country reports from Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, the United Kingdom.

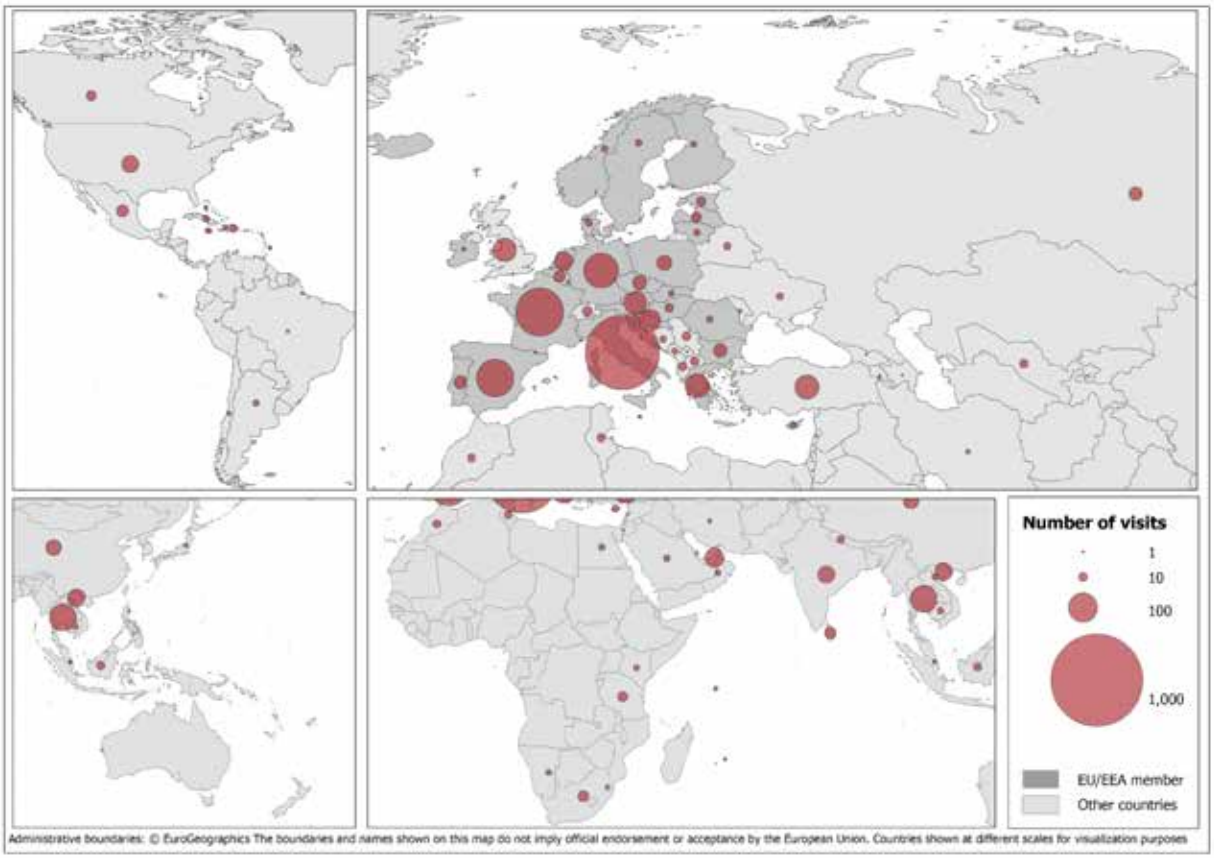
Outcome was provided for 1 036 (62.6%) TALD cases, with 26 (1.6%) known to have deceased by the time of reporting to ELDSNet. Deceased cases were between 43 and 91 years old, and 17 were male. A total of 1 553 TALD cases (94%) were classified as confirmed and 104 (6%) were probable cases. Of 1 801 laboratory tests, 85% were UATs, 12% were molecular tests (polymerase chain reaction, PCR) and 3% were cultures, while less than one percent were serological tests. Monoclonal subtyping results were reported for 14 cases with *L. pneumophila* serogroup 1: Philadelphia (five cases), Allentown/France (two cases), Benidorm (two cases), Knoxville (two cases), Bellingham (one case), Oxfolda (one case), and OLDA (one case). The sequence type was reported to ELDSNet for only 22 TALD cases from three countries: United Kingdom (15), Denmark (4), and Sweden (3). Three of the reported sequence types were ST42, three were ST62, two were ST1, two were ST37, and the others were a variety of single sequence types.

TALD case travel destinations

The 1 657 TALD cases had made a total of 2 410 international journeys. Of these, 1 723 (72%) were within the EU/EEA, 638 (26%) were outside the EU/EEA (Figure 8 and Figure 9), and 41 (2%) journeys were on ships. The three destination countries with most TALD associated travel visits were Italy (n=653, 28%), France (n=270, 11%), and Spain (n=164, 7%). Seventy-nine percent of the overnight stays were in hotels, 7% were in apartments, 6% on camping sites, 2% on ships, and 6% were reported as other types of accommodation.

Figure 8. Distribution of accommodation site visits made by travel-associated Legionnaires' disease cases, by destination country, EU/EEA and neighbouring countries, 2019

Figure 9. Distribution of accommodation site visits made by travel-associated Legionnaires' disease cases, by destination country, worldwide, 2019



In 2019, ELDSNet detected 176 new TALD clusters. A TALD cluster is an event involving two cases having visited the same accommodation site within a two-year period [4].The clusters were associated with accommodations in 30 countries worldwide (14 within the EU/EEA and 16 outside the EU/EEA), and two clusters were associated with vessels. Of the 176 new clusters from 2019, 125 (71%) comprised of only two cases. ELDSNet shared 60 summary reports of type 1 (non-EU/EEA clusters) with tour operators and 36 of type 2 (rapidly evolving clusters - i.e. three or more cases associated within three months).

For all 176 clusters, a preliminary site assessment report within two weeks of notification, followed by a final assessment report within six weeks of notification, were received by ECDC in accordance with the surveillance scheme operating procedures [4]. In 2019, the names of eight accommodation sites were published on ECDC's website, because assessment reports stated that recommendations from the competent authorities were not implemented in a satisfactory manner.

Outbreaks

In 2019, through the annual outbreak reporting surveillance scheme, five countries (France, Germany, Italy, Netherlands, and United Kingdom) reported a total of 29 community- or hospital-acquired outbreaks, ranging from three to nine per reporting country. The number of cases per reported outbreak ranged from two to 28 confirmed cases. Eight outbreaks were reported in association with hospitals and three in geriatric residences. Sixteen EU/EEA countries reported no outbreaks of Legionnaires' disease under 2019.

Discussion

In 2019, both the number and notification rate of Legionnaires' disease in the EU/EEA remained at the highest level observed, continuing an increase ongoing since 2013, although not an increase on the previous year. The main characteristics of Legionnaires' disease cases reported in 2019 were very similar to 2018, with most cases being sporadic and community-acquired and the disease mostly affecting males aged 65 years and above. A number of countries continue to have very low notification rates of below 0.5 cases per 100 000 population, which probably represents underestimation of the incidence in these countries. As only 10% of cases are reported with a culture-confirmed diagnosis there is probably an underestimation of the burden of disease caused by *Legionella* species other than by *Legionella pneumophila* across the EU/EEA.

Outbreaks of Legionnaires' disease of varying size and origin continue to be identified and investigated by public health authorities in the EU/EEA. However, the high number of cases reported annually is not caused by large outbreaks.

The cause for the continuing high levels of notified cases observed in 2019, as in 2018, remains unknown. Factors that could influence this include changes in national testing policy and surveillance systems; an ageing EU/EEA population and increasing travel trends; the design and infrastructure maintenance in building water systems, and changes in climate and weather patterns across Europe and worldwide that can impact both the ecology of *Legionella* in the environment and causes of exposure to water aerosols containing the bacteria.

Public health implications

Legionnaires' disease remains an important cause of potentially preventable morbidity and mortality in Europe and the burden appears to be increasing.

The overall EU/EEA notification rates has seen sharp rises in the last few years. However, variation in rates across EU/EEA countries remain, probably reflecting under-diagnosis of this disease in many Member States. A priority continues to be assisting those countries with very low notification rates in improving both the diagnosis and reporting of Legionnaires' disease to public health authorities.

Outbreaks of Legionnaires' disease of varying size and origin continue to be identified and investigated by public health authorities in EU/EEA countries. Due to the relatively high mortality associated with disease and considerable challenges for the rapid identification and control of environmental sources, it remains important to be vigilant through surveillance for the detection of clusters and outbreak events.

As detection of TALD clusters through the ELDSNet surveillance scheme leads to investigations and preventive action at accommodation sites by participating countries, the continuing detection of clusters primarily through this multi-country joint surveillance scheme shows its value for public health.

To support the strengthening of surveillance and outbreak investigation capacity in European countries, in 2019 ECDC started an annual EQA scheme on clinical and environmental samples of *Legionella* spp. The first report on the findings of the EQA scheme in participating laboratories from EU/EEA countries for the November 2019 distribution was published in 2020 [6].

Regular checks for the presence of *Legionella* bacteria and appropriate control measures applied to engineered water systems [5] may prevent cases of Legionnaires' disease at tourist accommodation sites and in hospitals, long-term healthcare facilities or other settings where sizeable higher-risk populations can be exposed.

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World Health Organization

Legionellosis

6 September 2022

العربية | 中文 | Français | Русский | Español

Key facts

- The bacterium L. pneumophila was first identified in 1977, as the cause of an outbreak of severe pneumonia in a convention centre in the USA in 1976.
- The most common form of transmission of Legionella is inhalation of contaminated aerosols produced in conjunction with water sprays, jets or mists of contaminated water sources. Infection can also occur by aspiration of contaminated water or ice, particularly in susceptible hospital patients.
- Legionnaires' disease has an incubation period of 2 to 10 days (but up to 16 days has been recorded in some outbreaks).
- Treatments exist, but there is currently no vaccine available for Legionnaires' disease.
- Death occurs through progressive pneumonia with respiratory failure and/or shock and multi-organ failure.
- Untreated Legionnaires' disease usually worsens during the first week.
- Of the reported cases, 75–80% are over 50 years and 60–70% are male.

Overview

Legionellosis varies in severity from a mild febrile illness to a serious and sometimes fatal form of pneumonia and is caused by exposure to the *Legionella* bacteria species found in contaminated water and potting mixes.

Cases of legionellosis are often categorized as being community, travel or hospital acquired based on the type of exposure.

Worldwide, waterborne *Legionella pneumophila* is the most common cause of cases including outbreaks. *Legionella pneumophila* and related species are commonly found in lakes, rivers, creeks, hot springs and other bodies of water. Other species including *L. longbeachae* can be found in potting mixes.

The bacterium *L. pneumophila* was first identified in 1977 as the cause of an outbreak of severe pneumonia in a convention centre in the USA in 1976. It has since been associated with outbreaks linked to poorly maintained artificial water systems.

The infective dose is unknown but can be assumed to be low for susceptible people, as illnesses have occurred after short exposures and 3 or more kilometres from the source of outbreaks. The likelihood of illness depends on the concentrations of *Legionella* in the water source, the production and dissemination of aerosols, host factors such as age and pre-existing health conditions and the virulence of the particular strain of *Legionella*. Most infections do not cause illness.

The cause

The causative agents are *Legionella* bacteria from water or potting mix. The most common cause of illness is the freshwater species *L. pneumophila*, which is found in natural aquatic environments worldwide. However, artificial water systems which provide environments conducive to the growth and dissemination of *Legionella* represent the most likely sources of disease.

The bacteria live and grow in water systems at temperatures of 20 to 50 degrees Celsius (optimal 35 degrees Celsius). *Legionella* can survive and grow as parasites within free-living protozoa and within biofilms which develop in water systems. They can cause infections by infecting human cells using a similar mechanism to that used to infect protozoa.

Transmission

The most common form of transmission of *Legionella* is inhalation of contaminated aerosols from contaminated water. Sources of aerosols that have been linked with transmission of *Legionella* include air conditioning cooling towers, hot and cold water systems, humidifiers and whirlpool spas. Infection can also occur by aspiration of contaminated water or ice, particularly in susceptible hospital patients, and by exposure of babies during water births. To date, there has been no reported direct human-to-human transmission.

Extent of the disease

Legionnaires' disease is believed to occur worldwide.

The identified incidence of Legionnaires' disease varies widely according to the level of surveillance and reporting. Since many countries lack appropriate methods of diagnosing the infection or sufficient surveillance systems, the rate of occurrence is unknown. In Europe, Australia and the USA there are about 10–15 cases detected per million population per year.

Of the reported cases, 75–80% are over 50 years and 60–70% are male. Other risk factors for community-acquired and travel-associated legionellosis include smoking, a history of heavy drinking, pulmonary-related illness, immuno-suppression, and chronic respiratory or renal illnesses.

Risk factors for hospital-acquired pneumonia are recent surgery, intubation (the process of placing a tube in the trachea), mechanical ventilation, aspiration, presence of nasogastric tubes, and the use of respiratory therapy equipment. The most susceptible hosts are immuno-compromised patients, including organ transplant recipients and cancer patients and those receiving corticosteroid treatment.

Delay in diagnosis and administration of appropriate antibiotic treatment, increasing age and presence of co-existing diseases are predictors of death from Legionnaires' disease.

Symptoms

Legionellosis is a generic term describing the pneumonic and non-pneumonic forms of infection with *Legionella*.

The non-pneumonic form (Pontiac disease) is an acute, self-limiting influenza-like illness usually lasting 2–5 days. The incubation period is from a few and up to 48 hours. The main symptoms are fever, chills, headache, malaise and muscle pain (myalgia). No deaths are associated with this type of infection.

Legionnaires' disease, the pneumonic form, has an incubation period of 2 to 10 days (but up to 16 days has been recorded in some outbreaks). Initially, symptoms are fever, loss of appetite, headache, malaise and lethargy. Some patients may also have muscle pain, diarrhoea and confusion. There is also usually an initial mild cough, but as many as 50% of patients can present phlegm. Blood-streaked phlegm or hemoptysis occurs in about one-third of the patients. The severity of disease ranges from a mild cough to a rapidly fatal pneumonia. Death occurs through progressive pneumonia with respiratory failure and/or shock and multi-organ failure.

Untreated Legionnaires' disease usually worsens during the first week. In common with other risk factors causing severe pneumonia, the most frequent complications of legionellosis are respiratory failure, shock and acute kidney and multi-organ failure. Recovery always requires antibiotic treatment, and is usually complete, after several weeks or months. In rare occasions, severe progressive pneumonia or ineffective treatment for pneumonia can result in brain sequelae.

The death rate as a result of Legionnaires' disease depends on the severity of the disease, the appropriateness of initial anti-microbial treatment, the setting where *Legionella* was acquired, and host factors (for example, the disease is usually more serious in patients with immuno-suppression). The death rate may be as high as 40–80% in untreated immuno-suppressed patients and can be reduced to 5–30% through appropriate case management and depending on the severity of the clinical signs and symptoms. Overall the death rate is usually within the range of 5–10%.

Response

Treatments exist, but there is no vaccine currently available for Legionnaires' disease.

The nonpneumonic form of infection is self-limiting and does not require medical interventions, including antibiotic treatment. Patients with Legionnaires' disease always require antibiotic treatment following diagnosis.

The public health threat posed by legionellosis can be addressed by implementing water safety plans by authorities responsible for building safety or water system safety. These plans must be specific to the building or water system and should result in the introduction and regular monitoring of control measures against identified risks including *Legionella*. Although it is not always possible to eradicate the source of infection, it is possible to reduce the risks substantially.

Prevention of Legionnaires' disease depends on applying control measures to minimize the growth of *Legionella* and dissemination of aerosols. These measures include good maintenance of devices, including regular cleaning and disinfection and applying other physical (temperature) or chemical measures (biocide) to minimize growth. Some examples are:

- the regular maintenance, cleaning and disinfection of cooling towers together with frequent or continuous addition of biocides;
- installation of drift eliminators to reduce dissemination of aerosols from cooling towers;
- maintaining an adequate level of a biocide such as chlorine in a spa pool along with a complete drain and clean of the whole system at least weekly;
- keeping hot and cold water systems clean and either keeping the hot water above 50 °C (which requires water leaving the heating unit to be at or above 60 °C) and the cold below 25 °C and

ideally below 20 °C or alternatively treating them with a suitable biocide to limit growth, particularly in hospitals and other health care settings, and aged-care facilities; and
- reducing stagnation by flushing unused taps in buildings on a weekly basis.

Applying such controls will greatly reduce the risk of *Legionella* contamination and prevent the occurrence of sporadic cases and outbreaks. Extra precautions may be required for water and ice provided to highly susceptible patients in hospitals including those at risk of aspiration (for example, ice machines can be a source of *Legionella* and should not be used by highly susceptible patients).

Control and prevention measures must be accompanied by proper vigilance on the part of general practitioners and community health services for the detection of cases.

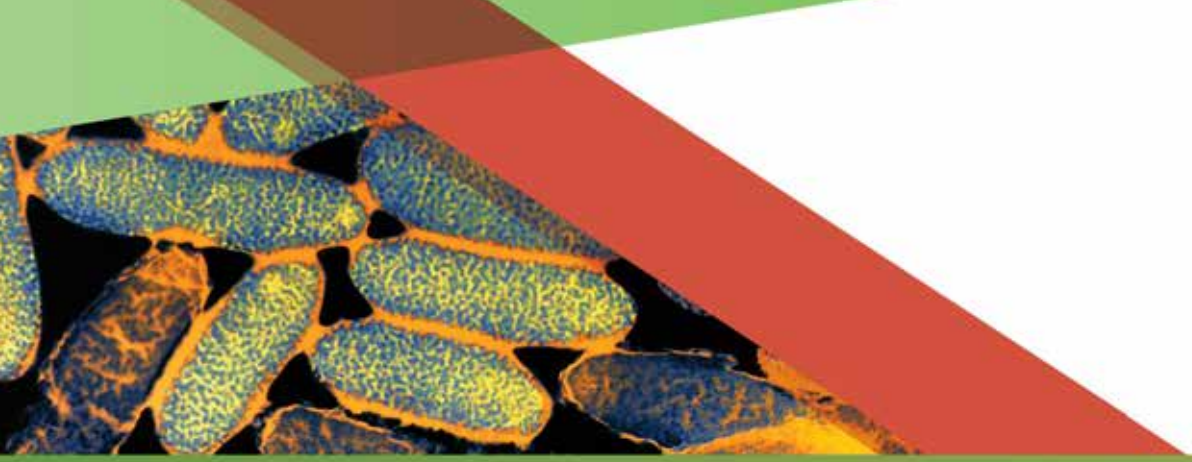
WHO makes available technical resources to support the management and control of legionellosis and advises Member States when specific queries are raised.

Publications

- Legionella and the prevention of legionellosis

Water and health

- Water safety in distribution systems
- Water safety in buildings



SURVEILLANCE REPORT

Legionnaires' disease

Annual Epidemiological Report for 2021

Key facts

- In 2021, the highest annual notification rate of Legionnaires' disease to date in the EU/EEA was observed, at 2.4 cases per 100 000 population.
- The rates are heterogenous across the EU/EEA region, with age-standardised rates varying by country between <1–5 cases per 100 000 population.
- Four countries (Italy, France, Spain, and Germany) accounted for 75% of all the notified cases.
- Males aged 65 years and above were the most affected group (8.9 cases per 100 000 population).
- Only 11% of the cases were reported as culture-confirmed. This is likely leading to an underestimation of cases of Legionnaires' disease caused by *Legionella* species other than *Legionella pneumophila*.
- The majority of the cases were considered to be community-acquired.
- Occurrence of at least one outbreak of Legionnaires' disease was reported by eight of the 27 EU/EEA countries reporting data to the outbreak reporting scheme.
- A total of 19 outbreaks involving 137 confirmed cases were reported.
- The travel-associated Legionnaires' disease (TALD) surveillance scheme observed a 38% increase in cases compared with 2020.
- Similar to previous years, 90% of the TALD cases occurred in individuals aged 45 years and above. A similar age distribution was observed in the annual retrospective data collection of cases of Legionnaires' disease.

Introduction

Legionnaires' disease is a multi-system disease which causes pneumonia due to an infection with the *Legionella* bacteria, most commonly of the species *Legionella pneumophila*. The bacteria are found in the natural environment, soil and water, but they can become a health risk when they grow within engineered systems that can produce inhalable water aerosols. Cooling towers, evaporative condensers, humidifiers, decorative fountains, hot tubs, showers, etc. are examples of water systems with identified *Legionella* risks. Conditions that are favourable for *Legionella* growth are water temperatures in the range of 25–42 °C, stagnant water with sediment build-up and low biocide levels. The aerosolisation of the contaminated water may cause sporadic cases or outbreaks.

Methods

This report is based on data for 2021 retrieved from The European Surveillance System (TESSy) on 9 September 2022. TESSy is a system for the collection, analysis, and dissemination of data on communicable diseases.

The methods used to produce this report are published by ECDC and can be found in the 'Introduction to the Annual Epidemiological Report' [1] together with an overview of the national surveillance systems [2]. A subset of the data used for this report is available through ECDC's online 'Surveillance Atlas of Infectious Diseases' [3].

The surveillance data were collected through three different schemes:

- annual retrospective data collection of cases of Legionnaires' disease (LD) reported in EU Member States, Iceland, Liechtenstein, and Norway;
- annual retrospective data collection of outbreak events detected and reported in EU Member States, Iceland, Liechtenstein, and Norway. The following thresholds for reporting outbreaks are used:
  - ≥ five cases, if these are not exposed in the same building, and there isn't evidence of exposure to the same aerosol-producing installation/device, nor microbiological evidence of linked cases;
  - ≥ three cases, if these are exposed in the same building, or if there is evidence for exposure to the same aerosol-producing installation/device, or microbiological evidence of linked cases;
- near real-time reporting of travel-associated cases of Legionnaires' disease (TALD) through the European Legionnaires' disease surveillance network (ELDSNet) [4], including reports from countries outside the EU/EEA. This scheme primarily aims at identifying clusters of cases that may otherwise not be detected at the national level, in order to quickly investigate them and take control measures at the implicated tourist accommodation site(s) to prevent further infections.

Cases of Legionnaires' disease should be reported to these surveillance schemes in accordance with the 2018 EU/EEA case definition [5] for confirmed or probable cases, that includes at least one positive laboratory test and a clinical diagnosis of pneumonia.

Annual case surveillance

Epidemiology

In 2021, 29 countries reported 10 723 cases (Table 1), of which 10 004 (93%) were classified as confirmed. The number of notifications per 100 000 population increased to 2.4, which was higher than any precedent year under surveillance. Four countries, Italy, France, Spain, and Germany, continued to account for the majority of notified cases (75%), although their combined populations represented approximately 50% of the EU/EEA population. Out of 8 054 cases with known outcome, 704 (9%) were reported to have a fatal outcome.

Table 1. Distribution of cases of Legionnaires' disease and rates per 100 000 population by country and year, EU/EEA, 2017–2021

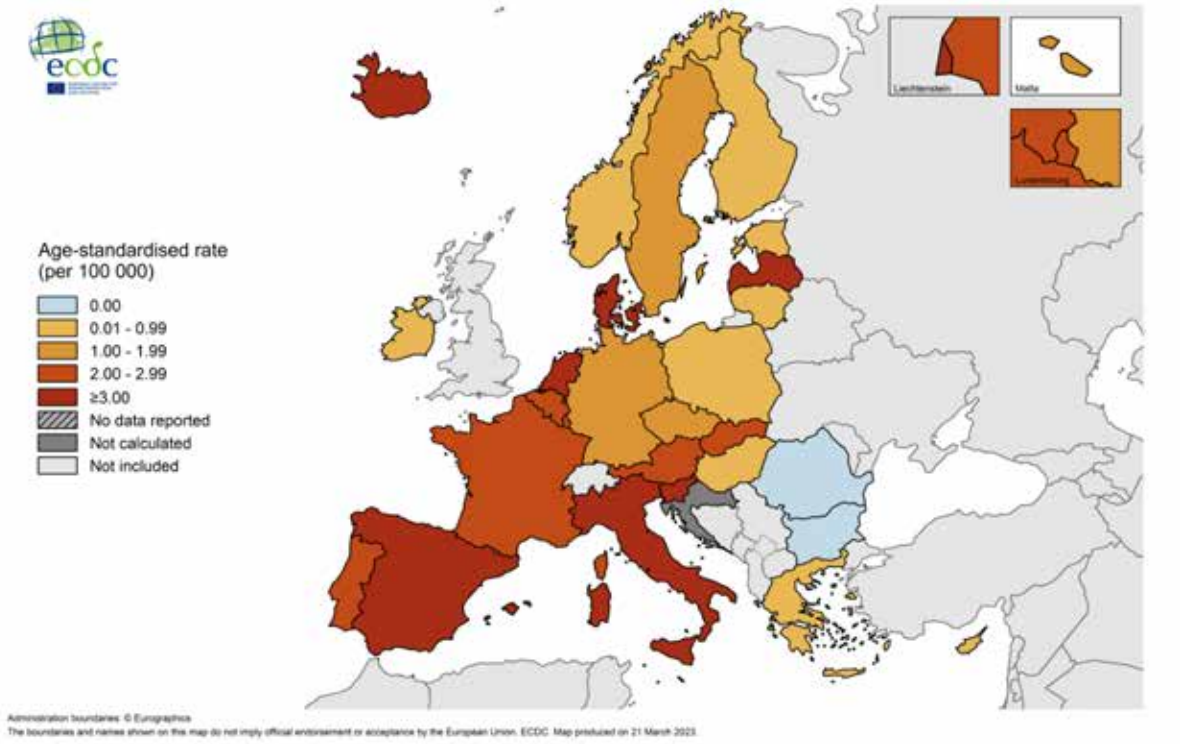
Country	2017		2018		2019		2020		2021		
	Number	Rate	Number	Rate	Number	Rate	Number	Rate	Number	Rate	ASR
Austria	219	2.5	237	2.7	255	2.9	249	2.8	278	3.1	2.8
Belgium	235	2.1	270	2.4	224	2.0	143	1.2	274	2.4	2.2
Bulgaria	2	0.0	11	0.2	5	0.1	7	0.1	1	0.0	0.0
Croatia	33	0.8	43	1.0	ND	NR	ND	NR	ND	NR	NR
Cyprus	1	0.1	5	0.6	4	0.5	3	0.3	4	0.4	0.5
Czechia	217	2.1	231	2.2	277	2.6	231	2.2	219	2.0	1.8
Denmark	278	4.8	264	4.6	269	4.6	278	4.8	281	4.8	4.3
Estonia	16	1.2	18	1.4	12	0.9	18	1.4	10	0.8	0.7
Finland	27	0.5	24	0.4	44	0.8	24	0.4	34	0.6	0.5
France	1 630	2.4	2 133	3.2	1 816	2.7	1 328	2.0	2 039	3.0	2.8
Germany	1 279	1.5	1 448	1.7	1 554	1.9	1 272	1.5	1 524	1.8	1.5
Greece	43	0.4	65	0.6	45	0.4	29	0.3	25	0.2	0.2
Hungary	62	0.6	74	0.8	113	1.2	101	1.0	85	0.9	0.8
Iceland	3	0.9	5	1.4	4	1.1	4	1.1	10	2.7	3.1
Ireland	25	0.5	25	0.5	21	0.4	12	0.2	4	0.1	0.1
Italy	2 037	3.4	3 018	5.0	3 205	5.4	2 120	3.6	2 726	4.6	3.6
Latvia	31	1.6	37	1.9	42	2.2	27	1.4	61	3.2	3.0
Liechtenstein	ND	NR	ND	NR	ND	NR	ND	NR	2	5.1	4.7
Lithuania	14	0.5	21	0.7	17	0.6	12	0.4	4	0.1	0.1
Luxembourg	9	1.5	10	1.7	14	2.3	10	1.6	17	2.7	2.8
Malta	11	2.4	13	2.7	5	1.0	16	3.1	8	1.6	1.5
Netherlands	561	3.3	584	3.4	566	3.3	461	2.6	658	3.8	3.4
Norway	52	1.0	69	1.3	65	1.2	39	0.7	43	0.8	0.8
Poland	38	0.1	70	0.2	74	0.2	46	0.1	46	0.1	0.1
Portugal	231	2.2	211	2.1	201	2.0	307	3.0	254	2.5	2.2
Romania	19	0.1	62	0.3	19	0.1	8	0.0	8	0.0	0.0
Slovakia	14	0.3	54	1.0	85	1.6	98	1.8	148	2.7	2.7
Slovenia	117	5.7	160	7.7	196	9.4	120	5.7	88	4.2	3.7
Spain	1 363	2.9	1 513	3.2	1 542	3.3	1 336	2.8	1 704	3.6	3.1
Sweden	189	1.9	198	2.0	182	1.8	135	1.3	168	1.6	1.4
United Kingdom[1]	504	0.8	532	0.8	517	0.8	ND	ND	ND	ND	ND
EU/EEA	9 260	1.8	11 405	2.2	11 373	2.2	8 434	1.9	10 723	2.4	2.1

Source: country reports
ASR: age-standardised rate
ND: no data reported
NR: no rate calculated.

[1] The United Kingdom (UK) was a former Member State of the European Union (EU). The UK withdrew from the EU on 31 January 2020.

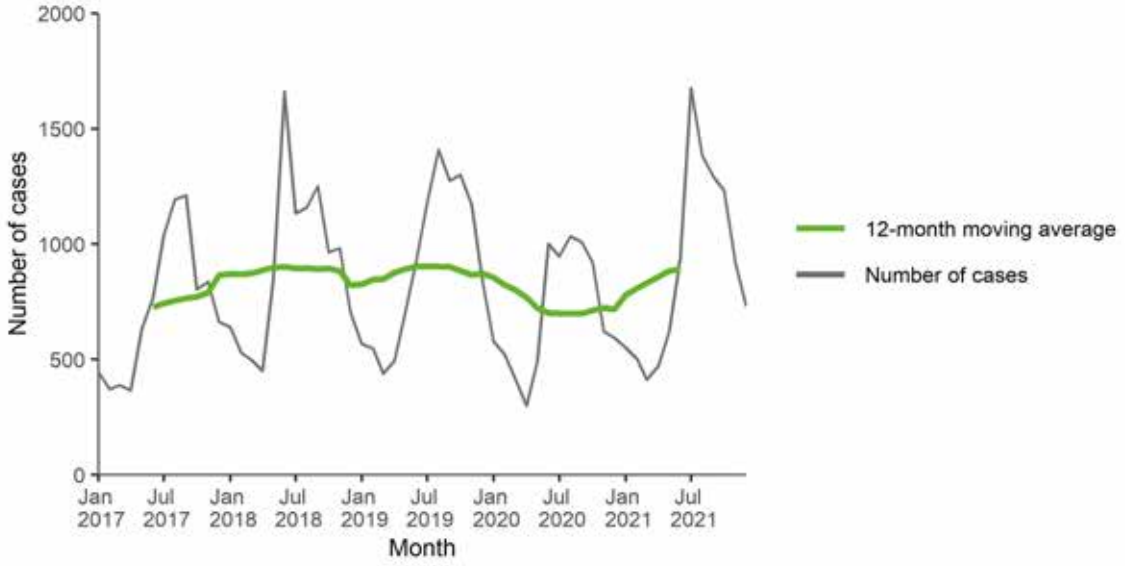
Age-adjusted notification rates ranged from less than 1.0 cases per 100 000 population in 11 countries (Bulgaria, Cyprus, Estonia, Finland, Greece, Hungary, Ireland, Lithuania, Norway, Poland, and Romania), to 3.0 cases or more per 100 000 population in eight countries (Denmark, Iceland, Italy, Latvia, Liechtenstein, Netherlands, Slovenia, and Spain; see Table 1 and Figure 1).

Figure 1. Distribution of cases of Legionnaires' disease per 100 000 population by country, EU/EEA, 2021



The general trend in the 2017–2021 period, has been of an increasing number of reported cases, other than the decrease during the COVID-19 pandemic period (Table 1; Figure 2).

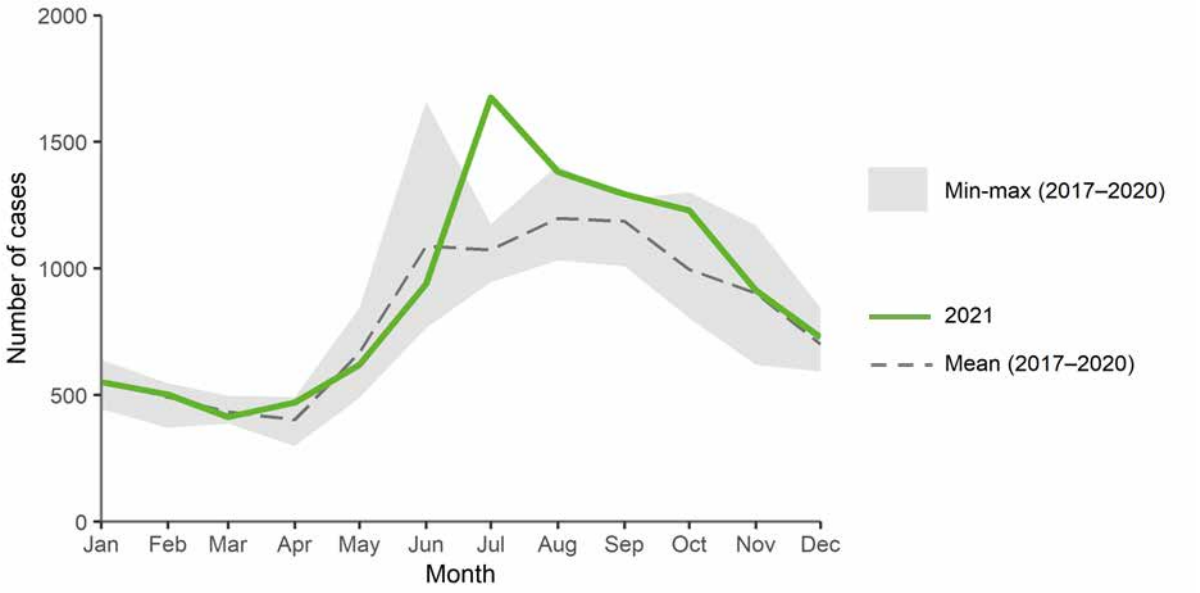
Figure 2. Distribution of cases of Legionnaires' disease by month, EU/EEA, 2017–2021



Source: Country reports from Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

In 2021, the distribution of cases by month of reporting shows that the majority (6 521; 61%) of cases occurred between June and October, similar to previous years (Figure 3). An unusual peak in the number of cases was reported in July (1 676 cases), which was similar to that observed in June 2018 (shown in the range distribution in Figure 3). These peaks occurred in the absence of any specific outbreak event in a country. The overall distribution for all other months was within the range of the previous four years.

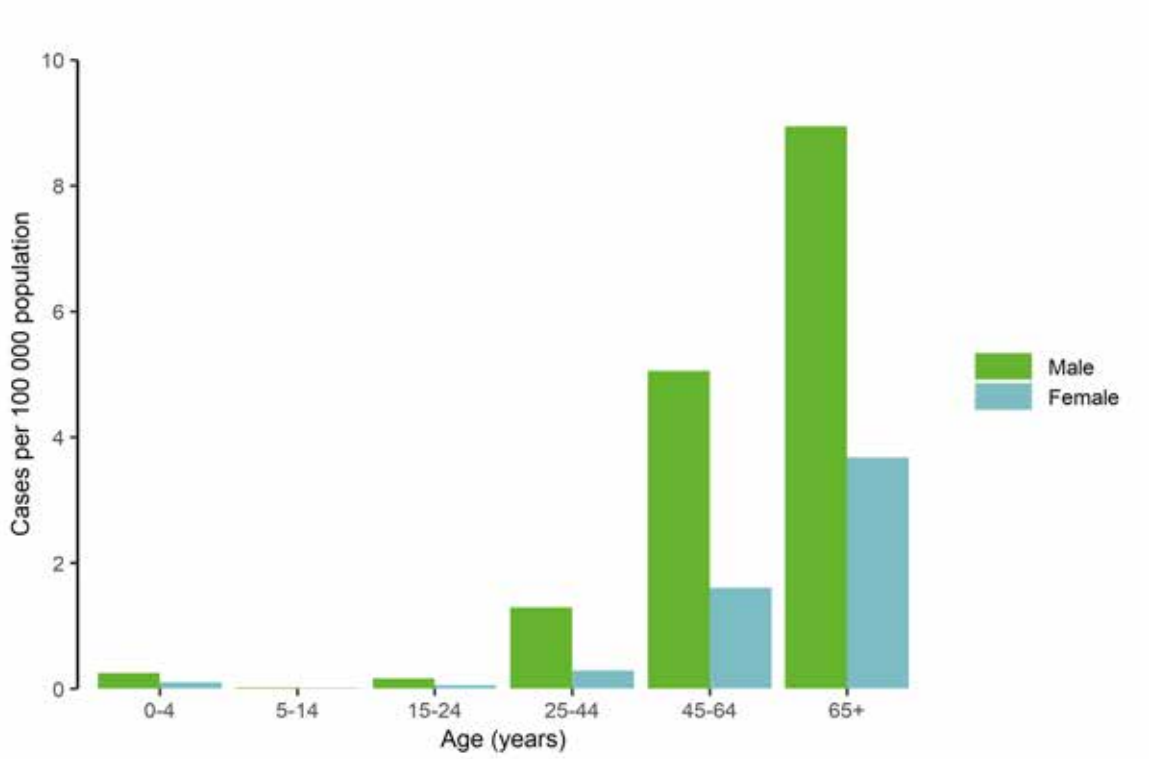
Figure 3. Distribution of cases of Legionnaires' disease by month, EU/EEA, 2021 and 2017–2020



Source: Country reports from Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

In 2021, people aged 45 years and above accounted for 9 706 (91%) of the 10 720 cases reported with known age. The notification rate increased with age, from ≤0.2 cases per 100 000 population in the age groups under 25 years, to 6.0 cases per 100 000 population in persons aged 65 years and above. The overall male-to-female ratio was 2.4:1, which remained comparable to previous years (range 2.3–2.4:1, from 2017–2020). The notification rate differed by gender, with the highest rate of 8.9 cases per 100 000 population reported in males aged 65+ years (3.7 cases per 100 000 population for females; Figure 4).

Figure 4. Distribution of cases of Legionnaires' disease per 100 000 population, by age and gender, EU/EEA, 2021



The majority of cases in 2021 (9 566/10 723; 89%) were reported to be diagnosed with a urinary antigen test (UAT). This was within the range of cases (88–90%) diagnosed with UAT testing reported since 2012. In comparison, fewer cases were reported having been diagnosed with a culture test (1 183 cases; 11%). This is in line with the low-level use of culture as a reported method of diagnosis, observed during the same period. The use of polymerase chain reaction (PCR) method tests was reported for 1 255 cases (12%).

Among culture-confirmed cases with the pathogen reported (1 133; 11%), a total of 32 *Legionella* non-*pneumophila* species were reported (3%): *L. anisa* (2), *L. bozemanii* (4), *L. longbeachae* (22), *L. micdadei* (3) and *L. cincinnatiensis* (1). Of the 1 133 cases, 14 were reported as *Legionella* species unknown.

Table 2 further illustrates that *Legionella pneumophila* isolates other than serogroup 1 were also detected and reported, but with a low proportion (<20%).

Table 2. Serogroups reported for culture-confirmed cases of *L. pneumophila*, EU/EEA, 2020 and 2021

Serogroup (SG)	2020		2021	
	Number	%	Number	%
1	685	83	890	82
2	5	<1	14	1
3	22	3	46	4
4	0	<1	3	<1
5	4	<1	5	<1
6	16	2	10	1
7	3	<1	6	1
8	5	<1	2	<1
9	3	<1	1	<1

Serogroup (SG)	2020		2021	
	Number	%	Number	%
10	1	<1	5	<1
11	0	-	0	-
12	1	<1	1	<1
13	2	<1	1	<1
14	0	-	1	<1
15	2	<1	0	-
16	1	<1	0	-
L. pneumophila non-serogroup 1	5	<1	6	1
L. pneumophila serogroup mixed	3	<1	3	<1
L. pneumophila serogroup unknown	70	8	93	9
TOTAL	828		1 087	

For over 75% of the cases (8 276), the setting of infection was reported as community-acquired. The increase in comparison with 2020 (Table 3) may be due to fewer cases reported with the setting of infection as unknown (19% to 5%). Healthcare-associated infection was identified as the source in 5% of all the cases reported, which was similar to previous years (range: 5–6%, from 2017–2020). The proportion of cases attributed to travel (domestic and international travel, including stays at private accommodations) was 10%, which was still lower than the travel-associated cases prior to the COVID-19 pandemic.

Table 3. Reported settings of infection for cases of Legionnaires' disease, EU/EEA, 2020 and 2021

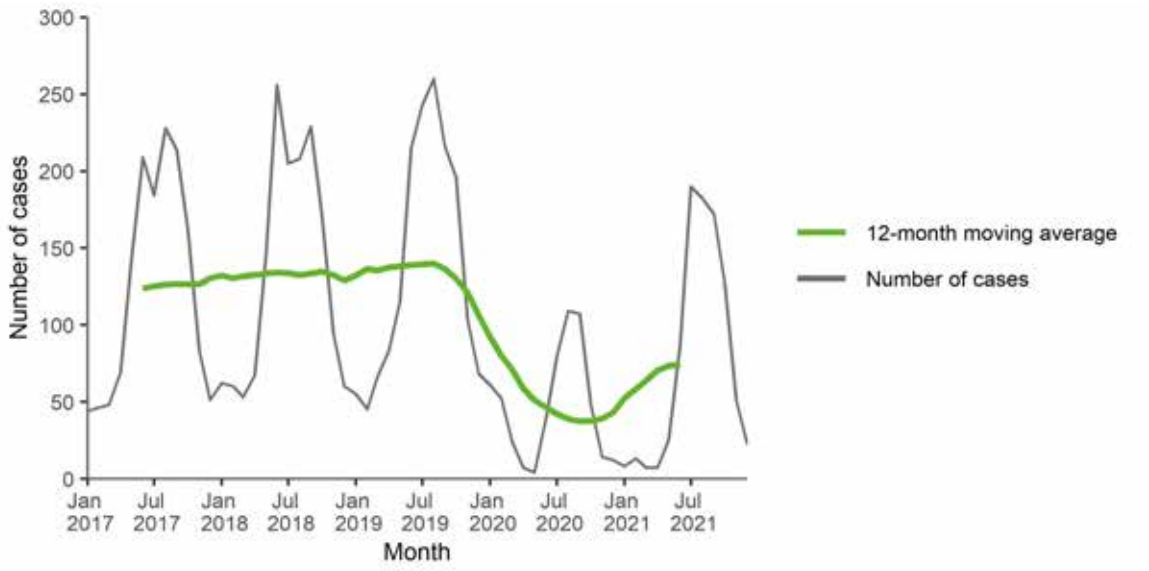
Setting	2020		2021	
	Number	%	Number	%
Community-acquired	5 643	67	8 276	77
Domestic travel	402	5	658	6
Healthcare-associated	432	5	584	5
Travel abroad	253	3	457	4
Other	147	2	268	3
Unknown	1 557	18	480	5
TOTAL	8 434	100	10 723	100

Travel-associated Legionnaires' disease (TALD)

TALD case reports

The European Legionnaires' disease surveillance network (ELDSNet) received reports of 895 cases of TALD with dates of onset in 2021, which is 38% more cases compared to 2020. The overall EU/EEA trend of reported cases of TALD (Figure 5) remained stable between 2017 to 2019, but decreased notably in 2020. This was probably an effect of the COVID-19 pandemic and associated travel restrictions. In 2021, the easing of travel restrictions is the likely reason for the observed increase in notified TALD cases compared to 2020.

Figure 5. Distribution of travel-associated cases of Legionnaires' disease by month, EU/EEA, 2017–2021

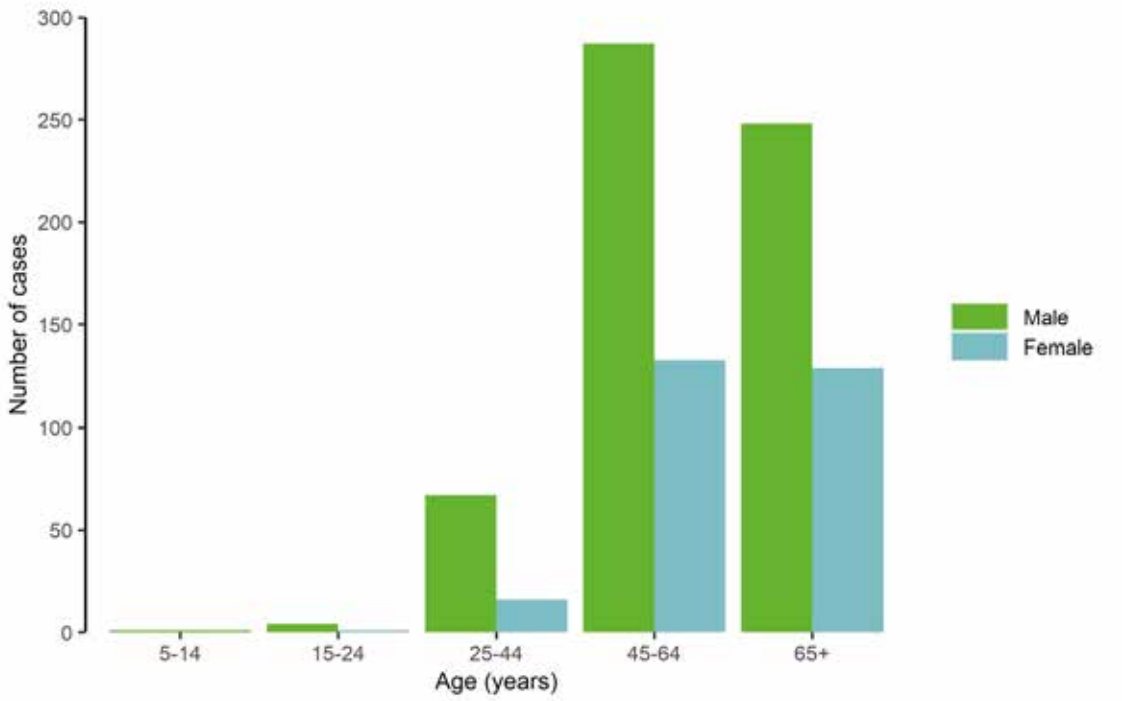


Source: Country reports from Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, and the United Kingdom (inclusive of data from 2017–2020). The other reporting countries have been excluded from this figure due to missing data from 2017–2021.

TALD cases were reported from 19 countries: 17 EU/EEA countries and two countries outside the EU/EEA. The two countries were, United States (one case) and Switzerland (19 cases). The UK no longer participated in the ELDSNet TALD surveillance scheme from January 2021. The majority (86%; n=722) of all the TALD cases were reported by only four countries: Italy (n=257; 36%), France (n=196; 27%), Germany (n=156; 22%), and the Netherlands (n=113; 16%).

Approximately two-thirds (68%; n=611) of the reported TALD cases were male, which is consistent with previous years. The cases had a median age of 62 years (interquartile range – IQR: 17.5, age range: 10–98 years); 90% of the cases occurred in people aged 45 years and above (Figure 6).

Figure 6. Distribution of travel-associated cases of Legionnaires' disease by age and gender, 2021

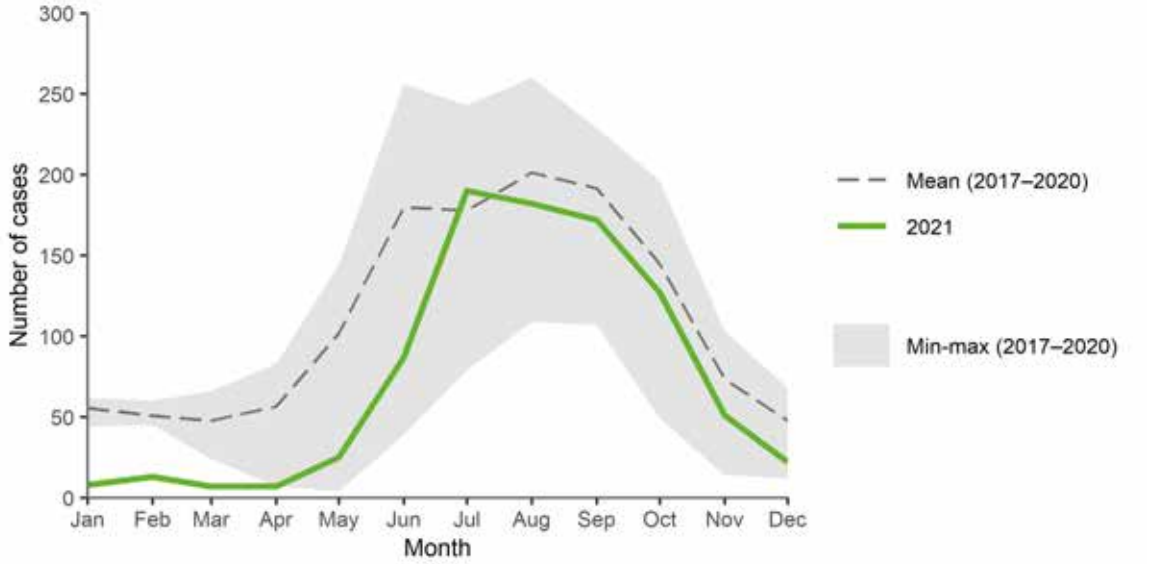


The reported TALD cases were resident in 20 countries. The majority of the cases resided in those countries that reported the most number of cases (Italy, France, Germany, and the Netherlands), while 26 of all cases (3%) were resident outside of the EU/EEA: Switzerland (19), the UK (5), and the United States (2).

In 2021, the median reporting time among countries (from the date of onset of illness, to reporting to ECDC) across countries was 18 days (IQR: 23 days) compared to 22 days (IQR: 42 days) in 2020.

In 2021, three quarters (n=662; 74%) of TALD cases fell ill between July and October, which is consistent with the known seasonality of Legionnaires' disease in Europe. However, there was a slightly delayed start of the summer peak season. This was likely due to the pandemic-related travel restrictions (Figure 7).

Figure 7. Distribution of travel-associated cases of Legionnaires' disease by month, EU/EEA, 2021 and 2017–2020



Source: Country reports from Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, and the United Kingdom (inclusive of data from 2017–2020). The other reporting countries have been excluded from this figure due to missing data from 2017–2021.

The disease outcome was provided for 473 (53%) TALD cases, with 11 (2%) known to have deceased by the time of reporting to ECDC. The deceased cases were between 47 and 95 years old, and 10 were male. A total of 859 TALD cases (96%) were classified as confirmed, and 36 (4%) as probable. Of 945 total laboratory tests reported in the diagnosis of 895 TALD cases, 90% were UATs, 7% were molecular tests (PCR), 3.5% were cultures, and less than one percent were serologic tests.

Among the cases with known information (n=860), the majority of pathogens were labelled as serogroup 1 *Legionella pneumophila* (n=797; 93%) or *Legionella pneumophila* serogroup unknown (n=40; 5%). A few cases were reportedly infected with other *L. pneumophila* serogroups, including serogroup 10 (three cases), serogroup 3 (one case), serogroup 6 (one case), serogroup 14 (one case), and non-serogroup 1 (16 cases). Monoclonal subtyping results were reported for five cases with *L. pneumophila* serogroup 1: France (one case), Allentown/France (one case), Philadelphia (one case), and Benidorm (two cases). The sequence types were reported to ECDC for only nine TALD cases from three countries: Czechia (three), Denmark (four), and Sweden (two). The sequence types reported for each of the nine cases were different (ST1, ST9, ST23, ST42, ST93, ST114, ST213, ST222 and ST1362).

Travel destinations for TALD cases

The 895 TALD cases reported in 2021 had made a total of 1 125 international journeys. Of these, 1 040 (92%) were within the EU/EEA, 75 (7%) were outside the EU/EEA, and 10 (1%) journeys were on ships. The three destination countries with most TALD-associated travel visits were Italy (n=475, 42%), France (n=220, 20%), and Spain (n=80, 7%). Seventy-seven percent of the overnight stays were in hotels, 10% were on camp sites, 10% in rentals, 1% on ships, and 2% were reported as other types of accommodation.

TALD clusters

In 2021, the ELDSNet surveillance scheme detected 79 new TALD clusters. A TALD cluster is the event of two cases having visited the same accommodation site within a two-year period [4]. The clusters were associated with accommodations in 14 countries worldwide (10 within the EU/EEA, and four outside the EU/EEA) and two ships. Of the 79 new clusters, 51 clusters (65%) comprised only two cases, 26 (33%) had between three and six cases, and one cluster each had 10 and 11 cases, respectively. In 2021, ECDC shared 11 summary reports of type 1 TALD clusters (clusters outside the EU/EEA) with tour operators, and 19 summary reports of type 2 TALD clusters (rapidly evolving clusters, i.e. three or more cases associated within a period of three months) [4].

The names of five accommodation sites were published by ECDC, because country assessments reported that recommendations from the competent authorities were not implemented in a satisfactory way.

Outbreak

In 2021, 27 out of 30 countries participated in the annual outbreak reporting surveillance scheme. Eight EU/EEA countries (Belgium, Germany, Italy, France, Finland, the Netherlands, Portugal, and Spain) reported a total of 19 outbreaks, ranging from one to five per reporting country. In total, 137 outbreak-related confirmed cases were reported. The number of cases per reported outbreak ranged from 3–18 confirmed cases.

Nineteen EU/EEA countries (Austria, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Greece, Hungary, Ireland, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Norway, Romania, Slovakia, Slovenia, and Sweden) reported no outbreaks of Legionnaires' disease in 2021.

Seven (37%) of the 19 reported outbreaks in the EU/EEA in 2021, were reported as community outbreaks, which were proportionally more than the previous years of reporting. During the period 2016–2020, the number of reported community outbreaks ranged between 2–8, contributing to about 14% of annual outbreaks. One outbreak was reported to be associated with a car wash, and another was reported to be linked with a municipal water system. Five outbreaks had a positive match with environmental samples. However, this information was only available for 12 out of the 19 outbreaks reported.

Discussion

The notification rate of cases of Legionnaires' disease increased in 2021 in comparison with 2020, reaching the highest level ever reported through ECDC surveillance in the EU/EEA. This increased annual notification rate may not be unexpected considering the increasing trend observed in recent years prior to the COVID-19 pandemic [6]. The seasonality pattern was similar to previous years, despite a higher peak in the number of cases observed in July. The occurrence of a sporadic high monthly count as noted in July had been previously observed in June 2018. No surveillance-related cause for this increase could be identified, e.g. reporting, definitions, or diagnostic practice. Similar to other years within the last decade, climate records indicate that temperatures are increasing in Europe in summer, with 2021 being among the highest recorded to date. Of note, some countries were also affected by severe flooding in July 2021 [7].

The main characteristics of cases of Legionnaires' disease reported in 2021 were similar to 2020, with most cases being sporadic, community-acquired, and among those aged over 45 years. The disease continues to affect males more than females, and reaches the highest rates in those aged 65 years and above.

A number of countries continue to have very low notification rates below 0.5 cases per 100 000 population. This probably represents an underestimation of the case incidence in these countries. As only 11% of cases are reported with a culture-confirmed diagnosis, there is a likely underestimation of the burden of disease caused by the *Legionella* species across the EU/EEA other than *Legionella pneumophila*.

In 2021, outbreaks were detected and investigated in several countries. Proportionally more community outbreaks were reported compared to previous years, though the number of cases per outbreak were similar.

The cause of the higher notification rate observed in Europe both in the years immediately preceding 2020, and in 2021 during the COVID-19 pandemic, remains unknown. Factors that may explain these increases include: changes in national testing policies and surveillance systems, an ageing EU/EEA population, the design, infrastructure, and maintenance of water systems used in buildings. Changes in climate and weather patterns across Europe and worldwide can also impact both the ecology of *Legionella* in the environment and the exposure to water aerosols containing the bacteria.

Public health implications

Legionnaires' disease remains an important cause of potentially preventable morbidity and mortality in Europe.

The overall EU/EEA notification rates have been rising in the last few years, although there was a decrease observed in 2020 during the first phase of the pandemic when stringent restrictions were in place. Variation in rates across EU/EEA countries remain, which likely reflect the under-diagnosis of this disease in many Member States. Support to countries with very low notification rates remains a priority to improve both the diagnosis and reporting of Legionnaires' disease to public health authorities.

Outbreaks of Legionnaires' disease with varying sizes and causes continue to be identified and investigated by public health authorities in EU/EEA countries. Due to the relatively high mortality associated with the disease and the considerable challenges for the rapid identification and control of environmental sources, it remains important to be vigilant to detect clusters and outbreak events through surveillance.

As the detection of TALD clusters through the ELDSNet surveillance scheme leads to investigations and preventive actions at accommodation sites by participating countries, cluster detection through this multi-country joint surveillance scheme shows its importance for public health.

To support the strengthening of surveillance and outbreak investigation capacity in European countries, in 2019, ECDC started an annual external quality assessment (EQA) scheme on clinical and environmental samples of *Legionella* species. Annual summary reports for the results of this EQA scheme are published by ECDC [8].

Regular checks for the presence of *Legionella* bacteria and appropriate control measures applied to engineered water systems [9] can prevent cases of Legionnaires' disease at tourist accommodation sites, hospitals, long-term healthcare facilities, or other settings where sizeable populations at higher risk may be exposed to aerosols containing the bacteria.

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A Large, Refractory Nosocomial Outbreak of *Klebsiella pneumoniae* Carbapenemase-Producing *Escherichia coli* Demonstrates Carbapenemase Gene Outbreaks Involving Sink Sites Require Novel Approaches to Infection Control

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ABSTRACT Carbapenem-resistant *Enterobacteriaceae* (CRE) represent a health threat, but effective control interventions remain unclear. Hospital wastewater sites are increasingly being highlighted as important potential reservoirs. We investigated a large *Klebsiella pneumoniae* carbapenemase (KPC)-producing *Escherichia coli* outbreak and wider CRE incidence trends in the Central Manchester University Hospital NHS Foundation Trust (CMFT) (United Kingdom) over 8 years, to determine the impact of infection prevention and control measures. Bacteriology and patient administration data (2009 to 2017) were linked, and a subset of CMFT or regional hospital KPC-producing *E. coli* isolates ($n = 268$) were sequenced. Control interventions followed international guidelines and included cohorting, rectal screening ($n = 184{,}539$ screens), environmental sampling, enhanced cleaning, and ward closure and plumbing replacement. Segmented regression of time trends for CRE detections was used to evaluate the impact of interventions on CRE incidence. Genomic analysis ($n = 268$ isolates) identified the spread of a KPC-producing *E. coli* outbreak clone (strain A, sequence type 216 [ST216]; $n = 125$) among patients and in the environment, particularly on 2 cardiac wards (wards 3 and 4), despite control measures. ST216 strain A had caused an antecedent outbreak and shared its KPC plasmids with other *E. coli* lineages and *Enterobacteriaceae* species. CRE acquisition incidence declined af-

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ter closure of wards 3 and 4 and plumbing replacement, suggesting an environmental contribution. However, ward 3/ward 4 wastewater sites were rapidly recolonized with CRE and patient CRE acquisitions recurred, albeit at lower rates. Patient relocation and plumbing replacement were associated with control of a clonal KPC-producing *E. coli* outbreak; however, environmental contamination with CRE and patient CRE acquisitions recurred rapidly following this intervention. The large numbers of cases and the persistence of bla_{KPC} in *E. coli*, including pathogenic lineages, are of concern.

KEYWORDS antimicrobial resistance, carbapenemase-producing *Enterobacteriaceae*, genome sequencing, infection control, molecular epidemiology

Carbapenem-resistant *Enterobacteriaceae* (CRE) represent a global public health threat (1). Major carbapenemases include the metallo-β-lactamases, some oxacillinases, and the *Klebsiella pneumoniae* carbapenemase (KPC) (encoded by bla_{KPC}), one of the most common carbapenemases globally (2). Transfer of carbapenemase genes on mobile genetic elements has resulted in rapid interspecies dissemination of carbapenem resistance (3, 4). Since few therapeutic options remain for CRE infections (5, 6), effective control is critical.

Escherichia coli is a major human pathogen, but it also a gastrointestinal commensal and can be transmitted between humans and the environment. Carbapenem resistance in *E. coli*, including that encoded by bla_{KPC}, is increasing (7, 8) but is uncommon, and KPC-producing *E. coli* outbreaks have not been observed to date. The emergence and persistence of carbapenem resistance in *E. coli* in human and/or environmental reservoirs are of concern.

CRE detections in England have increased since 2008 (9) and are approximately 10 times the national average in Greater Manchester (10). Central Manchester University Hospital NHS Foundation Trust (CMFT) has experienced an ongoing, multispecies, bla_{KPC}-associated CRE outbreak since 2009. Intensive infection prevention and control (IPC) measures, in line with national and international recommendations (11–13), have been implemented in response.

In 2015, a sudden increase in cases of fecal colonization with KPC-producing *E. coli* was detected in the Manchester Heart Centre (MHC) at the Manchester Royal Infirmary (part of CMFT). We retrospectively investigated the genomic epidemiology and evidence for nosocomial transmission of KPC-producing *E. coli* and KPC plasmids isolated from patients and the environment in this context, and we assessed the impact of guideline-compliant IPC bundles on CRE and KPC-producing *E. coli* incidence.

RESULTS

High prevalence of CRE colonization in the MHC. Between 1 April 2014 and 30 December 2014, 23 new CRE-colonized individuals were detected in the MHC, including 2 with *E. coli* (Fig. 1A). A CRE outbreak was declared on 2 January 2015, when 6 new CRE-colonized individuals were identified (4 with bla_{KPC} and 2 with bla_{NDM}; no *E. coli*). Consequently, intensified IPC measures were implemented (Fig. 1B; also see Table S1 in the supplemental material), and wards 3 and 4 were closed (on 6 January 2015), terminally cleaned (with hypochlorite), and decontaminated (with hydrogen peroxide vapor). Ward 3 was reopened on 11 January 2015, and ward 4 was reopened on 23 January 2015. High-risk patients (with previously detected CRE or a history of hospitalization abroad or in a UK hospital with known CRE transmission in the past 12 months) were screened; CRE-positive patients were transferred to a cohort ward or, if they required cardiac monitoring, to side rooms.

By January 2015, CMFT was operating a Trustwide CRE screening program (>110 screens/day) (Table S2). Between 1 September 2014 and 30 December 2014, screening transitioned from culture-based methods to PCR-based methods; during this period, 16,612 samples from 7,239 inpatients were screened using either culture (9,808 samples) or PCR and culture (6,804 samples), with an overall CRE prevalence of 3.8% (438

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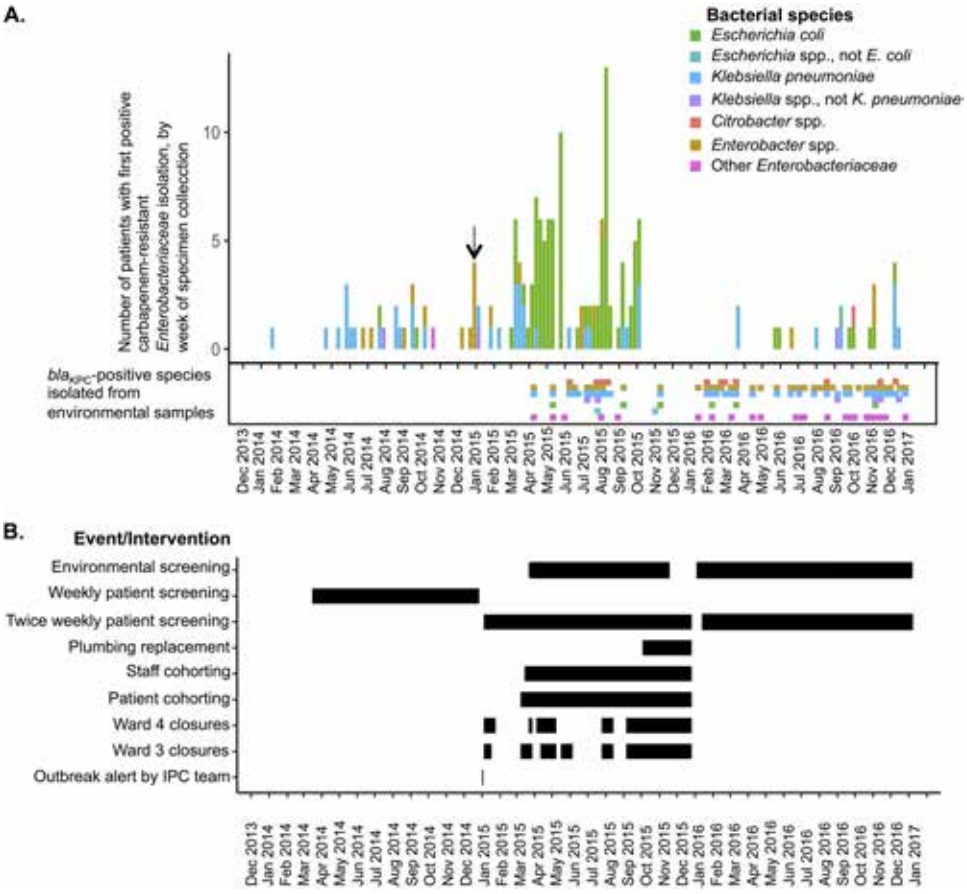

FIG 1 (A) Numbers of individuals in MHC wards with first CRE-positive detection, by week, stratified by genus group and species of the organism isolated. The bla_{KPC}-positive *Enterobacteriaceae* strains detected in environmental samples over the same time frame are also shown. The MHC outbreak was declared by the IPC team in the first week in 2015 (arrow). (B) Timeline of IPC measures instituted.

positive samples from 272 patients). Molecular mechanism data for 135/163 PCR-positive samples (83%) indicated that bla_{KPC} accounted for most carbapenem resistance (97%).

KPC-producing *E. coli* outbreak despite IPC interventions. Following the implementation of enhanced IPC activity, there was a further sharp increase in the number of CRE-colonized patients detected from 9 March 2015 (carbapenem-resistant [CR] *E. coli* and other species, mostly containing bla_{KPC} and a few with bla_{NDM}) (Fig. 1A). Ward 3 was again closed to admissions (from 11 March 2015 to 28 March 2015), and environmental decontamination was repeated; the following week, ward 4 was closed after detection of additional CRE-colonized patients (Fig. 1A and B). From 1 April 2015, KPC-producing *E. coli* predominated in the outbreak (Fig. 1A).

From April to September 2015, wards 3 and 4 were closed repeatedly, with 2 peaks in KPC-producing *E. coli* patient colonization (in April to May and in August) (Fig. 1B). Ward 3 capacity was reduced to 10 day-case beds (on 12 August 2015; day-case patients were not screened for CRE) and ward 4 capacity to 12 inpatient beds. Between 10 August 2015 and 28 September 2015, there were 27 new KPC-producing *E. coli* colonizations detected in the MHC (Fig. 1A) and 2 cases with other KPC-producing *Enterobacteriaceae* species. Of 88 KPC-producing *E. coli* cases between 24 February 2015 and 28 September 2015, 86 (98%) represented colonizations only; 1 individual additionally had a urinary tract infection and 1 a sternal wound infection (treated with gentamicin and ciprofloxacin, respectively, to which the isolates were susceptible).

CR *E. coli* cases in CMFT. CR *E. coli* had been isolated in CMFT prior to the 2015 MHC outbreak, with 514 CR *E. coli* cases (considering first positive results by patient from

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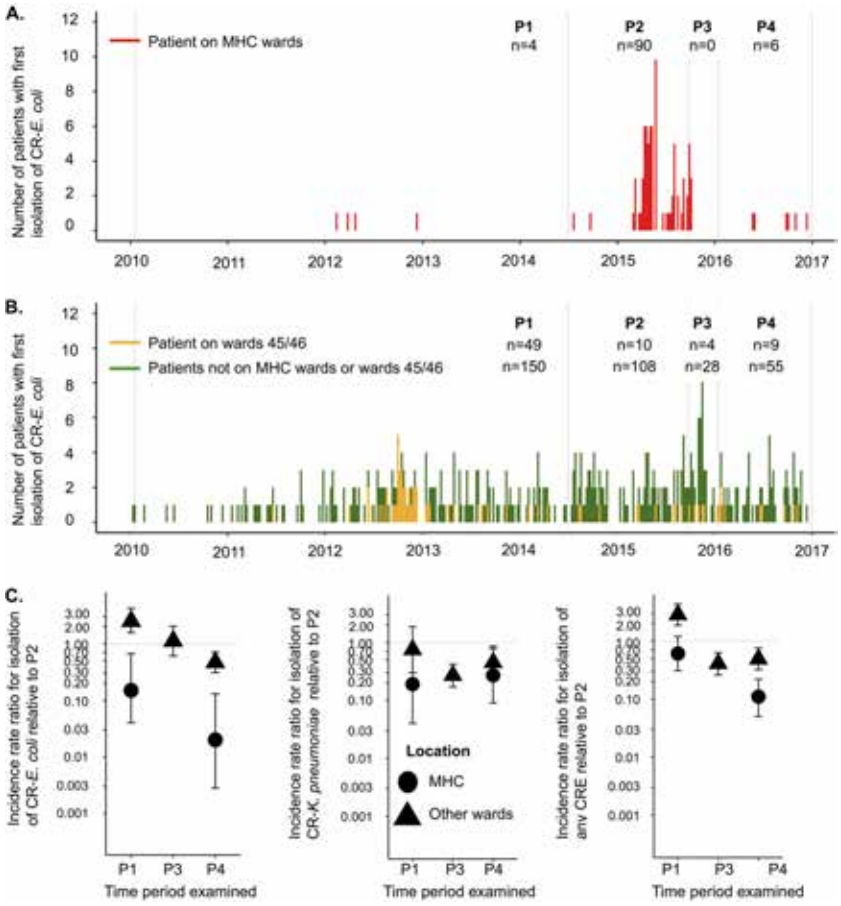

FIG 2 (A and B) Counts of individuals with first CR *E. coli* detection by ward location. Detections on days 0 and 1 of admission are excluded. Faint vertical lines correspond to the boundaries of the 4 time periods, as follows: period 1 (P1), prior to implementation of a systematic CPE rectal screening policy; period 2 (P2), implementation of a CPE rectal screening policy consistent with national guidance; period 3 (P3), closure of wards 3 and 4 and replacement of plumbing infrastructure; period 4 (P4), reopening of wards 3 and 4 to patient admissions. (C) Incidence rate ratios for rates of first positive CR *E. coli* detection, carbapenem-resistant *K. pneumoniae* detection, and any CRE detection ≥2 days postadmission, relative to period 2 in the same location (MHC versus the rest of CMFT). An incidence rate ratio is not shown for period 3 in the MHC due to unit closure during this period, to facilitate plumbing replacement.

clinical/screening isolates) in 2010 to 2016 (inclusive), including a separate outbreak on the gerontology wards (wards 45 and 46) in late 2012 (Fig. 2A and B). Of those, 434 cases were detected on day ≥2 of admission and 80 on day 0 or 1 of admission. Case peaks were not related to screening policy changes or rates (Fig. S6). CR *E. coli* strains were detected almost invariably from rectal screening samples (420/434 cases [97%]).

Environmental sampling yielding CRE from sinks and drains. Intermittent environmental sampling was undertaken to identify potential reservoirs. Overall, 927 samples from 833 sites were obtained between 9 April and 17 November 2015; 355 samples (38%) from 333 sites (40%) were from ward 3 or ward 4, and the remainder were from 11 other wards. A total of 850 samples were from sink/drain/shower/bath sites, 18 from toilets, hoppers, or sluices, and 33 from high-touch sites (including keyboards, door handles, and sponges; the labeling was unclear for 26 samples). Eighty-five samples (9%) and 72 sites (9%) were CRE positive, including 26/355 samples (7%) from 21/333 sites (6%) in wards 3 and 4. CRE-positive sites included shower drains ($n = 19$), sink taps ($n = 7$), sink drain tailpieces ($n = 10$), sink drain strainers ($n = 8$), sink trap water ($n = 1$), toilet bowls ($n = 1$), and other sites ($n = 26$). Common isolates cultured included *Klebsiella* spp. ($n = 34$), *Enterobacter* spp. ($n = 25$), and *E. coli* ($n = 11$) (Fig. 1A). All CRE-positive cultures were from wastewater/plumbing-associated sites; no other sites tested were CRE positive.

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TABLE 1 Incidence rate ratios for detection from screening swabs ≥2 days after admission (a proxy marker of acquisition) in CMFT for all CRE cases, CR *E. coli* cases, and CR *K. pneumoniae* cases, modeling the impact of the ward 3 and ward 4 closures and plumbing replacement on acquisition

Location and period[a]	All CRE (3,086 cases)		CR *E. coli* (502 cases)		CR *K. pneumoniae* (1,134 cases)	
	IRR (95% CI)	*P*	IRR (95% CI)	*P*	IRR (95% CI)	*P*
MHC						
Week 3, 2010, to week 26, 2014 (period 1)	0.61 (0.31–1.20)	0.15	0.15 (0.04–0.67)	0.012	0.19 (0.04–0.82)	0.026
Week 27, 2014, to week 39, 2015 (period 2; reference period)	1.00		1.00		1.00	
Week 40, 2015, to week 2, 2016 (period 3; wards 3 and 4 closed)						
Week 3, 2016, to week 52, 2016 (period 4)	0.11 (0.05–0.22)	<0.001	0.02 (0.00–0.14)	<0.001	0.27 (0.09–0.78)	0.015
Other hospital locations						
Week 3, 2010, to week 26, 2014 (period 1)	2.85 (1.87–4.34)	<0.001	2.51 (1.57–4.03)	<0.001	0.75 (0.30–1.86)	0.53
Week 27, 2014, to week 39, 2015 (period 2; reference period)	1.00		1.00		1.00	
Week 40, 2015, to week 2, 2016 (period 3)	0.41 (0.26–0.63)	<0.001	1.12 (0.61–2.05)	0.71	0.27 (0.17–0.42)	<0.001
Week 3, 2016, to week 52, 2016 (period 4)	0.49 (0.32–0.76)	0.002	0.47 (0.31–0.71)	<0.001	0.47 (0.28–0.77)	0.003
MHC vs other location in reference period (period 2)	1.69 (0.81–3.50)	0.16	9.05 (3.98–20.55)	<0.001	0.45 (0.24–0.86)	0.015
Heterogeneity for reduction in MHC vs other location						
Week 3, 2010, to week 26, 2014 (period 1)		<0.001		0.001		0.098
Week 40, 2015, to week 2, 2016 (period 3)						
Week 3, 2016, to week 52, 2016 (period 4)		<0.001		0.003		0.31

[a]Four time periods were evaluated, as follows: period 1, prior to implementation of a systematic CPE rectal screening policy; period 2, implementation of a CPE rectal screening policy consistent with national guidance; period 3, closure of wards 3 and 4 and replacement of plumbing infrastructure; period 4, reopening of wards 3 and 4 to patient admissions. Period 2 was chosen as the reference period because of the change in screening policies between period 1 and period 2 (see Table S2 and Fig. S6 in the supplemental material), meaning that a greater incidence would be expected in period 2, due to more patients being screened every week. IRR, incidence rate ratio; CI, confidence interval.

Of 10 sites yielding 11 KPC-producing *E. coli* isolates, 5 were in the ward 3/ward 4 kitchen (14 to 18 May 2015 [$n = 4$] and 10 September 2015 [$n = 1$]), 1 was a ward 4 staff sink (14 May 2015), and 4 were kitchen sinks or drains on wards 31 and 32 (sampling in response to a separate ward 31/32 outbreak, 12 to 17 November 2015). Ward 3/ward 4 sink-specific interventions included sink trap replacement for CRE-colonized sinks (16 April 2015, 31 July 2015, and 11 August 2015) and horizontal pipework cleaning with a brush to try to remove biofilms (11 August 2015).

Cardiac service relocation and decline in CRE colonization incidence. Given the ongoing difficulty in preventing KPC-producing *E. coli* acquisitions and the isolation of KPC-producing *E. coli* from sink and drain sites, wards 3 and 4 were closed from 25 September 2015 and patients were relocated to another ward to allow replacement of the plumbing infrastructure back to the central drainage stacks. Replaceable sink plughole devices designed to prevent water aerosolization in the sink U-bend and to limit biofilm formation (HygieneSiphon; Aquafree) were installed.

Controlling for screening and compared to the period immediately before intervention (when screening policies were the same), the incidence of first detection of any CRE or *E. coli* strain decreased significantly following the plumbing intervention, both in the MHC and elsewhere in the hospital (Fig. 2C and Table 1). The decline in incidence was significantly greater in the MHC (heterogeneity $P < 0.001$), where incidence fell by 89% for any CRE strain and by 98% for CR *E. coli*. The incidence of CR *K. pneumoniae* also decreased significantly in both settings, but there was no evidence that the declines differed between the two settings (heterogeneity $P = 0.31$) (Table 1). However, when patients were transferred back to wards 3 and 4 (from 18 January 2016), CR *E. coli* continued to be detected in patients (6 first detections in 2016) (Fig. 2A). Patient colonization with other CRE strains was also observed, in numbers similar to those for 2014 (Fig. 1A); environmental contamination with CRE in sink and wastewater sites recurred rapidly (Fig. 1A), and 2 environmental sites (both ward utility room sink drains) were CRE positive even prior to patient readmissions to the ward, suggesting residual contamination after the plumbing replacement or reintroduction following the plumbing replacement but prior to patient readmissions.

Genomic epidemiology of KPC-producing *E. coli*. A total of 268 clinical and environmental CR *E. coli* isolates were sequenced, including 82 isolates from the MHC

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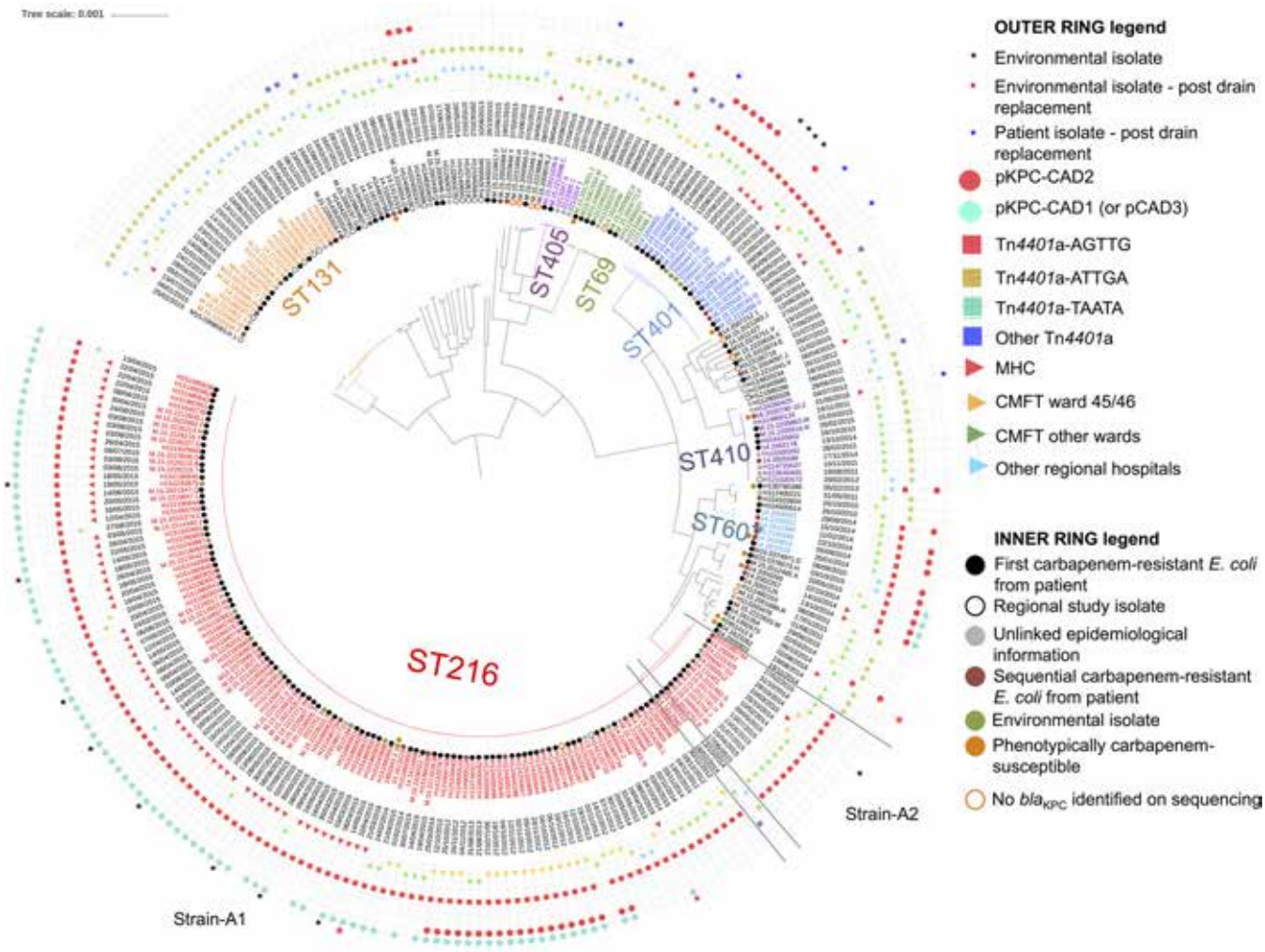

FIG 3 Recombination-corrected phylogeny of 259 sequenced KPC-producing *E. coli* isolates (and 9 *E. coli* isolates that were bla_{KPC} negative on sequencing) from CMFT and other regional hospitals in northwest England, annotated with collection date, ward/center location, Tn*4401* type, and outbreak plasmid types. The earliest available sequences per patient are denoted "first carbapenem-resistant *E. coli* from patient" if the stored isolate collection date was ≤7 days from the first isolation date in the TRACE database or "sequential carbapenem-resistant *E. coli* from patient" if the stored isolate date was after that. KPC-producing *E. coli* isolates from a Public Health England (PHE) project that sequenced the first 10 KPC-producing *Enterobacteriaceae* strains from hospitals in northwest England (2009 to 2014) are denoted "regional study isolate." "Environmental isolate" denotes KPC-producing *E. coli* strains cultured during an initial environmental prevalence survey on wards 3 and 4 (10 March 2015), any KPC-producing *E. coli* strain isolated as part of subsequent, intermittent, IPC-associated environmental sampling (9 April 2015 to 17 November 2015), and isolates available at the time of analysis from environmental and patient samples from a separate ongoing study (commenced January 2016).

(2015 to 2016 [16 environmental isolates]), 36 from wards 45 and 46 (2010 to 2016), 109 from other CMFT wards or units, and 41 from other regional hospitals (Table S3). Nine isolates were bla_{KPC} negative on sequencing; 5 of those isolates contained bla_{OXA-48}, 1 $bla_{OXA-181}$, and 1 bla_{NDM-5}, with no known carbapenem resistance mechanisms identified for the remaining 2. The 259 KPC-producing *E. coli* isolates included all 16 environmental CR *E. coli* isolates, 158 isolates that were the first CR *E. coli* isolates cultured from patients, and 38 sequentially cultured CR *E. coli* isolates from patients (longitudinal cultures from 12 patients); sequencing and patient epidemiological identifiers could not be linked for 47/259 isolates.

Forty sequence types (STs), including known pathogenic lineages (e.g., ST131), occurred among the KPC-producing *E. coli* isolates (Fig. 3; also see Table S3), highlighting regional KPC-producing *E. coli* diversity. In contrast, 67/80 MHC isolates (84%) were ST216, compared with 59/179 (33%) elsewhere. ST216 has rarely been reported in other settings.

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ST216 KPC-producing *E. coli*. The ST216 KPC-producing *E. coli* group ($n = 126$, including 1 bla_{KPC}-negative isolate [H134880341]; 9,118 variable sites) was represented by 2 main genetic subgroups, consisting of 112 isolates (the main outbreak strain [strain A1 in Fig. 3]; ≤65 single-nucleotide variations [SNVs] among isolates in this cluster [2012 to 2016]) and 12 isolates (the secondary outbreak strain [strain A2 in Fig. 3]; ≤25 SNVs among isolates in this cluster and >7,800 SNVs divergent from strain A1 isolates [2012 to 2015]). Although the SNV-based distances between strains A1 and A2 were large, review of the ClonalFrameML output suggested that these differences represented a single "mega-recombination event" affecting ~1 Mb of the genome (Fig. S7).

All except 3 ST216 isolates carried bla_{KPC-2} in a Tn*4401*a transposon (14), which is typically associated with high-level bla_{KPC} expression (15), flanked by a 5-bp target site duplication, AGTTG, which was previously observed only with the Tn*4401*b isoform in an isolate from Colombia (Fig. 3; also see Table S3). This relatively unique transposon-flanking sequence unit was also observed in other lineages within CMFT (e.g., ST401) (Fig. 3). However, plasmid and resistance gene profiles varied considerably, even to some extent within the ST216 KPC-producing *E. coli* outbreak strains (Fig. 3; also see Fig. S8). Overall, these results demonstrated clonal expansion of specific KPC-producing *E. coli* strains, with significant accessory genome mobility. Most notable were the emergence and persistence of ST216 KPC-producing *E. coli* strain A1, which was isolated from patients and the environment over 4 years and caused outbreaks in wards 45 and 46 (2012) and the MHC (2015).

Long-read sequencing demonstrated that the ST216 KPC-producing *E. coli* strain A1 isolate H124200646 (ward 46 [2012]) contained 2 plasmids, pKPC-CAD2 (307 kb; IncHI2/HI2A, with bla_{KPC} present) and pCAD3 (152 kb; IncFIB/FII, with bla_{KPC} absent); 83% of pKPC-CAD2 was highly similar (99% sequence identity) to pKPC-272 (282 kb, *Enterobacter cloacae*; GenBank accession no. CP008825.1), which was identified in a sink drain in the National Institutes of Health Clinical Centre in 2012 (16). The other long-read sequence, H151860951 (ward 4 [April 2015]), which was also an ST216 KPC-producing *E. coli* strain A1 isolate, contained a bla_{KPC} plasmid, pKPC-CAD1 (200 kb; IncFIB/FII), which had 99% sequence identity to pCAD3 over 76% of its length, together with a 48-kb contiguous region including bla_{KPC} that was 99% identical to part of pKPC-CAD2 (Fig. 4A). These results suggest the evolution of a bla_{KPC} plasmid similar to pKPC-272 in CMFT within ST216 KPC-producing *E. coli* strain A from 2012 to 2015, including recombination between pKPC-CAD2 and pCAD3, giving rise to pKPC-CAD1. Although plasmid typing based on mapping of short-read data to plasmid references should be interpreted cautiously, sequence comparisons with the outbreak plasmids pKPC-CAD1 and pKPC-CAD2 were consistent with the emergence of pKPC-CAD1 and its domination within ST216 KPC-producing *E. coli* strain A after 2014, as well as exchange of pKPC-CAD1, pKPC-CAD2, and pCAD3 with other *E. coli* STs (Fig. 3 and 4B).

Environmental CRE isolates. Thirty environmental CRE isolates from wards 3 and 4 were sequenced, 27 of which were isolated prior to the plumbing replacement and 16 of which were CR *E. coli*, as described above (13 isolated prior to the plumbing replacement). Eleven of the 16 *E. coli* isolates were ST216 KPC-producing *E. coli* strains (10 strain A1 and 1 strain A2), isolated on 8 separate days (in March, May, and September 2015 and February 2016), consistent with transmission between patients and the environment (Fig. 3) and persistence or reintroduction following the plumbing replacement. The other 14 isolates represented diverse KPC-producing CRE species, including *K. pneumoniae* ($n = 7$), *Citrobacter freundii* ($n = 4$), *Klebsiella oxytoca* ($n = 1$), *Enterobacter cloacae* ($n = 1$), and *Kluyvera intermedia* ($n = 1$). The KPC plasmids in these KPC-producing CRE isolates likely included the outbreak plasmids pKPC-CAD1 and pKPC-CAD2, pKpQIL, and other plasmids, consistent with the interspecies transfer of a diverse set of bla_{KPC} plasmids.

DISCUSSION

Our detailed analyses of the largest institutional KPC-producing *E. coli* outbreak described to date demonstrate a complex genetic and epidemiological picture, includ-

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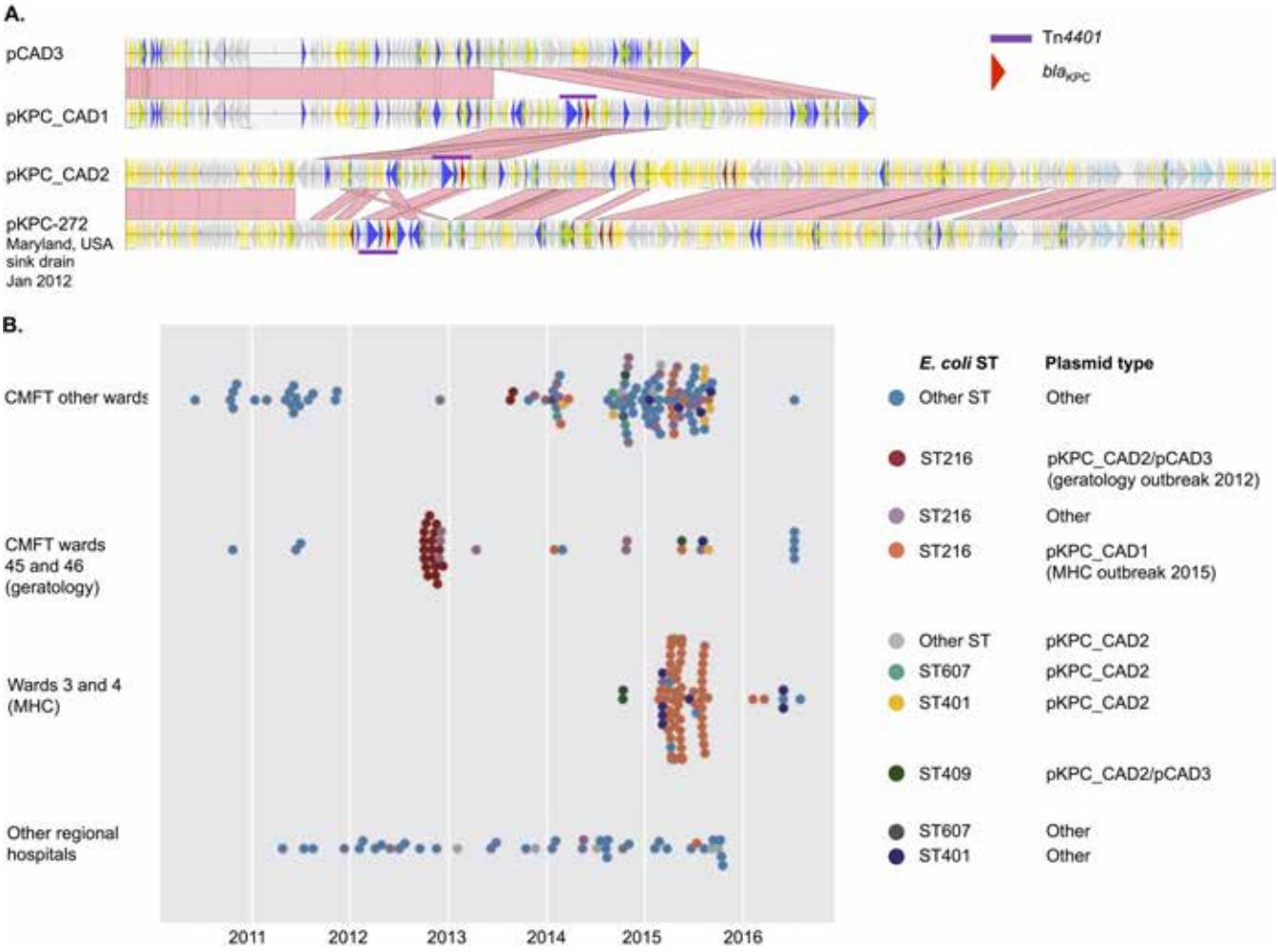

FIG 4 (A) Alignments of the 2012 MHC outbreak KPC plasmid pKPC-CAD2 (wards 45 and 46; Tn*4401a* plus bla_{KPC}) and the 2015 MHC KPC plasmid pKPC-CAD1 (Tn*4401a* plus bla_{KPC}), highlighting the recombination of the Tn*4401a*- and bla_{KPC}-harboring 48-kb segment from pKPC-CAD2 with pCAD3 to generate pKPC-CAD1. Regions of sequence homology are represented by pink links drawn between alignments. pKPC-272 (GenBank accession no. CP008825.1), a plasmid identified in an isolate from a sink drain at the National Institutes of Health Clinical Centre in Maryland in 2012, demonstrates significant sequence homology with pKPC-CAD2. (B) Incidence plot of different *E. coli* STs and likely MHC-related KPC plasmid types across hospital locations.

ing the emergence of ST216 KPC-producing *E. coli* strain A1 as a significant clone in CMFT, causing the major 2015 MHC outbreak, an antecedent outbreak in 2012, and sporadic cases and small clusters in other wards and regional health care settings. Plasmid-associated dissemination of bla_{KPC} to other *E. coli* lineages, including recognized high-risk clones such as ST131, was evident and the problem was substantial, with 514 confirmed patient acquisitions of CR *E. coli* over a 6-year period.

Environmental sampling on wards 3 and 4 confirmed that sinks and drains were colonized by multiple CRE strains, including the ST216 KPC-producing *E. coli* strains A1 and A2 and other CRE strains containing the outbreak KPC plasmids (pKPC-CAD1 and pKPC-CAD2), potentially representing a persistent reservoir between patient-associated outbreaks and plausibly explaining why this large outbreak was refractory to standard IPC bundles. Supporting this, the incidence of new CR *E. coli* detections declined substantially after ward plumbing replacement and temporary relocation of patients (Fig. 1A and 2A and C), consistent with a major contribution from the ward environment. After wards 3 and 4 reopened, however, the environment was rapidly recontaminated, including with ST216 KPC-producing *E. coli* strain A1, and CRE strains were again detected in patients, suggesting that this type of intervention has limited durability. National and international guidelines on CRE management recommend

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rectal screening, strict contact precautions, isolation/cohorting of cases, and antimicrobial stewardship to limit transmission (12, 13, 17), all measures already being implemented in CMFT. Current guidelines do not address the control of large persistent outbreaks or provide advice on the sampling and management of environmental reservoirs, and there is limited evidence in support of any given measure (18). It is unclear why a particular strain of KPC-producing *E. coli* predominated in the outbreak described, as opposed to other CRE strains found contemporaneously in the environment; differences in the gastrointestinal colonization ability of species or an unidentified point source are potential hypotheses.

The response to this outbreak caused major disruption to the hospital and regional cardiac services. Given that almost all cases represented colonizations and not infections, the risks of associated delays in cardiac interventions were debated, although the impacts were not formally quantified. The estimated cost to CMFT of CRE in the first 8 months of 2015 was £5.2 million (19), and the MHC outbreak contributed significantly to this, with approximately £240,000 being spent on the ward 3/ward 4 plumbing replacement.

The study has several limitations, including its observational nature, with only 1 year of follow-up monitoring after the ward 3/ward 4 plumbing replacement. Limited environmental sampling might have meant that the extent of contamination and the diversity of CRE in environmental niches were underestimated. Environmental sampling was restricted to wards in which CRE outbreaks had been detected, and it focused predominantly on sink/drain sites (because initial sampling suggested that those sites were most heavily contaminated); however, component parts of each sink drainage system were not sampled consistently due to resource issues, and the relative prevalence of CRE isolation from any given site type needs to be interpreted with caution. We sequenced only single isolates cultured from individuals at any given time point, due to resource limitations, and therefore might have underestimated the CRE strain diversity within patients. Other non-*E. coli Enterobacteriaceae* strains were not comprehensively sequenced, possibly underestimating dissemination of pKPC-CAD1 and pKPC-CAD2; however, even our limited sequencing of CRE strains from the environment in 2015 identified those plasmids (and other KPC plasmids) in multiple species. Although genetic overlap between environmental and patient isolates was consistent with transmission between these compartments (Fig. 3), the numbers were too small to infer directionality. Of the predominant KPC plasmid types present within the ST216 KPC-producing *E. coli* strain A1 outbreak clone, one (pKPC_CAD2) was transferred to multiple *E. coli* STs (Fig. 3 and 4B), and another (pKPC_CAD1) might have contributed to the clone's success from 2014 (Fig. 4B), although the genetic and biological mechanisms underpinning this have not been explored.

Our experience highlights the limited evidence for managing large CRE outbreaks, including environmental sampling protocols and interventions, despite numerous centers reporting similar experiences with wastewater sites acting as CRE reservoirs (18, 20–23). Widespread colonization with KPC-producing *E. coli* is a concern, as *E. coli* is a common gastrointestinal colonizer and cause of infection, and any stable association between *bla*$_{KPC}$ and *E. coli*, particularly in pathogenic lineages such as ST131 (Fig. 3), represents a significant clinical and transmission threat. Although our analyses focused on CRE, similar wider environmental contamination and dissemination of carbapenem-susceptible *Enterobacteriaceae* seem plausible. A more robust evidence base delineating transmission networks (including initial contamination of sink sites), drivers, and effective control measures (including differential impacts of decontamination methods on particular species and strains) is needed to minimize the financial, clinical, and social impacts of CRE outbreaks.

MATERIALS AND METHODS

Setting. CMFT is one of the largest hospital trusts in northwest England. The MHC manages >10,000 patients/year and in 2015 included two 28-bed inpatient wards (wards 3 and 4), an acute facility (ward 35), an intensive care unit, and a cardiac catheter laboratory. Ward 3 and ward 4 both included 3 bays and 4 single-patient side rooms, with a shared kitchen (see Fig. S1A and B in the supplemental material).

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IPC measures. CRE screening and IPC measures, based on UK guidelines (11), were implemented Trust-wide from mid-2014. Enhanced measures were introduced in April 2015 in response to the MHC KPC-producing *E. coli* outbreak (Table S1). In addition, wards 3 and 4 (where most KPC-producing *E. coli* cases were observed) were closed to replace the plumbing infrastructure back to the drainage stacks (Fig. S2) from September 2015. Staff screening was not undertaken, consistent with national guidelines (11).

Patient CRE screening. Rectal swabs were screened for CRE using selective chromogenic agar, i.e., ChromID CARBA (bioMérieux) (published sensitivity, 89 to 100%; specificity, 95% [24–26]) to August 2014 and the Cepheid Xpert Carba-R assay (published sensitivity, 97 to 100%; specificity, 99% [27, 28]) from August 2014, along with an in-house multiplex PCR (bla_{KPC}, bla_{NDM}, and bla_{OXA-48}) from November 2014. The Cepheid assay was used for specimens from patients with admissions to the Trust in the past 12 months, those admitted from overseas, or those due to be transferred to a district general hospital (to facilitate transfer planning). All other samples were tested using the multiplex PCR. Species identification of isolates was performed using matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectrometry (Bruker).

Epidemiological analyses. CMFT electronic bacteriology records were linked, based on NHS numbers, to patient administration data (1 January 2010 to 1 January 2017) and anonymized, and the first CRE-positive test result per patient (rectal screening or clinical specimen) was considered in the evaluation of CRE incidence trends. Trends and the impact of IPC interventions were analyzed retrospectively.

Because CMFT CRE screening rates changed over time in response to national guidance and local IPC interventions and a key aim was to evaluate specifically the impact of ward closure and a radical plumbing intervention in the MHC on CRE acquisition rates, we considered CRE detection rates in 4 periods delineated by 3 time points, namely, the implementation of national carbapenemase-producing *Enterobacteriaceae* (CPE) IPC policy in mid-2014 (which substantially increased the number of screens performed), the beginning of the MHC-specific intervention (patient relocation and plumbing infrastructure replacement in wards 3 and 4), and the end of the MHC intervention.

First CRE-positive screens were used as a pragmatic proxy for CRE acquisition (i.e., a "case"), given that 89% of patients with first CRE-positive results in the MHC had a negative rectal screen within the preceding 14 days (79% within 7 days) (Fig. S3 to S5). Information on specific carbapenemase mechanisms was not consistently available for all isolates, hampering our ability to perform these analyses specifically by carbapenemase gene family (Table S2).

We tested the hypothesis that CRE acquisitions (reflected by first CRE-positive screens) changed in the MHC more than in other hospital wards following the ward 3/ward 4 closure and plumbing intervention, using negative binomial regression models for the weekly counts of first (per person) CRE detection ≥2 days postadmission (i.e. cases), using weekly numbers of persons screened ≥2 days postadmission as an offset (i.e., adjusting for screening rates), and counting each patient as screened as long as they had ≥1 screen per week. Models were fitted (R v3.4.1) for CRE, CR *E. coli*, and CR *K. pneumoniae*. We included period and ward location (MHC versus other wards) as independent variables, with interaction terms for period and location (see the supplemental material for details).

Environmental sampling and sample processing. In 2015, environmental samples were taken from ward sites using charcoal swabs and were cultured on ChromID CARBA for 18 h at 37°C. After January 2016, ~20 ml of wastewater was aspirated from sink P-traps, shower drains, or toilets. Aspirates were centrifuged at 4,000 rpm for 10 min, 15 ml of supernatant was discarded, and the pellet was resuspended in the remaining 5 ml. One milliliter of sample was then incubated aerobically overnight at ~37°C in 5 ml of trypticase soy broth with an ertapenem disc; the multiplex PCR (as above) was performed on broths to identify bla_{KPC}-positive samples for subsequent culture on ChromID CARBA. Environmental sampling prior to January 2016 was not systematic; after January 2016, 75 wastewater sites on wards 3 and 4 were sampled fortnightly on rotation (one half of the sites 1 week and the other half the next); these sites included toilets, sink basins, and sink drains.

Genome sequencing and sequence data analysis. To provide genetic context for the outbreak, we sequenced retrievable, archived, KPC-producing *E. coli* patient and environmental isolates from CMFT and patient isolates collected for regional public health surveillance (see the supplementary methods and Table S3 in the supplemental material). We also sequenced a small subset of non-*E. coli* environmental CRE isolates that had been stored ($n = 14$) *ad hoc* as part of outbreak sampling prior to the plumbing replacement.

For Illumina sequencing (HiSeq 2500; 150-bp PE reads), DNA was extracted using the QuickGene system (Fujifilm, Japan), with an additional mechanical lysis step following chemical lysis (FastPrep; MP Biomedicals, USA). Two outbreak isolates (H124200646 and H151860951) were selected for long-read sequencing based on Illumina data. For long-read sequencing (with a PacBio [$n = 1$] or MinION [$n = 1$] system), DNA was extracted using the Qiagen genomic tip 100/G kit (Qiagen, Netherlands) (see the supplementary methods).

In silico species identification was performed using Kraken (29). Illumina reads were then mapped to species-specific references (*E. coli* CFT073 [GenBank accession no. AE014075.1] and the ST216 reference H151860951), and base-calling was performed as described previously (30). *De novo* assembly was performed using SPAdes v3.6 (31), and resistance gene, bla_{KPC} plasmid, and Tn*4401* typing was performed using BLASTn and mapping-based approaches (see the supplementary methods and Table S3).

Two-dimensional reads were extracted from MinION sequence data using poretools (32); hybridSPAdes (31) and Canu (33) were used to generate *de novo* hybrid assemblies from MinION and Illumina data (see the supplementary methods in the supplemental material). PacBio sequence data were *de novo*

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assembled using HGAP3 (34). *E. coli* phylogenies were reconstructed using IQ-Tree (35) and ClonalFrameML (36) and were visualized in iTOL (37) (see the supplementary methods).

Ethics approval. Because the investigations formed part of a Trust board-approved outbreak response, ethics approval was not required under NHS governance arrangements (see the supplementary methods).

Accession number(s). Sequencing data are available under NCBI BioProject PRJNA379782.

SUPPLEMENTAL MATERIAL

Supplemental material for this article may be found at https://doi.org/10.1128/AAC.01689-18.

SUPPLEMENTAL FILE 1, PDF file, 1 MB.

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We have no conflicts of interest to declare.

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"Down the drain": carbapenem-resistant bacteria in intensive care unit patients and handwashing sinks

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Abstract

Objectives: Clinical utility of carbapenem antibiotics is under threat because of the emergence of acquired metallo-β-lactamase (MBL) genes. We describe an outbreak in an intensive care unit (ICU) possibly associated with contaminated sinks.

Design, setting and participants: Four clusters of gram-negative bacteria harbouring the MBL gene bla_{IMP-4} were detected in the ICU at Dandenong Hospital between November 2009 and July 2012. Epidemiological investigations were undertaken in order to identify a common point source. During September 2012, screening using rectal swabs for all ICU patients, and environmental swabs targeting all ICU handwashing sinks and taps were collected. Samples were cultured onto selective carbapenem-resistant Enterobacteriaceae (CRE) agar. Suspected CRE isolates were further characterised using the modified Hodge test and VITEK 2 and confirmed by polymerase chain reaction and sequencing of MBL genes. Clinical and environmental CRE isolates were typed by pulsed-field gel electrophoresis.

Results: Ten clinical isolates and one screening isolate of CRE (consisting of *Klebsiella pneumoniae* [5], *Serratia marcescens* [4], *Enterobacter cloacae* [1] and *Escherichia coli* [1]) were detected with the bla_{IMP-4} gene over the 30-month period. *S. marcescens* was isolated persistently from the grating and drain of eight central sinks. Molecular typing confirmed that clinical and environmental isolates were related. Tap water cultures were negative. Several attempts to clean and decontaminate the sinks using detergents and steam cleaning proved unsuccessful.

Conclusion: This report highlights the importance of identification of potential environmental reservoirs, such as sinks, for control of outbreaks of environmentally hardy multiresistant organisms.

One of the most concerning emerging resistance traits among gram-negative bacteria is the ability of these organisms to produce carbapenem-hydrolysing β-lactamases, which confer resistance to almost all β-lactams.[1] Carbapenem-resistant Enterobacteriaceae (CRE) are increasing in prevalence worldwide, causing growing concern, as they are often combined with non-β-lactam resistance to produce isolates that are multidrug resistant, have few treatment options available and are associated with high mortality rates.[2]

Although multiple resistance mechanisms have been identified, carbapenem resistance is often plasmid-encoded, allowing gene dissemination and a propensity to cause nosocomial outbreaks.[3-6]

We describe a CRE outbreak due to the presence of the metallo-β-lactamase gene bla_{IMP-4} in an intensive care unit (ICU) associated with contaminated sinks. This report highlights the key role of bacterial environmental contamination and sink design and usage in the propagation of CRE outbreaks.

Methods

Dandenong Hospital is a 440-bed tertiary referral hospital in Melbourne, Australia. The ICU has a 14-bed capacity, admitting both medical and surgical patients and averaging 1400 admissions yearly.

Ten ICU patients were found to have clinical specimens with Enterobacteriaceae harbouring the bla_{IMP-4} gene between November 2009 and July 2012. The ICU routinely screens for vancomycin-resistant enterococci (VRE) carriage using rectal swabs on admission, weekly and on discharge. During the 4-week period from 6 September to 4 October 2012, CRE screening was performed in addition to the routine screen for VRE.

Environmental screening for CRE targeting all 28 wet area locations (including 11 sinks and taps, as well as water fountains and ice machines) was performed. Samples were recollected from CRE positive locations after successive decontamination attempts. A total of 97 samples were collected from taps, water, grates and drains (10 cm down and above the water trap interface where biofilm may be expected to persist).

All environmental and patient screening swabs were cultured onto chromogenic agar (*Brilliance* CRE Agar, Oxoid). Suspect colonies were further characterised using the modified Hodge test and VITEK 2 (Biomérieux). All isolates with a meropenem minimum inhibitory concentration (MIC) ≥ 0.25 mg/L and a positive modified Hodge test result were forwarded for confirmation by polymerase chain reaction and molecular sequencing. Molecular typing using pulsed field gel electrophoresis (PFGE) was conducted on clinical and environmental isolates and interpreted as per the reference guidelines.[7]

Guidelines on ICU handwashing sink styles were reviewed to establish whether sinks met clinical design standards.[8]

Results

Ten clinical isolates (*Klebsiella pneumoniae* [$n = 5$], *Serratia marcescens* [$n = 4$] and *Enterobacter cloacae* [$n = 1$]) and one screening isolate (*Escherichia coli*) containing the bla_{IMP-4} gene were detected over the 30-month period. There were four distinct CRE clusters, commencing with three cases of *K. pneumoniae* in November 2009, followed by two cases of *S. marcescens* 6 months later, three cases (two *S. marcescens* and one *E. cloacae*) after another 11 months, and three cases of *K. pneumoniae* in July 2012.

Clinical characteristics, patient demographics and ICU admission details of all 11 patients are summarised in Box 1. Patients acquired CRE after a median length of stay in ICU of 10 days (range, 3–134 days). No

1 Demographics and intensive care unit (ICU) admissions for patients with carbapenem-resistant Enterobacteriaceae isolates

Patient	Underlying condition	Year of first positive culture	Culture type	Organism	Total hospital stay (days)	ICU stay (days)	ICU admissions in past 12 months	Total carbapenem therapy (days)	Outcome
1	Small bowel perforation, post-hernia repair	2009	Blood	*Klebsiella pneumoniae*	229	134	0	14	Discharged
2	Urosepsis, multiorgan failure	2010	Urine	*K. pneumoniae*	44	16	0	0	Discharged
3	Bilateral pneumonia	2010	Bronchial washings	*K. pneumoniae*	61	33	0	0	Discharged
4	Pneumonia	2010	Intercostal catheter swab	*Serratia marcescens*	44	32	0	2	Discharged
5	Pneumonia	2010	Endotracheal aspirate	*S. marcescens*	46	6	0	0	Discharged
6	Buttock abscess	2011	Urine	*S. marcescens*	49	10	0	0	Discharged
7	Pneumonia	2011	Penile swab	*S. marcescens*	46	22	0	3	Discharged
8	Congestive cardiac failure	2011	Sputum	*Enterobacter cloacae*	57	4	0	0	Died
9	Ischaemic stroke	2012	Sputum	*K. pneumoniae*	31	3	0	3	Died
10	Periprosthetic hip fracture	2012	Urine	*K. pneumoniae*	46	8	0	0	Discharged
11	Ketoacidosis	2012	Rectal screen swab	*Escherichia coli*	11	4	2	0	Discharged

patient died due to clinical CRE infection. Patient 1 had a prolonged CRE bacteraemia that responded to removal of a central venous catheter, the presumed source of infection.

A total of 111 rectal swabs were collected from 71 patients. Only one patient (Patient 11) was CRE-positive with an *E. coli* isolate detected.

Antibiotic resistance profiles of clinical isolates indicated resistance to β-lactams and meropenem with MICs ⩾1 mg/L. All *S. marcescens* clinical isolates were sensitive to piperacillin/tazobactam, ciprofloxacin and amikacin, while *K. pneumoniae* and *E. coli* were only sensitive to amikacin. *S. marcescens* environmental isolates showed a higher meropenem MIC of ⩾16 mg/L.

S. marcescens was the only species recovered from environmental samples and was isolated persistently, even after six attempts to decontaminate the grates and drains of eight of the 11 central sinks in the ICU. Tap spout and water cultures were negative for CRE.

Three of the four *S. marcescens* clinical isolates from 2010 and 2011 were indistinguishable or closely related by PFGE to four isolates from sinks. *S. marcescens* was isolated from an intercostal catheter swab of Patient 4, matching two sink isolates; Patient 5 had an endotracheal aspirate identical to two different sink locations; and the urine isolate from Patient 6 was closely related to a different sink. The isolate from Patient 7 was unable to be typed by PFGE.

Sink inspection revealed aged and deteriorating porcelain, even though sinks were only installed in 2005. Sink design did not comply with Australasian clinical design standards,[8] with a small, shallow sink and a tap that directed water over the drain (Box 2). The design of the ICU sinks led to poor use for hand hygiene (although measured hand hygiene compliance using alcoholic hand rub was around 70% within the unit) and the potential for organisms residing down the drain to be splashed back onto staff hands or contaminate patient areas. It was also revealed that the handwashing sinks had been used incorrectly, with staff disposing clinical waste and residual antibiotics directly into drains. Further enquiry also revealed that a single brush had been used to clean down the drains of all sinks in the ICU without disinfection between sinks.

Cleaning was attempted in an effort to rid the organisms from the sinks.

2 Existing design of intensive care unit sink compared with a design that complies with Australasian standards[8]

A: Existing sink, showing water spray directly over drain. **B:** Compliant sink design, showing larger basin and less forceful water flow directed away from drain, to prevent splash back and contamination with drain contents. ◆

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First, cleaning of grates and drains using single-use, soft brushes was attempted, but repeat screening revealed continued CRE growth. Next, in addition to the brushes, hypochlorite deep cleaning was used after the scrub; however, heavy CRE growth was again evident 1 week later. Finally, an attempt using pressurised steam decontamination (Jetsteam Maxi with plunger tool attachment, Duplex) for 1 minute at 170°C on grates and drains appeared to eradicate almost all CRE at Day 1 (one sink remained colonised); however, repeat testing 3 days after steam treatment showed re-emergence of CRE in all previously affected sinks.

Discussion

We report an outbreak of CRE in an ICU with identical organisms isolated from patients and an environmental source (sinks).

Dissemination of carbapenemase-resistant bacteria has been reported previously in an ICU in Australia, with 62 patients infected or colonised with gram-negative bacteria from multiple genera containing the bla_{IMP-4} gene.[9] The gene is carried on a highly mobile plasmid making it efficient for nosocomial transmission. The gene can reside in multiple genera of hardy environmental organisms that can establish a reservoir within biofilm.

Identifying the outbreak using molecular methods allowed us to establish clonality between clinical and environmental isolates and to propose a mechanism whereby patient contamination may have occurred. Although we cannot prove that the sinks were the source of patient infection, the persistence of the organism within the environment was a concern. Attempts at sink sterilisation were futile, and complete eradication will require future sink removal and replacement with appropriately designed sinks.

Others have reported outbreaks of multiresistant bacteria such as extended-spectrum β-lactamase-producing *K. pneumoniae* linked to imperfect sink design requiring sink cleaning, replacement and/or improved sink practices to successfully control the outbreaks.[10]

Our data should act as a reminder on the importance of appropriate hospital design, adequate environmental cleaning and antimicrobial stewardship in the hospital setting.

Competing interests: No relevant disclosures.

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Stamps of greatness

Karl Landsteiner (1868–1943)

LANDSTEINER was born on 14 June 1868 in Vienna, Austria. He studied medicine at the University of Vienna and graduated in 1891. For 5 years he studied chemistry in Wurzburg (with Emil Fischer) and Munich, but then returned to Vienna and transferred his interest to pathological anatomy.

In 1898 he became an assistant to the institute of pathological anatomy in Vienna, in 1908 the prosector at the Wilhelminaspital, and in 1911 professor of pathology at the University of Vienna. After the upheavals of World War I he went first to Holland and then, in 1922, to the Rockefeller Institute for medical research in New York, where he continued work even after being made Emeritus Professor in 1939.

From 1900 he studied the agglutination of blood from different individuals, and in 1909 he outlined the human blood types, thus making blood transfusion possible. Landsteiner received the Nobel Prize in Medicine in 1930 for this work, which he continued at the Rockefeller Institute.

During his time in Vienna he also studied (in collaboration with others) poliomyelitis, first showing that the disease was infectious, and then isolating the causative virus.

In the early 1940s at the Rockefeller Institute, he was part of the team that discovered the Rh factor in blood, adding to his work on blood transfusion and compatibility of donors.

Throughout his career he contributed many fundamental principles to the science of immunology and knowledge of antigens and anaphylaxis, and was the recipient of many academic honours and awards. He died on 26 June 1943 after suffering a heart attack while working in his laboratory two days earlier.

Philatelically he was honoured on the centenary of his birth in 1968 by both Austria and Germany.

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ORIGINAL ARTICLE

A Cluster of Central Line–Associated Bloodstream Infections Due to Rapidly Growing Nontuberculous Mycobacteria in Patients with Hematologic Disorders at a Japanese Tertiary Care Center: An Outbreak Investigation and Review of the Literature

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BACKGROUND. Rapidly growing nontuberculous mycobacteria (RGM) are considered rare pathogens, causing central line–associated bloodstream infection. We identified an outbreak of central line–associated bloodstream infection due to RGM at a hematology-oncology ward during a 5-month period.

DESIGN. Outbreak investigation and literature review.

SETTING. A Japanese tertiary care center.

PATIENTS. Adults who were hospitalized at the hematology-oncology ward from October 15, 2011, through February 17, 2012.

RESULTS. A total of 5 patients with a bloodstream infection due to RGM (4 cases of *Mycobacterium mucogenicum* and 1 case of *Mycobacterium canariasense* infection) were identified; of these, 3 patients had acute myeloid leukemia, 1 had acute lymphocytic leukemia, and 1 had aplastic anemia. Four of the 5 patients received cord blood transplantation prior to developing the bloodstream infection. All central venous catheters in patients with a bloodstream infection were removed. These patients promptly defervesced after catheter removal and their care was successfully managed without antimicrobial therapy. Surveillance cultures from the environment and water detected *M. mucogenicum* and *M. canariasense* in the water supply of the hematology-oncology ward. The isolates from the bloodstream infection and water sources were identical on the basis of 16S-rRNA gene sequencing.

CONCLUSIONS. The source of RGM in the outbreak of bloodstream infections likely was the ward tap water supply. Awareness of catheter-related bloodstream infections due to nontuberculous mycobacteria should be emphasized, especially where immunocompromised patients are at risk. Also, using antimicrobials after catheter removal to treat central line–associated bloodstream infection due to RGM may not be necessary.

Infect Control Hosp Epidemiol 2015;36(1):76–80

The ubiquitous nontuberculous mycobacterium (NTM) constitutes a potential source of infectious disease in a broad range of animal species, including humans. Environmental studies have isolated NTM from natural and potable water sources worldwide. Water obtained from municipal treatment facilities, hospitals, and homes grew NTM in 10% to 95% of the samples in European and American surveys.[1]

Rapidly growing nontuberculous mycobacteria (RGM), a subset of NTM, are defined as mycobacteria that grow within 7 days.[2,3] RGM are capable of forming a protective biofilm that is important for their survival in a given environment. Among RGM, *Mycobacterium mucogenicum*, established as a separate species in 1995, is one of the most common organisms for central line–associated bloodstream infection (CLABSI).[4] *Mycobacterium canariasense* is a newly proposed RGM that is most closely related to *Mycobacterium diernhofer*.[5,6] We describe herein an outbreak of suspected CLABSI due to RGM including *M. mucogenicum* and *M. canariasense* during a 5-month period in a hematology-oncology ward at a Japanese tertiary care center. The investigations undertaken to identify clinical cases and sources of bloodstream infection are discussed together with the prevention and control measures implemented.

METHODS

Setting

An outbreak investigation was performed in the hematology ward at Tokyo Metropolitan Tama General Medical Center, a

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789-bed tertiary care center in Tokyo, Japan. The hematology-oncology ward has 15 inpatient beds, including 7 transplant-unit beds (all single room accommodations with en-suite showers and toilets) where patients undergoing bone marrow transplantation are treated in protective isolation. The remaining 8 inpatient beds are located in an adjacent ward, which has 4-bedded rooms, communal showers, sinks, and toilets. The hematology-oncology ward performs approximately 20 new transplantation operations annually.

Case Finding

Cases were initially identified with the assistance of the microbiology laboratory as all patients showing a positive NTM blood culture result from October 15, 2011, through February 17, 2012. We then reviewed the medical charts of patients with an RGM bloodstream infection to determine whether the epidemiologic link was identical for all of the patients. Demographic characteristics, clinical data including the grade of graft-versus-host diseases,[7] and microbiologic data were collected. No cases were detected before or afterward during a period of follow-up.

Standard Central Venous Catheter (CVC) Maintenance

The study institution's standard protocol for CVC dressing care at the time of the outbreak included hand hygiene prior to changing the dressing, wearing nonsterile clean gloves when doing so, using povidone-iodine or a chlorhexidine-based antiseptic to disinfect the site, and covering the site with a sterile, transparent dressing. Frequency of dressing change was every 7 days if the dressing barriers were intact. However, dressing changes were performed at intervals of less than 7 days if there were signs of blood, precipitate, submersion of water after showering or bathing, or other defects.

Environmental Investigation

To investigate potential sources of infection within the environment, a total of 74 different water and environmental samples were obtained. Water samples were obtained from the room faucets, bathroom faucets, showers from each single and 4-bedded room, and faucets in the nursing station, whereas environmental samples were obtained from the showerheads in each single room, showerheads and bathtubs from the communal shower room, and disposable wet wipes in the hematology-oncology ward. The municipal water system supplied water to the patient care units, lavatories, toilets, and showers in the patient rooms. The potable water in the transplant unit had been sterilized both by chlorination and by purification using a hollow fiber membrane ultrafiltration filter. Prior to collecting the samples, the taps were run for 2 min to minimize contamination from tap spouts. The water was collected in a sterile 0.2-L container for sampling[8,9] then centrifuged at 3000 rpm for 20 minutes and cultured on 2% Ogawa medium (Serotec) for 4 weeks at 37°C.

Bacterial Identification

Blood cultures from patients with an RGM bloodstream infection were grown using an automated BacT/Alert 3D (Sysmex, bioMérieux). Colonized catheter tips were sent for microbiologic analysis and were processed by qualitative culture. Acid-fast staining was performed with the colonies grown on sheep's blood. Species identification was performed using the standard method.[10] Isolates from the blood and the environmental/water cultures were sent to the Tokyo Metropolitan Institute of Public Health for final identification, after initial isolation by the Clinical Microbiology Laboratory at our hospital. To confirm the identity of the acid-fast bacteria from the blood cultures and environmental/water samples, the fragments encompassing the 16SrRNA gene were amplified by polymerase chain reaction and the amplified products were sequenced. Sequences were compared with those in the DNA Data Bank of Japan databases using blast analysis.[11–16] Pulsed-field gel electrophoresis of *Xbal*-digested genomic DNA was performed and banding patterns were compared visually.[10] In addition, amplification was performed using random amplified polymorphic DNA polymerase chain reaction. Similar isolates with the same banding pattern were assigned to the same random amplified polymorphic DNA type.[10,17]

RESULTS

Epidemiology

During the study period, a bloodstream infection due to RGM developed in 5 patients with a CVC (Table 1). The pathogens implicated in these cases were *M. mucogenicum* (n = 4) and *M. canariasense* (n = 1). All of the patients received a long-term CVC (i.e., Hickman catheter) inserted into the internal jugular vein. Four patients underwent cord blood transplantation for acute myeloid leukemia and acute lymphatic leukemia, and the remaining patient received antithymocyte globulin for aplastic anemia. None of the patients showed signs of disseminated NTM infection on the basis of examination and imaging studies. Long-term CVCs were immediately removed when RGM was identified in the blood culture. All of the patients defervesced immediately after catheter removal and were carefully monitored without antimicrobial therapy against RGM. All patients have had no evidence of relapses. In March 2012, the CVC management protocol and covering of the catheter-implantation site during bathing were also reinforced. No CVC-related mycobacterial bloodstream infections occurred during the following year.

Description of the Catheter Care after Insertion

The frequency of dressing changes was documented in the nursing notes on the electronic patient records. Four of 5 patients required frequent changes at the catheter insertion site (every 2–5 days) for reasons that included submersion of the catheter site during showering or bathing. Only 1 patient (case

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TABLE 1. Clinical Data for Patients with Central Line–Associated Bloodstream Infection Due to Rapidly Growing Non-Tuberculous Mycobacteria

Case	1	2	3	4	5
Sex	Female	Male	Male	Female	Male
Age, y	40	69	45	60	16
Primary diagnosis	AML	Aplastic anemia	AML	AML	ALL
Transplantation	S/P CBT day 29	N/A	S/P CBT day 23	S/P CBT day16	S/P CBT day 21
Concurrent chemotherapy	MMF and CyA	ATG day18	CyA and MTX	MMF and CyA	CyA
GVHD grade	Grade 3	None	Grade 1	Grade 1	None
Absolute neutrophil count (/μL) at the time of bacteremia	6059	1	322	180	5
Time from catheter insertion to BSI, d	30	51	37	32	29
Duration of bacteremia, d	10	6	7	9	7
Isolated organism(s)	*M. mucogenicum*	*M. canariasense*	*M. mucogenicum*	*M. mucogenicum*	*M. mucogenicum*

NOTE. All patients had a Hickman catheter, and all patients were cured. ALL, acute lymphocytic leukemia; AML, acute myeloid leukemia; ATG, antithymocyte globulin; BSI, bloodstream infection; CBT, cord blood transplantation; CyA, cyclosporine; GVHD: graft-versus-host disease; MMF, mycophenolate mofetil; MTX, methotrexate; N/A, not applicable; S/P, status post. The grading of GVHD was based on the Glucksberg grade.

patient 3) required a dressing change every 7 days, even without submersion of the catheter.

Microbiological Results

Clinical Samples. All of the patients had multiple blood cultures performed, and for each patient more than 1 blood culture result was positive for mycobacteria. The median time from catheter insertion to a positive blood culture was 32 days (range, 29–51 days). The median duration of bacteremia was 7 days (range, 6–10 days). Four of 5 catheter tip cultures (80%) showed mycobacterial growth.

Environmental/Water Samples. Water samples from different sites in the unit were cultured for NTM. NTM was not isolated from sterilized potable water. However, *M. mucogenicum* was isolated from shower water from 1 of the single rooms and a communal shower room. *M. canariasense* was also isolated from toilet water from 1 of the 4-bedded rooms. The remaining water and environmental cultures showed no mycobacterial growth.

Water chlorination in the main water tank at the hospital was measured daily. This hospital considers chlorine levels between 0.10 to 0.40 ppm to be adequate for maintaining sterility. During the outbreak, the chlorination level was kept at approximately 0.11 ppm.

Microbiologic Analysis

Typing by pulsed-field gel electrophoresis and random amplified polymorphic DNA revealed a genetic match between blood isolates of *M. mucogenicum* from patients 1, 3, and 4 and a shower water isolate of *M. mucogenicum* from the single rooms. A blood isolate of *M. canariasense* from patient 2 matched *M. canariasense* isolated from a toilet of the 4-bedded room. The other isolate of *M. mucogenicum* from patient 5 was found to have different patterns from that of patients 1, 3, and 4 by pulsed-field gel electrophoresis and random amplified polymorphic DNA typing. No organism genetically matched with that from patient 5 was isolated from the water or the environmental culture.

DISCUSSION

We experienced a cluster of RGM bloodstream infections in a hematology ward over a 5-month period. This outbreak was caused by 2 different clones of *M. mucogenicum* as well as *M. canariasense*. *M. mucogenicum* is commonly implicated in outbreaks of bloodstream infections resulting from contaminated hospital equipment and contaminated tap water, whereas *M. canariasense* is a rare species of RGM and the spectrum of clinical diseases attributable to it is not clearly understood.[5,6]

Although the incidence of CLABSI due to RGM, especially *M. mucogenicum*, in hematopoietic stem cell transplant recipients or patients on intense immunosuppressive agents, appears to be low, 6 outbreaks of bloodstream infections among such patients have been reported between 2004 and 2012 (although the outbreak reported in 2004 actually occurred in 1998; Table 2).[8,9,11,18–20]

In this outbreak, 4 of 5 patients received dressing changes at the catheter site owing to submersion of the catheter during showering. Moreover, the result of the environment/water culture and type matching of isolates from the blood cultures with isolates from the environmental/water cultures indicated that the origin of these organisms was the tap water supply. As with previous instances,[8,9,19] we considered the portal of entry for both of these organisms into the bloodstream in this outbreak was likely to be the submersion of CVC during bathing, showering, or toileting. Enhancing the CVC dressing prior to bathing or showering is crucial. The latest US guideline

TABLE 2. Outbreaks of Central Line–Associated Bloodstream Infection Due to Rapidly Growing Non-Tuberculous Mycobacteria

Author	Publication year	Patient population (no. of cases)	Contamination of RGM	Management	Outcome
Kline et al.	2004	Adult/pediatric BMT and oncology patients (6)	Hospital water supply	N/D	N/D
Livni et al.	2008	Pediatric patients with hematologic malignancies, solid organ malignancies, and aplastic anemia (5)	Hospital water supply	Catheter removal and antimicrobial therapy	One patient died without catheter removal and antimicrobial therapy
Cooksey et al.	2008	Adult oncology patients (5)	Hospital water supply	N/D	N/D
Shachor-Meyouhas et al.	2011	Pediatric oncology patients and a patient with thalassemia major with BMT (8)	Unknown	Catheter removal and antimicrobial therapy	All patients were cured with no recurrences
Baird et al.	2011	Adult patients with leukemia and lymphoma (5)	Hospital water supply	Catheter removal and antimicrobial therapy	One patient died of unrelated posttransplant complications
Ashraf et al.	2012	Adult patients with sickle cell disease (4)	Hospital water supply	Port removal and antimicrobial therapy	All patients were cured with no recurrences

NOTE. BMT, bone marrow transplant; N/D, not documented; RGM, rapid growing mycobacteria.

regarding prevention of catheter-related bloodstream infections also noted that submerging a catheter in water should be avoided and an impermeable covering should be applied to the catheter during showering.[21]

The present study also highlighted the treatment strategies for CLABSI due to RGM. Given the lack of high-quality evidence, ideal treatment strategies remain unclear. In the outbreak discussed here, all of the patients defervesced after prompt catheter removal following the detection of the bloodstream infection, and all were carefully observed without antimicrobial therapy. Follow-up blood cultures revealed no bacterial growth, and there was no clinical evidence of recurrence. In most case series or outbreaks of NTM bloodstream infection, catheter removal was the most important step to achieving a successful outcome although many patients in these studies also received antimicrobial agents against NTM.[22–26] Single case series also demonstrated successful management of RGM CLABSI by prompt catheter removal without antimicrobial therapy.[27] Furthermore, removal of the catheter was associated with a significant decrease in the rate of bacteremia relapse.[24] These findings correlate with the pathogenicity of RGM species, specifically with reference to their tendency to form a microbial biofilm matrix on the surface of the indwelling catheters.

In summary, we experienced a cluster of CLABSI due to RGM among patients with hematologic disorders. Since hospital tap water can be contaminated even with adequate chlorination, it is imperative that precise instructions for infection control in patients with an indwelling vascular catheter should be provided to the patients themselves, the healthcare workers, and family members/friends who may be providing care, especially when patients shower or bathe.

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Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

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